The self-management of hypertensive pregnancies

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For my parents

Because the best parts of me are from them.

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Abstract

Background

Hypertension occurs in between 8 to 10% of pregnancies in the UK. While there has been a decline in maternal deaths from hypertensive disorders in pregnancy, it can still cause increased cardiovascular disease risk in later life. Therefore, better management strategies for hypertensive pregnancies, such as combining blood pressure monitoring, self-testing for proteinuria, and self-titrating blood pressure medication, are needed. In the general population, self-management interventions are becoming increasingly common place in the management of chronic conditions such as hypertension and diabetes. The evidence for self-management in pregnancy, however, is thin.

Methods

This thesis brings together qualitative and quantitative evidence on self-management to contribute to the evidence base for self-management interventions in pregnancy. A diagnostic accuracy study was conducted to determine the accuracy of proteinuria self-testing in pregnancy, and three qualitative interview and focus group studies with pregnant people and healthcare professionals were conducted to explore their thoughts on self-testing and self-management interventions.

Results

The diagnostic accuracy study showed that pregnant people are able to self-test in pregnancy with a similar accuracy to healthcare professionals. Meanwhile, the qualitative work revealed that while pregnant people and healthcare professionals find self-testing and the self-monitoring of blood pressure an acceptable self-management intervention that has the potential to empower patients, there were hesitancies from healthcare professionals,

and some pregnant people, around the self-titration of blood pressure medication. Finally, a pervasive discourse of paternalism was explored in healthcare professional's attitudes towards self-testing, and how the burden of self-management may affect pregnant people's adherence to a self-management intervention.

Conclusion

This thesis has found that while there is an appetite, and growing evidence, for self-management in pregnancy from both pregnant people and healthcare professionals, both have concerns over self-titration of blood pressure medication. Self-management interventions in pregnancy are made more complex by paternalism, gatekeeping, concerns for maternity safety, and the unique burden of treatment that accompanies pregnancy – considering the additional life of the baby.

Abbreviations

ACR	albumin:creatinine ratio
BMI	Body Mass Index
BNF	British National Formulary
CI	Chief Investigator
CIS	Critical Interpretive Synthesis
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CPMS	Central Portfolio Management System
CRF	Case Report Form
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ISSHP	International Society for the Study of Hypertension in Pregnancy
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OSOP	One Sheet of Paper
PCR	protein:creatine ratio
PPI	Patient Public Involvement
PI	Principle Investigator
RCT	Randomised Control Trial
REC	Research Ethics Committee
ROC	Receiver Operating Characteristic
STARD	Standards for Reporting Diagnostic Accuracy Studies
TMG	Trial Management Group
WHO	World Health Organisation

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Chapter 1 : Introduction

1.1 Overview

Self-management interventions are becoming increasingly common in the general population for chronic conditions such as hypertension and diabetes, but this concept is relatively unexplored in pregnancy, particularly in hypertensive pregnancies. Self-management in hypertensive pregnancies is made up of three aspects of care: proteinuria self-testing, blood pressure self-monitoring, and the self-titration of blood pressure medication. Combining these activities has the potential to be a valuable self-management intervention, providing patients with more agency and theoretically improving the management of hypertensive disorders in pregnancy. This thesis will explore the burden of managing chronic conditions in pregnancy, particularly hypertension with or without pre-eclampsia. It will also aim to determine the accuracy of self-testing in pregnancy for the presence of proteinuria with a diagnostic accuracy study, bridging an evidence gap that currently exists in the field. The linked qualitative work will explore the thoughts of patients and healthcare professionals regarding self-testing and self-management, the impact self-management may have on the perception of patient autonomy, the desire for patient empowerment in this population, and the pervasive discourse of paternalism and gatekeeping in antenatal care.

1.2 Objectives

The thesis aims to expand the current evidence base on self-management in hypertensive pregnancies and provide evidence for some of the gaps in our knowledge about the different components of self-management. This comprises of determining the accuracy of self-testing

in pregnancy with a diagnostic accuracy study, and exploring the thoughts of healthcare professionals and pregnant people about self-testing and self-management. This thesis aims to gather evidence to improve our understanding of self-management in pregnancy, what a self-management intervention would involve, and how it could be integrated into antenatal care. The research questions for this thesis are reported at the end of this chapter (Section 1.10).

1.3 Definitions

1.3.1 Hypertension, pre-eclampsia, and eclampsia

Hypertensive disorders in pregnancy include gestational and chronic hypertension, pre-eclampsia, and eclampsia. Hypertension in pregnancy can either be pre-existing (chronic) or acquired during the pregnancy (gestational) and is defined as a systolic blood pressure of ≥140mmHg, and/or a diastolic blood pressure of ≥90mmHg, without the presence of proteinuria (protein in the urine) (1) (2). Pre-eclampsia is defined as new onset hypertension, over 20 weeks gestation, with evidence of proteinuria and/or evidence of fetal growth restriction and/or maternal organ damage (2). Proteinuria is defined as urinary protein:creatinine ratio (PCR) of ≥30 mg/mmol, or a urinary albumin:creatine ratio (ACR) of ≥8mg/mmol (1). Eclampsia is a serious condition associated with pre-eclampsia, characterised by tonic-clonic seizures caused by high blood pressure, and can be fatal for the pregnant person and the baby (3).

1.3.2 Self-management

In the general population, Schulman-Green defines self-management as "*the ability of an individual, in conjunction with family, community and health care professionals, to manage symptoms, treatments and lifestyle changes*" (4). However, a definition that has been modified for the pregnant population and takes into account the different motivating factors

for the efficacy of self-management in pregnancy is absent from the literature; therefore, this thesis will use Schulman-Green's definition as a guide. Some of the work in this thesis will demonstrate that pregnant people's motivations to self-manage are primarily driven by the desire for a healthy baby (Chapter 2), which is not accounted for in current self-management definitions and frameworks. In terms of the specific self-management activities for hypertensive pregnancies, this thesis considers self-testing for proteinuria, self-monitoring blood pressure, and self-titrating blood pressure medication, either in isolation or concurrently, as an appropriate definition of self-management. Expanding a self-management definition that accounts for the specific needs and motivations of pregnancy could account for better tailored self-management interventions in pregnancy. Therefore this thesis will be guided by both definitions from the general population, and the specific self-management activities attributable to monitoring hypertension and pre-eclampsia in pregnancy.

1.4 Epidemiology

Hypertensive disorders in pregnancy, including pre-eclampsia, are serious conditions that cause significant maternal morbidity and mortality globally (5). Worldwide, pre-eclampsia and eclampsia cause an estimated 30,000 maternal deaths per year, the burden of this mostly in low and middle income countries (5). Hypertensive disorders affect around 8 to 10% of pregnancies in the UK (1), and recent years have seen a marked reduction in maternal deaths from pre-eclampsia and eclampsia. This strong downward trend is particularly notable considering hypertensive disorders were previously the leading cause of avoidable maternal death in the UK (6) (7). The decline has been linked to improved detection of pre-eclampsia, improved antenatal care, better communication between health settings (i.e. community and hospital) and improved nutrition. Public health factors

speculated to contribute to the trend include increased access to healthcare and a decrease in home births (7).

However, as Shennan et al discuss, complacency is now the risk regarding hypertensive disorders; pre-eclampsia is only safe for the pregnant person if it is identified early and well managed (8). Moreover, hypertension can lead to serious long term health complications for the pregnant person, including increased cardiovascular risk in later life (1). Crucial to the effort to reduce maternal mortality from hypertensive disorders is early detection and good management of hypertension and pre-eclampsia during pregnancy (both antenatally and postnatally).

1.5 Management of hypertensive pregnancies: evidence and guidelines

Pre-eclampsia is a multi-organ syndrome and is defined, primarily, by two measures: hypertension and proteinuria (9). Hence, blood pressure monitoring and proteinuria testing are two of the most commonly performed antenatal screening tests. In the UK, for uncomplicated pregnancies, it is recommended that nulliparous pregnant people have ten antenatal appointments, and primiparous/multiparous pregnant people, eight (10). Blood pressure monitoring and urine testing is carried out at the majority of these appointments to monitor and screen for pre-eclampsia. The following section will give a brief overview of the care pathways for those with gestational and chronic hypertension.

The majority of the data collected in this thesis was in a UK, National Health Service (NHS) setting. However, there are also data from other settings and contexts (specifically in Chapter 2), therefore it is prudent to acknowledge both the National Institute for Health and Care Excellence (NICE) guidelines for hypertensive pregnancies and, briefly, the International Society for the Study of Hypertension in Pregnancy (ISSHP) guidelines, for international context.

1.5.1 Antenatal care pathway: gestational hypertension

There are several risk factors associated with gestational hypertension, including: nulliparity, advanced maternal age, pregnancy interval of 10+ years, a high Body Mass Index (BMI), multi-fetal pregnancy, and previous history of pre-eclampsia or gestational hypertension. If a pregnant person is determined to have gestational hypertension (see 1.3.1 definitions), healthcare professionals aim for a target blood pressure of 135/85 mmHg (1). For those with hypertension, blood pressure monitoring is recommended once or twice a week. Labetalol is the primary anti-hypertensive medication used to treat pregnant people, with nifedipine recommended if labetalol is not suitable, and methyldopa as a third line choice if the latter drugs are not suitable (1). Hospitalisation for the pregnant person is recommended if there is severe hypertension, over 160/110mmHg (1). Planned early birth is not recommended for those with non-severe gestational hypertension (a blood pressure of less than 160/110mmHg) unless there are other medical indicators (1).

1.5.2 Antenatal care pathway: chronic hypertension

There are few differences in the management of chronic hypertension compared to gestational hypertension, the blood pressure targets and recommendations for early birth are the same. However, pregnant people with chronic hypertension are also offered lifestyle and diet advice, including advice on weight management, exercise, healthy eating, and lowering their salt intake (1). Anti-hypertensive medication change is only recommended if the current treatment is not safe to use in pregnancy.

1.5.3 Proteinuria assessment in pregnancy

Proteinuria is one of the clinical indicators of hypertensive disorders in pregnancy. The NICE guidelines for hypertension in pregnancy recommend, along with a full review of clinical symptoms, using an automated reagent strip reading device for dipstick screening (1). If the

dipstick is positive[1] to quantify with an protein:creatinine ratio (PCR) or albumin:creatinine ratio (ACR) laboratory test (1). NICE no longer recommend using 24-hour urine collection to quantify proteinuria in pregnancy, instead recommending PCR or ACR. The ISSHP guidelines state that proteinuria is not mandatory for a diagnosis of pre-eclampsia and instead include it on the list of clinical and biomedical indicators alongside raised blood pressure i.e. pre-eclampsia is diagnosed if there is hypertension with proteinuria and/or evidence of fetal growth restriction and/or abnormal maternal organ function (11). ISSHP guidelines concur with NICE that an automated reagent strip reading device is the best method to assess proteinuria, alongside using a PCR test as the quantifier.

1.5.3.1 *Accuracy of proteinuria screening methods*

Previously, 24-hour urine collection was considered the 'gold standard' of proteinuria quantification. This has been phased out of antenatal care in light of the improved accuracy offered by PCR and ACR laboratory tests (12). 24-hour urine tests were often incomplete if a person did not collect every void, or they went into labour, meaning an "*under-estimation of the quantity of protein*" was likely (13). Other issues with 24-hour urine collection include a lengthy wait for results delaying treatment or unnecessary hospitalisations based on false positive dipstick test results (13) (14). A recent systematic review and meta-analysis concluded that PCR and ACR have a higher accuracy than standard 24-hour urine collection (13). This review also found that the specificity of PCR at a threshold of 60mg/mmol was consistently high, but there was more variability in results in the 30 - 60mg/mmol thresholds, suggesting the need for repeat PCR tests if results are returned within that range

[1] Classified as 1+ or more, categories on a dipstick test are negative, trace, 1+, 2+, 3+, 4+

(13). ACR is less widely used in pregnancy than PCR[2], but the review still suggested it was more accurate than 24-hour urine collection, despite the relative lack of data.

While an automated reagent strip reader is recommended for screening for proteinuria, there is evidence that they may not be regularly used: an online survey of 150 UK obstetricians found that the majority of respondents used a visual assessment of a reagent strip to screen for proteinuria initially (15). A further survey, where the majority of respondents were midwives, reported similar findings – visual readings were used to assess proteinuria with very few respondents reporting the use of an automated reader (16). Automated readers are expensive and may not be feasible in all antenatal care settings, such as in primary care practices where many antenatal screening clinics take place. Considering that visually assessed dipsticks are, therefore, the most commonly used method of screening for proteinuria, it is worth considering their accuracy. There have been three studies that have compared visually assessed dipsticks against an automated reader. The studies report a low sensitivity[3] for visually assessed dipsticks (see Table 1) when compared to an automated reader, suggesting that automated readers are the most accurate method of assessing for proteinuria. The sensitivity of visually assessed dipsticks is only around 50% in these studies, which is not an adequate for a screening test intended to rule out serious disease. When dipsticks are used in an automated reader, the sensitivity can increase to 82%, depending on the dipstick used. However, these studies often used outdated reference tests as a comparator, such as 24-hour urine collection, or have not been conducted in the appropriate study population (hypertensive pregnant people). Additionally, none of these studies have assessed pregnant people self-testing and the dipstick testing was often conducted by

[2] It is often used for assessing renal function outside of pregnancy

[3] Sensitivity is the proportion of samples that are true positives. Specificity is the proportion of samples that are true negatives

members of the study team or healthcare professionals. This suggests that there is a need for a comprehensive study assessing the accuracy of self-testing, alongside examining the accuracy of an automated reader alongside a more accurate reference standard, such as PCR.

Table 1: Sensitivity and specificity of visually assessed proteinuria dipsticks and automated readers

Authors	Title	Sensitivity (visually assessed)	Specificity (visually assessed)	Sensitivity (automated reader)	Specificity (automated reader)
Correa et al, 2017	Visual or automated dipstick testing for proteinuria in pregnancy? (17)	**Multistix 10SG** 41.3% [28.3–55.7]	**Multistix 10SG** 98.4% [96.1–99.4]	**Multistix 10SG/Clinitek 50** 65.2% [50.7–77.3]	**Multistix 10SG/Clinitek 50** 92.6% [88.7–95.2]
Gangaram et al, 2009	Accuracy of the spot urinary microalbumin:creatinine ratio and visual dipsticks in hypertensive pregnant women (18)	**Makromed** 51% [41–61]	**Makromed** 91% [81–96]	**Microalbumin/Clinitek 50** 63% [52–72]	**Microalbumin/Clinitek 50** 81% [70–89]
Waugh et al, 2005	Optimal bedside urinalysis for the detection of proteinuria in hypertensive pregnancy: a study of diagnostic accuracy (19)	**Multistix 8SG** 51% [39–62] **Microalbumin** 49% [38–61]	**Multistix 8SG** 78% [68–86] **Microalbumin** 83% [74–90]	**Multistix 8SG/Clinitek 50** 82% [71–90] **Microalbumin/Clinitek 50** 58% [47–70]	**Multistix 8SG/Clinitek 50** 81% [71–88] **Microalbumin/Clinitek 50** 83% [74–90]

1.6 Self-management of hypertension: lessons from the general population

There is evidence from the management of hypertension in the general population that self-monitoring of blood pressure and self-titration of blood pressure medication is safe and effective (20). A recent study in hypertensive patients showed that medication titration based on self-monitoring with or without telemonitoring in patients with poorly controlled blood pressure led to better blood pressure (21). Telemonitoring refers to the "*transmission of symptom scores, physiological data including heart rate, blood pressure, oxygen saturation, and weight directly to care providers either via automated electronic means or by web-based or phone-based data entry*" (22). Self-monitoring blood pressure in the general population is widely incorporated into primary care (23), and there is no evidence to suggest that self-monitoring or management poses any risk to patients, but actually results in better controlled blood pressure (20, 24, 25).

Studies have reported that patients feel confident self-monitoring and tend to view their home readings as more representative of their blood pressure than clinic readings (26). There has been slightly more hesitation reported on self-titration; one qualitative study with hypertensive patients who had self-managed found that patients were hesitant to change medication based on borderline blood pressure readings, but additional support from healthcare professionals could overcome this hesitancy (26). Vasileiou et al reported similar findings in patients who were hesitant to self-monitor their blood pressure. Involvement from healthcare professionals helped them overcome any difficulties or uncertainties faced when monitoring their blood pressure at home (27). Another qualitative study found that healthcare professionals whose patients had self-managed were also positive about self-monitoring, and wanted patients to have the opportunity to be more involved in their care, provided there were adequate safety measures and frameworks to operate within (28). This is supported by data from the TASMIN-SR trial, which demonstrated the importance of care

training and fidelity to self-management regimes; this trial found that patients were not only monitoring their blood pressure accurately, but fidelity to the self-management regime was associated with lower achieved blood pressure (29).

While there is a solid body of evidence for self-management in the general population, the evidence for self-management in pregnancy and its multiple components, is thin.

1.7 Self-management in pregnancy

Self-management in hypertensive pregnancies is made up of three main aspects of care; blood pressure monitoring, self-testing for proteinuria, and self-titrating blood pressure medication. Self-management has the potential to detect pre-eclampsia earlier and manage the condition better, while offering pregnant people more autonomy and involvement in their antenatal care. The existing evidence for self-management in pregnancy, both quantitative and qualitative, is sparse; however, there have recently been studies conducted on the self-monitoring of blood pressure during pregnancy and the self-management of hypertensive pregnancies in the postnatal period (see Sections 1.7.1.1 and 1.7.1.3). The knowledge base for self-managing hypertensive pregnancies stems predominantly from evidence gathered in the general population, as described above, and evidence from the self-management of other chronic conditions in pregnancy, primarily diabetes, which will be explored in chapter 2.

Although the evidence for self-managing hypertensive pregnancies is sparse, there have been a few studies to date looking at the individual components of self-management.

1.7.1 Self-management of hypertensive pregnancies

1.7.1.1 *Self-monitoring blood pressure*

A feasibility Randomised Control Trial (RCT) of blood pressure monitoring in hypertensive pregnancies, OPTIMUM-BP, showed that pregnant people had high adherence and

persistence with home blood pressure monitoring (30) and there was no difference in systolic blood pressure between the control (not self-monitoring) and the intervention (self-monitoring) group. This feasibility trial showed that a large scale RCT of self-monitoring blood pressure was feasible, and this trial is currently underway.

A qualitative study with pregnant people who took part in a small pilot study of self-monitoring demonstrated that pregnant people were willing to engage with self-monitoring during their pregnancy and, on the whole, felt it could reduce their health anxiety (31). Pregnant people generally found that integrating blood pressure monitoring into daily life was straightforward during the antenatal period; incorporating self-monitoring into a daily routine helped people adhere to the monitoring schedule (31).

1.7.1.2 *Proteinuria self-testing*

As described above (Section 1.5.3) there have been several studies conducted on assessing the accuracy of proteinuria dipsticks; however, none of these studies involved pregnant people testing their own urine. A pilot study for self-testing compared 100 pregnant people testing a range of synthetic urine samples to 96 healthcare professionals testing the same set of samples (32). The study showed that pregnant people tested with a similar accuracy to healthcare professionals, particularly at the clinically relevant threshold of 1+, and indicated that a full diagnostic accuracy study using real urine samples was feasible (32). The qualitative work conducted alongside the self-testing study included an online survey for pregnant people, who reported that they found self-testing, with support from healthcare professionals, easy to carry out and acceptable, and improved their involvement in their care (32). The study also reported that healthcare professionals had concerns about the suitability of some pregnant people to self-test, and whether they would test accurately.

There were mixed findings on health anxiety, with pregnant people split over whether self-testing would increase or decrease their anxiety during pregnancy (32).

1.7.1.3 *Self-titrating blood pressure medication*

While there have not been any studies looking at self-titrating blood pressure medication in the antenatal period, there has been a study examining this in the post-natal period. The SNAP-HT feasibility trial was a self-management intervention for pregnant people with gestational hypertension or pre-eclampsia requiring postnatal anti-hypertensive treatment (33). The intervention included daily blood pressure monitoring and automated blood pressure medication reduction via tele-monitoring (33). The results of the study showed that self-management resulted in better diastolic blood pressure control up to six months postpartum and well after cessation of anti-hypertensive medication (33). This study is the only RCT on self-management, both in the postnatal and antenatal period.

In order to understand self-management in pregnancy as a whole, it is necessary to bridge some of these evidence gaps. The lack of data on self-testing for proteinuria in particular, is a gap that needs addressing. The main study reported in this thesis aims to determine the accuracy of pregnant people self-testing their urine for proteinuria (Chapter 3), with the associated qualitative study exploring pregnant people and healthcare professional's views on self-testing (Chapter 4, 5).

1.8 Concepts and Theories

As demonstrated above, while self-management and its components are relatively unexplored in pregnancy, understanding pregnant people and healthcare professional's attitudes towards these ideas is also critical to any future implementation. There are several theories utilised in this thesis to understand the potential impact that self-management could have, on both patients and healthcare professionals. These theories are introduced here, and will be explored in greater detail throughout the thesis.

1.8.1 Paternalism

Paternalism is, in essence, how "*persons possessing knowledge and power have made assertions about how other members of society should live*" (34). Cody asserts that paternalism has been invoked to "*dominate and control persons on the basis of their sex, sexual orientation, race, ethnicity, religion, class, and other's judgements about their sanity and health*" (34). Paternalism is rife in relationships where there is an inherent power imbalance, as is the case in healthcare, where interactions between patients and healthcare professionals have often been described as paternalistic or "*doctor-centred*" (35). Paternalism is also described in healthcare as when a patient's "*preferences, decisions, or actions are denied out of concern for the patient's wellbeing*" (36). Beauchamp and Childress, in their seminal work on biomedical ethics, cast paternalism into two extremes from the perspective of the patient: weak paternalism, in which the individual is unable to make a decision due to a compromised state, and strong paternalism, which involves interventions that are anticipated to benefit the person even if the person refuses the intervention, and has made a well-informed decision (37). In antenatal care, or maternity care more broadly, paternalism is present in almost every facet of care, from who is responsible for surveillance, to the information given about specific risk factors and conditions (38). This thesis examines the evidence on self-management in a moment of transition for maternity care, which is

rapidly moving towards remote forms of care, accelerated by the COVID-19 pandemic (39), but at the same time as the evidence for remote care activities (i.e. self-management) is still being developed (40). When it comes to surveillance (self-monitoring, self-testing), this is a role traditionally held by healthcare professionals; exploring a change in this set up, whereby patients carry out elements of this surveillance remotely, theoretically shifts the balance of power between patients and clinicians. Paternalism is a useful lens through which to explore this changing relationship and whether it is a significant barrier to implementing self-management in antenatal care.

1.8.2 Patient empowerment and patient autonomy

A concept that challenges the paternalistic nature of antenatal care is patient empowerment, or patient autonomy. These terms are used interchangeably throughout this thesis as sometimes the benefits of self-management are described by participants as empowerment and, other times, as patient autonomy. Understanding the potential benefits of self-management include grappling with the implications of increased patient autonomy. The concept of patient empowerment has been predominantly developed in chronic disease literature; patient empowerment has emerged as a vital component of care, an essential part of the effort to improve healthcare for those with chronic conditions (41). In this thesis, a broad definition of patient empowerment is considered. Small et al offer a definition with a wide scope: "*an enabling process or outcome arising from communication with the health care professional and a mutual sharing of resources over information relating to illness*, *which enhances the patients' feelings of control*, *self-efficacy*, *coping abilities and ability to achieve change over their condition*" (42). This, theoretically, condenses patient empowerment down to several concepts; shared decision making, patient education, and self-management. All of these ideas are prevalent in chronic illness literature. Thorne et al's

work on self-care[4] among diabetic, multiple sclerosis, and HIV patients found that *"participants shared a commitment to controlling the disease rather than being controlled by it".* The participants in that study also mentioned *"shopping around"* for healthcare professionals who would be *"self-management partners"* (43). These central tenets of patient empowerment are explored in later chapters (Chapter 4), as is the idea that the experience of chronic illness in pregnancy is different to the general population, and therefore patient empowerment may be experienced and expressed differently (Chapters 2, 4). In this thesis, patient empowerment and autonomy in pregnancy is explored in multiple chapters, using Small's broad definition that identifies the key features of patient empowerment.

1.8.3 Patient-centred care

According to Coulter, patient-centred care means "*treating patients as individuals and as equal partners in the business of healing; it is personalising, coordinated and enabling*" (44). A patient-centred care approach focuses on working with patients to ensure they develop the knowledge and skills to manage and engage with their own healthcare effectively (44). Many areas of chronic disease management have progressed towards a patient-centred care model, following explicit guidance from the Department of Health in 2002 on user-led self-management (45). Since then, a patient-centred approach has been enshrined in the NHS's 2019 Long Term Plan, with a focus on some of the specific elements in Coulter and other's definitions of patient-centred care, such as joined up and coordinated care and a more individualised approach to medicine (46). The Long Term Plan has committed to providing "*more personalised care when* [people] *need it*" (46).

[4] Self-care and self-management are often referred to as similar concepts in the literature

Patient-centred care involves the key features of patient empowerment described above: shared decision making, patient education, and self-management. Patient-centred care should, theoretically, lead to empowered patients. But there are critiques of both patient empowerment and, implicitly, patient-centred care that are worth considering.

1.8.4 The Burden of Treatment theory

One such critique is the Burden of Treatment theory, developed by Carl May, Frances Mair and others. One of the early definitions of self-management for this thesis emerged from Carl May et al's paper on the Burden of Treatment theory, a new theory of the relationship between "*sick people, their networks, and healthcare services*" (47). Developed in response to the rising cases of non-communicable diseases burdening healthcare systems, May et al argue that these systems have now delegated disease management to patients (47).

The Burden of Treatment theory has roots in "*the new proactive work of re-engineered patient-hood*", arguing that because chronic conditions rely on management rather than cure, patients are expected to engage in "*routine work*" to avoid exacerbating the condition, or to mitigate the long term effects and poor outcomes. Patienthood, as May et al describe it, has changed as healthcare systems adjust to the new burden of managing chronic illness. This new concept of re-engineered patienthood describes the patient as needing to be active (engaging in shared decision making), expert (possessing knowledge and skills for self-management), resourceful (able to operationalise knowledge), and prudent (willing to minimise the burden they place on healthcare provisions) (47).

May et al explain that patient work in this context includes symptom monitoring, treatment management, and lifestyle changes while "*maintaining* [these tasks] *alongside the demands of other aspects of everyday life*" (47). This work can be interpreted as self-management, as almost all definitions of self-management include symptom monitoring and treatment self-

adjustment. The model accounts for the different actors involved with self-management, suggesting the burden of treatment lies not only with the patient but with the patient's social network as well. Crucially, this model suggests that interventions that aim to improve the patient experience also fulfil the dual purpose of dismantling "*dysfunctional structures of healthcare utilisation*" which could have a tangible impact on the way patients interact with their health services (47). However, May et al also stipulate that when self-care and self-management interventions fail, in this case by creating a burden of treatment, it is often due to inadequate resources that prevent patients from becoming "*self-actualised*" (47).

This theory became a lens through which to analyse some of the data collected for this thesis, particularly in the systematic review reported in chapter 2. How pregnant people perceive the burden of self-management could determine the efficacy of a self-management intervention. Pregnancy adds a new layer of complexity to the demands of everyday life that May et al refer to in their paper, and while the theory accounts for many of the actors involved in self-management it fails to account for an additional life that is demonstrably, as reported in this thesis, the reason pregnant people are motivated to self-mange in the first instance – the baby.

Equally, while this theory helps us to understand the burden that is placed on patients and the ripple effects on their support networks, further qualitative research is needed to understand the impact of this burden on patients, and whether it is an acceptable normative shift. In pregnant people, the period of self-management is significantly shorter than the long trajectory of chronic illness that underpinned the original thesis, yet the burden is no less onerous.

1.9 Language

There are several language considerations to grapple with in this thesis. The first is how to contend with the term 'patient' in a population that are not necessarily receiving medicalised care or interventions, or even perceive themselves to be a patient. The second is a personal reflection on gender inclusive language and pregnancy. The following section will explore both of these linguistic concerns.

1.9.1 The patient or the client: medicalised pregnancies

The debate over the term patient is not limited to antenatal care. There is an ongoing discussion about whether those seeking healthcare should be referred to as patients, or whether updated terms such as clients, service users, or customers are more appropriate (48). Costa et al write that "*the gradual shift from the paternalistic to the patient-centred model of healthcare,* [has] *prompted debate about the use of alternative labels to describe 'patients'*" (49). According to Costa, patient invokes images of passivity, whereas client or service user is supposedly more empowering and suggests greater equality between the healthcare professional and the client (49). Shevell writes that "*words function as metaphors that literally shape our reality and expectations*" and that the term patient reduces a person to an object of an action, and is, perhaps, best suited to a paternalistic model of healthcare (50). On the other hand, while it is argued client conveys a "*non-medical, humanistic, less acute care model*" (50), evidence suggests it is not widely used, nor do patients prefer to be referred to as clients (48). There is a danger, as Raphael and Emerson note, that the term client risks the patient losing access to the 'sick role' (51), a concept coined by Parsons that postulates that being ill, or being identified as being sick, is not just a biological condition but a societal role (52). Raphael and Emerson theorise that the term client could remove the sick person's access to certain rights associated with the sick role, and even result in denial that the person has an illness (51). The debate regarding the use of the term patient or client, or

even other terminology such as service users, remains unresolved, but it is worth remaining alive to the connotations of this debate when considering the pregnant population.

There are particular challenges in the pregnant population regarding the use of the term patient and the medicalisation it invokes. Pregnancy itself is not a medical condition, it is a natural state, but within the period of pregnancy it is possible to travel across the boundaries of medicalised and non-medicalised care; this creates linguistic problems. Are pregnant people considered patients or, as sometimes referred to in this thesis, clients? The perception of pregnant people themselves is also important to consider, do they consider *themselves* patients, and does that differ based on how medicalised their pregnancy has become?

Despite the fact pregnancy is not a disease, or an illness, and is a natural phase in a person's life, it does require monitoring and a level of clinical surveillance. There has long been resistance to over medicalising pregnancy and the dominance physicians hold over pregnant bodies in the process of that medicalisation; Henley-Einion goes as far to say that birth has now become a medical event, as opposed to a social event (53). Martin's work on the pregnant body critically describes it as a machine, and the doctor as responsible for fixing it (54). There has been resistance to the medicalization of pregnancy and birth; Our Bodies, Ourselves by the Boston Women's Health Book Collective in the 1980's contested the medicalised narrative of pregnancy and offered instead an alternative view that emphasised birth choices and a positive, safe birthing experience (55). More recently, The Positive Birth Movement, popularised by Milli Hill, has campaigned to "*challenge the epidemic of negativity and fear that surrounds modern birth*" (56).

Yet, it must also be understood that pregnancy can rapidly transition from an uncomplicated, non-medicalised state, to one that becomes highly medicalised and in need

of either constant surveillance or intervention. Hypertension is one such condition that can onset very rapidly, and risks the health of the pregnant person and the baby if it progresses to eclampsia. In an uncomplicated pregnancy, pregnant people may not consider themselves patients, or even high risk, even if they do have certain risk factors for conditions such as hypertension (e.g. family history or high BMI) (see Section 1.5.1). Even in uncomplicated pregnancies though, the pregnant person is expected to engage in risk averse behaviour and self-surveillance, often at the behest of their healthcare professionals (57). In this thesis, the participants are considered higher risk due to their diagnosis of hypertension or pre-eclampsia, and some were even in-patients. But there were still pregnant people, attending hypertension clinics or other routine appointments, who may not consider themselves patients – just pregnant people. The debate over medicalised pregnancies, and thus, the concept of the patient, is present throughout this thesis and will be explored in relation to the qualitative data gathered from patients and healthcare professionals. For ease, and to reflect the language used by participants in this instance, the term patient will be used in this thesis.

1.9.2 Pregnant person/people

This thesis will, where possible, use the terminology 'pregnant people' or 'pregnant person'. The reason for this is twofold; firstly, the primary data collected for this thesis did not include the gender of the participant recruited. Therefore, it would be wrong to conclude that all the participants in our dataset identify as women. Secondly, the field of maternal health has long been criticised for its lack of inclusivity, particularly when it comes to people who identify as non-binary or transgender. As described by Hoffkling, Obedin-Maliver, and Sevelius, making space in maternity care for trans and non-binary people is frustrated by "*anti-transgender stigma, strongly gendered norms around pregnancy, institutional structures that do not recognise the possibility…and lack of research and available*

information for providers and patients" (58). The choice to use gender inclusive language comes from both the practicalities of the data collected and a desire to see our field as a more inclusive, safe space for the LGBTQ+ community. Lastly, it should be noted that the publications associated with this thesis use terminology for trial participants that are currently the norm in the field, and are thus not gender inclusive. This is partly for editorial reasons, to match the style guides of journals, and partly reflective of the language used widely in the field of pregnancy healthcare. However, it is also indicative of the paucity of data currently available on trans and non-binary experiences of pregnancy.

The decision to use gender inclusive language has come after a period of personal reflection and therefore previous work, drafts, topic guides, and trial documents referenced in this thesis may not reflect this inclusive language. This was a choice made during the write up of this thesis and had no bearing on the analysis or data collection. When quoting interview and focus group participants their language will not be changed for reporting accuracy and research integrity.

1.10 Research Questions

The following research questions are being addressed in this thesis:

1. **What are the current behaviours and attitudes among pregnant people regarding the self-management and self-monitoring of chronic conditions in pregnancy?**

A systematic review was undertaken of the qualitative literature on the self-management of chronic conditions in pregnancy. The results of this review are reported in chapter 2.

2. **Can pregnant people with hypertension accurately self-test for proteinuria compared to healthcare professionals and an automated colorimetric reader?**
3. **Can pregnant people, healthcare professionals, and an automated colorimetric reader accurately test for proteinuria compared to a primary reference test (PCR)?**
4. **Can pregnant people, healthcare professionals, and an automated reader accurately test for proteinuria, compared to a secondary reference standard (ACR)?**

A diagnostic accuracy study was conducted comparing pregnant people self-testing to healthcare professional testing and an automated reader, using laboratory PCR and ACR as reference tests. The results of this study are reported in chapter 3.

5. **Is self-testing of proteinuria acceptable to pregnant people and healthcare professionals?**
6. **What are the barriers and facilitators for self-testing for proteinuria during pregnancy becoming integrated into pregnant people's lives?**
7. **What are the barriers and facilitators for self-testing for proteinuria during pregnancy becoming integrated into antenatal care?**

A qualitative study, linked to the diagnostic accuracy study, collected a range of qualitative data from healthcare professionals and pregnant people to understand their views on self-

testing. Interviews were conducted with pregnant people and healthcare professionals, additional focus groups were held with healthcare professionals, and pregnant people who took part in the diagnostic accuracy study were given the opportunity to feedback on free test postcards. The results from these studies are reported in chapters 4 and 5.

8. **What are the barriers and facilitators for self-management during hypertensive pregnancy becoming integrated into pregnant people's lives?**

9. **What are the barriers and facilitators for self-management during hypertensive pregnancy becoming integrated into antenatal care?**

The interviews and focus groups collected for the self-testing qualitative study also included data on self-management. After exploring their views on self-testing, pregnant people and healthcare professionals were asked about self-management in pregnancy, what their thoughts were on self-titrating medication, and whether they felt it was a suitable intervention in antenatal care. The results of this study are reported in chapter 6.

1.11 Statement of Contribution and Funding Acknowledgements

This DPhil has been completed while I have been working as a Research Associate on a National Institute for Health Research (NIHR) programme grant (Programme for Applied Research RP-PG-0614-2000, led by Professor Richard McManus) researching the self-monitoring of blood pressure in pregnancy. The funding for the Urine Detection in Pregnancy (UDIP) study was acquired through this programme grant. As part of my role, I was the trial manager and lead researcher of the UDIP study, the diagnostic accuracy study reported in this thesis (Chapter 3). I was responsible for writing the protocol and obtaining ethics approval for the studies reported in this thesis, with support from my supervisory team and the wider study group. The recruitment for the UDIP study was carried out by research midwives at each site, with lead midwives Layla Lavallee, Hannah Wilson, and Lesley Brittain

providing oversight. The statistical analysis plan was written by myself, with support from the senior statistician on the work stream, Richard Stevens, who supervised me for the statistics aspects of the study. I conducted the quantitative analysis, again with support from Richard Stevens. Professor Richard McManus was the Chief Investigator (CI) for the UDIP study, and Professor Lucy Chappell (Guy's and St Thomas' NHS Foundation Trust), Dr Lucy Mackillop (Oxford University Hospitals), and Lesley Brittain (Birmingham Women and Children's Hospital) were the Principle Investigators (PI) for each site (see Chapter 3, Section 3.4.9 for further details on the trial management group).

The EMPOWER study was funded by a grant from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care Oxford (NIHR CLAHRC Oxford) now recommissioned as NIHR Applied Research Collaboration Oxford and Thames Valley (Grant no. P2-515), which was led by Dr Katherine Tucker. I conducted all of the qualitative interviews and focus groups reported in this thesis, as well as the analysis, with support and supervision from Dr Lisa Hinton. The recruitment for the qualitative study was supported by the lead research midwives at sites. I developed the question and scope of the systematic review reported in chapter 2, the search was completed with assistance from librarian Nia Roberts, and I was the first reviewer. Dr Jaspreet Khaira was the second reviewer, and Dr Katherine Tucker provided oversight as a third reviewer. Chapters two and three have been submitted to journals for publication (59) (60), I am the lead author on both papers. The Primary Care Research Trust also provided funds for the completion of this DPhil project.

1.12 Publication of Results

Chapters 2 and 3 of this thesis are under review for publication and, as such, sections of the methods, results, and discussions are reproduced (60) (59).

1.13 Overview of thesis structure



Chapter 2 : Is self-management a burden? The self-management of chronic conditions during pregnancy: a systematic review

2.1 Overview

This chapter reports a systematic review of the self-management of chronic conditions in pregnancy, exploring the qualitative literature to elucidate lived experiences. As previously stated in chapter 1, the knowledge base for self-management in pregnancy predominantly stems from diabetes management and the general population. This chapter aimed to explore how the self-management of other chronic conditions in pregnancy can shed light on the self-management of pregnancy hypertension, particularly through the lens of qualitative research. This chapter, in paper form, has been accepted for publication by the BMJ Open, subject to minor revisions (see Chapter 1, Section 1.12).

2.2 Objectives

This review aimed to understand the literature concerning the lived experiences of those who have self-managed during pregnancy, and subsequently focused on qualitative research in this area. While self-management has been explored in various chronic conditions in the general population (24, 26, 28, 61, 62) (see Chapter 1, Section 1.6), there has been little qualitative research on self-management in the pregnant population. This review explored the research to date and examined how self-management in pregnancy differs to self-management in the general population.

The research question for this review was:

What are the current behaviours and attitudes among pregnant people regarding the self-management and self-monitoring of chronic conditions in pregnancy?

2.3 Methods

2.3.1 Critical Interpretive Synthesis

This review was influenced by the critical interpretative synthesis (CIS) approach (63). A CIS approach leaves more space for interpretation than a conventional systematic review (63), and in theory using this approach allows this review the room to consider lived experiences across a range of chronic conditions. This approach was chosen over other approaches (for example, a narrative synthesis) because a CIS approach integrates evidence from across different studies into one theoretical framework (63). In this review, this approach allowed the space to engage with, and critique elements of, the Burden of Treatment theory in the context of pregnancy.

Dixon-Woods asserts that a CIS approach "*recognises the need for flexibility in the conduct of a review*" (63), particularly regarding the research question and the search itself. Dixon-Woods notes that a "*conventional systematic review methodology emphasises the need for review questions to be precisely formulated*" (63) and for some research this can be restrictive. As this review progressed the lack of research on the self-management of chronic conditions in pregnancy became apparent and the parameters of the review had to be adapted accordingly. As Dixon-Woods describes, in a CIS approach this does not mean research questions are absent in the initial stage of the review but that they are "*tentative, fuzzy and contested at the outset of the project*" (63). The question for this review was, therefore, iteratively developed alongside the inclusion criteria as the search progressed. In light of initial evidence searches, it was necessary to limit the scope of the review. In practice, this meant the research question was initially broadly defined as examining the

literature on the experiences of self-management in pregnancy, but was then further refined to looking specifically at 'behaviours and attitudes' and a broader range of self-management activities (self-weighing, diet management etc.).

2.3.2 Prospective registration and reporting

A protocol with research questions, inclusion criteria, approaches to measuring study quality, and data synthesis was developed and registered in PROSPERO: International Prospective Register of Systematic Reviews (Prospero no. CRD42019136681, Appendix 1.1). Due to the iterative nature of the research question and search, the review was registered after the conclusion of the search, but prior to any data extraction. The guidelines for the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement were followed (Appendix 1.2) (64).

2.3.3 Data sources and searches

Searches were performed in PubMed (which includes MEDLINE) and Cumulative Index to Nursing and Allied Health Literature (CINAHL) [EBSCOHost] (1982-present) from inception to February 2021 (Appendix 1.3). Reference lists were hand searched for further studies to include.

2.3.4 Inclusion criteria

Potentially eligible studies were screened by two independent reviewers against the following inclusion criteria:

1. Chronic condition: including but not exclusively diabetes (gestational or chronic), hypertension (gestational or chronic), obesity, kidney disease.
2. Pregnancy.
3. Self-management: including but not exclusively self-monitoring, self-weighing, self-care.

4. Qualitative methods.

No date or language restrictions were imposed but only human studies were considered. This review limited its search to qualitative studies, as it was felt qualitative methods were best placed to explore the lived experiences of self-management during pregnancy. Papers were only included if commonly recognised qualitative methods were used, i.e. interviews, focus groups, or ethnographic observations.

CIS also influenced the search strategy; the search criteria was retrospectively expanded to include risk factors for chronic conditions in order to capture as much data as possible, and in response to acknowledging the scarcity of data in this field. This was also reflected in the definition of self-management used which was as follows: "*the ability of an individual, in conjunction with family, community and health care professionals, to manage symptoms, treatments and lifestyle changes*" (4) (see Chapter 1, Section 1.3.2). A broad definition meant that a wider range of patient experiences could be included in the review, including those who were managing the risk factors for a chronic condition. While this review maintains some of the formalities of a conventional systematic review search (described by Dixon-Woods as "*explicit searching strategies*" that are reproducible), the iterative nature of the inclusion criteria and self-management definition lent itself to a more interpretive approach.

2.3.5 Study selection

The primary author and the second reviewer independently reviewed the titles and abstracts of identified articles and a full text assessment of the relevant papers by both reviewers followed. The reference lists of included studies were screened but no further articles were found. Disagreements on articles were resolved by consensus or discussion with a third reviewer (see Chapter 1, Section 1.11).

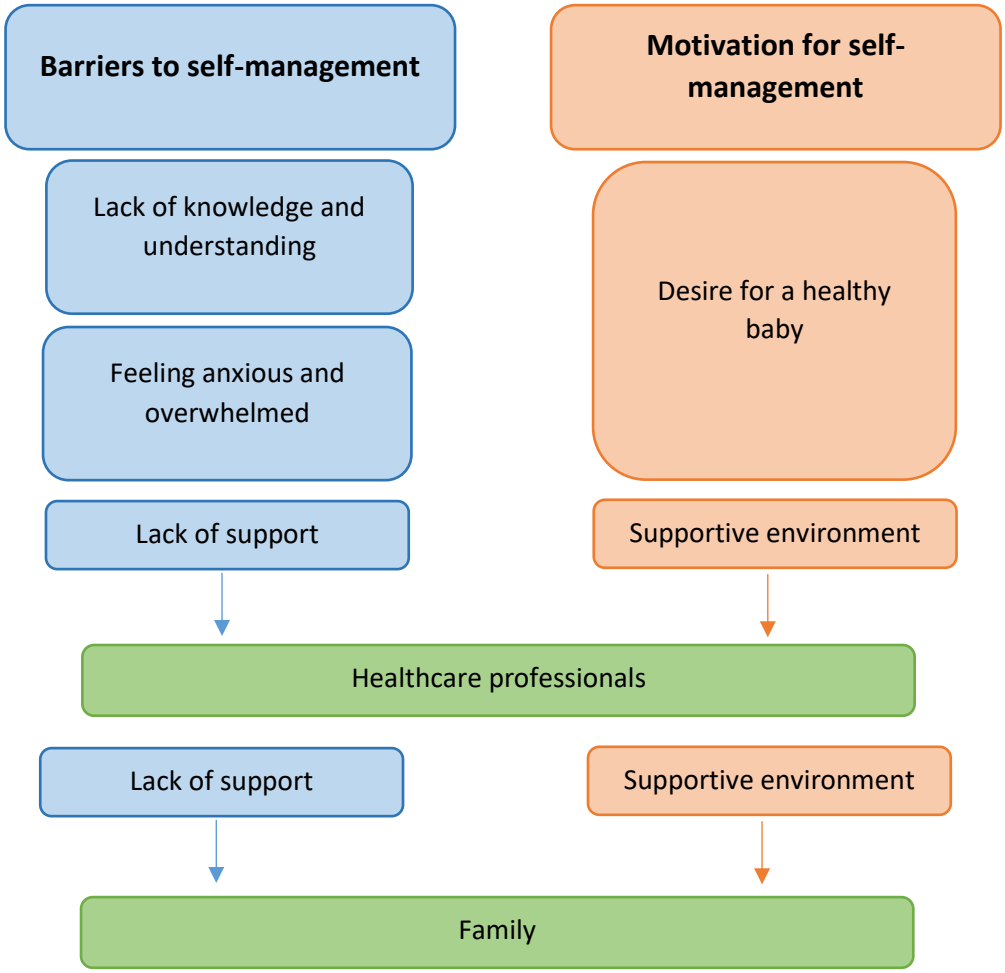
2.3.6 Data extraction and quality synthesis

As Dixon-Woods et al discuss, in qualitative research "*no hierarchy of study designs exist*", thus making a quality synthesis challenging (63). While there are some guidelines and checklists for qualitative research, such as the Consolidated Criteria for Reporting Qualitative Research (COREQ) (65), this review had a low threshold for inclusion based on quality. Influenced by the critical interpretive synthesis method, only papers "*deemed fatally flawed*" were excluded (63). A full quality review was conducted using the COREQ guidelines (Appendix 1.4). Data extraction was conducted by the primary author and checked by the supervisory team.

2.4 Data analysis

Analysis began with a detailed examination of the included papers, identifying themes and developing an understanding of the material. Dixon-Woods et al emphasise what distinguishes a systematic review using a CIS approach is *"the aim of being critical*" and questioning "*taken-for-granted-assumptions*" (63) meaning that the coding framework for this review was developed to critique the idea that general population self-management research was applicable to pregnancy. During the initial analysis, the Burden of Treatment theory, developed for chronic condition management in the general population, was identified as having the most synergy with the included literature (see 2.4.1 below). The coding framework was therefore revised to consider this theory's key concepts, such as the effect of patient work on self-management efficacy and the role of support networks, allowing for a more nuanced interpretation of the patient's experience of self-management. Data extraction was conducted using NVivo 12 Pro (QSR International Pty Ltd, released 2018), and a coding framework was developed and agreed upon by after consultation with the supervisory team and co-authors of the manuscript prepared for journal submission (Figure 1) (59).

Figure 1: Coding framework for the systematic review



2.4.1 The Burden of Treatment theory

May et al developed a theory (described in Chapter 1, Section 1.8.4), explaining the relationship between sick people and their healthcare providers in the context of chronic disease (47). In the absence of a possible cure for chronic health conditions, patients must engage in 'routine work' to manage the conditions. In the context of most chronic disease management, self-management is the 'work' patients and those in their support networks take up. May et al describe patient work as "*symptom monitoring, treatment management, and lifestyle changes*" while "*maintaining [these tasks] alongside the demands of other aspects of everyday life*" (47). May et al discuss the idea of "*re-engineered patient-hood*" in chronic condition management; he refers to self-management as "'*proactive patient-hood*'", describing healthcare services as seeking to hold patients and their supporters as accountable for self-management.

In chapter 1, this theory was explained in relation to how it critiques elements of self-management. Patient work is framed in a negative light; May et al suggest that patients are overwhelmed by self-management and speculates on the possibility of poorer health outcomes in these patients (47). This review considers whether this framing holds true in the pregnant population, which constitutes more than just the individual patient, and instead accounts for both the pregnant person and the baby dyad. The theory itself is orientated towards understanding the adherence of self-management in different healthcare settings and contexts, hence it is prudent to consider it in the context of antenatal care. Transferring the burden of treatment to the patient prompts a change in the patient-clinician relationship. Within pregnancy this could theoretically provide pregnant people with more agency, as well as more responsibility. Considering the debate around the medicalisation of pregnancy (described in Chapter 1, Section 1.9.1) it is also worth considering how self-management could change the nature of surveillance that has traditionally been the

responsibility of the clinician, and how transferring that particular burden of treatment could reduce some of the medicalisation, and paternalism, in antenatal care.

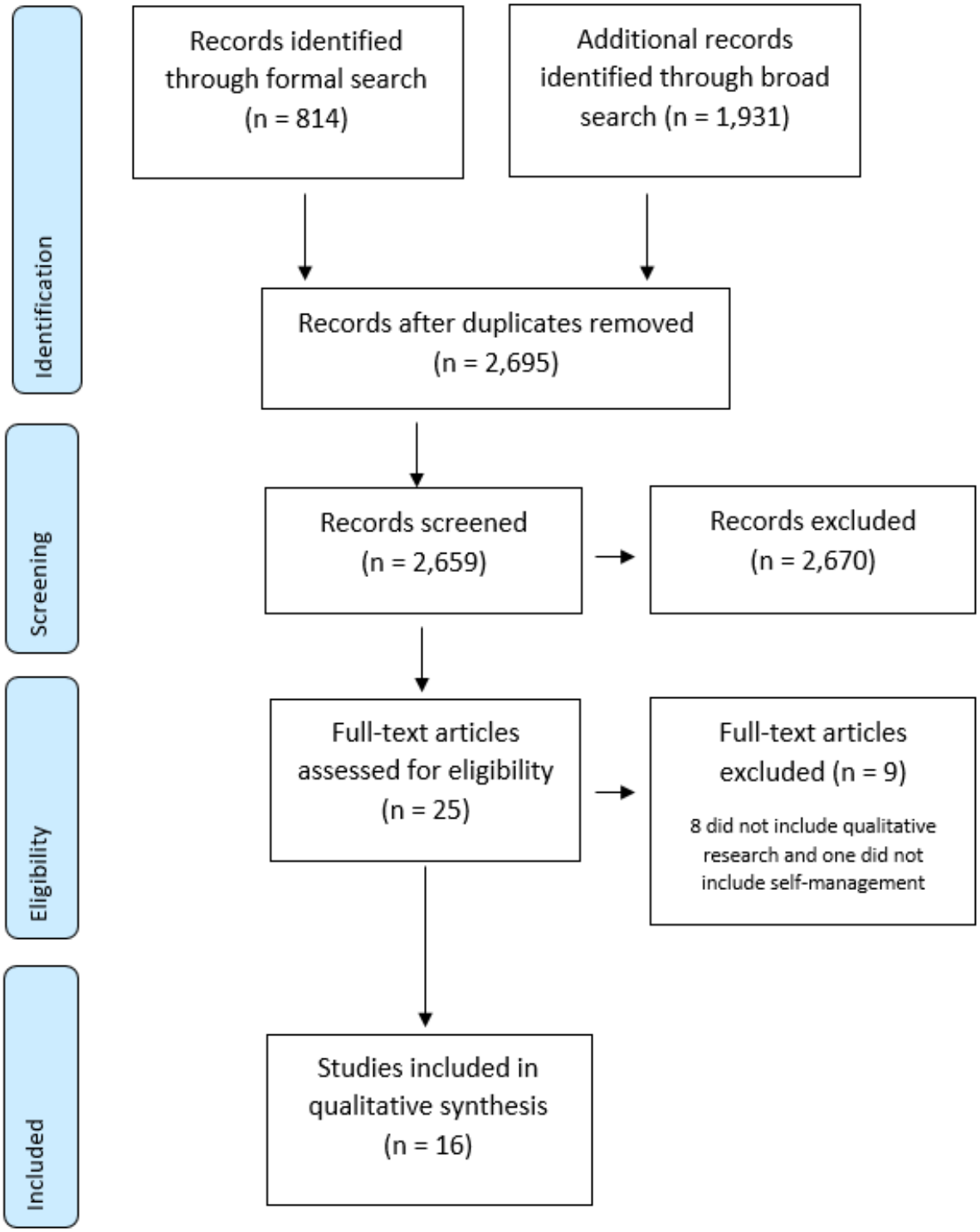
The first interpretation of the data, reviewing the themes that already existed in the included papers, revealed the synergy with the Burden of Treatment theory; therefore, the coding framework was iteratively mapped to two broad themes reflecting elements of the burden of treatment. These themes were grouped around motivations for self-management and barriers to self-management. As the coding progressed, additional elements of the theory were incorporated into the analysis. One element of the theory is "*the structure and performance of patient work*" a process that May et al call "*sense making*" where "*people and members of their social networks are expected to identify, understand and explain the diverse tasks that make up their work*" (47). This idea was reflected in the themes concerning support from health care professionals and family, the impact of a lack of support, and patient's anxiety and understanding of their diagnosis.

2.5 Results

2.5.1 Search results

Searches identified 2,695 unique articles for screening (Figure 2, Appendix 1.3). 25 articles were identified for full text review (Appendix 1.4), of which 16 fulfilled the inclusion criteria (Table 2). Of the articles excluded at the full text review, one did not include self-management activities and the remaining eight were not qualitative research. Data quality checks using the COREQ guidelines were carried out (Appendix 1.5) and revealed that 15 of the included studies were of medium to high quality and one was considered low quality because of small sample size.

Figure 2: PRISMA flow diagram



2.5.2 Characteristics of included studies

Included studies were published between 2011 and 2020. All focused on diabetes in pregnancy (Table 2), leading to the results focusing on the challenges of self-management in this disease. Six were conducted in the United States, four in Australia, and the remaining studies were carried out in Canada, Spain, Thailand, China, Singapore and New Zealand. The studies recruited from a range of settings: gestational diabetes clinics, antenatal clinics supporting low-income pregnant people, health care provider's offices, day care centres, and hospital based obstetric clinics. Fifteen papers used one-to-one interviews and one used focus groups for primary data collection. Two studies supplemented the interviews with focus groups, one supplemented with additional diary entries. One study was a mixed methods study, including one-to-one interviews alongside survey data. The study population in each case was pregnant people, although one had a mixed population of those who were currently pregnant, those planning on getting pregnant, and those who had previously been pregnant.

Table 2: Characteristics of included studies

Title	Year	Authors	Chronic Condition	Journal	Sample Size	Setting	Qualitative Method
Living with gestational diabetes in a rural community	2014	Abraham, K. Wilk, N.	Diabetes	The American Journal of Maternal and Child Nursing	10	USA	One on one interviews
Women's experiences of gestational diabetes self-management: A qualitative study	2013	Carolan, M.	Diabetes	Midwifery	15	Australia Diabetes clinic	One on one interviews, focus group
Women's experiences of factors that facilitate or inhibit gestational diabetes self-management	2012	Carolan, M. Gill, G. Steele, C.	Diabetes	BMC Pregnancy and Childbirth	15	Australia Diabetes clinic	One on one interviews, focus group
Experiences, perceptions and self-management of gestational diabetes in a group of overweight multiparous women	2014	Chavez-Courtois, M. Graham, C. Romeo-Perez, I. Sanchez-Miranda, G. Sanchez-Jimenez, B. Perichart-Perera, O.	Diabetes	Cien Saude Colet	5	Spain	One on one interviews
'Is gestational diabetes a severe illness?' exploring beliefs and self-care among women with gestational diabetes living in a rural area of the south east of China	2016	Ge, L. Wikby, K. Rask, M.	Diabetes	Australian Journal of Rural Health	17	China Obstetric clinics, wards	One on one interviews
The maternal experience of having diabetes in pregnancy	2011	Nolan, J. McCrone, S. Ilana, R. Chertok, A.	Diabetes	Journal of the American Academy of Nurse Practitioners	8	USA	Focus groups
Self-monitoring lifestyle behaviour in overweight and obese pregnant women: qualitative findings	2018	Sheih, C. Draucker, C.B	Overweight/ obese	Journal of Clinical Nursing	13	USA Clinics (community health centre and health network)	One on one interviews
Socio-cultural aspects of self-management in gestational diabetes	2012	Wazqar, D. Evans, M.	Diabetes	Diabetes Nursing	12	Canada	Secondary analysis of one on one interviews
'I was tired of all the sticking and poking': Identifying barriers to diabetes self-care among low-income pregnant women	2015	Yee, L. McGuire, J. Taylor, S. Niznik, C. Simon, A.	Diabetes	Journal of Healthcare for the Poor and Underserved	10	USA Clinic	One on one interviews
Factors promoting diabetes self-care among low-income, minority pregnant women	2016	Yee, L. McGuire, J. Taylor, S. Niznik, C. Simon, A.	Diabetes	Journal of Perinatology	10	USA Diabetes clinic	One on one interviews
Lived experience of blood glucose self-monitoring among pregnant women with gestational diabetes mellitus: a phenomenological research	2017	Youngwanichsetha, S. Phumdoung, S.	Diabetes	Journal of Clinical Nursing	30	Thailand Antenatal clinic, diabetes clinic, obstetric ward	One on one interviews
Self-management of gestational diabetes among Chinese migrants: A qualitative study	2018	Wah, Y. McGill, M. Wong, J. Ross, G. Harding, AJ. Krassa, I.	Diabetes	Women and Birth	18	Australia Antenatal clinic	One on one interviews
Ethnic Differences in Dietary Management of Gestational Diabetes Mellitus: A Mixed Methods Study Comparing Ethnic Chinese Immigrants and Australian Women	2019	Wan, C. Teede, H. Nankervis, A. Aroni, R.	Diabetes	Journal of the Academy of Nutrition and Dietetics	83	Australia Maternity services, tertiary hospitals	One on one interviews and diary entries
The experience of gestational diabetes for indigenous Māori women living in rural New Zealand: qualitative research informing the development of decolonising interventions	2018	Reid, J. Anderson, A. Cormack, D. Reid, P. Harwood, M.	Diabetes	BMC Pregnancy and Childbirth	10	New Zealand Primary care clinic	One on one interviews
"Diabetes Just Tends to Take Over Everything": Experiences of Support and Barriers to Diabetes Management for Pregnancy in Women With Type 1 Diabetes	2019	Singh, H. Ingersoll, K. Gonder-Frederick, L. Ritterband, L.	Diabetes	Diabetes Spectrum	15	USA Diabetes clinic	One on one interviews
Barriers to Gestational Diabetes Management and Preferred Interventions for Women With Gestational Diabetes in Singapore: Mixed Methods Study	2020	Hewage, S. Audimulam, J. Sullivan, E. Chi, C. Yew, T. W. Yoong, J.	Diabetes	JMIR Formative Research	15	Singapore Gestational Diabetes clinic	One on one interviews, in a mixed methods study also including a survey

The two broad themes that emerged from the data were motivations for and, conversely, barriers to self-management (Table 3). Under the former, pregnant people reported that having a healthy baby, supportive families, and supportive health care professionals were their primary motivating factors. Barriers to self-management included a lack of knowledge and understanding of the condition leading to feelings of anxiety, as well as a lack of support from families and healthcare professionals. The following sections will address each sub-theme in detail.

2.5.3 Motivations for self-management

2.5.3.1 *Desire for a healthy baby*

The most significant motivating factor for self-management was the desire for a healthy baby. Pregnancy comes with specific concerns and anxieties and many felt anxious about the burden of self-management and the health of their baby. It was clear that many patients wanted to *"do the right thing by the baby"* (66), to ensure they had a healthy start in life. Some expressed fear about the potential to pass their ill health onto the baby. Most often, the initial response to their diagnosis was concern for the baby; "*oh my God…you know is the baby gonna be OK?"* (67). Some pregnant people expressed feelings of responsibility for their condition, and their desire to minimise the effect on their baby's health; *"I knew I had brought it on myself by being overweight*[5]*…I felt very responsible"* (66).

2.5.3.2 *Supportive environment: family*

When the familial support was positive, pregnant people were motivated to self-manage for reasons beyond the health of the baby: *"The biggest thing I can recommend is getting support. If you try to do it on your own, it's going to seem very confusing and tedious"* (68). When speaking about their partner one person said *"he was very supportive in helping me*

[5] Weight management is a self-management activity particularly relevant to gestational diabetes, although it is advisable in the management of other chronic conditions, like hypertension.

get over things" (69), due to their partner's support they were able to overcome their fear of blood glucose self-testing. Families and partners who got involved in the recommended lifestyle changes and self-management activities, such as following the same diet, was motivational for pregnant people and increased adherence to self-management.

2.5.3.3 *Supportive environment: healthcare professionals*

Similarly, a supportive and constructive relationship with health care professionals proved to be a strong motivator for self-management, often minimising feelings of anxiety and uncertainty. Healthcare professionals who provided self-management advice gave pregnant people more autonomy over their pregnancy, *"the diabetes educator is really friendly…she did a demo in front of me, how to inject yourself"* (69). Those who understood their condition better were able to make positive choices about their self-management; *"I would limit my foods in order to control my blood sugar"* (70).

2.5.4 Barriers to self-management

2.5.4.1 *Feeling anxious and overwhelmed*

In this dataset, pregnant people often described feelings of anxiety and were overwhelmed by the prospect of managing their new condition. They reported feelings of unhappiness or low mood while learning to self-manage, calling it "*frustrating*". Some found trying to follow self-management guidelines created lot of anxiety: *"It creates a lot of anxiety. Like I am hungry but I don't want to eat now because I don't know if I harm the baby. But I feel hungry and could not eat"* (71). While it was often a lack of information that made them feel anxious, there was some evidence that being given *"too much information (about gestational diabetes)"* (66) also made them feel overwhelmed. They were often negative about self-management when they perceived that it had not gone to plan: *"When I took the higher dose [of insulin], I felt defeated…this is crazy, I don't think my body is ever going to be perfect"* (67).

2.5.4.2 *Lack of knowledge and understanding*

A lack of knowledge and understanding often led to a lack of motivation to self-manage. Those who did not understand their condition often underestimated the seriousness of their diagnosis or heard anecdotally from friends and family that it was not *"a severe illness"* (72) thus preventing them from committing to self-management as they did not understand the benefits or the need to manage the condition. Contrastingly, others felt as though it was *"the end of the world"* (68) leading to them feeling too overwhelmed to self-manage effectively. Central to the lack of understanding was a perception of insufficient education from health care professionals; one participant said that they were given *"a list of food but no instructions"* meaning *"you really have to work it out for yourself"* (66).

2.5.4.3 *Lack of support: family*

This dataset reported traditional forms of support networks: families, friends, and their healthcare professionals. A key theme to emerge from the data was the negative effect of a lack of familial support, which made pregnant people feel isolated and alone. Without strong family support networks, they either stopped complying with self-management or lost the motivation to self-manage. Concerning dietary self-management, many reported their families being unwilling to follow the same dietary restrictions because *"you can't expect everybody to change everything"* (66), or failing to understand the importance of the dietary guidelines. Some expressed that adhering to the strict diabetes diet made them feel socially isolated.

2.5.4.4 *Lack of support: healthcare professionals*

A discordant relationship with healthcare professionals made pregnant people feel less motivated to self-manage*, "I love my OBGYN, but I feel they are always in a hurry. Like they don't have time to sit there and talk to you about what to do about it (GDM), but they are*

always in a hurry" (68). One described their healthcare professional's attitude as *"here, you take the ball, and you run with it" (73),* but found that when their family were not informed about their self-management needs it was difficult to stay on track. Those who wanted to self-manage reported either not being supported adequately by their healthcare professionals or subject to paternalistic responses: *"you have no idea what you're doing, I know best, here's what we're going to do"* (74). Some had difficulty accessing information and understanding the self-management tasks, particularly when there were language barriers: *"It's a bit difficult because my English isn't very good…I have always been asking for an interpreter, but I have never got one"* (75). There were also concerns ranging from a lack of information (*"they didn't tell me what's the side effects for the baby"* (66)) to accusations of patronising healthcare professionals who *"talked down to [me]"* and *"didn't trust me"* (68).

Table 3: Quotes relating to the systematic review thematic analysis

Theme	Quotes
Motivations for self-management	
Desire for healthy baby	*"I have a responsibility to care for my child…and to care for this baby inside of me…For me, I wasn't going to let anything get in the way…"* (76) *"You have me doing it for a reason and the main reason is to have a healthy baby so you have to kind of just keep on pushing through no matter how aggravating, annoying, irritated you get with it."* (67)
Supportive environment: family	*"If it's not because of my husband, I couldn't have made it this far, like he would remind me, sometimes when I want to eat something he would just remind me not to, and like when we go for shopping he would buy the healthy stuff."* (75) *"He (husband) he's fond of sweet. Now he eats, but not as much as before. He always – like, he try to control, as well...he won't eat it in front of me…'cause whenever he, like, have sweet or other things, I want to eat."* (66)
Supportive environment: HCP	*"The diabetes educator is really friendly...she explained things very like, in a very good way Yes, yes and – like, she did a demo in front of me, how to inject yourself. It was really scary first time. They told me everything."* (70) *"The first pregnancy I had a lady (educator) that was really excellent, very understanding, very approachable. She would listen to my concerns and we had a conversation rather than just a one-way flow of information. And so I had a very positive experience with her."* (66)

Theme	Quotes
Barriers to self-management	
Lack of knowledge and understanding	*"Actually, I didn't know anything about it...So, I...thought that if you were diabetic then you kind of get it. But then I didn't know something you can just develop during pregnancy as well. So, it was quite new to me."* (77) *"Well, they scared the crap out of me…50% mortality rate for the fetus"* (74)
Feeling anxious and overwhelmed	*"With the fourth pregnancy, I had sort of lost control. I was living in the garage with my three children [and husband]. I was huge and six-months [along in my pregnancy] when I was diagnosed with depression….I didn't want to do anything. I'd just wake up [and] went through the motions."* (78) *"Well, at first I was a little sad when they told me, as well as I was afraid to eat. The truth is, I was always afraid I did not even know what to eat, there comes a time when I said it will be fine, it will be wrong, as if I worried. As if at the beginning it was like that, no, no, no or nothing or not even see it like that almost, and not everything that had sugar."* (79)
Lack of support: family	*"I need to cook for my husband and I can't make him eat the same thing…I need to follow him because he needs energy for his work…and I can't avoid using sauce, you know how on the menu it says you need to avoid sauces and stuff, I can't do that, my husband wouldn't want to eat according to that."* (75) *"The other week I had a small bowl of pasta…my sugars were very high then. Because when I'm eating with my Mum...it's like you can't expect everybody to change everything."* (66)

Theme	Quotes
Lack of support: HCP	*"You are told that you have this and nobody spends time with you, it's kind of frustrating because you want to cry. You think that it's something you did wrong."* (68) *"According to my experience, what they (health professionals) discussed are all about the dietary habit of women here (in Australia), so if the suggestions could be more relevant to Chinese lifestyle, a lot of things that have been taught currently are not meaningful."* (71)

2.6 Discussion

This review has found that pregnant people with diabetes are predominantly motivated to undertake self-management during pregnancy for the health of their baby. Support networks are crucial in alleviating the burden that comes with managing a chronic condition, particularly a new one, such as gestational diabetes. When these networks are less effective patients may feel overwhelmed by the self-management, which is compounded by a lack of knowledge and understanding.

One of the most notable findings from this review was the lack of research dedicated to managing chronic conditions in pregnancy. Diabetes was the only condition represented in the literature, but with only 16 papers eligible for inclusion, the qualitative evidence base around managing gestational or chronic diabetes in pregnancy was still thin, particularly in the UK where no studies were identified. While the findings of this review are framed by the self-management challenges of diabetes, a number of generic activities are applicable across other chronic conditions. Self-management of diabetes includes self-testing (of blood glucose levels) and diet and exercise management, all of which are applicable more widely in pregnancy. However, it is clear there is a lack of specific research on other chronic conditions in pregnancy, such as hypertension. It is also worth noting that in the general population chronic conditions are self-managed due to the absence of a 'cure', but this is not strictly the case in pregnancy where conditions are temporarily bounded by the pregnancy; gestational diabetes and hypertension (or pre-eclampsia) can be resolved with delivery, and if they are not resolved, they are re-categorised as type 2 diabetes or hypertension (80) – thus, they are no longer conditions brought about by pregnancy.

This review has demonstrated that the factors motivating pregnant people to self-manage are different to those motivating the general population; none more so than the desire to

improve outcomes for the baby. To my knowledge, this is the first review to use the burden of treatment theory as a theoretical lens to explore experiences of chronic disease management in pregnancy. Although this theory does not fully account for the specific challenges of pregnancy, as demonstrated by this review, it still broadly accounts for the actors and work involved in self-management in this context. In particular, the importance placed on social networks in this theory is applicable to pregnancy. May et al assert that "*knowledge and beliefs about health and healthcare are often shared [within social networks]…decisions about what to do, and how to access services, are often distributed amongst multiple participants in a social process*" (47). In pregnancy, the sharing of lay knowledge and expertise is commonplace. Hinton et al demonstrated the nature of information sharing among pregnant people, often now in the form of online communities, in those with pregnancy hypertension or raised blood pressure (38). Pregnant people with hypertension valued the advice and support of their peers, and in the online space peer advice tended to trump the advice of medical professionals (38). Support networks are a central part of any self-management model in the general population, often emphasising that "*self-management is manifested as both an individual and family construct*" (81). As both a barrier and a facilitator of self-management, it is evident family support is an important factor in continued adherence. While current self-management models do not accommodate pregnancy entirely, this review demonstrates that elements of existing models, such as social networks and the need for education around diagnosis, are applicable.

May et al argue that the work of self-management in the general population is often done in the context of "*holding together something larger and more complex*" (47), alluding to everyday life. While this applies in pregnancy, the work of self-management is also done in the context of maintaining the health of the unborn baby. Previous literature has touched on

pregnant people acting "*not for the self but also for the unborn "other"*' (82) and the burden of pregnant people having to be accountable for the health of their baby alongside their own health cannot be underestimated. Lupton noted the growing discourse around "*the importance of pregnant [people] protecting the health of their fetuses*" (57). This review demonstrates that pregnant people see their baby as the primary reason to engage in self-surveillance and self-monitoring. This motivation should be considered alongside the growing societal expectation that they adhere to medical monitoring and risk-averse behaviour, again, for the benefit of the baby (57). As Lupton posits, in this new era of pregnancy defined "*in terms of risk…almost all the focus is upon the risks to the fetal body rather than to the pregnant body*" (57). In this review, pregnant people often vocalised a lack of understanding of their condition, but nonetheless were very concerned about the effects on their baby rather than themselves. Lupton discussed the idea that pregnant people "*are becoming very aware of the risk discourse*" and this causes anxiety which in turn leads to them seeking "*to contain and control risk as much as possible*" (83). In the aftermath of a diagnosis of a chronic condition, this review demonstrates that control is sought via self-management activities, but this presents its own challenges and anxieties. Current self-management models are not equipped to consider the additional burden of treatment of the unborn baby and behaviours associated with risk aversion in pregnancy.

The debate on medicalisation in pregnancy was introduced in chapter 1 (Section 1.9.1), and it was posited that although pregnancy is natural phase in a person's life, there is a requirement for monitoring and surveillance, particularly if the pregnancy is high risk. While some of the resistance to the medicalisation of childbirth focuses on the contested term 'natural birth' – the definition of which can range from a hospital birth sans painkillers to a birth with no medical intervention at all (84) – Clesse et al instead discuss the idea of the "*humanisation of birth*" which "*advocates a rebalancing of the role of medicine among*

[people] *in childbirth*" (85); in practice this means a focus on empowerment, openness to a diversity of beliefs and practices, and reasserting the role of the midwife (85). Self-management redistributes some of the surveillance and monitoring, traditionally carried out by physicians, rebalancing the role of medicine as Clesse et al discussed. How self-surveillance fits into the resistance to medicalisation remains to be seen, on the one hand it could empower patients, and on the other it has the potential to medicalise uncomplicated pregnancies.

2.7 Strengths and Limitations

The research question evolved throughout the search and the screening as it became apparent that little data on self-management in pregnancy existed, and none outside of diabetes management, therefore this review addresses a gap in the literature. Lived experiences are often over looked in the self-management literature, yet are important in understanding how individuals do or do not engage with self-management, and using qualitative literature has addressed some of these research gaps.

Limitations include that the coding framework was constrained by how the original researchers interpreted the interviews and their interactions with patients. Distinguishing between pre-existing chronic conditions and pregnancy acquired chronic conditions is important, but it was not a distinction that was reflected in the dataset; it was both a limitation of the included studies and this review. As previously discussed, the burden of treatment theory does not perfectly map to pregnancy, however elements of this theory are helpful in understanding how and why patients interact with self-management. Many of the included papers specifically considered barriers to self-management, as opposed to facilitators, thus potentially creating a negative bias towards self-management.

Included studies took place across a variety of international settings, operating within different health systems, ranging from those dominated by private insurance-based systems to those with national healthcare systems aimed at universal healthcare coverage. Individualised medicine is intertwined with self-management; six of the included studies took place in the United States, where they operate within an insurance-based system that lends itself to an individualised approach to medicine (86). With the exception of Canada, New Zealand, and Singapore, none of the other countries included in this review have health systems based on almost near universal health care coverage (87) (88) (89). A patient's relationship with their healthcare system also affects their relationship with the acceptability of self-management and their efficacy undertaking it. As none of the included studies were conducted in the UK, this review raises questions about how pregnancy self-management would operate within the NHS, which this thesis will try to address.

2.8 Conclusions

This review suggests there are several ways to improve adherence to self-management interventions in pregnancy. These interventions often involve self-monitoring and titrating medication. Health care professionals communicating the importance of self-management in terms that focus on the health of the baby, and educating their patients on the condition they have been diagnosed with, could have a positive impact on self-management adherence. Assessing the evidence base for self-management in pregnancy has provided a deeper understanding of the differences between self-management in the pregnant population and self-management in the general population. This review shows that the primary motivating factor for self-management in pregnancy is the health of the baby, a consideration that is beyond general population self-management models. However, there was also some synergy with existing self-management models, particularly regarding social

networks; as the review demonstrated, support networks and pregnant people's understanding of their condition contribute to whether they self-manage effectively.

The burden of treatment shifting to the patient in antenatal care requires further research: as patient work increases, feelings of anxiety can also increase. In this dataset, it was clear that some found this treatment shift to be overwhelming but their anxiety largely stemmed from a lack of knowledge and understanding of the condition with which they had been diagnosed. Evidently, education is a barrier to pregnant people effectively self-managing, as when these issues are addressed they are willing and able to self-manage.

This review should act as a wakeup call, more research is needed on the self-management of chronic conditions in pregnancy, particularly in conditions other than diabetes. This thesis will aim to contribute to the literature on the self-management of hypertension, as how self-management of other chronic conditions will fit into usual care remains to be seen.

Chapter 3 : Cross sectional diagnostic accuracy study of self-testing for proteinuria during hypertensive pregnancies: The UDIP study

3.1 Overview

This chapter reports the findings of a diagnostic accuracy study on self-testing for proteinuria in hypertensive pregnant people. Self-testing by pregnant people was compared to healthcare professional visual testing and an automated colorimetric reader, using laboratory protein:creatinine ratio (PCR) as the primary reference test, and albumin:creatinine ratio (ACR) as a secondary reference test.

3.2 Objectives

Chapter 1 of this thesis discussed the idea that self-management of hypertension in pregnancy is made up of three aspects of care: self-testing for proteinuria, blood pressure self-monitoring, and self-titrating blood pressure medication (Chapter 1, Section 1.3.2). To date, there has been very little data collected on self-testing for proteinuria, which would be an important part of a self-management regime in hypertensive pregnancies. Alongside blood pressure monitoring, dipstick proteinuria analysis is the most commonly performed antenatal screening test and is central to screening for pre-eclampsia (10). Research has previously been conducted on the accuracy of various methods of proteinuria assessment (see Chapter 1, Section 1.5.3.1) but these tests are often carried out by members of the research study team, midwives or other healthcare professionals.

The primary aim of the research reported in this chapter was to determine the accuracy of self-testing for proteinuria by hypertensive pregnant people compared to healthcare professionals and an automated reader. The research question for this was as follows:

1. Can pregnant people with hypertension accurately self-test for proteinuria compared to healthcare professionals and an automated colorimetric reader?

The secondary aim of this study was to establish the accuracy of visual testing by pregnant people, healthcare professionals and an automated colorimetric reader, compared to the laboratory reference standard, PCR. The research question for this was as follows:

2. Can pregnant people, healthcare professionals, and an automated colorimetric reader accurately test for proteinuria compared to a primary reference test (PCR)?

The tertiary aim of this study was to compare the accuracy of pregnant people, healthcare professionals, and an automated reader to a secondary reference standard (laboratory ACR). The research question for this was as follows:

3. Can pregnant people, healthcare professionals, and an automated reader accurately test for proteinuria, compared to a secondary reference standard (ACR)?

3.3 UDIP study development

The hypothesis underpinning this study was that pregnant people could self-test for the presence of proteinuria as accurately as a healthcare professional using the same visual dipstick test. Testing is currently carried out by midwives, maternity support workers or, sometimes, other healthcare professionals at routine antenatal visits (1). There has been relatively little research to date on self-testing for proteinuria in pregnancy (see Chapter 1, Section 1.7.1.2).

NICE and ISSHP recommend the use of an automated reagent strip device to screen for proteinuria, with quantitative confirmation of positive tests using a laboratory PCR or ACR (1) (see Chapter 1, Section 1.5.3). Previous studies in pregnancy have shown a superior test performance for an automated reader over dipstick tests (17-19, 90). However, some of these studies were not in hypertensive populations or they used 24-hour urine collection as the reference standard, which is less accurate than a laboratory PCR test and is no longer recommended as usual care (13). There is also evidence to suggest that the majority of healthcare professionals normally use a visually assessed dipstick for an initial assessment of proteinuria, rather than the recommended automated reader (15, 16). For these reasons an automated reader was included in the study as an index test, and a secondary aim of the study was to test its accuracy. In sum, examining the evidence on self-testing demonstrated there is a gap in the evidence regarding the accuracy of self-testing compared to healthcare professional testing, and there is a need for further research on the accuracy of automated readers.

3.3.1 Pilot study

The UDIP pilot study used synthetic urine samples, and demonstrated that pregnant people could test as accurately as healthcare professionals. This study also showed a higher sensitivity and specificity for dipsticks than previously reported (32) (Chapter 1, Section 1.7.1.2). A full diagnostic accuracy study of self-testing in a clinical setting was indicated to be feasible, and needed, research.

3.4 Trial set-up and management

3.4.1 Protocol

A protocol was developed for a diagnostic accuracy study to determine the accuracy of self-testing for the presence of proteinuria (Appendix 2.1).

Three index tests were specified:

Primary index test

- Pregnant people self-testing using a visually assessed dipstick

Secondary index tests

- Healthcare professional testing using a visually assessed dipstick
- Automated colorimetric reader

Two reference tests were specified:

- Laboratory PCR as the primary reference test
- Laboratory ACR as the secondary reference test

The study flowchart is shown in Figure 3.

3.4.2 Patient and public involvement

Public and patient (PPI) representatives were involved in the development of a funding proposal for this study, and were also reported back to throughout the study via the all investigators group and steering group for the wider programme of work.

3.4.3 Safety reporting

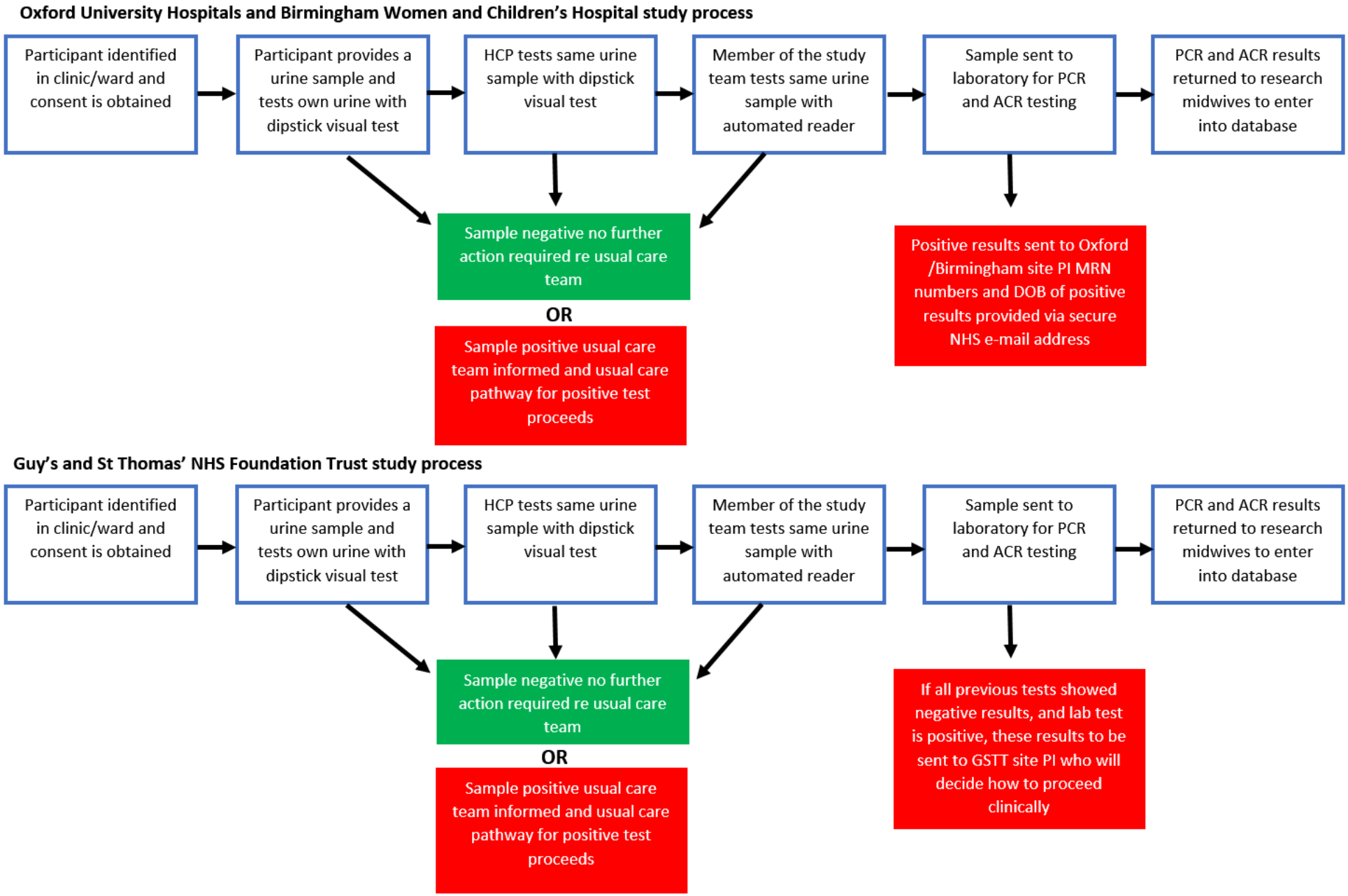
The urine testing that was part of the study took place outside of usual care. In order to ensure the safety of the participants, study flow charts were produced for each site in order to map the reporting of discordant results. The flow charts also outlined the process for sending the urine samples to the laboratory and the reporting of these results back to the

study team. These flow charts were agreed with the Principle Investigator (PI) at each site and were adapted to the individual needs of each site (Figure 3).

3.4.4 Staff training

Prior to the start of the study, recruitment midwives were shown how to use the automated reader provided for the study, this training was recorded on a delegation log for all staff who worked on the study.

Figure 3: Flow chart and safety reporting for the UDIP study



3.4.5 Study documents

3.4.5.1 *Participant Information Sheets*

A participant information sheet (PIS) was developed to provide participants with detailed information about the study if they expressed an interest in taking part. Advice was sought on the structure and content of this information sheet from the study sponsor (University of Oxford). The PIS's were updated midway through the study to reflect the new General Data Protection Regulation (GDPR) guidance, the study sponsor provided a template and appropriate wording to reflect the changes (Appendix 2.2).

3.4.5.2 *Informed consent form*

An informed consent form for both the main diagnostic accuracy study and the qualitative study was developed with advice from the study sponsor (Appendix 2.3). The consent forms were retained by the recruitment teams on site and stored securely.

3.4.5.3 *Case report forms*

A single case report form (CRF) captured the participant, healthcare professional, and automated reader results (Appendix 2.4). The form was secured in a locked filing cabinet at hospital sites. The data was then transferred to the study database by the recruitment team. Participants had the same study ID for their informed consent form and the CRF. No participants requested to be withdrawn from the study.

3.4.6 Study database

A database was designed using both Access and Excel, in order to suit the requirements for each site, and tested by the recruitment team prior to the study starting. The recruitment team, consisting mainly of research midwives, entered the information into the database from the participant's CRF forms and the laboratory results when they were received. The

database was shared with the trial managers periodically throughout the study in order to track the number of participant's testing positive.

3.4.7 Statistical analysis plan

A statistical analysis plan was prepared prior to the end of recruitment (Appendix 2.5) and signed off by the study team at the monthly trial management group (TMG) (see Section 3.4.9). The analysis plan was drafted by the author and the trial statistician. The analysis was carried out with support from the trial statistician.

3.4.8 Study sponsor

The study protocol, associated documents, funding letters, and CV's for the CI and PI's were submitted to the study sponsor (University of Oxford) and was approved in April 2018 (Appendix 2.6). The University of Oxford has a specialist insurance policy in place, which would operate in the event of any participants suffering harm as the result of their involvement in the research.

3.4.9 Trial management group

A TMG was established to provide supervision for the trial. The TMG was comprised of the CI, the PI's from Oxford University Hospitals and Guy's and St Thomas', the trial statistician, the trial manager, the lead research midwives from Oxford University Hospitals and Guy's and St Thomas', and members of the research team (Dr Lisa Hinton, Dr Katherine Tucker, Dr James Hodgkinson) (see details in Chapter 1, Section 1.11). The group met once a month for the duration of the trial and for six months following the end of the trial for analysis purposes.

3.4.10 Research ethics committee approval

The study was approved by the Yorkshire and the Humber Leeds East Research Ethics Committee (REC) (Reference: 18/YH/0208) and the HRA (Health Research Authority) on the 21st May 2018 (Appendix 2.7).

3.4.11 Substantial amendment

A substantial amendment was submitted on the 25th June 2018, before recruitment commenced, and was approved on the 20th August 2018 (Appendix 2.8) by the REC. In this amendment, the index tests for the study were clarified to include a visual test from a healthcare professional.

3.4.12 Minor amendments

3.4.12.1 *Minor amendment 1*

A non-substantial amendment was submitted on the 21st January 2019 to add Birmingham Women and Children's Hospital as an additional site, this was approved on the 28th January 2019 by the sponsor and the HRA on the 21st February 2019 (Appendix 2.9).

3.4.12.2 *Minor amendment 2*

A second non-substantial amendment was submitted on the 9th April 2019 to change the site PI for Birmingham Women and Children's Hospital, this was approved by the sponsor on the 10th April 2019 and the HRA on the 11th April 2019 (Appendix 2.10).

3.4.12.3 *Minor amendment 3*

A third non-substantial amendment was submitted on the 15th April 2020 to extend the study until the end of the year due to the COVID-19 pandemic, this was approved on the 16th April 2020 and did not require HRA approval (Appendix 2.11).

3.4.13 CPMS registration

The study was registered for NIHR Portfolio adoption in the IRAS form. It was accepted for adoption to the NIHR portfolio on 30th August 2018. Monthly recruitment figures were uploaded to the Central Portfolio Management System (CPMS) by sites.

3.5 The UDIP study

3.5.1 Methods

3.5.1.1 *Participants*

Pregnant people aged 18 to 50 years with a diagnosis of gestational or chronic hypertension or pre-eclampsia (defined by criteria set out by the International Society for Study of Hypertension in Pregnancy (2)) and ≥20 weeks' gestation were recruited to the study at three hospital sites (Oxford University Hospitals, Guy's and St Thomas' Hospital, Birmingham Women and Children's Hospital). Participants were recruited at ≥20 weeks' gestation because pre-eclampsia is a condition that usually affects pregnant people during the second half of their pregnancy, from approximately 20 weeks (3) (1).

3.5.1.2 *STARD guidelines for diagnostic accuracy studies*

The study followed the Standards for Reporting of Diagnostic Accuracy Study (STARD) 2015 guidelines for reporting diagnostic accuracy studies, which influenced the study design, the statistical analysis plan, and the reporting (Figure 5 and Appendix 2.12).

3.5.1.3 *Procedure*

Participants were recruited from a variety of settings within hospitals, including pregnancy hypertension and renal clinics, maternity assessment units, and inpatient wards. Pregnant people interested in taking part were provided with information about the study prior to written informed consent. Participants were provided with simple instructions for protein testing (Appendix 2.4), a urine sample pot with a funnel, and dipstick tests (ALBUSTIX

reagent strips, SIEMENS, Surrey UK) and undertook sample testing in the clinic or at the bedside on the same day they were recruited. Participants were asked to record their urinary proteinuria result on a CRF. Healthcare professionals, masked to the participant's result, re-tested the same urine sample using the same dipstick method. The same urine sample was then further tested using a dipstick test (URISTIX reagent strips, SIEMENS, Surrey, UK) in an automated colorimetric reader (Clinitek Status + Analyser, SIEMENS, Surrey, UK) by a member of the study team before being sent to the laboratory for PCR and ACR testing by a member of the laboratory team who were masked to other results. There was no concern over sample degradation as urine samples were stored in line with current guidance and tested expediently (91).

3.5.2 Study outcomes

The performance of dipstick tests were compared to laboratory PCR (primary reference test) and laboratory ACR (secondary index test). The primary index test was the dipstick result as read by the study participant, but secondary index tests were also considered: a healthcare professional visual read and an automated reader. Following STARD guidelines (92), performance measures were sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios.

Index tests were categorised as negative, trace, 1+, 2+, 3+, 4+, except when using the automated reader which used categories negative, trace, 1+, 2+ and 3+. Categories ≥1+ were considered index test positive and categories 'negative' and 'trace' were considered index test negative (1, 93). Laboratory PCR test values of ≥30 mg/mmol and laboratory ACR test values of ≥8 mg/mmol were considered reference test-positive, following recommendations from the NICE guidelines (93) (see Chapter 1, Section 1.5.3).

3.5.3 Power calculation

It was anticipated that the index tests could have 80% to 90% sensitivity with respect to the primary index test, based on previous research (32), and that at least 100 complete cases of laboratory-confirmed proteinuria would be required to estimate a sensitivity in this range with a standard error of no greater than 4%. To ensure sufficient cases, allowing for possible missing data, the case rate was monitored during recruitment and was stopped when 110 cases with laboratory-confirmed proteinuria had been recorded.

3.5.3.1 *Recruitment plan*

Participants were recruited until at least 110 proteinuria positive patients (confirmed by the laboratory PCR test) were known to have taken part across the three NHS sites.

3.5.4 Statistical analysis

Data were analysed using STATA-14. Descriptive statistics were reported for baseline characteristics. The sensitivity, specificity, PPV, and NPV of the index tests were calculated against the primary reference test (PCR) and the secondary reference test (ACR) using the thresholds described above (Section 3.5.2). Results for all dipstick thresholds (negative, trace, 1+, 2+, 3+, 4+) were shown on Receiver Operating Characteristic (ROC) graphs. Likelihood ratios were calculated for all index tests. Samples missing index test or primary reference test data were excluded from the study.

3.5.5 Results

3.5.5.1 *Recruitment progress*

Recruitment is detailed in Figure 4 and Table 4. The study lasted for 19 months. The recruitment rates divided by site are detailed in Table 4.

Figure 4: Recruitment progress for the UDIP Study

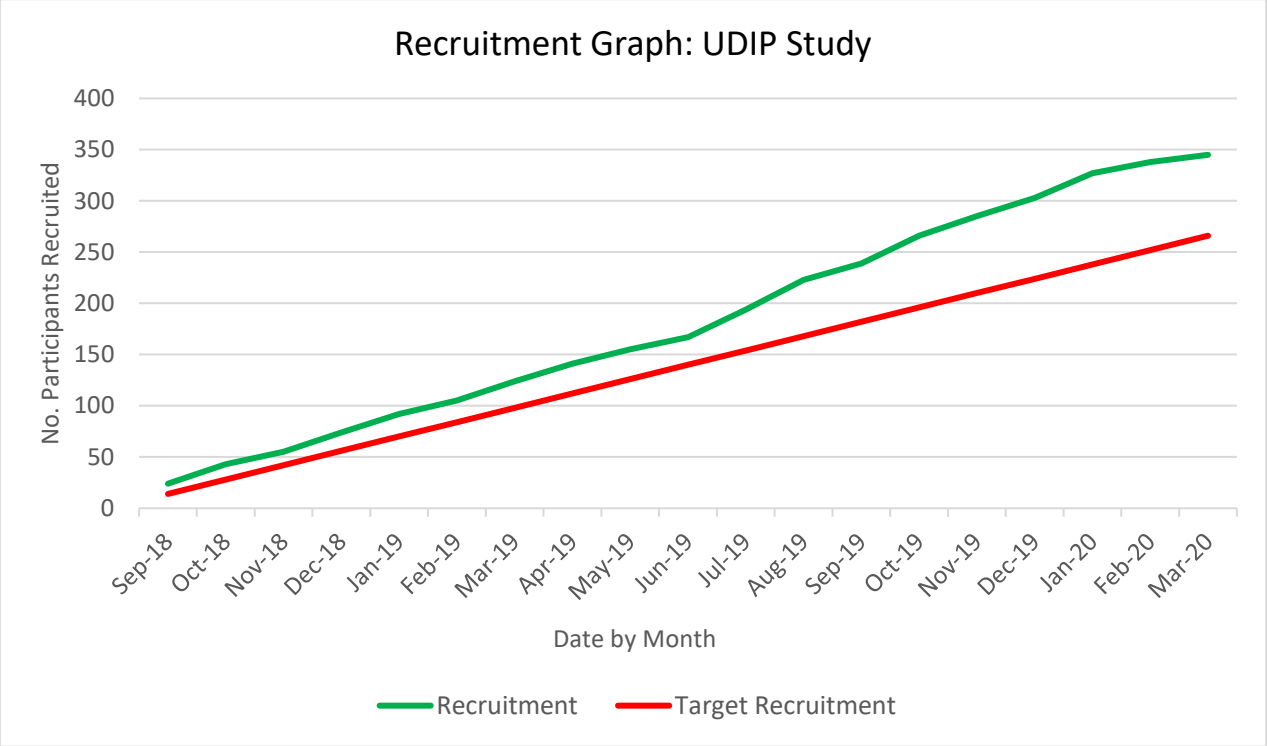


Table 4: Recruitment breakdown by site

Site	Participants Recruited
Guy's and St Thomas' NHS Foundation Trust	155
Oxford University NHS Foundation Trust (John Radcliffe Hospital)	174
Birmingham Women and Children's Hospital	16

3.5.5.2 *Protocol deviations*

One protocol deviation was recorded for this study. A participant was recruited above the specified maternal age range (recruited at 52 years old). This deviation was recorded as a study note (Appendix 2.13). 12 participants were found, at the analysis stage, to have been recruited below the gestational age specified in the inclusion criteria. The study team decided to include all these participants in the study as part of an "intention-to-treat" principle (see main results for further details).

3.5.5.3 *Main results*

A total of 345 pregnant people completed the study (Figure 5). One exclusion was made due to a missing healthcare professional visual read result and nine exclusions were made due to unavailable laboratory PCR results leaving 335 (97%) complete cases for the primary analysis. Eleven participants were missing only ACR results but were included in the primary analysis. Thirteen (4%) participants were recruited but subsequently found not to meet the inclusion criteria: one was above the maternal age range and twelve were recruited below the gestational age specified in the inclusion criteria (at 12-19 weeks' gestation). All thirteen were included in the analysis using an 'intention-to-treat' principle as it was considered that these protocol deviations were unlikely to bias the study.

Participating pregnant people had a median age of 33 years (IQR 29 - 37), with a median gestational age at recruitment of 34 weeks (IQR 27 - 36). The majority of people were in their first ongoing pregnancy (52%) and 118 (35%) tested positive for proteinuria by the reference standard (PCR) of ≥30 mg/mmol (Table 5).

Table 5: Demographic data for UDIP participants

Demographics of study population (n=335)		
	Median	**IQR**
Age	33	29 - 37
Gestational age at recruitment in weeks	34	27 - 36
	Frequency	**Percentage %**
Ethnicity		
Asian or Asian British	34	10.2
Black or Black British	56	16.7
Mixed	12	3.6
White British	175	54.3
Other	58	15.2
First pregnancy	173	51.6
Prevalence of proteinuria	118	35.0

Participants' self-testing had a sensitivity of 0.71 [95% CI 0.62 - 0.79] and a specificity of 0.89 [95% CI 0.84 – 0.92] compared to the primary reference test of PCR. The sensitivity of healthcare professionals and the automated reader respectively were 0.73 [95% CI 0.64 – 0.80] and 0.78 [95% CI 0.69 – 0.85] with a specificity of 0.88 [95% CI 0.82 – 0.92] and 0.83 [95% CI 0.78 – 0.88], again compared to the primary reference test (Table 6).

The analysis was repeated for the secondary reference test, ACR. Participants self-testing had a sensitivity of 0.68 [95% CI 0.59 – 0.79) and a specificity of 0.88 [95% CI 0.83 – 0.92] compared to the secondary reference test, ACR. The sensitivity of healthcare professionals and the automated reader respectively were 0.71 [95% CI 0.62 – 0.79] and 0.75 [95% CI 0.66 – 0.82], with a specificity of 0.88 [95% CI 0.83 – 0.92] and 0.83 [95% CI 0.77 – 0.88] when compared to the secondary reference test, ACR (Table 6).

In a sensitivity analysis which excluded the 13 participants recruited in error, similar results were obtained (Appendix 2.14).

Participants had a false negative rate of 0.29, with 22 of 34 having a laboratory PCR in the range of 30-50 mg/mmol. Healthcare professional testing and the automated reader had a false negative rate of 0.27 and 0.22 respectively, with 21 of 32 false negatives and 17 of 26 false negatives in the 30-50 mg/mmol range for PCR respectively. The false positive rate was 0.11, 0.12, and 0.17 respectively (Table 6).

Against the secondary reference test, ACR, participants had a false negative rate of 0.32. Healthcare professionals and the automated reader had a false negative rate of 0.29 and 0.25 respectively. The false positive rate was 0.12, 0.12, and 0.17 respectively (Table 6).

Test performance of the index tests compared to both primary and secondary reference tests is shown in a receiver-operator characteristic (ROC) plot (Figure 6, 7). The ROC curves

demonstrate comparable sensitivity across the index tests at multiple cut offs (negative, trace, 1+, 2+, 3+, 4+).

Figure 5: Diagnostic accuracy study flow diagram based on the STARD guidelines

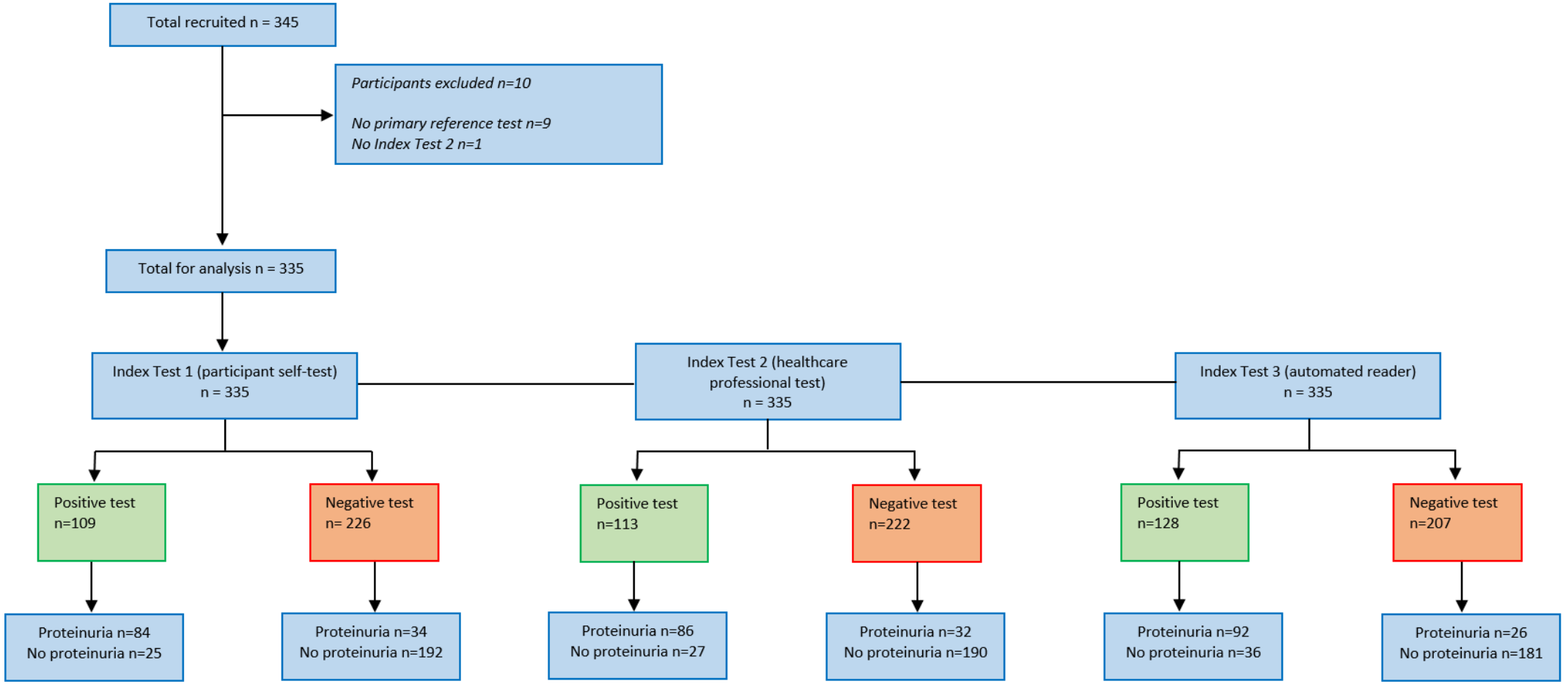


Table 6: Test performance for primary and secondary index tests against the primary and secondary reference standards

Threshold 1+ PCR (protein:creatinine ratio)	Participants (Albustix) n=335	Healthcare professionals (Albustix) n=335	Automated Reader (Clinitek Status + Analyser, URISTIX) n=335
Sensitivity **n/N**	0.71 (0.62 - 0.79) 84/118	0.73 (0.64 – 0.81) 86/118	0.78 (0.69 – 0.85) 92/118
Specificity **n/N**	0.89 (0.84 – 0.92) 192/217	0.88 (0.82 – 0.92) 190/217	0.83 (0.78 – 0.88) 181/217
Positive predictive value **n/N**	0.77 (0.68 – 0.85) 84/109	0.76 (0.67 – 0.84) 86/113	0.72 (0.63 – 0.80) 92/128
Negative predictive value **n/N**	0.85 (80.0 – 0.90) 192/226	0.86 (0.80 – 0.90) 190/222	0.87 (0.82 – 0.92) 181/207
Positive likelihood ratio	6.2	5.9	4.7
Negative likelihood ratio	0.3	0.3	0.3
False positive rate	0.11 24/217	0.12 26/217	0.17 35/217
False negative rate	0.29 34/118	0.27 32/118	0.22 26/118
*Threshold 1+ ACR (albumin:creatinine ratio)**	Participants (Albustix) n=335	Healthcare professionals (Albustix) n=335	Automated Reader (Clinitek Status + Analyser, URISTIX) n=335
Sensitivity **n/N**	0.68 (0.59 – 0.79) 83/122	0.71 (0.62 – 0.79) 87/122	0.75 (0.66 – 0.82) 91/122
Specificity **n/N**	0.88 (0.83 – 0.92) 187/213	0.88 (0.83 – 0.92) 187/213	0.83 (0.77 – 0.88) 176/213
Positive predictive value **n/N**	0.76 (0.67 – 0.84) 83/109	0.77 (0.68 – 0.84) 87/113	0.71 (0.62 – 0.79) 91/128
Negative predictive value **n/N**	0.83 (0.77 – 0.87) 187/226	0.84 (0.79 – 0.89) 187/222	0.85 (0.79 – 0.90) 176/207
Positive likelihood ratio	5.6	5.8	4.3
Negative likelihood ratio	0.4	0.3	0.3
False positive rate	0.12 26/213	0.12 26/213	0.17 37/213
False negative rate	0.32 39/122	0.29 35/122	0.25 31/122

Figure 6: ROC plot of all index tests against the primary reference test, PCR

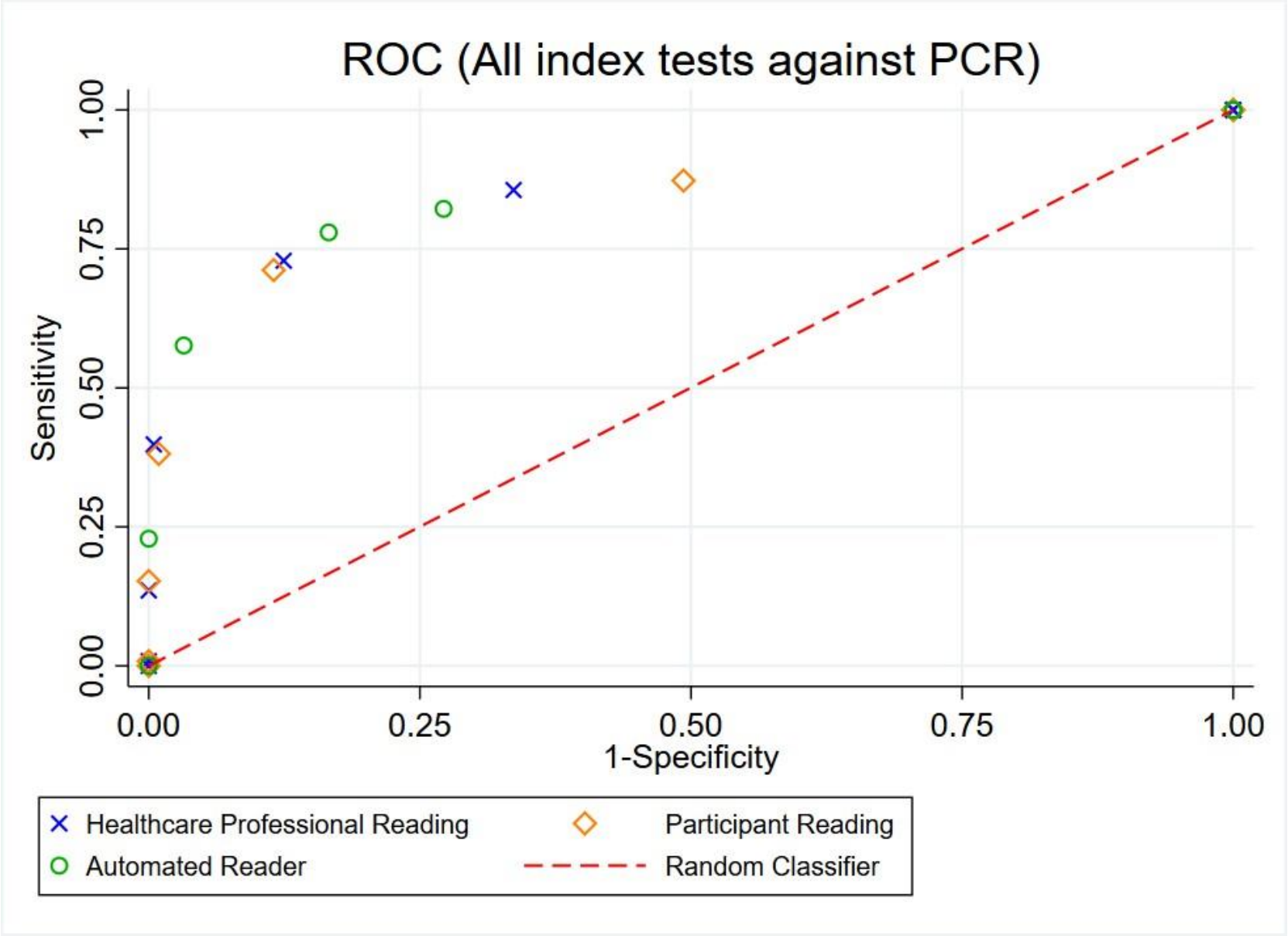
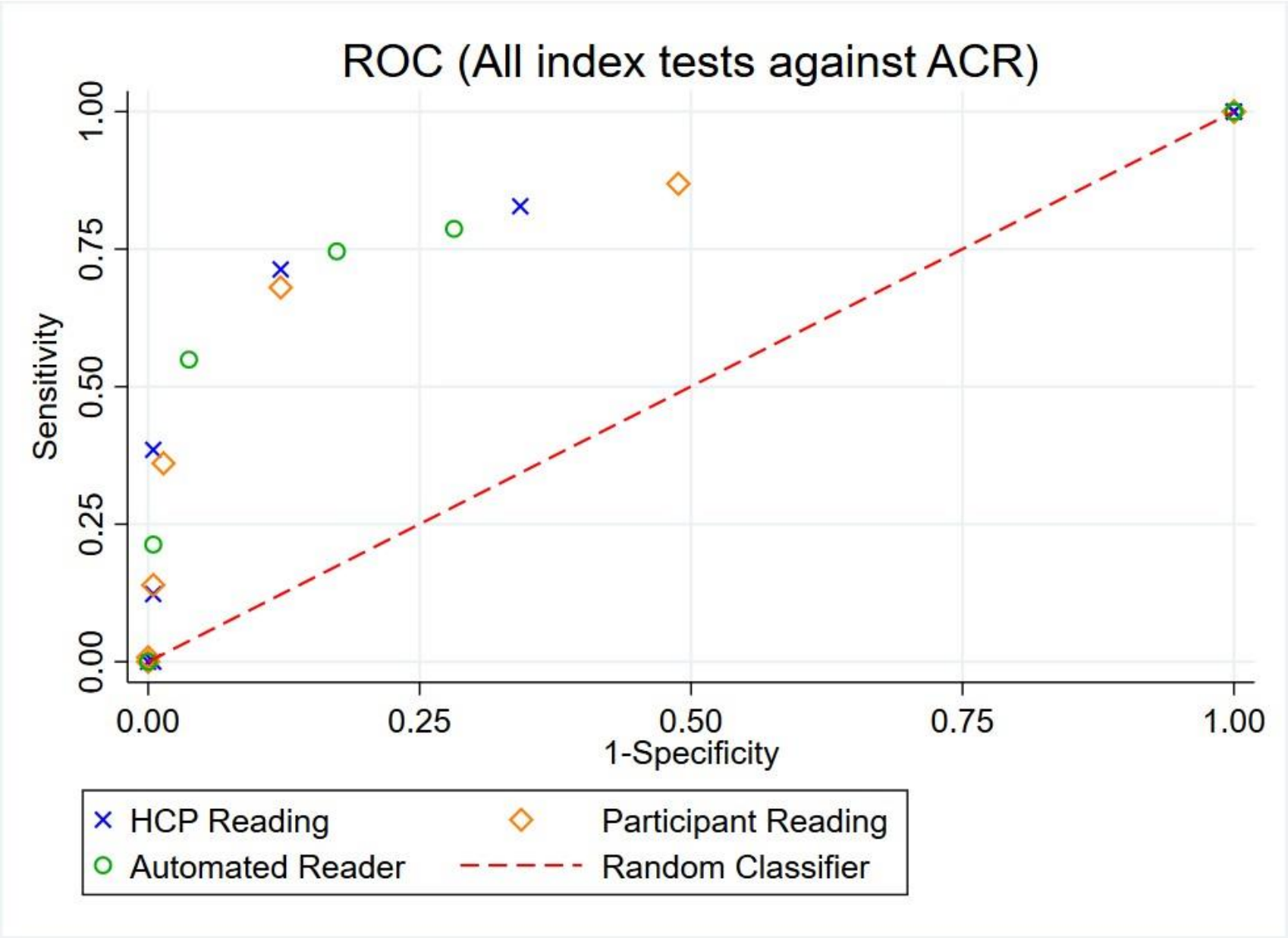


Figure 7: ROC plot of all index tests against the secondary reference test, ACR



3.5.6 Discussion

Pregnant people self-tested for proteinuria (≥1+) with similar accuracy to both healthcare professionals and a colorimetric reader. This held true whether laboratory PCR (≥30mg/mmol) or ACR (≥ 8 mg/mmol) was used as the reference standard.

This research shows that dipstick tests have limitations regardless of who reads them, with around one in five false negative results (compared to a laboratory PCR); however, the majority of false negatives in this study were within the 30-50mg/mmol range (1+). NICE recommend repeat testing for any laboratory PCR result above 30mg/mmol if diagnostic uncertainty remains; for example, if there are no other clinical signs or symptoms of pre-eclampsia (blood pressure of ≥140 mmHg, maternal organ dysfunction, fetal growth restriction). This is motivated by the variation in protein excretion during the day and from day to day, and intended to prevent a diagnosis of pre-eclampsia on the basis of one raised PCR result (1). Previous evidence suggested that 30-50mg/mmol (1+) is the range in which repeat laboratory testing would be beneficial (13, 94).

Importantly, urinalysis is not done in isolation: pregnant people are asked about symptoms and have their blood pressure checked, and where any sign or symptom is of concern, tests are repeated. The low proportion of false positives has fewer clinical implications as this is a screening test where positive results are quantified with a laboratory test.

Dipstick urinalysis is cheap, convenient, easily repeatable, non-invasive, and the most commonly used method of urinalysis in antenatal care. Repeat testing has shown to increase the accuracy of other diagnostic screening tests, like blood glucose monitoring in diabetic care (95). Hypothetically, this would be the case with self-testing for proteinuria, in order to reduce the number of false negatives. For example, self-testing twice a week, as opposed to

a one-off test, is likely to increase the sensitivity, thus reducing the chance of a falsely reassuring negative test (96).

3.5.6.1 *Strengths and Limitations*

The strengths of this study include its size, with 335 people included in the analysis representing a fully powered diagnostic accuracy study. The majority of participants (97%) completed the study and missing results were largely due to laboratory errors. To my knowledge, it is also the first study to compare accuracy across pregnant people, healthcare professionals, and an automated reader, with two reference tests. Participants were recruited from a variety of hospital settings and included data from a range of pregnant people in the population most likely to be appropriate for self-testing (10). Nearly half of the study population were from ethnic minority groups and this is important in the context of hypertension and pre-eclampsia research. In the UK, black pregnant people with chronic hypertension are five times more likely than white pregnant people to experience adverse birth outcomes, such as stillbirth, and Asian pregnant people with chronic hypertension are three times more like to experience adverse birth outcomes than white pregnant people (97).

A further strength of this study was the use of PCR as the primary reference standard. As explained in chapter 1, 24-hour urine collection was previously considered the appropriate comparator for proteinuria quantification (98) but has since been replaced in the UK with laboratory PCR testing (Chapter 1, Section 1.5.3.1). Recommended by NICE (1), PCR testing is more accurate (13), less time consuming, and more convenient for people than 24-hour urine collection (9, 14). The majority of studies examining point-of-care testing for proteinuria have used 24-hour urine collection as a primary reference test, and those using PCR have not reported on self-testing (90).

A limitation to the study was that pregnant people performed a one-off test in a clinic environment. This was over and above what happens in usual care, and results may not perfectly reflect accuracy if carrying out repeated testing at home where there will be more importance placed on the home test result. Study participants did not have the responsibility of deciding on the appropriate course of action following their test, as they would if self-testing was included in a remote management regime. However, the results demonstrate that home self-testing appears feasible and should be formally tested in future work with the aim of improving early detection of pre-eclampsia in people with pregnancy hypertension (99). Additional limitations include that participants were largely recruited from two sites (Oxford University Hospitals, Guy's and St Thomas' NHS Foundation Trust), with the third (Birmingham Women and Children's Hospital) only providing a small number of participants, due in part to the COVID-19 pandemic.

3.5.6.2 *Comparison with other literature*

The results of this study showed that there was no clinically important difference between self-testing by pregnant people and healthcare professionals. It also found no clinically important advantage to using an automated reader. This is discordant to previous findings, discussed in chapter 1 (see Section 1.5.3.1), which have reported a low sensitivity for healthcare professionals using visually assessed dipstick urinalysis (as low as 41%) (17-19) compared to automated readers. Of the studies that included an automated reader the results varied but they consistently reported a sensitivity for the automated reader below 70%, using a range of dipsticks (17-19). The ISSHP and NICE guidelines recommend using an automated reader (1, 11) to reduce observer error and increase the sensitivity of the test (100).

These findings align with the pilot work which used synthetic urine samples and reported that healthcare professionals and pregnant people tested with similar accuracy; the sensitivity and specificity of both index tests were comparable to those reported in this study (>70%) (32) (Chapter 1, Section 1.7.1.2). The differences between this study and previous studies could be due to the reference test; two studies that reported a low sensitivity for dipstick urinalysis used 24-hour urine collection as the reference standard (18, 19), which is less accurate than a PCR test (13). Population differences could also account for discordant findings; one previously conducted study included non-hypertensive pregnant people, and therefore had a lower prevalence of proteinuria (17). Interpretation error may also account for the differences; this study used a single test dipstick which only has one test to interpret (protein), as opposed to previously used multi-test dipsticks.

This study has reported findings consistent with previous studies on specificity (>80%) (17-19). The studies conducted previously (17-19) did not include self-testing and the visual testing elements were performed by healthcare professionals or members of the study team.

The current method of in-clinic urinalysis has limitations but is also easily repeatable, non-invasive and usually used in combination with other tests. Urinalysis dipsticks are cheap and convenient, and therefore a self-testing regime that incorporates either repeated home tests and/or a combination of home and clinic testing could support improved early detection of pre-eclampsia. The qualitative work reported in chapters 4 and 5 suggests that self-testing, potentially in a home setting, is acceptable to clinicians and pregnant people (101). Furthermore, automated readers are expensive and not suitable in all antenatal care settings. The comparable accuracy of these two methods suggests that a visually read dipstick is an appropriate alternative to an automated reader.

3.5.7 Conclusions

Self-testing has comparable accuracy to the current methods of urinalysis used in antenatal care, and can be easily repeated to reduce the false negative rate. Self-testing appears a feasible alternative to an 'in clinic' dipstick test performed by a healthcare professional and suggests a home self-testing regime could be considered. These findings also suggest that future work on repeat home testing is appropriate.

In light of the on-going COVID-19 pandemic, finding feasible and safe alternatives to in-person care has become a priority. This study demonstrates that pregnant people can accurately self-test urine for proteinuria, but further health systems research is needed to examine how this can best be utilised in practice. Chapters 4 and 5 of this thesis will explore pregnant people and healthcare professional's views on self-testing, to understand how it would fit into antenatal care and pregnant people's lives.

Chapter 4 : “It’s a bit like Dulux isn’t it?” Exploring proteinuria self-testing during pregnancy: a qualitative study

4.1 Overview

This chapter reports the results of a qualitative study on the self-testing of proteinuria during a hypertensive pregnancy. This study recruited pregnant people who took part in the UDIP study (see Chapter 3) for a series of in-depth interviews, supplemented with free text postcards, to explore whether self-testing is acceptable and how it can be, or whether it should be, integrated into antenatal care.

4.2 Objectives

This study had two overarching aims: to assess whether self-testing for proteinuria is acceptable to pregnant people and to explore pregnant people’s thoughts on self-testing in the context of the UDIP study and as a hypothetical home self-testing programme. There is a lack of qualitative research regarding self-testing for proteinuria in pregnancy - on how it should be integrated into usual care and on the lived experiences of self-testing. The views of healthcare professionals on self-testing will be explored in chapter 5.

The specific research questions for this chapter were:

1. Is self-testing of proteinuria acceptable to pregnant people?
2. What are the barriers and facilitators for self-testing for proteinuria during pregnancy becoming integrated into pregnant people’s lives?

3. What are the barriers and facilitators for self-testing for proteinuria during pregnancy becoming integrated into antenatal care?[6]

4.3 Methods

This qualitative study ran alongside the UDIP study (reported in Chapter 3). Pregnant people used a dipstick reagent strip to test their urine sample for the presence of proteinuria, a one off test in a clinical setting. This study, reported in chapter 3, demonstrated that pregnant people were as accurate at testing for proteinuria as antenatal healthcare professionals and an automated reader.

4.3.1 Participants and Recruitment

The eligibility criteria and recruitment of participants to the study is described in the following section.

4.3.1.1 *Inclusion criteria*

- Pregnant people aged 18 to 50 years.
- A diagnosis of gestational or chronic hypertension or pre-eclampsia (defined by criteria from the International Society for Study of Hypertension in Pregnancy (2)).
- ≥20 weeks' gestation.
- Completed the UDIP study (see Chapter 3).

4.3.1.2 *Recruitment of interview participants*

Participants consented to an interview on their UDIP study consent forms (Chapter 3, Section 3.4.5.2, and Appendix 2.3.). They were recruited by research midwives at antenatal appointments (Chapter 3, Section 3.5.1.3) to both arms of the study. The research midwife offered them an in-person interview or a telephone interview, either to take place on the

[6] This will also be explored in chapter 5 with healthcare professionals

day of their participation in the study, or at a later date. The participants were then re-approached by the interviewer, either in-person or over e-mail or text, to ensure they still wished to participate and then the interview proceeded or was arranged for a later date. The interviews took place in a variety of settings: bedside if the participant was an inpatient, at the participant's home, or in a hospital room near the clinic the participants were attending.

I conducted semi-structured, in-person or telephone, one-on-one interviews with pregnant people who took part in the UDIP study to explore their experiences of the in-clinic self-testing they undertook and their thoughts on home self-testing. Interviews were sought in order to gain in-depth understanding of self-testing, particularly of a hypothetical home self-testing scenario.

The interviews were audio recorded, transcribed verbatim by an independent transcriber, and I proof read the transcripts for accuracy.

4.3.2 Topic guides

An iterative approach was used to develop a topic guide; the questions and prompts were originally developed in collaboration with the study team from a review of existing literature, they were then re-defined over the course of the study in order to explore some of the themes and concerns raised by the participants in more depth (Appendix 3.1). Participants were asked specifically about the UDIP study and if they had any problems carrying out the study itself. Then they were asked about a hypothetical home self-testing regime, whether they foresaw any barriers, and what the benefits of self-testing would be for them. The healthcare professional and patient relationship was also explored, pregnant people were asked to speculate on any possible changes to that relationship if self-testing were to be implemented in antenatal care.

4.3.3 Free text postcards

After completing the primary self-testing study, all participants were provided a free text response postcard in their study packs and were invited to share their thoughts on the self-testing process (Appendix 3.2). Free text postcards have been successful in previous studies at capturing data from a wider group of participants (102) and allow researchers to *"access subjects who are usually hard to get in touch with"* (103). In this study, postcards were included to ensure more participants' views were captured over the course of the study. The free text postcards were collected by the study team over the course of the study. They were transcribed by an independent transcriber and I proof read the transcripts for accuracy.

4.4 Data Analysis

Analysis began with a detailed examination of the interview transcripts and the free text postcards, identifying some initial themes and developing an understanding of the material. The interview transcripts and free text postcards were then uploaded to NVivo 12 Pro (QSR International Pty Ltd, released 2018) for a thematic analysis, using Braun and Clarke's guidelines (104). After the first round of coding, the initial themes were mapped using the 'One Sheet of Paper' (OSOP) method (105) to visualise the data as a whole (Figure 8). This visualisation suggested that there was a need to group the themes into two categories.

First, there were a set of themes that reflected participant's thoughts on the feasibility and practicalities of home-based self-testing, which was posed as a hypothetical scenario to participants during the interview (see Section 4.3.2), as although they had done a one off self-test during the study that was in a clinic based setting without the added pressure of carrying out the test at home and then deciding upon the appropriate course of action.

Second, the discussions in the interviews often went beyond the practicalities and general acceptability of self-testing; participant's feelings about self-testing often reflected their feelings about antenatal care more broadly. Concerns around patient agency, control, and medical surveillance were raised over the course of the interviews. It felt pertinent to separate these themes from those that resonated with feasibility and implementation as they were addressing different aspects of the self-management 'puzzle'. In light of this, the themes that spoke to feasibility and practicalities were grouped as 'exploring the hypothetical: self-testing as a pregnancy intervention', and the themes around patient agency, surveillance, and anxiety were grouped as 'beyond feasibility: patient agency and surveillance' (Figure 9).

Themes were discussed with supervisors and the wider UDIP study team at multiple stages throughout the analysis process. This study was embedded in a wider programme grant focusing on the self-monitoring of blood pressure in pregnancy. Previous qualitative work with pregnant people on self-monitoring blood pressure reported themes on health anxiety and how it interacts with self-monitoring, as well as exploring the practicalities of self-monitoring blood pressure at home (31). The coding framework for this study was influenced by elements of this previous qualitative work, particularly regarding health anxiety, allowing for a nuanced interpretation of self-testing in the wider context of antenatal care and self-monitoring.

The two methods of data collection, the interviews and the postcards, were initially coded together in order to understand the breadth of the dataset. As the analysis developed, the postcards were considered in isolation to ensure the themes were reflected in both sets of data. While the themes were cross cutting the interviews provided, as expected, more depth and nuance. This was particularly noticeable in the overarching theme of patient agency and

surveillance; the interviews gave participants the space to reflect on their wider concerns about their place in antenatal care as a high risk pregnancy.

However, there were some instances of contradictory statements within individual accounts. While there were rarely instances where the postcards and interviews directly contradicted each other, there were occasions where participants made contradictory statements either in a postcard response or during the course of an interview. These occasions were not left out of the analysis, as the contradictory statements reflected themes that already existed in the analysis and were captured in the wider coding framework. Nonetheless, it is important to highlight some of these moments of tension and some of these contradictory accounts are discussed in the results (Section 4.5).

Figure 8: First visualisation of the data using the OSOP method

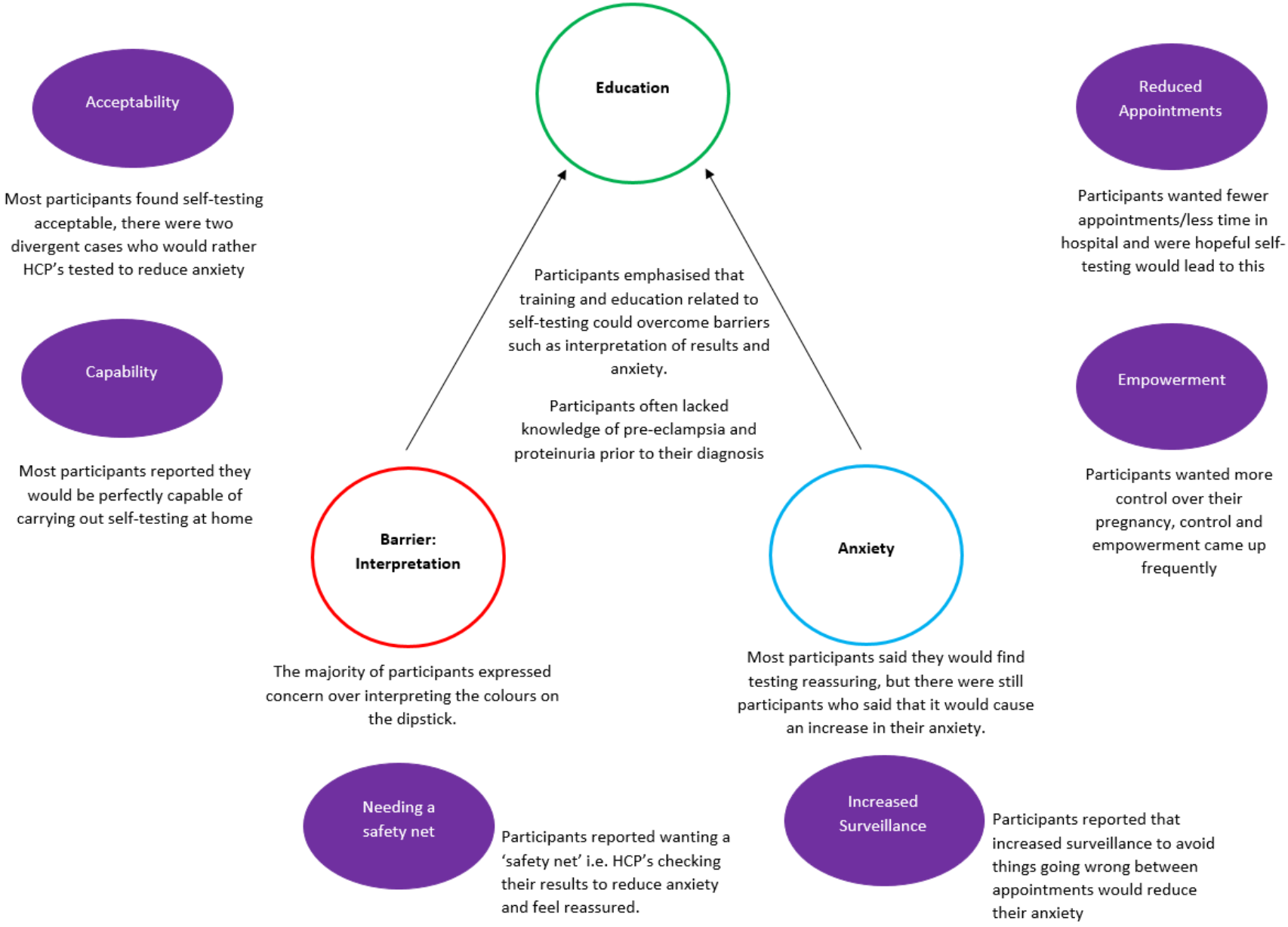


Figure 9: Final visualisation of the data using the OSOP method



4.5 Results

A total of 21 participants agreed to take part in an interview (Table 7, Table 8). Of the 21 interviews, 19 were conducted in-person and two over the phone. The median age of the interview participants was 36 (IQR 32 – 40), the median gestational age at the time of recruitment to the UDIP study was 33 weeks (IQR 27 – 36) (participants' gestational age at interview was not recorded), and the majority were nulliparous. The length of the interviews ranged from 5 minutes to one hour, often reflective of the interview setting (those that took place in participant's homes were longer). 106 free text postcards were collected during the course of the study across the three sites: Guy's and St Thomas' NHS Foundation Trust, Oxford University Hospitals (John Radcliffe Hospital), and Birmingham Women and Children's Hospital. The population recruited to this study was representative of the British population, with approximately 52% of participants white British, 14% of participants Asian or Asian British, and 10% Black or Black British (106).

Table 7: Demographics of UDIP qualitative participants

Demographics of study population (n=21)		
	Median	**IQR**
Age	36	32 - 40
Gestational age at recruitment in weeks	33	27 - 36
	Frequency	**%**
First pregnancy	12	57.1
Ethnicity		
Asian or Asian British	3	14.3
Black or Black British	2	9.6
Mixed	1	5.8
White British	11	52.4
Other	4	19.0

Table 8: Individual characteristics of UDIP qualitative participants

ID	Gestational age at recruitment in weeks	Age	First Pregnancy?	Ethnicity
Participant 1	35	33	Yes	Other
Participant 2	34	29	No	White British
Participant 3	36	27	No	White British
Participant 4	33	34	Yes	White British
Participant 5	35	40	No	Other
Participant 6	37	33	Yes	White British
Participant 7	29	40	Yes	White British
Participant 8	39	30	Yes	White British
Participant 9	36	47	Yes	White British
Participant 10	32	35	Yes	White British
Participant 11	15	44	No	Black or Black British
Participant 12	30	36	Yes	Other
Participant 13	30	43	No	White British
Participant 14	25	37	Yes	Asian or Asian British
Participant 15	37	40	No	Asian or Asian British
Participant 16	37	39	No	Black or Black British
Participant 17	20	40	Yes	Asian or Asian British
Participant 18	19	28	No	Mixed
Participant 19	23	35	Yes	Other
Participant 20	30	31	Yes	White British
Participant 21	34	40	No	White British

The first theme reported below is 'exploring the hypothetical: self-testing as a pregnancy intervention', which includes the sub themes of acceptability of dipstick testing, practical barriers such as interpretation concerns, healthcare professional oversight, and the importance of patient education. The second theme reported is 'beyond feasibility: patient agency and self-surveillance', which includes the sub themes of patient agency and involvement in care, increased surveillance, and anxiety.

Overall, participant's had positive attitudes towards self-testing and expressed their desire to be more involved in their antenatal care (Table 9). The role of healthcare professionals, and their level of oversight regarding self-testing, was raised by participants. While almost all participants found the concept of home self-testing acceptable, they also raised concerns

about how self-testing would be implemented and, in the interviews, offered potential solutions. Participants believed that patient education has a significant role to play in how self-testing should be rolled out, regardless of the setting. Many of their concerns reflected broader concerns about antenatal care for high risk pregnancies; participants had a desire to be more involved in their care and welcomed the additional surveillance of self-testing. There were also concerns around anxiety, often framed within the context of their high-risk pregnancy; some participants reported that self-testing itself could be a source of anxiety.

4.5.1 Theme 1. Exploring the hypothetical: self-testing as a pregnancy intervention

Self-testing was posed as a hypothetical scenario in these interviews. From their brief experience of self-testing as part of the UDIP study, participants were asked to consider whether they would want to self-test at home. The themes below reflect their thoughts on self-testing, often coalescing around the practicalities and implementation of home testing.

4.5.1.1 *Acceptability of self-testing*

Broadly, participants found self-testing an acceptable concept, both in the context of the study and when asked about home self-testing. Almost all those interviewed said they would be willing to self-test, with many commenting that self-testing was straight forward. The majority who fed back via a free text postcard also found the idea of self-testing acceptable. Participants often spoke of how easy and uncomplicated self-testing seemed to be, and how little time it took out of their day.

4.5.1.2 *Practicalities: Interpretation of the dipstick*

One of the most common issues raised with self-testing was the interpretation of the dipstick. A result is ascertained from a urine dipstick by interpreting the colour at the end of the stick (in this study, a shade of green) that correlates to the amount of protein in the

urine[7]. While the study demonstrated participants were as accurate as health care professionals interpreting the dipsticks (Chapter 3, Section 3.5.5.3), a common concern raised in the interviews and on the postcards was that interpretation could be a challenge as the colours are difficult to distinguish.

Participants pointed to the importance of making sure the instructions for interpreting the dipstick were clear and the colours were consistent throughout the instructions given.

> "*Or a card that's made of the same material so you're comparing like for like as opposed to, 'Ooh, yeah it sort of matches.' It's a bit like Dulux isn't it?"* **Interview Participant 7**

> *"Testing straightforward but can be difficult to identify the different colours."* ***Participant Postcard***

There were a few instances in the data where contradictory statements were made within an individual account, highlighted by the postcard response above. While testing was considered 'straightforward' this participant also found interpreting the colours of the dipstick difficult. This particular quote speaks to both the acceptability of self-testing, and the shared concern among participants about interpretation of the results.

4.5.1.3 *Needing a safety net: healthcare professional oversight*

Despite participants often saying that the testing process was easy and straightforward, they felt that a safety net, in the form of a healthcare professional checking their test results, would be welcome and reassuring. Participants felt that it would alleviate some of the

[7] The shade of green gets darker if there is more protein in the urine

anxiety that would come with self-testing. One participant speculated that pregnant people would be anxious at the beginning, but would gain in confidence the more they self-tested.

There were mixed views about the role of healthcare professionals and the balance of responsibility, and the potential burden of treatment for the patient (Chapter 2), if self-testing were to be implemented in antenatal care. While many felt that self-testing would give them more agency in their pregnancy, a few participants were more comfortable with healthcare professionals retaining control over this element of their care.

> *"Not that I can think of because it's very easy just to dip in and read. As I said before, can be a bit confusing but as long as you have a health professional to help you and say, "No, you're right," or "you're wrong," after you have done it. Apart from that, I just think it's very easy."* **Interview Participant 12**

This is also another example of contradictory statements existing within the same individual account. This participant stated that self-testing was easy, but goes on to say that elements of it were confusing. In this case, the participant presented healthcare professional oversight as a solution; these solutions were, understandably, easier to tease out in the interviews.

Shared responsibility was brought up a few times in the dataset, often in discussions about healthcare professional oversight. Some participants wanted a 'link' between patients and healthcare professionals if they were self-testing, indicating a scenario where the patient self-tested but the healthcare professional advised on the next steps to take.

> "*Healthcare people still play a very vital part because they're the ones that can confirm. They've got a trained eye and the trained knowledge, so it helps the women to do it at home, but I think there's still space for the professionals to still say, "Okay, we agree, or maybe it's a bit, you know, higher or bit lower."* **Interview Participant 11**

4.5.1.1 *The importance of patient education*

Over the course of the interview, participants often suggested that in order for self-testing to be effectively implemented in antenatal care, patients have to be shown how to do a dipstick test and understand the importance of the test. Participants often suggested that healthcare professionals should demonstrate how to do the testing:

> "*I think if you were going to be getting somebody to do it at home, I think it would reassuring to do it alongside somebody."* **Interview Participant 13**

Participants also suggested that patient education should be integrated with face to face or telephone consultations to alleviate any concerns.

Some participants suggested that alongside being shown the practicalities of self-testing, pregnant people needed to be educated about proteinuria.

> "*And it's just a matter of getting educated, you know, what the parameters are and what you need to look out for and it's not that, it's not rocket science."* **Interview Participant 14**

4.5.2 Theme 2. Beyond feasibility: patient agency and self-surveillance

Some of the themes that were developed during the analysis went beyond the practicalities involved with self-testing. Participant's discussed deeper concerns or feelings about their antenatal care during a high risk pregnancy, using self-testing as a proxy. The following themes reflect those thoughts, going beyond the feasibility and implementation of self-testing and instead focusing on wider issues in antenatal care for high risk pregnancies.

4.5.2.1 *Patient agency and involvement in care*

Participants expressed a desire to be more involved in their antenatal care. Often these feelings of autonomy centred on the baby and were driven by participants hope for, and focus on, a positive birth outcome and a desire not to put their babies at risk. Participants

rarely used the word empowerment or agency, instead expressing hopes of increased involvement and control.

> *"So, I think it would be like if we can do more self-testing, nobody wants to put themselves or their babies at risk. That's not what it's about but it's just having a bit more control over the situation if that's possible."* **Interview Participant 10**

These themes around control and patient agency came up frequently in the data, in both the interviews and the postcards. One participant, interviewed in hospital, said it would help their mental health, as they felt they did not have any independence as an inpatient.

> *"Everything's kind of done for you but [um] and having some sort of autonomy early on would just be nice for your mental health because you sort of feel like you're part of looking after your health."* **Interview Participant 7**

Participants alluded to control and increased agency when discussing knowledge, the more they knew about their condition and their care the more they felt in control of the situation. Participants often said if they had more knowledge of their condition they would feel more involved in their antenatal care. The majority did not have extensive knowledge of proteinuria prior to being diagnosed with hypertension or pre-eclampsia.

> "*It will give women more insight about what's going on and make them understand, so when they do come to these type of appointments where they are reading their urine, they're more involved and they know more about what's going on."* **Interview Participant 11**

4.5.2.2 *Increased surveillance*

A theme that often came up when discussing the 'safety net' of the healthcare professional was the concept of increased surveillance. The participants in this study were all considered higher risk, due to their diagnosis of hypertension or pre-eclampsia, and they felt self-testing would be reassuring, adding a level of surveillance to their current care. Several participants mentioned the rapid onset of pre-eclampsia as a particular area of concern, they were

worried about the extended time period between antenatal apppointments where they felt a lot could go wrong and symptoms could be missed. Self-testing was welcomed as a way to monitor potential changes in between appointments.

> *"Not just when you have an appointment because, I mean some people start developing hypertension, you know, during pregnancy without knowing that they are developing it, so it's good to sort of be on top of it."* **Interview Participant 14**

Notably, this was also a strong theme in the free text postcards. Several respondents suggested that self-testing would catch symptoms in between antenatal appoints and would allow pregnant people to contact their healthcare professional before things get worse.

> *I think it's a really good idea as it could pick up problems earlier on in the pregnancy and you could seek help/medical care earlier.* **Interview Participant Postcard**

4.5.2.3 *Anxiety*

Participants brought up anxiety frequently but there were mixed views on whether self-testing would increase or decrease anxiety. For those participants who felt self-testing would be reassuring, there was concern about how quickly hypertension or pre-eclampsia can progress if left undetected and untreated. Participants expressed their worry and fear that they could get sick without realising it, and by the time it was picked up by a healthcare professional it would have progressed into severe disease. They felt that self-testing would be reassuring and would stop them from 'overreacting' between antenatal appointments.

> *"Yeah,* [self-testing is] *very, very good and reassuring I think as well for people because it does usually start of, like what I've heard and speaking to the midwives it does usually kind of creep. Whereas, what you don't want it to do is get into that level where's it's really, really bad, and then it's just terrifying."* **Interview Participant 6**

However, there were some participants who felt that increased testing would make them feel anxious. One participant said self-testing would make them panic if their result was

positive, and they would not know what course of action to take. The prospect of further anxiety was a strong deterrent for another participant who that it would stop them from considering home self-testing.

> *"I kind of panicked, said, "Oh my God, if I was home, had to do this, I would panic and that would probably stop me doing it."* **Interview Participant 15**

Some participants were torn over whether testing would make them feel more or less anxious, one participant felt that initially the testing would cause anxiety but they would feel more comfortable with the concept the more they self-tested, as their confidence would grow. This uncertainty was expressed in the postcards as well, with one participant writing:

> *I do worry this could cause paranoia in some women who may have previously had PET. Nonetheless, I think this is a positive step forward."* **Participant Postcard**

Table 9: Quotes from the thematic analysis of pregnant people self-testing for proteinuria

Theme	Quotes
Exploring the hypothetical: self-testing as a pregnancy intervention	
Acceptability of self-testing	*"N-, I mean, I don't foresee any changes. It's just, I think, yeah, it's just a very minor thing that routinely gets done at an appointment. Yeah, you just get, you save time on, I mean, I don't see any, any barrier whatsoever, that's all."* ***Participant 14*** *"I like the idea of being able to test from home, sometimes you feel as though you over react so being able to see from home would be better"* ***Participant Postcard***
Practicalities: Interpretation of the Dipstick	*"Found the colour really hard to match up as it was more the colour of between 0.3-1."* ***Participant Postcard*** *"Seemed quite easy to do however the colours are quite similar so deciding on the levels of protein wasn't the easiest."* ***Participant Postcard***
Needing a Safety Net: Healthcare Professional Oversight	*"Yes, yes, yes, I feel comfortable. Well, I feel comfortable doing that urine test at home as well, as long as, you know, somebody, a professional could check it."* ***Participant 12***

Theme	Quotes
Patient Education	*"I think as long as there's clear guidelines, it's fine because, you know, you're talking to a wide variety of people out there and some people are going to be, not being, more educated about it because, you know, some people read everything under the sun and that's, you know, I've been told, "Do not go…" and I get the reasons why [um] but, you know, you've got to be sensible about it"* ***Participant 9*** *"But I suppose if you have the right guidance then it'll be easier and the more you do it, I suppose at home, the more comfortable you'll get doing it, so it's just like taking your blood pressure at home. Once you get into the routine of it, I can't see why it wouldn't be helpful for women to do it at home."* ***Participant 11***
Beyond feasibility: patient agency and self-surveillance	
Patient control and involvement in care	*I believe the self-testing at home might give women a sense of control and knowledge about their condition. I know to me it would. Knowing would prompt me to see a midwife soon or not attend the clinic if all was normal.* ***Participant Postcard***
Increased Surveillance	*"Not just when you have an appointment because, I mean some people start developing hypertension, you know, during pregnancy without knowing that they are developing it, so it's good to sort of be on top of it."* ***Participant 14***
Anxiety	*It was easy. If I did it at home I'd probably forget to remove the excess most of the time. I guess knowing the levels might make some people more anxious (as opposed as just having the med professional saying that it's ok/not ok).* ***Participant Postcard*** *Great way of monitoring protein from home and keeping on top if it! Useful for women with anxiety – allows them to check instead of worrying and waiting for a midwife/GP appointment.* ***Participant Postcard***

4.6 Discussion

This qualitative study has found that self-testing for proteinuria was acceptable to participants in the UDIP study and they were positive about a future role for self-testing in antenatal care. Participants had detailed thoughts on how to make self-testing feasible for a home testing regime and discussions around implementation often focused on the practicalities of interpreting the dipstick and the desire for a 'safety net'.

There were also wider discussions about antenatal care, with self-testing used as a proxy to discuss patient agency and the roles and responsibilities of pregnant people and their healthcare professionals. There were divergent views on the role of healthcare professionals should self-testing be implemented. While some participants said they would welcome the 'safety net' of a healthcare professional checking their results, others felt that education and training would be enough to counter the anxiety and uncertainty around self-testing. There was also concern among participants about the manner in which pre-eclampsia can onset, suddenly and without symptoms, and they were supportive of the increased surveillance they perceived self-testing would provide. These participants, because of their high-risk pregnancies, had insights into hypertension and pre-eclampsia that most pregnant people would not, and this may have made them more inclined to support increased surveillance. It should be noted that participants in this study were speculating about the future role of self-testing and had not tested anywhere outside of hospital at the time the study was conducted. Despite this, they were still broadly positive about the concept of home self-testing.

4.6.1 Exploring the wider context: self-surveillance and patient empowerment

4.6.1.1 *Medicalisation of childbirth and self-surveillance*

There is a rich literature on the medicalisation of pregnancy and the medicalised environment around childbirth (discussed in Chapter 1, Section 1.9.1). The data in this study

should be interpreted in light of this work. Those who consider birth to be overly medicalised argue that increased obstetric intervention is down to a multitude of factors, including, as Johanson argues, not involving pregnant people fully in decision making (107). The debate around medicalisation is varied; Lupton suggests that pregnancy is no longer seen as a natural state but *"rather as the province of experts and medical monitoring"* (57). Chapter one of this thesis described the commentary of Henley-Einion, who has gone as far to claim that birth is a now medical event rather than a social one (53), and Martin, who has referred to the pregnant person's body as a machine and the doctor as the mechanic who's role is to fix it (54). The role of pregnant person in this medicalised environment is also debated. Lupton suggests that the focus is not on the optimal health of the pregnant person, but the baby. Lupton argues that pregnant people are "*expected*" to *"ensure the health and optimal development of their fetuses"* (57) and that it is an expected "*ethical responsibility*" that they seek out "*expert advice on how best to protect* [their] *fetus"* (57).

Self-testing must be considered in the context of this contested debate on medicalisation, a process which is often disempowering of pregnant people. A non-medicalised pregnancy, as discussed in chapters one and two, does not necessarily mean the absence of medical intervention, depending on the definition, but broadly tends to focus on "*the humanisation of birth*" (85) – in essence, empowering pregnant people to make their own choices. But in this case, medicalisation in the form of self-testing also has the potential to foster and support patient agency. It is often acknowledged in these debates on medicalisation that there is a new emphasis on a "*need for heightened surveillance and expert advice and guidance*" (108). In this dataset we see evidence of pregnant people expressing a desire for increased surveillance in antenatal care. They were positive about the potential for self-testing to provide increased surveillance, and much of their desire for this surveillance stemmed from their pregnancy being classed as high risk. Wagnild et al's study on exercise in

pregnancy discusses the idea of 'self-surveillance', in which pregnant people *"are taking responsibility for monitoring their own pregnancies…thus functioning as an extension of the medical gaze"* (109). Participants in the UDIP study were seeking a level of control over their pregnancies, but were hesitant to lose the medical gaze, potentially due to the high risk nature of their pregnancies. Self-testing, like exercise in pregnancy, could be an extension of that medical gaze, allowing pregnant people to take an active role in their antenatal care while also retaining the surveillance that acts as the desired 'safety net'.

4.6.1.2 *Patient empowerment*

As previously discussed (Chapter 1, Section 1.8.2), patient empowerment is a concept that has long existed in the chronic disease literature. In the current study, participants communicated a need to shift the balance of who is responsible for certain elements of their care. As previously discussed in chapter one, much of the patient empowerment literature stems from the chronic illness discourse, which is broad and diverse, but often focuses on elements of self-care or self-management. As Storni reports "*a series of ideas have entered the public discourse with particular relation to chronic disease*", including patient empowerment, self-care and self-management (110). Patient empowerment aims to "*increase patient's autonomy and participation in care*" (111), and in the context of chronic illness this sometimes becomes an issue of *regaining* autonomy. In chapter one (see Section 1.8.2), an expansive definition of patient empowerment was put forward; Small et al's definition condenses patient empowerment down to three features – shared decision making, patient education, and self-management (42). The data presented in this chapter speaks to some of the concepts in Small et al's definition; self-management, the need for patient education, and a sense of shared responsibility between patients and healthcare professionals. While shared decision making is not fully realised in this dataset, as much of

the questioning was hypothetical, these data still link to the wider concept of patient empowerment.

Much of the literature on self-care and empowerment frames the concept of self-management as a tool for patients to regain and retain control over aspects of their care. However, there are other ways to frame patient empowerment, some of which are critical of patient education and self-management as the basis of empowerment. Traditional patient empowerment frameworks focus on the experiences of patients managing their treatment regimens and how they relate to healthcare professionals; they assume that patient powerlessness is due to a lack of medical knowledge and skill, and they also assume that patients would value being in control of their treatment, medical decisions and management (112). However, Aujoulat et al frames the concept of patient empowerment differently. This work depicts patient powerlessness as the result of a crisis or loss of personal identity when dealing with a chronic illness (113), framing patient empowerment "*as evolving from a threat to one's senses of security and identity*" (112). The concept of self in pregnancy is complex – the identification of the pregnant self is temporal, tentative in the first if not all pregnancies, and considerations are not purely focused on the individual but encompass both the pregnant person and the child. Wide ranging discussions around identity were not present in this dataset, however, engaging with these critiques, and accepting that patient empowerment does not simply come from patient education and shared decision making, but there are other factors at play in this complex concept, is worth further exploration when considering self-management interventions and the success of those interventions. Building on Aujoulat's work, Vázquez et al point out that "*patients with a chronic illness must be involved in their own care. Empowerment is an omnipresent facet of the way that patients live their illness*" (114). This concept is slightly different in pregnancy when the medical condition may have only recently developed, but the overarching message that

"*participation is not the result of a preference but an inescapable task in the case of chronic patients*" (114) is salient. Again, in pregnancy, this is further complicated by the considerations of an additional life - the baby.

A broader critique of patient empowerment can be found in McLaughlin (2001) and Fitzpatrick's (2015) work, where they discuss the idea that medical interventions are compromising the autonomy of the individual and therefore the person has become an object of a medical intervention "*rather than the subject seeking medical care or treatment*" (115) (116). What these arguments fail to grapple with, however, is what the patients themselves want. This dataset clearly demonstrates an appetite for greater involvement in care, as much of the qualitative literature on chronic illness has also reported. However the concept of patient empowerment is framed, whether it be a realisation of the self or the result of patient education or self-management, it is the mechanism through which patients – in this case, pregnant people – might regain autonomy, not lose it.

There is an implicit critique of elements of patient empowerment in May et al's Burden of Treatment theory (Chapter 1, Section 1.8.4, and Chapter 2), notably that in reimaging the concept of patienthood we may have placed further undue pressure on patients to self-manage their chronic conditions (47). Certainly, the assumption that self-management (in this instance represented by self-testing) is the cause of, and solution to, patient empowerment should be scrutinised. Indeed, in these data there were concerns from participants about whether self-testing would exacerbate their anxiety during an already stressful time, creating a potentially unnecessary burden of treatment. Nonetheless, these data also demonstrated that traditional forms of patient empowerment were still desirable, as seen in the themes around patient education, increased surveillance, and involvement in care.

4.6.1.3 *From patient empowerment to patient-centred care*

The overarching concepts that make up patient empowerment – shared decision making, self-management, and patient education – have been thrust to the forefront of healthcare over the past decade. These concepts are often now packaged as patient-centred care. In chapter one, patient-centred care was introduced as a model primarily focused on treating patients as equal partners in health decision making and ensuring that patients have the knowledge and skills to manage their health effectively. Patient-centred care also aims to find "*mutually agree*[d] *upon management*" (117) and, often, this includes self-management. Definitions often theorise that engaging patients in their care could improve adherence to self-management and medication regiments (117) (118). Such is the focus on patient empowerment that the NICE guidelines for uncomplicated pregnancies have a focus on 'women centred care'[8]: "[pregnant people] *should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals*" (10). Moreover, as Epstein and Street argue "*respecting patients' preferences, should be justified on moral grounds alone, independent of their relationship to health outcomes*" (118).

The drive towards patient-centred care stems from a desire to change "*centuries of physician-dominated dialogues*" (118), and is "*perceived to be the solution to excessive paternalism in clinical medicine*" (119). Paternalism in antenatal care (see Chapter 1, Section 1.8.1) is particularly challenging. Hinton et al found a paternalistic discourse was strongly present in the information pregnant people are given regarding hypertension and pre-eclampsia, suggesting that *"responsibility and knowledge rest(s) with doctors and midwives"*,

[8] This is the specific language used by the NICE guidelines. In keeping with the language choices specified in the introduction of this thesis (Chapter 1, Section 1.9) patient-centred care will be used from here onwards

but similarly found that pregnant people wanted to be more involved in their care, and this was expressed through themes on lay knowledge and expertise (38).

4.6.2 Implementation Considerations

4.6.2.1 *Patient anxiety and education*

There was an extensive discourse about anxiety in this dataset. The pilot work for this study (see Chapter 1, Section 1.7.1.2) included an online survey with pregnant people who had experience of self-testing, which found equally conflicting views on whether self-testing would make pregnant people more or less anxious (32). Conversely, previous research on home blood pressure monitoring in pregnancy reported that pregnant people found it reassuring (31), suggesting that there is a dichotomy of views regarding anxiety and the general concept of self-management in pregnancy. Participants in this study had been diagnosed with hypertension or pre-eclampsia and were classed as having high risk pregnancies. Thus, their perception of risk and the anxiety associated with that risk was heightened compared to an uncomplicated pregnancy. Chapter 2 of this thesis reported that a diabetes diagnosis during pregnancy caused additional anxiety for pregnant people and the complexities of processing that diagnosis alongside learning to manage it caused some to feel anxious and overwhelmed.

Over the course of the interview, participants said that patient education and training would be an effective way to counter some of the anxiety caused by self-testing. As previously suggested, chronic illness literature often equates patient education with patient empowerment; chapter 2 reported strong evidence that a lack of knowledge and understanding of chronic conditions led to pregnant people becoming more anxious and less motivated to self-manage that chronic condition throughout the pregnancy (59). Patient education and information is an integral part of providing a patient-centred approach, as

Stewart notes, "*being patient-centred actually means taking into account the patient's desire for information*" (117). Participants in this dataset felt that the more knowledge they had about their condition and their symptoms, the more at ease they would feel over the course of their pregnancy.

4.6.3 Strengths, Limitations, Reflections

Qualitative data on self-testing for proteinuria during pregnancy is sparse, as such this study addresses a current gap in the literature. The strength of this study lies in the mixed methods data collection, by having in depth interviews with participants (n=21) and free text postcards from a large number of people (n=106) the data has both depth and breadth, and a wide range of views were captured.

There were several situational challenges due to the nature of the study set up. Often, there was limited time with participants as they were often due at appointments, or were staying behind after an appointment to take part. Other times, the participants were in-patients, with all the stress and vulnerability that entails, particularly when pregnant. Out-patient interviews conducted in-person took place in empty hospital rooms near the clinic they were attending or a private meeting room on a separate floor. Interviews conducted postnatally took place at participant's homes. Interviews took place either on the day the participant conducted the UDIP study or over the following weeks as they attended other antenatal appointments, or in some cases, following the birth. Subsequently, interviews were often short and had a tendency to be ended prematurely. The in-patients were interviewed bedside or, if they were allowed to walk around, in the recreation room in their hospital ward. Inpatient interviews took place shortly after participants had completed the UDIP study and were often longer, as they had more time, but tended to be interrupted,

understandably, by healthcare professionals or participant's partners and family, reflecting the day to day activity on a maternity ward.

The interview guide changed in accordance with the discussions had with participants and also due to the circumstances of particular interviews. Some questions that seemed appropriate to ask participants who were out-patients or who were participating postnatally, did not feel appropriate to ask an inpatient who was facing the prospect of being induced due to pre-eclampsia, or facing an uncertain period in hospital. Therefore, often the interview guides would be set aside in favour of responding more intuitively to the moment and whether the participant was comfortable with the direction of the conversation.

Despite the situational challenges of the interviews, the majority of the data that was collected was captured at a time when hypertension and pre-eclampsia were at the forefront of participant's minds, and this would have impacted participant's responses. Antenatal interviews had a different, more immediate feel than the postnatal interviews and participants were often much more forthcoming and positive about self-testing while they were pregnant. The group of pregnant people interviewed for this study were potentially more likely to be positive about self-testing due to many of them being in-patients, and self-testing/self-management may be viewed as a way to spend the remainder of their pregnancy at home. As such, not all discordant views on self-testing may have been captured in this study.

Upon reflection, the later interviews in the study were more robust as the interviewer had adapted to the unusual circumstances and setting of the interviews. Early interviews were often short, lacking depth, but covered the topic of self-testing in broader strokes. Interviews that took place in participants homes (n=2) were much more wide ranging and often included lengthy discussions around the participant's birth story and chronic

conditions. This may also have been due to the fact the interviews were conducted postnatally. The mix of interviews and free text post cards revealed a broad depiction of how pregnant people viewed self-testing, both in the context of the study and their thoughts on the future of home self-testing and ultimately, the postcards amplified the themes identified in the interviews. While there were very few instances where the postcard and the interview data contradicted each other, there were a few examples of contradictory statements within individual accounts. These were not always possible to explore in full in this analysis as themes were developed to be representative of the data as a whole, and often these contradictions took place within postcard accounts which lack the depth and nuance of one-on-one interviews.

4.7 Conclusions

Overall, pregnant people found self-testing acceptable and felt that home self-testing would make them feel more involved in their pregnancy care. There was concern among participants about the manner in which problems can arise in pregnancy, quickly and without warning, and they felt self-testing could ease some of these anxieties. However, there was not a consensus about whether self-testing would alleviate those anxieties entirely or, in fact, contribute to them – although patient education was a potential solution to increased anxiety. While concerns were raised about the implementation of home self-testing, participants in this study felt that they could be overcome with a combination of patient education on hypertension and pre-eclampsia and training from healthcare professionals. The complexities of implementing a home self-management programme, and the potential solutions, will be explored in chapter 6.

Chapter 5 : Discourses in conflict: the myth of patient autonomy in a paternalistic system

A discourse analysis of healthcare professional views on self-testing

5.1 Overview

This chapter reports the results of a qualitative study on the views of healthcare professionals, working at the UDIP study sites, about self-testing for proteinuria during a hypertensive pregnancy. The qualitative study ran alongside the UDIP diagnostic accuracy study reported in chapter 3. A series of in-depth interviews and focus groups were conducted with healthcare professionals to explore their thoughts on self-testing. This chapter used a discourse analysis approach (120) and, building on the findings from the previous chapter with pregnant people, explores the conflicting discourses around patient autonomy/empowerment and paternalism, and reveals that gatekeeping and paternalism are prevalent in attitudes towards self-testing

5.2 Objectives

This study aimed to explore healthcare professionals' views on self-testing for proteinuria.

The specific research questions were:

1. Is self-testing of proteinuria acceptable to healthcare professionals?

2. What are the barriers and facilitators for self-testing for proteinuria during pregnancy becoming integrated into antenatal care?

5.3 Methods

This qualitative study with healthcare professionals aimed to run at three sites but was only able to recruit from two: Guy's and St Thomas' NHS Foundation Trust in London and the John Radcliffe Hospital in Oxford. The study was unable to recruit from the Birmingham Women and Children's Hospital, where the UDIP study also ran, due to the impact of the COVID-19 pandemic at the time of recruitment.

5.3.1 Inclusion Criteria

Healthcare professionals were recruited if they fulfilled one, or more, of the following inclusion criteria:

- Participant was part of the UDIP participant's usual care team.
- Participant had patients who participated in the study.
- Participant had experience of managing pregnant people who self-monitor BP during pregnancy or is in a role where this could be the case: midwife (both hospital and community), obstetrician or obstetric physician.
- Participant worked at a participating NHS Trust.

5.3.2 Interviews and Focus Groups

Semi-structured, in-person, one-on-one interviews were conducted with healthcare professionals to explore their thoughts on a home self-testing programme and the UDIP study. Focus groups with healthcare professionals were also conducted to explore these thoughts in further depth after the majority of the interviews had been conducted. A range of healthcare professionals participated; midwives, obstetricians, healthcare support

workers, and junior doctors were all approached to capture broad views across the healthcare profession.

Healthcare professionals were approached with assistance from the lead research midwives at each site and were provided with a patient information sheet (Appendix 4.1). They were invited to participate in an interview or focus group, and once informed consent was given (Appendix 4.2) the interview or focus group took place on the day they were approached. The in-person interviews took place in hospital, either in a pre-booked room, a break room, or in any available room on the ward. The focus groups took place in either a pre-booked room or a room on the floor of the delivery suite. The interviews and focus groups were audio recorded, transcribed verbatim by an independent transcriber, and proof read for accuracy.

5.3.3 Topic Guides

An iterative approach was used to develop the topic guide; the questions and prompts were re-defined over the course of the study in order to explore some of the themes and concerns raised by the healthcare professionals in more depth (Appendix 4.3). Healthcare professionals were initially asked what they thought about a hypothetical home based self-testing regime and as the interview or focus group progressed, they were asked to speculate on the barriers and potential benefits of such a regime. They were also asked to reflect on whether they thought the patient clinician relationship would change if patients were able to self-test for proteinuria at home. The suitability of patients to self-test came up frequently in early interviews, therefore healthcare professionals were specifically asked about who they felt would be best suited to self-test in later interviews, to explore this idea in more depth.

5.3.4 Discourse Analysis

Discourse analysis was considered the best method of analysis for this study in order to explore the dynamics of power in the patient clinician relationship that were alluded to throughout the data collection, which ultimately manifested in discourses of paternalism and gatekeeping. A discourse analysis involves the study of "*power, resistance, contests and struggles*," and to do so involves looking for "*patterns within much larger contexts*" (120); for example, studying language to seek an understanding about the power dynamics within certain relationships, such as the patient clinician relationship. Wetherell, Taylor, and Yates discuss the idea that language enables people to express certain ideas, or conversely, restrains them (120). In the context of this study, language provides an insight into paternalistic systems of power; discourse analysis should, according to Shaw and Bailey, explore how groups acquire status and power through amassing and maintaining systems of knowledge (121). Shaw and Bailey situate discourse analysis on three levels; micro, meso and macro. The meso level approach they describe, which is where this study is situated, emphasises connections with broader social and cultural contexts, meaning there are "*certain ways of talking about a topic, defining 'acceptable' ways to talk, write or conduct oneself*" (121). The healthcare system is inherently paternalistic in nature (35) and is built on the assumption that the physician "*knows better than the patient what is good for the patient*" (122). This is a powerful discourse, and situating this study at the meso level allowed meaningful insight into how this overarching discourse affected the way healthcare professionals engaged with the concept of self-testing. Paternalism was, therefore, one of the theoretical concepts explored in relation to this data.

Healthcare professionals are gatekeepers, it is their role within the healthcare system, and this system is maintained in part because of the unequal distribution of knowledge between patient and clinician. Foucault, a theoretician of power, referred to discourse as "*describing*

rules, divisions, and systems of a particular body of knowledge" (123). The body of knowledge, in this case, would be healthcare professionals. According to Carrabine, at the heart of a discourse analysis is an understanding of power and knowledge, and how they interact with one another, specifically, how they "*intermesh*" (124). In the patient clinician relationship traditionally the clinician is seen to have the most knowledge and, therefore, has power (125). Self-testing and self-monitoring narratives challenge the distribution of knowledge in that relationship and, therefore, changes the balance of power (126). How healthcare professionals react to the possibility of changing power dynamics is central to our understanding of self-testing and self-management going forward. While Foucault is useful in understanding how power, knowledge, and surveillance co-exist and interact, Foucault's theories of power were not primarily used in this discourse analysis. The purpose of this analysis was to explore the *exchange* of knowledge and power between healthcare professionals and patients, facilitated by self-testing. By not specifically engaging with, or limiting the analysis to, Foucault's more top down theories of power, this analysis was afforded the space to understand how the sharing of medical knowledge, customarily held by healthcare professionals, disrupts traditional, paternalistic models of power in healthcare systems.

Carrabine writes that discourses are fluid, opportunistic, can draw upon existing discourses and at the same time, interact with others (124). Antenatal care in the UK, and other high income countries, is in the midst of a transitional phase (discussed in Chapter 1, Section 1.8.1), where self-management and remote forms of care challenge a long standing tradition of paternalistic medicine. Patient empowerment narratives include self-management as a central tenet (119) (Chapter 4, Section 4.6.1.2 and 4.6.1.3) and the data in this chapter is critically explored with this consideration in mind, as well as how patient empowerment contradicts and challenges the notion of paternalistic medicine. Several theoretical lenses

are used to explore the data presented in this chapter; paternalism, autonomy, and patient empowerment – and crucial to the analysis presented here, is how these concepts relate to and juxtapose one another.

5.3.5 Data Analysis

Analysis began with a thematic approach, the interview and focus group transcripts were examined in detail and some initial themes were identified. The transcripts were then uploaded to Nvivo 12 Pro (QSR International Pty Ltd, released 2018) for a more detailed examination of the data. Using the thematic analysis guidelines produced by Braun and Clarke as a guide (104) codes were developed to capture commonalities within the data. Several themes that were developed were grouped into an overarching theme of implementation considerations, as they reflected various barriers that would need to be overcome in order to implement an effective self-management intervention in pregnancy. At this stage of the analysis a pervasive discourse of paternalism was identified in the data and the analysis then progressed to the second stage, which was identifying further discourses present.

A close examination of the language used by healthcare professionals found that not only was paternalism the overarching discourse, but this had manifested into gatekeeping by healthcare professionals (Section 5.3.8). According to Carrabine, discourses can draw upon other existing discourses, and these can contradict or enrich each other (124). Patient empowerment was already grouped into a theme, and closer examination of the data suggested that these were the two conflicting discourses in play – paternalism and patient empowerment.

The final stage of the analysis was to consider the effect of these conflicting discourses, and how they shed light on the patient clinician relationship in antenatal care. Self-testing, self-

monitoring, and self-management narratives ultimately challenge the traditional paternalistic structure of the patient clinician relationship. Healthcare professionals are used to being the knowledgeable party within the relationship and self-testing challenges that perception. The language of power was an important consideration here, how healthcare professionals discussed/talked about their patients is an insight into the broader narrative of paternalism in antenatal care and how healthcare professionals are positioned as gatekeepers. Questions that informed this part of the discourse analysis included: how does self-management challenge traditional power structures of paternalism in antenatal care? Is paternalism a barrier to implementing self-testing? How does patient empowerment interact with paternalism in this dataset?

5.3.6 Results

18 healthcare professionals agreed to be interviewed (Table 10) and all interviews were conducted in-person. Five focus groups were conducted with 15 participants across the two sites (Table 11). A mix of healthcare professionals were recruited: midwives, community midwives, obstetricians, junior doctors, and healthcare assistants. The length of interviews ranged from five minutes to half an hour, the length of focus groups ranged from to ten minutes to twenty five minutes.

Table 10: Characteristics of interview participants

Participant	Position	Site
Participant 1	Healthcare assistant	John Radcliffe Hospital
Participant 2	Midwife	John Radcliffe Hospital
Participant 3	Midwife	John Radcliffe Hospital
Participant 4	Midwife	John Radcliffe Hospital
Participant 5	Midwife	John Radcliffe Hospital
Participant 6	Midwife	John Radcliffe Hospital
Participant 7	ST2 Obstetrics and Gynaecology	John Radcliffe Hospital
Participant 8	Consultant Obstetrician and Gynaecologist	John Radcliffe Hospital
Participant 9	Midwife	Guy's and St Thomas' NHS Foundation Trust
Participant 10	Midwife	Guy's and St Thomas' NHS Foundation Trust
Participant 11	Doctor	Guy's and St Thomas' NHS Foundation Trust
Participant 12	Doctor	Guy's and St Thomas' NHS Foundation Trust
Participant 13	GP Trainee	Guy's and St Thomas' NHS Foundation Trust
Participant 14	Junior doctor	Guy's and St Thomas' NHS Foundation Trust
Participant 15	Junior doctor	Guy's and St Thomas' NHS Foundation Trust
Participant 16	Midwife	Guy's and St Thomas' NHS Foundation Trust
Participant 17	Midwife	Guy's and St Thomas' NHS Foundation Trust
Participant 18	Midwife	Guy's and St Thomas' NHS Foundation Trust

Table 11: Characteristics of focus group participants

Focus Group	No. of Participants	Position of Participants	Site
1	5	Participant 1: Senior midwife Participant 2 Midwife support worker Participant 3: Midwife Participant 4: Community midwife Participant 5: Midwife	Guy's and St Thomas' NHS Foundation Trust
2	4	Participant 1: Midwife Participant 2: Senior House Office Participant 3: Senior Registrar Participant 4: Midwife	Guy's and St Thomas' NHS Foundation Trust
3	2	Participant 1: Senior Registrar Participant 2: Consultant Obstetrician	Guy's and St Thomas' NHS Foundation Trust
4	2	Participant 1: Consultant Obstetrician and Gynaecologist Participant 2: Medical student	John Radcliffe Hospital
5	2	Participant 1: Midwife Participant 2: Consultant Obstetrician	John Radcliffe Hospital

Both the thematic analysis and the discourse analysis are presented in this chapter. The thematic analysis is presented first, while the discourses of paternalism and patient empowerment are present in some of the themes developed. It is prudent to report these themes separately as they speak to the implementation of self-testing in antenatal care and our understanding of the potential practical barriers.

The discourses that were identified early in the analysis process are presented second; paternalism is explored in relation to healthcare professional's views on patient suitability and trust within the patient clinician relationship. The counter discourse of patient empowerment contradicts many of the speculations healthcare professionals made about which patients are suitable for self-testing.

The findings in this study both compare and contrast to the views of pregnant people on self-testing, which were reported in chapter 4. Broadly, healthcare professionals agreed with pregnant people and found self-testing to be acceptable (see Chapter 4, Section 4.5.1.1), and there was little variation on these views across the different healthcare professions (i.e. midwife, obstetrician etc.). Questions were deliberately posed to healthcare professionals to tease out the barriers and benefits of self-testing. These are reflected in the thematic analysis. Some barriers identified by healthcare professionals mirrored those identified by pregnant people such as interpretation of the dipstick and anxiety. They also raised concerns about pregnant people contextualising proteinuria results, but many of these barriers could be overcome with patient education.

5.3.7 Results from the thematic analysis: implementation considerations

There were extensive discussions around the implementation of a home testing regime. These discussions followed the hypothetical scenario posed to healthcare professionals of a home self-testing regime, as the study itself was a one off test. The themes below explore

the acceptability of such a regime, as well as the potential barriers and motivators identified (Section 5.3.7.1 – 5.3.7.6). The discourses reported later (Section 5.3.8) were also present among these themes, particularly in relation to acceptability; healthcare professionals were positive about self-testing and found it an acceptable concept but still retained hesitancies about who it would be acceptable *for*.

5.3.7.1 *Acceptability*

The healthcare professionals in this study were broadly positive about self-testing for proteinuria, they perceived it to be an acceptable intervention in antenatal care. One healthcare professional framed it as being a good first indicator of a pregnancy that is progressing normally, or to catch things before they go wrong. Reasons that healthcare professionals found self-testing acceptable were varied, some felt it would be useful in the community, others felt that while it would not negate the need for healthcare professionals to test urine it could be a useful way to triage over the phone.

> *"I think self-testing could definitely work depending on what kind of environment it's in [um] and how that kind of, yeah, works out day to day but I think, yeah, it definitely has potential to be really helpful for women and for midwives.*" **Interview Participant 2, Midwife**

Healthcare professionals often caveated their positivity with speculation over whether pregnant people would, or could, self-test accurately. While the majority found that self-testing was acceptable there were paternalistic overtures when healthcare professionals speculated whether pregnant people would do it accurately, if it was right for every patient, and if they were capable of doing the test.

> *"I think it's a good idea but you have to pick the right clients who you think are responsible and capable and will do it accurately and important to keep a link with*

them, make sure they feedback to you and you act accordingly, yeah." **Interview Participant 14, Junior Doctor**

There were only a few instances in this data of healthcare professionals referring to pregnant people as clients. Chapter 1 introduced the linguistic concerns around the term patient in pregnancy, and its wider use in healthcare (Chapter 1, 1.9.1). Client is positioned as the more empowering of the two terms, but the use of client in this context does not necessarily allude to empowerment. The healthcare professional in the above excerpt brackets a term of empowerment with a sentiment that is less than empowering and in essence, paternalistic – deciding who should and should not self-test in pregnancy.

5.3.7.2 *Interpretation of the dipstick*

In chapter 4, pregnant people expressed concerns over interpreting the dipstick; healthcare professionals echoed these concerns, often based on their own uncertainties interpreting dipstick tests. Healthcare professionals thought that dipsticks could be difficult to read and often had trouble determining the colour change at the end of the stick themselves.

"No, I think that's quite good [um] to see how people see it or analyse, I think. I remember when I first started here, and looking at it myself, you know, watching it and then also the timeframes that you see as well because some pe-, I was like, 'Oh look that's the reading,' and wrote it down and then I'd go back think, 'Oh, it's darker.' and then look at it and you haven't read it right or waited long enough." **Interview Participant 5, Midwife**

While this was one of the main concerns for pregnant people, healthcare professionals mentioned it less; nonetheless, the presence of this theme across both datasets suggests it could be a barrier for implementation.

5.3.7.3 *Contextualising results*

Healthcare professionals stressed the need for proteinuria results to be considered in light of other symptoms, such as blood pressure and maternal organ function, the combination of which is an essential part of diagnosing pre-eclampsia (Chapter 1, Section 1.5). The need to assess the whole clinical picture, rather than the result of one test, meant healthcare professionals were often in favour of self-management, rather than self-testing in isolation. As will be explored in chapter 6 (Section 6.5.1), participants were asked in the interviews about self-management, but the concept of assessing the whole clinical picture was frequently raised prior to any discussions of self-management. Often, healthcare professionals stated they needed a fuller clinical picture before suggesting any further medical treatment.

> *"Well, it depends on lot of clinical indications I suppose of the woman as well. Her blood pressure is normal and there are no concerns for proteinuria, I would go by her face value as well how consistent is she in following medical treatment. So all, like, weighing up all those things I may rely on her, but if there's any clinical suspicion I might test her again."* **Interview Participant 11, Doctor**

Healthcare professionals indicated they would be inclined to re-test patients for proteinuria if there were any other concerning symptoms and remained sceptical that self-testing would detect pre-eclampsia any earlier in the absence of the wider clinical picture.

5.3.7.4 *Patient education*

Healthcare professionals emphasised that self-testing would only be successful in antenatal care if pregnant people were educated regarding how to carry out the test and about the relationship between proteinuria and pre-eclampsia. When discussing a home self-testing regime, healthcare professionals often suggested that specific instructions should be provided, including demonstrations from healthcare professionals.

> *"I think the way how they're checking because you have to hold the box and remove. I think before you introduce this, each woman should be properly informed how to hold the sticker, the stick after the dip stick urine and because always you have to, it's different way. Majority of the woman which was tested by GP would be saying, is showing protein because they checking like that, doesn't turn over, you know what I mean?"* **Focus Group 1 Participant 2, Midwife Support Worker**

Healthcare professionals emphasised that pregnant people needed to understand the significance of proteinuria in the context of other symptoms and how to interpret the clinical significance of results; for example, understanding that 1+ is the threshold for further clinical action. In chapter 4 (Section 4.5.2.1), pregnant people said they had little knowledge of proteinuria prior to their diagnosis of hypertension or pre-eclampsia; healthcare professionals made it clear that raising awareness of the condition should be a crucial implementation consideration.

One healthcare professional suggested patient education was important because there was a sense of legitimacy about the importance of the test when healthcare professionals did it, and that pregnant people may not be aware of the clinical relevance. Often, healthcare professionals said they would be best placed to teach pregnant people how to self-test and to explain the clinical context of proteinuria testing.

> *"I, I think the other difficult part would be making people understand that if you have protein that this is really serious and something quite significant could happen and could go wrong if you have it. I think, if people that they're given responsibility of it; 'Ah it's not a big thing and if, if it was that important the doctor or the midwife would do it.'"* **Focus Group 2 Participant 1, Senior Midwife**

Here, there is evidence that self-testing challenges the traditional paternalistic system of antenatal care; the current perception is that important tests and monitoring will be done by healthcare professionals. Self-testing shifts that narrative, but there is a legitimacy barrier

present, and the question remains whether monitoring and testing performed by pregnant people will hold the same weight and importance as if they were done by a healthcare professional.

5.3.7.5 *Anxiety*

Healthcare professionals often discussed whether self-testing would increase, or decrease, anxiety. Similarly to pregnant people, healthcare professionals did not convey a consensus view. An exchange in one of the focus groups made reference to the "*worried well*", and the participants in that group discussed the possibility that previously non-anxious pregnant people would become anxious because of self-testing.

> *Participant 1: Having, I don't know, there's just a lot of pre-, yeah, pregnancy brings out anxiety in people who didn't remotely have it in the first place.*
>
> *Participant 3: Yeah.*
>
> *Participant 1: So there's the danger that you're just making the worried well.*
>
> *Participant 5: Mm.*
>
> **Focus Group 1**

This discussion also aired concerns about whether the anxiety caused by self-testing would then increase healthcare professional's workloads. One healthcare professional was unsure about the overall impact on their workload, and depicted a scenario whereby pregnant people might make more frequent visits to hospital worried about their test results, although they hoped this would be negated by appropriate education.

> *"However, having said that if you teach people properly and it's picking up protein and we're not just routinely just seeing people over and over and over again, essentially it'll either make the workload ten times worse by having loads of anxious people running through the door or ten times better because you'll only need to see people when you need to see them and I'm not sure which way it would go. I guess."*

Focus Group 1 Participant 1, Senior Midwife

There were a few healthcare professionals who, conversely, felt that self-testing would be reassuring for pregnant people. They anticipated self-testing would reduce anxiety, particularly in pregnant people who were either already anxious or dealing with high risk pregnancies.

> *"Yeah, because if women tested at home, they will know beforehand and they won't have anxiety when they come to the clinic, 'Oh what is going to come up today?' so that will decrease their anxiety."* **Interview Participant 11, Doctor**

5.3.7.6 *Reduced appointments and saved time*

Some healthcare professionals disagreed that self-testing would increase healthcare professional's workloads, and in particular felt that a home based self-testing regime had the potential to reduce appointments, or save time during existing appointments, thus decreasing their day to day workload. However, they often caveated this by suggesting that combining self-testing with other self-management activities would be more effective at reducing appointments than self-testing in isolation. One healthcare professional felt that for uncomplicated pregnancies, rather than the high risk pregnancies included in the UDIP study, self-testing alongside other self-management activities could replace some of the in-person care that takes place in GP surgeries.

> *"Well, so I'm working as a junior doctor in the obstetric and gynae unit here but I'm actually a GP trainee. So I've just come from six months in GP and so we do, often our thirty-two, thirty-four week checks and stuff like that and I, I don't know, I kind of have in my, in the ones that I've done recently who have been completely well uncomplicated pregnancies. Literally, basically just check their, their blood pressure, check their protein, have a listen to their foetal heart, you kind of like, is this a bit of a waste of appointment, it kind of feels like."* **Interview Participant 13, GP Trainee**

Healthcare professionals also pointed out that patient education was central to whether

self-testing would reduce appointments; inaccurate readings would lead to re-testing and therefore, fail to save any time or appointments and once again add to healthcare professional's workloads.

5.3.8 Discourses in conflict: paternalism and patient empowerment

Analysis of the data revealed two discourses in conflict: paternalism and patient empowerment. Self-testing and self-management discourses challenge the paternalism of medicine, transferring knowledge and power to patients (a key component of patient empowerment) and this was realised in these data. The juxtaposing discourses of paternalism and patient empowerment are compounded by the views of pregnant people, who expressed a desire to be more involved in their care and saw self-testing as an access point (see Chapter 4, Section 4.5.2.1).

The paternalism identified in this dataset could be a barrier to self-testing being introduced into antenatal care. Paternalism was most evident when healthcare professionals were discussing patient suitability for self-testing. Throughout the interviews and focus groups healthcare professionals communicated their hesitancies around who should and should not self-test in pregnancy; in the process a portrait emerged of an *unsuitable patient*, one considered too chaotic to self-test throughout their pregnancy.

The discussions on the suitability of patients to self-test were wide ranging; some of the conversations focused on the clinical characteristics of patients and there was a general consensus that high risk patients (i.e. high risk for pre-eclampsia or previous history of a high risk pregnancy) would not only benefit the most from self-testing, but would best suited for it.

> *"Probably the women who are at risk of pre-eclampsia mostly because that's what we'd be looking for with protein. So, if they've had [um] any admissions with raised blood pressure, get them to do that and they could do it at home. [um]…we don't book an appointment just for a protein dip, but it probably would save health professionals' time because she could, they could do it at home and they could call into us if they had any problem, if they and a raised result or something."* **Interview Participant 4, Midwife**

There were a few divergent cases where healthcare professionals preferred self-testing to be used in uncomplicated pregnancies due to how quickly pre-eclampsia, or other complications, can onset. But discussions often moved away from the clinical suitability of patients and centred on patient's personal or social circumstances. Healthcare professionals often advocated for a 'case by case' approach to self-testing based on the individual, rather than offering it to patients across the board. Healthcare professionals often described patients, or their lifestyles, as chaotic. This term encompassed a wide range of personal, social, or economic circumstances; patients who were busy, had multiple other children, could not take time off work, or did not turn up to their regular appointments.

> *"People with chaotic lifestyles who aren't going to engage with it and just, you know, you see, 'She's very sensible, she'll, she'll be able to manage this study,' and then you see people who clearly you just they can't barely make their regular routine appointments, how they going to deal with the additional like yeah, so I think that."* **Focus Group 1 Participant 1, Senior Midwife**

Patients who did not go to their appointments or comply with other components of their care were seen as unsuitable for self-testing. This is notable because it is particularly discordant with the views of pregnant people, who said they would value self-testing in order to better engage with their care (see Chapter 4, Section 4.5.2.1).

In several focus groups and interviews healthcare professionals considered non-English speakers to be unsuitable for self-testing.

"I work with caseload women, so that's vulnerable women safeguarding, women who don't, who don't speak English and my initial thought is, this might work for some but not for all. So, I think that would be my first reservation." **Focus Group 2 Participant 1, Midwife**

"Women who don't speak English; women who don't engage with healthcare professionals very well or that are not good at attending appointments." **Focus Group 2 Participant 1, Midwife**

One particular exchange in a focus group highlighted that healthcare professionals seemed more comfortable with a case by case approach to self-testing. Again, non-English speakers and patients who do not regularly attend appointments were considered unsuitable for self-testing.

Moderator: Mm. So, we touched on who might not be suitable. [um] So who would you advise this for, mostly?

Participant 4: People who speak English, like, if they've had a history of good attendance.

Moderator: Okay.

Participant 4: I think women who have got like, special needs, like, learning disabilities that can comprehend it.

Moderator: Mm.

Participant 1: I, I think you'd have to do it case by case. It would be quite difficult to generalise that all this type of people will engage well with it. I think it would have to be case by case.

Participant 3: You just have to be able to be very sort of able basically, yeah.

Focus Group 2

The language in many of these excerpts is othering[9], there are certain groups and patients

[9] Othering is to view or treat a person, or a group of people, as different to, or from, oneself

that are considered by healthcare professionals to be unsuitable candidates, or too high risk for self-testing, due to personal, social, or economic circumstances. Many of these exchanges also speak to gatekeeping within the medical community regarding self-testing and self-monitoring.

In determining who would be suitable for self-testing, healthcare professionals are implying they do not trust certain patients. At the core of the discussions around suitability was the issue of trust, and whether healthcare professionals trust their patients. Some healthcare professionals suggested that they believed pregnant people would lie about their test results in order to avoid hospitalisation or treatment, speaking to a larger issue of trust within the patient clinician relationship.

> *"[um] I think a lot of people are afraid of what their results might be and if they, if something could cause them to end up as an inpatient in hospital, that they might be a little bit dubious to look at it slightly differently and say, "Oh no, that's, it's not that because if it was one over, I know I might end up admitted." So, you wanted want to put their care at risk, if that makes sense?"* **Interview Participant 5, Midwife**

This also possibly links back to healthcare professional's concerns about patient education, and teaching patients to contextualise their proteinuria results and understand the serious implications of a positive test. One healthcare professional speculated that a home self-testing regime could fracture that relationship further, suggesting that if a clinician re-tests a patient in clinic after they have reported their home results, and they might think that the healthcare professional does not trust them.

> *"Well, based on if they want to re-test here, a patient might think that we don't trust her and it might, you know, it's like, it might destroy the relationship what a patient and clinician have…"* **Interview Participant 11, Doctor**

However, there were a few healthcare professionals who thought a home self-testing regime could improve the patient clinician relationship and if healthcare professionals trust patients to self-test, then patients will trust them more too.

> *"Well, I think it shows more trust, you know, and I think the women think, 'Oh well she trusts me to do my own thing and she believes what I'm saying.'"* **Interview Participant 17, Midwife**

Conversely, patient empowerment was depicted as potentially transforming the patient experience, and, by extension, the patient clinician relationship. Despite healthcare professionals initially arguing that self-testing would empower pregnant people, they often undermined that narrative by expressing hesitancies about who would be suitable for self-testing, creating a jarring juxtaposition.

There was a general consensus among healthcare professionals that self-testing could improve patient autonomy and empowerment; this was echoed by pregnant people (as reported in chapter 4). On the surface these views appear harmonious, and some healthcare professionals even went as far to reflect that empowering patients could lead to a better relationship with their clinician.

> *"I kind of, I feel like it's empowering the women isn't it to be, to feel like they, they can take control kind of, of their own healthcare. [um] So it helps, I think it helps sort of build that relationship between the clinician and the patient in a way."* **Focus Group 3 Participant 1, Senior Registrar**

One healthcare professional framed their role as very authoritative, issuing instructions and maintaining control over every aspect of care, highlighting the paternalism in the antenatal care system. They went on to suggest self-testing could be a way to change the power dynamics between healthcare professionals and patients.

> *"I think there's lots of good aspects, for example, I think lots of women like to take, be able to take some kind of control of their own care and if, I feel like it puts a bit more power into those ladies because they're often, if they are eligible for this study, they're probably coming in for regular and multiple consultant appointments and I think the consultants here are really empowering and supportive, but I can only imagine that it can feel a lot like, "Do this, do that. Change this medication. Stop taking that medication," and it perhaps puts a little bit more power and control into the patients."* **Interview Participant 10, Midwife**

Where pregnant people and healthcare professional's views diverge, however, is the perception of the level of agency patients have in the current system of antenatal care. There is an interesting contradiction within this excerpt, while the participant sees clinicians as empowering patients, they depicts patients as not sharing the same view. There is a dissonance between healthcare professionals believing they are empowering pregnant people and the realities of antenatal care, which can often feel disempowering and paternalistic. In chapter 4 (Section 4.5.2.1) pregnant people suggested they lacked power and control in their care; particularly in-patients, who felt they did not have any independence or control. In the previous chapter, pregnant people were enthusiastic about self-testing in order to feel more involved in their care, suggesting a lack of agency in the current antenatal care set up.

Table 12: Quotes from the thematic analysis on healthcare professionals and self-testing for proteinuria

Theme	Quote
Implementation Considerations	
Acceptability of dipstick testing	*"I think it's a really positive thing. I think as long as people have instructions about how to do it. We have calibrated kit that is [um] you know, for use in pregnancy. I, I welcome that, yeah, I think it's the way forward*." **Interview Participant 3, Midwife** *"I think at home would potentially be quite useful especially for out in the community if women could yeah test their urine at home and then come to their midwife appointment saying whatever the results is."* **Interview Participant 2, Midwife**
Interpretation of the dipstick	*Participant: I worry about [um] patients doing their own testing….* *Interviewer: Okay.* *Participant: ….in non-automated fashion anyway.* *Interviewer: Hm-mm.* *Participant: ...because you're then relying on them both for interpretation and communication*. **Interview Participant 8, Consultant Obstetrician and Gynaecologist**
Contextualising Results	*"And also, I mean, from what I understand about pre-eclampsia, you know, you can have, you can have pre-eclampsia without protein. You can have, you know, is, does it help us diagnose these conditions any earlier? Is it any valuable? I don't have a problem with women doing it themselves as long you're, if you're, as long as they're able to be trained and they're sensible, then I don't see an issue with that. But I don't think it would necessarily be a blanket implementation."* **Interview Participant 9, Midwife**

Theme	Quote
Patient Education	*"I, I think the other difficult part would be making people understand that if you have protein that this is really serious and something quite significant could happen and could go wrong if you have it. I think, if people that they're given responsibility of it; 'Ah it's not a big thing and if, if it was that important the doctor or the midwife would do it."* **Focus Group 2: Participant 1, Midwife** *"I think, yeah, I agree with what [senior registrar] said, [um] as long as they're trained, and I think it can be, maybe in the future more reliable than healthcare professionals doing it because we're often not trained how to do it. We just watch and pick up and that way of doing it, right you think? I remember from training, I was never trained to do urine dipstick."* **Focus Group 3: Participant 2, Consultant Obstetrician**
Anxiety	*"But for a woman that might be very, very anxious, it might just add to that and having that responsibility [um] yeah."* **Interview Participant 3, Midwife** *"Yeah, because if women tested at home, they will know beforehand and they won't have anxiety when they come to the clinic, 'Oh what is going to come up today?' so that will decrease their anxiety."* **Interview Participant 11, Doctor**
Reduced appointments and saved time	*"I think it'll be useful if they get accurate, if it will be accurate and it will, as you say, could reduce the time of, time taken for diagnosis and it also saves them coming repeatedly back to the, you know, the antenatal day unit, especially if we can combine with them monitor their blood pressure themselves because a lot of the visits are just BP and urine dip. You know, if it's twice weekly then women do have to come in quite often or they have to go to their GP or midwife has to attend quite often, so it will be time saving for them, yeah."* **Interview Participant 15, Junior Doctor**

5.3.9 Discussion

There were two contrasting discourses present in this data; firstly, the pervasiveness of paternalism in antenatal care was evident as healthcare professionals made judgments about the suitability of patients to self-test, demonstrating their tendency towards gatekeeping even as they discussed the potential benefits of a home based self-testing regime. The second, subtler, discourse present was patient empowerment and autonomy, which was evident when healthcare professionals speculated about how self-testing could improve the patient clinician relationship. Broadly, healthcare professionals found self-testing acceptable, but there was a conflicting narrative regarding which patients were clinically best suited to self-test, whether the benefits would be wide ranging for healthcare professionals, and how it would affect the trust between patients and clinicians.

5.3.9.1 *Paternalism, gatekeeping, and candidacy in antenatal care*

In chapter 1 (Section 1.8.1) the concept of paternalism was introduced as the way knowledge and power is accumulated by the few in order to dominate and control the many in society (34). In healthcare, paternalism is evident in explicit and implicit ways, sometimes manifesting as the medical practitioner overriding the patient's autonomy (127) or in "*subtler one-on-one acts of provider-practitioners who behave paternalistically towards individuals*" (34). In this data, the subtler discourse of paternalism is present as healthcare professionals decide, on an individual basis, who is and is not suitable for a self-testing regime. The paternalism on display in this dataset is "*benign paternalism"*, which is described by Coxon as the process in which "*maternity health professionals reach conclusions they believe to be in the best interests of* [patients]*, sometimes without exploring* [their] *views, beliefs and values*" (128).

One of the ways paternalism was compounded in this dataset was the language used when discussing *suitability*. Much of this language was othering - singling out pregnant people who did not speak English and referring to those with more complex social backgrounds as chaotic. The language around competency was ableist in nature, when asked about patient suitability in one focus group a participant said that the self-testing patient had to be very able. Ableism, as defined by one prominent disability scholar, is "*a network of beliefs, processes and practices that produces a particular kind of self and body (the corporeal standard) that is projected as the perfect, species-typical and therefore essential and fully human. Disability then, is cast as a diminished state of being human*" (129) (130). There are significant barriers to accessing healthcare for those with disabilities (131), which include the availability of accommodating care (132). In these data, ableism and othering encompassed a wide group, including anyone who experienced language barriers in antenatal care, pregnant people with complex social backgrounds or disabilities, or even simply pregnant people with 'chaotic lifestyles' - the definition of which ranged from patients who did not regularly attend appointments or those with caring responsibilities at home. For this broad group, accessing healthcare or accessing their regular appointments may be a challenge, therefore providing a safe alternative to in-person care is especially relevant. Much of the language used by healthcare professions in this study speaks not only to paternalism, but gatekeeping in antenatal care.

Gatekeeping describes *"the role of primary care physicians or general practitioners in authorising access to speciality care, hospital care, and diagnostic tests*" (133). Gatekeeping is a necessary function of the NHS, which operates by providing healthcare on a population level rather than an individual basis, and has been adopted as a metaphor to "*describe the action of health professionals who exercise control over the demand for care, by selectively determining which patients are given access to the more specialized secondary services*"

(134). It also is a "*communication tactic that involves limiting or facilitating access to information*" (135). In healthcare, this manifests as providing or limiting access to healthcare itself (135), such as withholding referrals to specialist facilities, or withholding information about the implications of a particular type of treatment. In maternity care, gatekeeping can be employed as a method of protection, limiting information in order to protect the pregnant person and the healthcare professional (136). In this study, healthcare professionals often worried about self-testing causing pregnant people unnecessary anxiety, so by limiting the availability of self-testing, healthcare professionals may see this as protecting patients. Gatekeeping is inherently intertwined with paternalism, particularly relating to the information or access granted by healthcare professionals, who can "*keep patients under their power either by applying information or withholding it*" (137). In this sense, healthcare professionals are liable to inhibit patient choice, shared decision making, and other tenets of a patient-centred care model (133) through withholding information and access. Certainly, gatekeeping in relation to information flow and decision making is an issue in maternity care, one qualitative study, conducted with delivery ward staff, found instances of maternity healthcare professionals withholding information, giving information in a hurry, or making decisions on the patient's behalf (137). Healthcare professionals demonstrate gatekeeping in a myriad of ways in the study reported in this chapter, they are not necessarily withholding information but they are withholding access, and this is particularly prescient in the use of othering language and the decisions they make around patient suitability.

Candidacy is a theory that describes "*the ways in which people's eligibility for medical attention and intervention is jointly negotiated between individuals and health services*" (63), and was developed as a way to synthesise our understanding of how socially disadvantaged groups access healthcare. In this context, candidacy is "*the ways in which people's eligibility*

for medical attention and intervention is jointly negotiated by individuals and health services" (63). This theory helps to frame the dynamic described in this dataset between healthcare professionals and patients. In particular, the concept of adjudications in the candidacy theory is useful context for the data in this study. After the patient has navigated the process of asserting their candidacy by making appointments and seeking healthcare, there is then a process of adjudication whereby healthcare professionals make judgements or decisions which will "*allow or inhibit the continued progression of candidacy*" (63). This is another way in which gatekeeping manifests in healthcare and it is especially challenging in light of Dixon-Woods et al's finding that socially disadvantaged people appear "*at risk of being judged to be less eligible*" for interventions (63). This is certainly evidenced in this dataset where healthcare professionals risk disadvantaging those who would potentially benefit most from self-testing by excluding pregnant people who they judged to be disengaged with their care or had chaotic lifestyles.

Intertwined with the concepts of gatekeeping and paternalism, is patient autonomy. In healthcare, autonomy is described as patients being allowed, or enabled to "*make autonomous decisions about their health care*" (138). Beauchamp and Childress ascertained, in their seminal work on bioethics, that "*as assertions of autonomy rights have increased, the problem of paternalism has loomed larger*" (37). According to Armstrong, patient autonomy "*created a space in which agency could crystallise*" but the consequence of this new space was that medicine "*at once became paternalistic*" (125). Thus, the new patient clinician relationship, in Armstrong's view, involves "*a transfer of that very autonomy that had so recently been identified as a defining characteristic of professional status*" (125). This new and tentative balance is apparent in this data in the manner healthcare professionals express their resistance to self-testing. Although they discussed how self-testing could lead to increased patient autonomy their gatekeeping manifested in their advocacy of a case by

case approach to self-testing. While not outright condemning self-testing, their hesitancy around the suitability of patients remains a barrier.

There is some justified critique of the concept of patient autonomy, in particular around the idea of competency. Beauchamp and Childress discuss this idea in their work; they consider patient autonomy an important principle in healthcare, yet also discuss exceptions to this rule of patient autonomy. For example, they suggest that patients who are not considered competent by healthcare professionals to make autonomous decisions should be excluded from patient autonomy (37). Entwistle et al challenge the idea of competency and query what happens to patients who are "*basically competent*" but who "*struggle to choose between healthcare options…lack confidence…have conflicting priorities*" (138). There is also the question of *who* is deciding patient competency; indeed, in this dataset healthcare professionals have a long list of personal, social, and economic characteristics that they feel speak to competency. Although not explicitly discussed by Dixon-Woods et al, adjudications of competency likely play into decisions made by healthcare professionals regarding the progression of candidacy. Rather than branding it as decisions made on competency, Dixon-Woods et al discuss the idea of "*social deservingness*" playing a role in adjudications of candidacy, for example, GP's being more likely to refer the "*economically active and those with dependents*" for medical intervention. For patients, it is clear from their feedback in chapter 4 that these are factors should not, and do not, speak to their ability to self-test. Even within the theoretical discussions on patient autonomy, there is implicit paternalism if patients are only permitted to be autonomous if healthcare professionals judge them competent.

5.3.9.2 *Patient-centred care, an aspiration or reality?*

Despite the evidence of paternalism in this dataset, patient autonomy and empowerment is, theoretically, more prevalent in health systems. Chapter 4 (Section 4.6.1.2) discussed the recent shift towards patient empowerment, particularly in chronic disease management, and there has been renewed commitment from healthcare providers to focus on patient-centred care. In chapter 4, the three tenets of patient empowerment were discussed: shared decision making, self-management, and patient education (see Chapter 4, 4.6.1.2) (42). These are also the principles on which patient-centred care is based; the NICE guidelines emphasise that patient decisions should be made "*in partnership*" with their healthcare professional (10). While healthcare professionals broadly discussed empowerment, shared decision making was not realised in this dataset. Healthcare professionals were asked about the potential changes in the patient clinician relationship if self-testing were to be implemented in antenatal care, but were not specifically asked about shared decision making as a concept. However, what was alluded to was a lack of space for patient decision making; in excluding the possibility of patient choice from their discussions around patient suitability, healthcare professionals unconsciously created a space where patient preference and choice was absent. Dixon-Woods et al's concept of candidacy depends on eligibility being jointly negotiated between patient and healthcare provider (63), in this dataset there is evidence of the decision being taken out of the hands of the patient.

5.3.10 Strengths, Limitations, Reflections

Qualitative data on self-testing for proteinuria in pregnancy is sparse, as mentioned in chapter 4. There is even less data available on healthcare professional's views of self-testing, as such, this study addresses a gap in the literature. A strength of this study is the mixed qualitative methods used to collect data, by using both interviews and focus groups the data had more depth. Supplementing the interviews with focus groups allowed an exploration of

topics that had been brought up in the interviews, and allowed healthcare professionals to tease out thoughts and viewpoints from each other that the moderator, or interviewer, may not have been able to as an outsider to the profession and the group.

The interview guide was iteratively adapted to include topics that came up in the early interviews. Often, in the focus groups, healthcare professionals were more forthcoming about their concerns with self-testing, perhaps bolstered by the support of their fellow healthcare professionals. The focus groups tended to have more depth and nuance than the interviews, in part due to the easy flow of conversation and healthcare professionals prompting each other to discuss their thoughts and concerns in more detail. Keeping the focus groups relatively small allowed everyone who participated a chance to speak, ensuring all voices were heard equally.

As with the interviews with pregnant people in the previous chapter, there were several situational challenges. The interviews were collected on an ad hoc basis, which proved challenging. Due to the busy and hectic nature of healthcare professional's work lives, interviews were often short and conducted in empty rooms on busy wards. Focus groups were similar, healthcare professionals were approached on the day and could spare no more than half an hour in between seeing patients or on their lunchbreak. A few of the interviews were interrupted because the participants were understandably called away and needed back at work. Some of the focus groups had participants arriving and leaving at different times and this, combined with some of the groups being smaller than expected, was challenging to the flow of conversation.

5.4 Conclusions

Although there has been a concerted move towards healthcare systems, including the NHS, promoting patient-centred care and all that entails - shared decision making, patient

empowerment, and self-management – these data shows there is still a prevailing discourse of paternalism in antenatal care; evidenced through healthcare professionals making judgments about who should and should not self-test through their pregnancy. Traditionally, healthcare professionals have been the knowledgeable party in the patient clinician relationship, self-testing disrupts that narrative and challenges the balance of power that has, to date, swayed towards the healthcare professional. The conflicting discourses in this chapter demonstrate that while healthcare professionals are open to self-testing and believe it would empower patients, as well as have other benefits, paternalism remains a barrier. Healthcare professionals are clearly hesitant about certain aspects of self-testing and understanding this dynamic is important for the implementation of a home based self-testing regime.

Chapter 6 : Self-management in pregnancy: The EMPOWER study

6.1 Overview

This chapter reports the results of a qualitative study on the views of pregnant people with hypertension and healthcare professionals about self-management in pregnancy. As specified in chapter 1, self-management in this thesis is the combination of self-monitoring blood pressure, self-testing urine for proteinuria, and self-titrating blood pressure medication. Few qualitative data exist on the views of pregnant people and healthcare professionals about self-management in pregnancy. This exploratory study sought to understand their views on the concept, whether it might be an acceptable intervention in antenatal care, and the potential barriers to implementation.

6.2 Objectives

The previous two chapters have explored pregnant people and healthcare professional's views on self-testing. This chapter takes that concept one step further and explores self-management in the form of self-testing, self-monitoring, and self-titrating. The overarching aim of this study was to explore pregnant people and healthcare professional's views on the self-management of hypertensive pregnancies.

The specific research questions for this study were:

1. What are the barriers and facilitators for self-management during hypertensive pregnancy becoming integrated into pregnant people's lives?

2. What are the barriers and facilitators for self-management in hypertensive pregnancy becoming integrated into antenatal care?

6.3 Methods

The EMPOWER study ran alongside the qualitative data collection reported in chapters 4 and 5. The interviews and focus groups conducted with healthcare professionals and pregnant people reported in previous chapters focused on self-testing in the first instance, but participants were also asked about their thoughts on a home based self-management regime. Inclusion criteria, method of approach, timing, and locality of these interviews and focus groups are reported in chapters 4 and 5 (see Chapter 4, Section 4.3.1, and Chapter 5, Section 5.3). The free text postcards that were collected for the self-testing portion of the qualitative study were excluded from this analysis as they held no information about self-management.

6.3.1 Topic guides

The interviews and focus groups were split into two halves, the first half focused on exploring participant's thoughts about a home based self-testing regime and the UDIP study (Chapter 4, Section 4.3.2), and the second half focused on exploring a home based self-management regime which was explained to participants as self-testing for proteinuria, self-monitoring blood pressure, and self-titrating blood pressure medication (Appendix 4.3). If participants were unfamiliar with self-management the interviewer explained it was a combination of these activities. After discussing self-testing, participants were asked about home blood pressure monitoring to understand how familiar they were with this additional component. They were then asked about combining all three self-management activities and self-titration was explored extensively in response to concerns from both groups of participants. If participants expressed extensive concerns about self-titration, after exploring

these, the conversation was paired back to consider a self-management regime that featured just self-testing and self-monitoring. Participants were asked to consider barriers to implementation, patient benefits, and patient suitability for either a self-management regime with self-titration, or without.

An iterative approach was used to develop the self-management section of the topic guide; the questions and prompts were re-defined over the course of the study in order to explore some of the themes and concerns raised by the participants in more depth (Appendix 4.3).

6.4 Data analysis

Prior to beginning the analysis, the interview and focus group transcripts were edited to remove the first section of the interview/focus group that specifically focused on self-testing for proteinuria. In some interviews and focus groups, the conversation moved back to focusing on self-testing in the latter stages. If the data in these moments spoke directly to self-testing and not self-management, they were left out of the analysis along with the first half of the interview data. Naturally, discussing self-management still included discussing self-testing, and this meant separating out the data was a complex process and there was inevitably some overlap in the analysis and the themes that were developed.

Analysis began with a detailed examination of the interview and focus groups transcripts in order to develop an understanding of the material and identify some initial themes. The interview and focus group transcripts were uploaded to Nvivo 12 Pro (QSR International PTY LTD, released 2018) for a thematic analysis, using the guidelines produced by Braun and Clarke (104).

Four overarching themes were developed after close examination of the data. It was prudent to create a theme around self-management as a concept. In this theme the acceptability of self-management was explored, and a sub theme was created to reflect the

concerns healthcare professionals and pregnant people had around self-titrating medication. A second theme was developed to reflect the numerous patient benefits that healthcare professionals and, in particular, pregnant people identified. Reduced appointments and staying out of hospital alongside increased surveillance and patient autonomy were grouped together under the overarching theme of patient benefits. To reflect pregnant people and healthcare professional concerns around patient anxiety and the potential solution of patient education, a theme was developed grouping these themes together as 'overcoming anxiety: how to utilise patient education'. Finally, noticeable in the data were the different perspectives pregnant people and healthcare professionals had regarding their relationship. A theme was developed around 'differing perspectives: the patient clinician relationship', and included the sub theme of patient suitability which speaks to paternalism, this was also prevalent in the previous chapter (Section 5.3.8),

At this stage, it was acknowledged there was some repetition in themes between the self-testing and self-management databases. Repetition in themes was potentially attributable to circularity in the conversation; participants recalled barriers or concerns about self-testing they had raised earlier in the interview or focus group and repeated those themes later in the conversation in relation to self-management. These themes were included in the analysis if they were identified clearly in the self-management data. In order to better visualise the data and understand how themes from the previous analysis in chapters 4 and 5 influenced the themes that were developed from the self-management database, the data was mapped used the 'One Sheet of Paper' (OSOP) method (105) (Figure 10). This visualisation suggested there was synergy with themes reported in previous chapters; patient autonomy, increased surveillance, anxiety, patient education, and paternalism were all identified as recurring themes that were present in both the self-testing and the self-management data.

Figure 10: Visualisation of the data using the OSOP method



6.5 Results

21 pregnant people and 18 healthcare professionals took part in an interview, and five focus groups with 15 participants were conducted (see Chapter 4, Tables 7 & 8, and Chapter 5, Tables 10 & 11). Pregnant people were recruited from three hospital sites and healthcare professionals were recruited across two hospital sites. It was not possible to recruit from Birmingham Women and Children's Hospital due to the impact of the COVID-19 pandemic.

Self-management is a multifaceted concept in pregnancy, involving multiple self-management activities, which meant that pregnant people and healthcare professionals were grappling with a hypothetical home self-management regime that involved activities they were unfamiliar with. This was realised in the hesitancy regarding self-titration, and this is explored in the theme 'self-management as a concept: breaking down the components'. Both healthcare professionals and pregnant people contemplated the potential benefits of a self-management regime, such as reducing appointments and increased surveillance, and these ideas are explored in the theme 'patient benefits'. Once again, reflecting the self-testing data (Chapters 4, 5), there was a dichotomy of views on anxiety; both healthcare professionals and pregnant people were divided about whether anxiety would increase or decrease with self-management, and how patient education could combat uncertainty. This is explored in the theme 'overcoming anxiety: how to utilise patient education'. The final theme explored in this chapter is 'differing perspectives: the patient clinician relationship' which explores the contrasting views that pregnant people and clinicians have regarding their relationship (Table 13).

6.5.1 Theme 1: Self-management as a concept: breaking down the components

Self-management was explained to participants as a combination of self-testing urine, self-monitoring blood pressure, and self-titrating medication. Often, these components were

broken down to understand the potential stumbling blocks for integrating self-management into antenatal care. Overall, both groups had concerns about self-titration, mostly pertaining to safety, but were more positive about pairing back a self-management intervention to just self-testing for proteinuria and self-monitoring blood pressure.

6.5.1.1 *Acceptability of self-management*

The majority of healthcare professionals and pregnant people had concerns about self-management as a whole package, these concerns mainly centred on self-titrating blood pressure medication. These concerns held true regardless of the job title of the healthcare professional; there was no discernible difference between the views of midwives, obstetricians and healthcare support workers. However, there were a few divergent cases that are worth exploring in both pregnant people and healthcare professionals. Some healthcare professionals believed that all three self-management activities could have a positive effect on patients, and were supportive of the idea. While it was often caveated with paternalistic speculation about who would be suitable for self-management, it was thought that self-management may reduce anxiety.

> "*But it's quite good I think for the right people. It'd be good if you could, I think there's some people that you could put more at ease by doing it that way and there's some people that you could make more anxious by doing it that way. It's about all individuals, I think.*" **Healthcare Professional Interview 5, Midwife**

Pregnant people were more supportive of self-management as a whole package than healthcare professionals but, again, these views were in the minority. One pregnant person listed several reasons why they were supportive of self-management, including being able to go home, having more control over their pregnancy, and being worried about pregnancy outcomes.

"That's a good idea. For the simple fact, that because my blood pressure had been so high the last few days, they whacked me on lots of drugs. Well, today, guess what it's done, gone the other way, so now it's low. So now they're going, "Do we send her home with all these drugs or not?" you know, they're um and ah-ing. So if I could go home and test it myself and like, self-medicate as such, it takes all the worry out of them and then also I know it's in my hands and only my hands which I'm quite a control freak and I would prefer that. I really would because especially at the moment, it's my baby's life that's in my hands and I don't like, the thought of it being in somebody else's." **Participant Interview 4**

This particular participant was an inpatient, and their pregnancy was considered high risk, their desire to go home and have more control over their pregnancy is reflective of their immediate situation.

However, the majority of pregnant people and healthcare professionals were more supportive of blood pressure monitoring and self-testing in tandem, self-titrating medication was considered a step too far for most (see Section 6.5.1.2). Both groups believed it would increase patient autonomy (see Section 6.5.2.4). Healthcare professionals also thought that some pregnant people were already monitoring their blood pressure at home, so felt that being supportive of other self-management activities that were related to monitoring, not titrating, was a reasonable next step.

6.5.1.2 *Titration hesitation*

The majority of healthcare professionals and pregnant people were concerned about self-titrating blood pressure medication. Healthcare professionals had concerns ranging from handing over responsibility for medication to those without medical training, to the consequences of a patient taking medication incorrectly, and the burden of responsibility and treatment for pregnant people.

"Participant 1: I think that's maybe a step too far. I think we need to start with the basics before we get patients walking rather than running if you know what I mean.

Moderator: Okay.

Participant 1: So it's a big responsibility isn't it?

Moderator: Hm-mm.

Participant 1: I think, that, that bit's like, you know, just saying, "Here are my results," and then asking a medical professional to kind of say, 'So how do I act on these results?' is different from say, 'Okay here are my results and I'm going to decide how I'm going to act on these with no medical knowledge.' I think, no, I don't think so." **Healthcare Professional Focus Group 4 Participant 1, Consultant Obstetrician and Gynaecologist**

This extract highlights the tension between medical knowledge and lived experience. Patients may not have the same medical knowledge as healthcare professionals, but they do have lived experience of their condition, a knowledge base that healthcare professionals will often lack. Some healthcare professionals were particularly forceful in their opposition to self-titration. After the above exchange, one healthcare professional went onto say that they didn't believe patients had the *right* to titrate their own medication.

"So maybe there's a way of remote, [er] remote [er] advice titration rather than them having to park the car, come and see the consultant, come up to DAU, maybe there would be a way that the health care professional would still have some input into titrating it but I don't think, I really don't think patients should have the right to titrate their own medication." **Healthcare Professional Focus Group 4 Participant 1, Consultant Obstetrician and Gynaecologist**

In chapter 5, paternalism was a dominant discourse in the dataset (see Section 5.3.8) and it was also present in the self-management data. This exert highlights the paternalistic nature of antenatal care. This participant went on to explain some of their hesitancies over self-titration was because of safety concerns and an understandable desire to do no harm. While

not expressed explicitly in the interview, there are also litigation concerns to contend with for clinicians. The blame, should there be a poor outcome in the pregnancy, falls on the physician responsible for the pregnant person's care.

Paternalism was again evident in the following exert, one healthcare professional felt that allowing patients to self-titrate medication when some healthcare professionals, in this case a midwife, cannot prescribe or titrate blood pressure medication was handing over too much control and responsibility.

> *"That's an interesting, considering as a qualified midwife, I'm not able to prescribe or titrate blood pressure medication, the idea of giving to somebody who's not, who might necessarily not even be medically trained or in any capacity is a bit concerning because if we're saying as midwives, as nurses, we can't prescribe these things, but a patient can self-medicate, self-titrate these medications, it's kind of, it seems a bit, it doesn't seem to add up. It doesn't quite make sense. I'm not saying you shouldn't do it, but it does seem to be, like, 'Hang on, why are we saying?' But then are we saying, 'because it's yourself, it's your own responsibility,' but then again, are we kind of giving women a bit too much control in something that they shouldn't really, they don't necessarily have the knowledge behind it to make those decisions."* **Healthcare Professional Interview 16, Midwife**

While this particular extract is orientated towards the midwifery profession, the hesitancy expressed by this participant about handing over control to patients encapsulates the paternalistic nature of antenatal care. In this instance, paternalism is justified by concerns that patients do not have the knowledge and expertise to self-titrate. However, this concern was also reflected by some pregnant people. One pregnant person explained that they were concerned about the knowledge gap, and explained that healthcare professionals have a knowledge base not accessible to patients, and they preferred to leave changing a medication dose to the clinician.

> *"Yeah, I mean, I think because otherwise there's, there's a, I mean there's a reason why the doctors know, you know, what's best for you. They're probably more experienced of knowing whether this is just an odd increase in, in blood pressure, or this means the medication needs to be changed. Because of course BP medication, you know, when you change the dosage or you change the medicine, they do have side effects, so I think that's something that I'd like the doctor to tell me. But, yeah I think that's something that I, I think would be better for a doctor to sort of, you know, give their opinion on."* **Participant Interview 14**

The self-management programme explained to patients and healthcare professionals in this dataset was a hypothetical scenario. In response to the misgivings expressed by both groups about self-titration, the interviewer asked whether a stringent protocol would affect their feelings about self-management. Pregnant people were more positive about self-management, particularly self-titration, if they would be able to follow an easy, understandable, pre-approved protocol. Healthcare professionals remained sceptical, their concerns were not allayed by the prospect of a carefully approved protocol and they remained concerned about the dangers of self-titration.

6.5.2 Theme 2: Patient benefits

Patient benefits were explored extensively in the interviews and focus groups. These benefits were wide ranging, but there was a split between patient and healthcare professional views. Patients saw benefits such as staying out of hospital, reduced appointments, and increased surveillance, while both groups saw the benefit of increased patient autonomy. Some of these themes were repetitive of the self-testing data, reduced appointments, increased surveillance and patient autonomy have been discussed before in this thesis (Chapter 5, Section 5.3 and Chapter 4, Section 4.5).

6.5.2.1 *Staying out of hospital*

One of the most significant benefits to self-management for pregnant people, with or without self-titration, was staying out of hospital. This view was not shared by healthcare professionals, who rarely mentioned this particular benefit. Around half the pregnant people interviewed for the study were in-patients, so this was reflective of their current situation. For one participant, who lived a long way from the hospital, they were feeling isolated as an in-patient because it was difficult for family and friends to visit. Being able to stay at home and monitor their progress would have been a significant benefit for them.

> *"Participant: I would be able to stay at home.*
>
> *Interviewer: Hm-mm.*
>
> *Participant: [um] I'm in a county where I don't know anybody, so that'd be really important to me to be with my friends and family and my cat and just, I'm not, I like to spend a lot of time by myself, so I find it quite stressful being surrounded by people all the time…"* **Participant Interview 7**

6.5.2.2 *Reduced appointments*

In addition to staying out of hospital, pregnant people also thought that self-management would reduce the number of appointments they would have to attend. This theme was present mainly among pregnant people in the self-management data, but healthcare professionals raised this previously in relation to self-testing (Chapter 5, Section 5.3.1.6). It was hypothesised adding more self-management activities would be more likely to reduce appointments.

Pregnant people found it difficult to fit antenatal appointments into their busy lives, they were often juggling work and other children. They felt that, if their pregnancy was low risk, they could do some monitoring safely at home, meaning less time spent trying to attend appointments. For one participant, trying to fit in early clinic appointments around the

school run was challenging, although they understood that being higher risk equated to more appointments on top of the regular antenatal appointments. Their hope was that self-management might reduce some of the additional appointments that were difficult to attend, with the reassurance that they would be seen by a healthcare profession if there was an urgent need.

> *"But when you've got other children, you know, you're needed to go into clinics at eight o'clock which affects the school run times which involves, you know, a lot of craziness in the morning. I think you'd still have your antenatal appointments anyway and if you've got a plain sailing pregnancy, you wouldn't be expecting to see additional people. It's when there's an issue that you're called back regularly. I think, I think if it can reduce some of those, you know, it's got, it'll be in a safe environment anyway. They're not going to let you, if you needed to be seen, you'll be still seen anyway."* **Interview Participant 2**

6.5.2.3 *Increased surveillance*

Another theme present across the self-testing data and the self-management data was increased surveillance (Chapter 4, Section 4.5.2.2). This issue was mostly raised by pregnant people, who wanted an early indication that the pregnancy was progressing normally, or if there were issues. One participant who was self-monitoring their blood pressure at home already, could see their blood pressure going up and then called their midwife and was brought in for further testing, which confirmed the hypertension.

> *"Participant: …and in my case it was very good because I could see that something is not going the ideal direction.*
>
> *Interviewer: Yeah, right.*
>
> *Participant: I could see the blood pressure going up and up and up and, at that point, I could contact my midwife and then mention this at the clinic here on* [redacted] *that this is what's happening and they could have a closer look and, and then they tested*

my urine themselves first and realised there are two issues which are not perfect in my condition." **Interview Participant 5**

As reported in chapter 4 (Section 4.5.2.2) the rapid on-set of pre-eclampsia was a particular area of concern for pregnant people. They wanted to be able to monitor potential changes between antenatal appointments, and reduce the worry associated with waiting for a long time between those appointments.

6.5.2.4 *Patient autonomy*

In chapter 5, two conflicting discourses were present in the data on self-testing and healthcare professionals – patient empowerment and paternalism (Chapter 5, Section 5.3.7). These discourses were also present in the self-management data, but were perhaps quietened by the inclusion of pregnant people's data, where paternalism was much less evident. However, patient empowerment and autonomy was, once again, a palpable benefit of self-management. Pregnant people expressed their desire for empowerment using terms such as control, or involvement in care. Healthcare professionals were more likely to explicitly use the term empowerment.

Healthcare professionals thought that self-management would help pregnant people regain control, which is particularly important during pregnancy when perceptions of bodily autonomy may be low. One healthcare professional pointed out that if the chronic condition was pre-existing then pregnant people would have more knowledge of managing that condition than their midwives.

"Well it could be, in some ways it could be good because then they'd feel like they're, they feel a bit more in control, like their losing the control is really hard when you're pregnant especially if you don't necessarily know what's going on and it's very easy to feel like you're not in control of your body and everything else as well but equally, women know their own bodies quite well and if they're used to having chronic

condition they know how to, to look after themselves sometimes better than the midwives do because they've had it for so long." **Healthcare Professional Focus Group 5, Participant 1, Midwife**

Pregnant people often used the word control as a way to express their desire for increased involvement in care and their hope for increased patient and bodily autonomy. There were occasional references to shared decision making, although this was not explicitly asked about in the interviews, one pregnant person referred to the patient clinician relationship as being like a team, working together throughout the pregnancy.

"I think it's good. I think it is good. I mean, again, you can't be putting too much pressure on healthcare people, too much reliance on them to pick up everything. If you're both working as a team, it frees up the team to do other things. It gives you the confidence that you know what's going on with your pregnancy, have more control, you know, so I think it's a positive movement." **Participant Interview 10**

6.5.3 Theme 3: Overcoming anxiety: how to utilise patient education

Anxiety and patient education was another theme that was evident in both the self-testing and self-management datasets. In both chapter 4 (Section 4.5.2.3) and chapter 5 (Section 5.3.7.5) a lack of consensus was reported regarding healthcare professional and pregnant people's views on whether self-management was the cause of, or solution to, anxiety in higher risk pregnancies. Reflecting chapters 4 and 5 (Section 4.5.1.1 and Section 5.3.7.4) patient education was discussed as a potential solution for easing self-management anxiety.

6.5.3.1 *Anxiety*

There were some healthcare professionals who thought self-management would lead to pregnant people becoming anxious, particularly if their blood pressure or proteinuria results were borderline.

"I suppose one disadvantage for the women is it might increase their anxiety and worry [um] as to, as to how they're, whether they feel that they're healthy and

whether their concerns are allayed [um] by doing it [um] and, you know, whether we have increased referrals for very kind of minor blood pressure infringements and that kind of thing." **Healthcare Professional Interview 6, Midwife**

On the other hand, some healthcare professionals thought that self-management would help pregnant people who were already anxious about their pregnancy, and that it would be reassuring to have regular normal results in between appointments.

"Participant 2: It could be reassuring and would probably save unnecessary visits if they're kind of quite anxious about their pregnancy it can be reassuring to do their test and [um] to see that there's nothing coming up on the…

Participant 1: Yeah you get a lot of anxious patients isn't it? Kind of want to come to hospital for reassurance but if there's a measure they could reassure themselves in a way that would be quite good for them." **Healthcare Professional Focus Group 4**

Pregnant people were equally divided over whether self-management would increase or decrease their anxiety. One participant thought that it depended on the individual, and that some pregnant people would find medical tasks anxiety inducing.

"I mean I like, I would like to think that if you felt as though you were, you knew what to do and that you were in control that it would decrease anxiety, but some people seem to find having to medical things anxiety provoking. I think it just totally depends on the woman." **Participant Interview 12**

There was no clear consensus about anxiety in this dataset, similar to the self-testing data. The participant above suggested that it depends on the individual whether self-management would cause anxiety, which is a sentiment shared by the majority of healthcare professionals and pregnant people across both the self-testing and self-management data.

6.5.3.2 *Patient education*

Similar to the data reported in chapter 4 and 5 (Section 4.5.1.1 and Section 5.3.7.4) regarding self-testing there was a general consensus among healthcare professionals and

pregnant people that patient education was required for self-management to be successful in antenatal care. Pregnant people wanted to be shown how to do the various self-management activities by healthcare professionals to avoid any additional anxiety.

> *"I think as long as that person, if, if you are doing self-care, as long as you're shown how to do it properly [um] when to do it and not do it too often because otherwise you could, you know, you could have a, I could be watching something that could scare me and my blood pressure would be sky high and I'd decide to do it, so the, I think you just need to be stringent in teaching that person how to do it, how to do it properly, you know, what kind of [um] elements could, could skew, skew the results and things like that."* **Participant Interview 20**

Healthcare professionals also wanted assurance that patients were doing self-management activities correctly, but also reiterated that patients need to understand their diagnosis and why regularly testing their urine and monitoring their blood pressure was important for managing hypertension.

> *"Well I guess it is again, it's having the facts and doing it properly isn't it? I think that's the main thing that I think as long as they're doing it properly and following the guidelines properly."* **Healthcare Professional Focus Group 5, Participant 1, Midwife**

Patient education was often mentioned in discussions around anxiety, and it was implicitly suggested that educating patients on how to do self-management activities correctly alongside why they were important in the larger context of hypertension management would help to reduce any anxiety caused by the self-management itself.

6.5.4 Differing perspectives: the patient clinician relationship

Pregnant people and healthcare professionals were asked about potential changes to their relationship if self-management was introduced into antenatal care. Pregnant people had a positive view of their relationship with their healthcare professional, whereas healthcare professionals presented a different view of the relationship, one that lacked trust and was

dominated by paternalistic attitudes. Echoing the findings in the self-testing data, paternalism was identified in the way healthcare professionals discussed the suitability of certain patients to self-manage.

6.5.4.1 *Patient clinician relationship*

In chapter 5 (Section 5.3.8), the issue of trust between clinicians and patients was explored, which shed light on the contentions that lie beneath the surface of the patient clinician relationship. That data showed healthcare professionals had concerns about whether pregnant people would report results accurately, whether deliberately to avoid hospitalisation, or unknowingly due to inaccurate testing. Those concerns remained when it came to self-management, once again highlighting the delicate balance of trust in the relationship, from the healthcare professional's point of view.

In these data, the gulf between the patient's view of their relationship with their healthcare professional, and healthcare professional's view of that same relationship, was stark. Patients felt that their healthcare professional should trust them to self-manage, and that the relationship would improve because they were more involved in their care. Patients either had a positive view of their current relationship with healthcare professionals, or believed that self-management would strengthen their relationship.

> *"I think they would trust me, you know, if they trained me properly, I think but I'm still not what the question is alluding to, I feel it will be a better relationship and I think I'd feel more comfortable having extra measurements because they'd be and they explain it, instead of just having it done once in every appointment."* **Participant Interview 14**

Healthcare professionals echoed some of these views; some of them believed that self-management would improve the patient clinician relationship because it demonstrated they were putting trust in their patients while still being a safety net for them when required.

"and so potentially that could improve relationships between doctors and patients because if they think, 'oh yeah the doctors trust in me to look after my own care but they're still there if I need them,' so I think it's the careful balance of them not thinking we're not just fobbing them off because we don't have the time and we can't be bothered to see them but balancing with we're actually putting that trust in them that we believe that they can help manage that but we but we are still there if they need us to. So, I don't see why it would be a bad thing." **Healthcare Professional Interview 7, ST2 Obstetrics and Gynaecology**

But while these views were harmonious on the surface, there remains an issue of trust. Although healthcare professionals believed self-management would improve their relationship with their patients, they still implied they did not think patients would report results back correctly, whether through deliberate deceit as these participants suggested, or through inaccuracies.

"*Participant 1: Whereas, if you put someone in charge of something, they're more likely to be more diligent with it. So, if you put someone in charge of monitoring their blood pressure, they're more likely I guess to be, you know, taking their anti-hypertensives and be more aggressive with their management of that. You do get people who will then just be completely paranoid.*

Participant 2: Yeah, we have the paranoid people are the people that are trying to [um]…

Participant 1: Skew.

Participant 2: Skew and make numbers up.

Participant 3: Yeah, yeah." **Healthcare Professional Focus Group 3**

6.5.4.2 *Patient suitability*

In chapter 5 (Section 5.3.8) patient suitability was discussed in relation to paternalism. Both healthcare professionals and pregnant people were asked about patient suitability, a topic that required exploration based upon earlier interviews, but healthcare professionals had

more thoughts on this particular issue than pregnant people, who tended to suggest most pregnant people would be suitable to self-test (with the exception of those who may be colour blind and find interpreting the proteinuria dipstick difficult).

Healthcare professionals had similar thoughts about who would be clinically best suited to self-manage as reported in chapter 5 (Section 5.3.8), some felt it was best suited for uncomplicated pregnancies, yet a few healthcare professionals felt that self-management would be best suited for high risk pregnancies. There were also similar thoughts about the unsuitability of certain patients due to their personal and social characteristics as reported in chapter 5 (Section 5.3.8). The following exert highlights many of the same characteristics of patient suitability that healthcare professionals raised when discussing self-testing, for example, patients who are not compliant with their care and patients who do not have the intellectual capacity to understand self-management.

> *"Somebody that I believe is very high-risk and therefore medically perhaps not the right person to engage in this. [um] Somebody who I feel perhaps doesn't have the intellectual or educational ability to be able to reliably increase from a hundred to two hundred. You know, for example, who doesn't understand that information and therefore might benefit from more of a face to face change of a prescription. [um] Somebody who's not compliant with medication generally."* **Healthcare Professional Focus Group 5, Participant 2, Consultant Obstetrician**

Table 13: Quotes from the thematic analysis on self-management

Theme	Quote
Self-management as a concept: breaking down the components	
Acceptability of self-management	*"Participant: I think if the guidelines are clear enough as to when and what you're increasing by, then I don't see a problem with that.* *Interviewer: Hm-mm.* *Participant: But I haven't got any experience of taking blood pressure medication, so I don't know the effects. But as long as it is clear then I don't see, I think a lot of people would prefer to stay at home rather than go backwards and forwards all the time."* **Participant Interview 2**
Titration hesitation	*"My initial reaction is that sounds risky potentially. [um] Just because, I don't know, it's quite a big thing to be dealing with yourself, like blood pressure medication if it's not quite right can have quite serious effects of either really bad hypotension or uncontrollable hypertension."* **Healthcare Professional Interview 2, Midwife** *"Participant: I'd be feeling quite uncomfortable about changing my, the, my medication to be honest……* *Interviewer: Okay.* *Participant: ….on my own for example. Yeah, if I didn't, if I had to do it right there and then from a result, I'd feel quite anxious about doing so."*

Theme	Quote
	Participant Interview 14
Patient Benefits	
Staying out of hospital	*"I think it would be a fantastic idea, especially, I'm desperate to get home. I really am. I'm fed up of being in here and I know that because my blood pressure has been so much lower today than it has the other days, the drugs that they were giving me yesterday aren't suitable for today which makes me think, 'Well, tomorrow, if I take those same drugs, are they going to OD me? because it's quite possible and problems I'm also allergic to quite a few drugs anyway and that's the last thing I need is back in here through an OD. Especially on the pharmaceuticals. It's, it's not a party is it? No. no."* **Participant Interview 4**
Reduced appointments	*"Yes, definitely, yeah, I think if it could save time spent in hospital and travelling to hospital, definitely because, also, I think, not so much proteinuria, but with blood pressure, the environment that you're in affects it and if you walk into the hospital, then immediately your blood pressure goes up, so you almost get more accurate readings at home. As long as the machines are proven to be, you know, to be accurate then I think, yeah, you're probably less likely to get so many high readings at home, so."* **Participant Interview 3**
Increased surveillance	*"I actually think it's a really good idea. I'd be interested to know the outcome really, if it does succeed. I'd, I personally like to know what's going on, so it would, for me I think it would be reassuring that how things were progressing. It's just added information that's quite healthy, I think. But I think, if some patients are natural worriers, that might be where the cause for concern is because they'll be worrying every time. Yeah, but they're still going to be having their antenatal clinics anyway, so it's…"* **Participant Interview 2**
Patient autonomy	*"I think self-management is, to me how I interpret it is, patients being more involved than they have been previously in part of our screening or our testing so for example in this context being able to check blood pressure themselves using calibrated facilities, being able to monitor urine dipstick themselves and identify I there's proteinuria [um] and then potentially ideally us being able to then, if it's safe to do so, titrate medication."* **Healthcare Professional Focus Group 5, Participant 2, Consultant Obstetrician**
Overcoming anxiety: how to utilise patient education	

Theme	Quote
Anxiety	*"I mean I like, I would like to think that if you felt as though you were, you knew what to do and that you were in control that it would decrease anxiety, but some people seem to find having to medical things anxiety provoking. I think it just totally depends on the woman."* **Participant Interview 12**
Patient Education	*"Yeah, I'm not sure, I'm not sure. [um] I think, I think that what I would suggest is there needs to be a long kind of period of settling in with people feeling confident to do blood pressures, we being assured that they're doing it correctly, that it's reliable, that they're doing their urine. They would need to, before we can sort of talk about self-titration and then the next step would be kind of lots of kind of, you know, education [um] maybe, maybe there's a role for something similar to how they have it in diabetes where they send the blood sugars in and then the community, then the diabetics specialist midwives have a look at it and then say do this and do that."* **Healthcare Professional Focus Group 4, Participant 1, Consultant Obstetrician and Gynaecologist**
Differing perspectives: the patient clinician relationship	
Patient clinician relationship	*"[um] I mean, I don't know if I think about myself, if I was at home checking my own blood pressure, was doing my own wee, even if I wasn't medical and then I had to go to hospital where I have to see my community midwife, I don't think it's going to change my relationship with my provider. I think it'll just be like, 'Oh that's my bit,' and then I come to see them about something, other stuff that I don't know how to do."* **Healthcare Professional Focus Group 4, Participant 1, Consultant Obstetrician and Gynaecologist**
Patient suitability	*"I think people who have probably language, language problems, you know, ethnic minority, oh, yeah, language problem can be a barrier, and also, women with very hectic lifestyles."* **Healthcare Professional Interview 15, Junior Doctor** *"[um] Probably women who find it difficult to get into hospital for various reasons but then I guess on the flip side of that you are saying are those women actually at higher risks of other things and then so are they appropriate to be self-monitoring, so that's a bit difficult to decide I guess. [um] Maybe women who need to have lots of monitoring of these things so sort of like weekly or twice weekly measurements. I guess it's really difficult actually to determine what you're inclusion criteria's going to be because you want to make sure that there's someone that you, that does engage with services enough that they would be able to do this themselves and know that they will come in if there's*

Theme	Quote
	a problem or they're not able to do it and they won't just say, "Oh, yeah I've done it," and actually they haven't done it." **Healthcare Professional Interview 7, ST2 Obstetrics and Gynaecology**

6.5.5 Discussion

The results of this study suggested that while some aspects of self-management were acceptable to healthcare professionals and pregnant people (self-testing for proteinuria and self-monitoring blood pressure), there was hesitancy over self-titrating blood pressure medication. For healthcare professionals, their concerns stemmed from the dangers of patients incorrectly titrating medication. There was an attitude of paternalism reflected in the belief held by the majority of healthcare professionals that titrating medication is the responsibility of clinicians, although it has historically been their domain. Pregnant people were more open to the idea of self-titration, but on the whole there were still concerns around safety and they eschewed the responsibility of titrating medication.

Reflecting the data on self-testing reported in chapters 4 and 5, both healthcare professionals and pregnant people saw a considerable number of patient benefits to self-management. Staying out of hospital, reducing appointments, or saving time in existing appointments were some of the main benefits for pregnant people. Both healthcare professionals and pregnant people reflected on the possibility of self-management leading to increased patient autonomy, echoing the thoughts expressed in the self-testing data. While there was uncertainty about whether self-management would increase or decrease anxiety for pregnant people, patient education was suggested as a way to combat not only anxiety, but any other practical barriers associated with self-management.

Finally, pregnant people and healthcare professionals had contrasting perceptions of their relationship, indicating a fractious relationship of trust. Pregnant people felt that self-management would strengthen their relationship with healthcare professionals, while healthcare professionals were concerned about false results, either as a result of deliberate deceit or mistaken reporting, and this spoke to a lack of trust in patients.

6.5.5.1 *Hesitation over self-titration: patient safety and litigation*

Patient safety was not a strong or overt theme in this data, but it was alluded to when healthcare professionals shared concerns that patients would incorrectly titrate medication, or hinted at uncertainties over handing responsibility for medication titration to patients. The hesitancy around self-titration was perhaps the strongest indication that patient safety was an underlying concern for many healthcare professionals, which is unsurprising in the context of maternity care where patient safety concerns are irreparably intertwined with litigation concerns; the most significant contributor to clinical negligence costs in the UK are maternity related claims. According to the NHS Resolution's Annual Report, in 2020/21 obstetrics claims "*continue to dominate the cost of clinical negligence, amounting to 59% of the total estimated value of incoming new claims*" despite accounting for only 11% of the total number of claims received (139). Considering the amount of surveillance and intervention involved with childbirth, adverse events "*cannot be considered natural process in which the outcomes are the product of chance and adverse outcomes are unpreventable accidents*" (128). Litigation consequences are steep considering almost all adverse events in maternity care are seen as "*avoidable*" (140).

The outsized cost of any adverse events arising from maternity care weighs, understandably, on clinician's minds when considering any new facet of care, such as self-titrating blood pressure medication during pregnancy. As Scammell and Alaszewski found, midwives were exceptionally aware of their accountability in relation to adverse outcomes: "*if the birth did not go to plan, then not only could the* [pregnant person] *and baby be harmed, but also the midwife would also need to account for her actions in an inquiry which would start from the premise that errors had been made"* (141). Safety concerns would be paramount with any self-management intervention but in pregnancy, where concerns exist for the pregnant person and baby dyad, these concerns are elevated and account for most of the hesitation

among healthcare professionals. Healthcare professionals were relatively positive about blood pressure monitoring and self-testing for proteinuria compared to self-titrating medication, perhaps in part because these two self-management activities feel safer and less consequential than an adverse event occurring from incorrect medication usage.

The exclusion of pregnant people in clinical trials is well-documented and this is often driven by concerns about maternity safety. While this has changed in recent years, the "*reluctance to include pregnant* [people] *in clinical trials remains*" (142). Therefore, the development of new therapies, treatments and drugs for obstetric and non-obstetric related illnesses is "*a slowly evolving process*" (143). The widespread reluctance to include pregnant people in clinical trials is often due to the potential to cause harm to the fetus (143), a concern with roots in the thalidomide scandal of the 1950's and 60's (142). However, this can also slow progress and innovation in the treatment of obstetric related illnesses; for example, there is only one anti-hypertensive drug approved for use in pregnancy due to the lack of safety data available (144). Labetalol (see Section 1.5.1) is the only hypertensive drug approved by the British National Formulary (BNF) for use in pregnancy, with methyldopa considered "*safe for use*" and nifedipine often used in an unlicensed capacity (145). Indeed, the consequences of excluding pregnant people from clinical trials has been seen, and felt, acutely during the COVID-19 pandemic. The majority of COVID-19 trials have excluded pregnant people (146), and in the early stages of the pandemic they were excluded from all vaccine trials (147). As Knight et al write, in the midst of a pandemic "*ensuring equity of trial inclusion…so that pregnant* [people] *can benefit fully from potentially lifesaving treatments is thus even more urgent"* (148). Einav et al note that while the inclusion of pregnant people in clinical trials is a contentious ethical issue, COVID research trials excluding pregnant people need to justify doing so, particularly in the face of a pandemic that is both seeing pregnant people die with COVID-19 and being treated with experimental drugs anyway (149). The cost of excluding

pregnant people from clinical trials is high, pregnant patients are routinely prescribed therapies that have not been studied in pregnancy and, often, it is unknown what interventions are truly effective (150). The hesitancy around self-titration from healthcare professionals perhaps stems from a long history of anxiety in the medical community over trialling new therapies and interventions in the pregnant population.

6.5.5.2 *Risk in the context of pregnancy*

Paternalism has been discussed extensively in this thesis and it was identified again in this dataset in relation to self-titration hesitation. While paternalism exists in almost every aspect of medicine, it is more ubiquitous in maternity care, where "*collective anxieties about the safety of babies…underpin a system of surveillance*" (128). Patient safety concerns run parallel to paternalistic attitudes, as the perception of risk in pregnancy is distorted by the additional life of the fetus. As discussed above, concerns about the safety of the fetus are the primary reason pregnant people are excluded from clinical trials (142). Risk perception is "*a key element in the conflict of hegemony and autonomy in maternity care*" (128). Maternity healthcare professionals must deal with a number of fears and stressors when deciding on a patient's care – "*avoidance of litigation; fear of negative outcomes (from one perspective, infant death and from another, the loss of a 'normal' or 'natural' birth), and the cultural pressures of 'how things are done here'*" (128). This lends itself to a more paternalistic model of care; if there are any concerns about patient safety, risk avoidance will be the default for many healthcare professionals.

Low and high risk pregnancies are treated differently, with high risk pregnancies falling under the care of consultants and obstetricians, whereas low risk pregnancies mainly remain under the care of midwives. The effect of self-management on the perception of risk in pregnancy remains to be seen. Midwives and other maternity care workers operate in an

area of medicine dominated by risk aversion, safety concerns, and litigation. They already see the majority of pregnancies as capable of becoming high risk due to this culture, as Scamell and Alaszewski found midwives "*created an imagined future colonised by potential high risk that could at any moment be made visible through their continual surveillance*" (141). Giddens characterises this as a 'risk society' – a society that is increasingly occupied with the notion of risk and safety (151). Ruhle expands on this, writing "*there is no 'no risk' category*" (152) in pregnancy. While this is the view of the healthcare profession writ large, it is at odds with the perception pregnant people have of their pregnancy. Often, pregnancies that are categorised as high risk by healthcare professionals are not perceived that way by the pregnant person (153). Risk perception is, therefore, complicated in pregnancy. This study mainly contended with medically classified high risk pregnancies, due to the diagnosis of hypertension or pre-eclampsia, but not all of the participants were in-patients, some were out-patients attending routine appointments and their perception of risk would be different to those who were spending the remaining duration of their pregnancy in hospital.

6.5.5.3 *The burden of treatment*

In chapter 1 (Section 1.8.4) the Burden of Treatment theory was introduced as a critique of the new phenomenon of self-management, and chapter 2 used this theory as a lens to engage with the existing qualitative literature on the self-management of chronic conditions. It should also be considered in relation to the data collected for this chapter, which considers the additional complexity of self-titrating medication, a perhaps more burdensome self-management task than previously considered. Frances Mair, who also developed the Burden of Treatment theory, reflects on the additional strain of treatment regiments that include "*coordinating multiple drugs*" and what such complex self-management require from a patient: "*high levels of numeracy, literacy, and sometimes, technical knowledge. Manual dexterity and practical skills…"* (154). Healthcare professionals, in this dataset, felt that self-

titration was asking too much of patients, but according to Mair, not all treatment burden is "*unreasonable or avoidable*". Indeed, one crucial point that Mair makes is pertinent to pregnancy – some treatment burden may be "*situational and transient, relating to a specific acute crisis*" (154). The short period of management required during pregnancy may lessen the feeling of burdensome treatment. However, an additional stressor when considering the burden of treatment is the work that pregnant people are already expected to throughout the duration of their pregnancy. As Hinton et al note, 'responsible' pregnant people are expected to maintain a good diet or an appropriate weight, and stop smoking or drinking alcohol (38). Essentially, they are expected to engage in risk averse behaviour as part of their ethical responsibility (57), but this involves work and, what Lupton describes as, "*self-regulation and discipline*" (57). Whether self-management over burdens pregnant people at a time they are already navigating the daily work of pregnancy is an important question for future research. Quite simply, as Mair and May both concede, we do not yet have the ability to measure the burden of treatment (154) (47), and it remains an even more significant unknown quantity in pregnancy due to the potentially bounded period of management and the additional life of the baby.

6.5.6 Strengths, Limitations, Reflections

The data reported in this chapter were challenging to work with; separating out the instances in the interviews and focus groups where self-management was the subject of conversation, as opposed to self-testing was difficult. On occasion, the conversation in the interview or focus group could circle back round to specifically discussing self-testing if the participant recalled something they had meant to say earlier, but forgot. Therefore, teasing out true moments when the subject of conversation was self-management was made more complex and messy. This was perhaps compounded by having both healthcare professionals and pregnant people in the same dataset; however, this choice also allowed for a deeper

reflection on the hesitancies around self-titration, as examining the data for each group in isolation would have meant the data lacked detail and would have been thin.

As suggested above, there were concerns around idea generation for this dataset. Whether the barriers, benefits, or reflections on self-management would have been the same if the interview solely focused on self-management, and excluded self-testing, remains to be seen. But considering the situational challenges of recruiting for this study (reported in Chapter 4, Section 4.6.3, and Chapter 5, Section 5.3.10) combining the self-testing and self-management data collection was the practical option; attempting to carry out two sets of interviews and focus groups was not feasible for the timeline of the study.

6.5.7 Conclusions

The most significant finding from the EMPOWER study was the hesitation displayed by healthcare professionals and pregnant people regarding self-titrating blood pressure medication. Healthcare professionals had concerns regarding the safety of patients titrating their own medication, and patients shared some of these concerns, even though they were, on the whole, more positive towards self-management as a concept. When blood pressure monitoring and self-testing for proteinuria were explored separately to self-titration, in response to the hesitation, this was more acceptable to both healthcare professionals and pregnant people. There were echoes of paternalism in the language and the manner in which some healthcare professionals discussed self-management, some speculated that patients did not have the right to self-manage. Reflecting on this, alongside the paternalism explored in chapter 5, suggests that paternalism may be a considerable barrier to self-management interventions in pregnancy. Future research should focus on whether there is a self-management scenario that involves self-titrating medication that would be acceptable to healthcare professionals.

Chapter 7 : Discussion and Conclusions

7.1 Summary of Results

There is a lack of data on self-management in pregnancy, both as a whole and regarding the various individual components (i.e. self-testing, self-monitoring, self-titrating). This thesis has synthesised qualitative and quantitative evidence on self-testing for proteinuria and self-management as a concept in pregnancy, to contribute to the evidence base for the self-management of hypertensive pregnancies.

Firstly, the systematic review reported in chapter 2 found that the knowledge base for self-managing chronic conditions in pregnancy predominantly stems from diabetes management. While it may seem self-evident that pregnant people primarily self-manage for the health of their baby, the review found that communicating the importance of self-management in terms that focus on the baby was important to the adherence of these interventions. The burden of self-managing chronic conditions in pregnancy has different challenges to self-management in the general population; the consideration of an additional life, the baby, means that the motivating factors are inherently different. Patient education was also identified as a key part of the success of self-management interventions, able to counteract the potentially overwhelming burden of treatment pregnant people face.

In this thesis, self-management was guided by a broad definition, but was primarily related to three activities specific to pregnancy: self-testing for proteinuria, self-monitoring blood pressure, and self-titrating blood pressure medication. The evidence for these individual activities, as previously mentioned, is thin; therefore it was prudent to study the accuracy of self-testing for proteinuria. In chapter 3, a diagnostic accuracy study found that pregnant

people can self-test for the presence of urinary protein with comparable accuracy to a healthcare professional, and an automated reader. The study suggested that self-testing was a feasible alternative to current in-clinic testing.

Demonstrating the accuracy of self-testing however, is only a small of part of the self-management puzzle. Chapter 4 explored how pregnant people viewed self-testing and how it might be integrated into antenatal care. For pregnant people, the most substantial benefit of self-testing would be the prospect for increased involvement in their antenatal care. Self-management is at the heart of many patient empowerment narratives in chronic illness, and it emerged as an important consideration for these types of interventions in antenatal care. While healthcare professionals mirrored pregnant people's thoughts on patient empowerment, chapter 5 revealed another discourse in sharp contrast – paternalism. Both of these studies started to build a picture of the challenges of implementing self-management in pregnancy. Some of these barriers were practical in nature, and could potentially be overcome with effective patient education, such as how to interpret the dipstick, contextualising results, and patient anxiety. The more significant barrier, however, is the culture of paternalism in maternity care.

In chapter 6, self-management was explored as a whole. The most notable finding was the uncertainty and hesitation around the self-titration of blood pressure medication. Patient safety and, again, the consideration of the additional life of the baby played into healthcare professional's concerns about allowing patients to self-titrate. They were not alone in their concerns, pregnant people had similar trepidations regarding self-titration, and while they had safety concerns, they also felt that they did not have the knowledge for self-titration and it was a responsibility better left to healthcare professionals. Chapter 6 also explored the

possibility that self-titration was an additional burden of treatment that might be regarded as a step too far by both healthcare professionals and pregnant people.

This thesis has gathered evidence on several components of self-management; while there seems to be enthusiasm for self-testing of proteinuria and self-monitoring of blood pressure in pregnancy, there are significant barriers to overcome regarding self-titrating blood pressure medication. The overarching story woven through much of the data collected for this thesis is one of paternalism and patient empowerment juxtaposed in a system that traditionally disempowers pregnant people. How self-management, or even elements of self-management, could change this narrative in antenatal care is a question that this thesis has been grappling with - both healthcare professionals and pregnant people find the concept of self-management empowering, but it faces substantial implementation barriers that extend beyond many of the practical barriers reported in chapters 4, 5, and 6.

7.2 Discussion

7.2.1 A paternalistic system

Reflecting on the data in this thesis, the dominant narrative is one of paternalism. This thesis has also been written at a specific moment in time, one of enormous transition for antenatal care; maternity care is contending with more self-management, more remote care, and less centralised services meaning the traditional structures of paternalism are being challenged (155, 156). This transition has been exacerbated by the COVID-19 pandemic; over the course of the pandemic the majority of antenatal appointments have been conducted remotely and remote management such as blood pressure monitoring increased even as normal antenatal appointments and consultations decreased (39). Although the data in this thesis were collected before the COVID-19 pandemic, it remained omnipresent during the write up. The pandemic has accelerated the move towards remote care and self-management in maternity

care, despite a lack of evidence available pertaining to safety, acceptability, and feasibility; we are seeing the results of a "*real world experiment*" (156) play out as the nature of the pandemic changes and face-to-face consultations resume. This thesis has shown that paternalism remains a barrier for self-management, but whether healthcare professional's opinions have changed in the wake of the COVID-19 pandemic, and the wealth of remote management it created, remains to be seen.

Lambrinou et al consider collaboration in the patient clinician relationship as the most important element in ensuring self-management adherence, patient satisfaction and improved health outcomes (157). Without supportive healthcare professionals, adherence to self-management interventions is a struggle for patients; chapter 2 found that healthcare professional support was a key motivator for pregnant people. This, potentially, is a considerable barrier for the successful implementation of self-management in antenatal care; all parties need to be equally engaged for patients to adhere to self-management and not be unduly burdened by the various self-management activities.

7.2.2 Changing the narrative: patient empowerment

Throughout this thesis there was a clear desire for patient autonomy and empowerment that was expressed by both healthcare professionals and pregnant people. Empowerment is a relatively new phenomenon in healthcare, part of a "*move away from paternalism towards more equitable and collaborative models of healthcare delivery*" (158). The appetite for greater patient empowerment in a traditionally paternalistic space such as maternity care was tested in this thesis. This thesis chose to define patient empowerment rather more narrowly than other definitions, honing in on three main components: shared decision making, patient education, and self-management (42).

7.2.2.1 *Shared decision making*

The data in this thesis did not necessarily speak to shared decision making; at times, it was alluded to, but the interviews and focus groups offered no space for this to be brought up. Briefly, it is worth reflecting on shared decision making in relation to patient empowerment. Shared decision making is championed by both NICE and the NHS (46, 159), and is described as "*a joint process in which a healthcare professional works together with a person to reach a decision about care*" (159) that brings together "*the clinician's expertise...*[and] *what the patient knows best: their preferences, personal circumstances, goals, values, and beliefs*" (160). Shared decision making is essential for respecting patient autonomy and ultimately aims to "*improve health literacy, improve patient provider communication, and empower individuals to be more involved in their healthcare*" (161). Pregnant people expressed a desire for increased involvement in their care, partly to understand more about their condition and their pregnancy. Historically, healthcare professionals have been in charge of screening regimes, making choices about who should be screened for particular diseases and who should not. This thesis found evidence that this attitude remains prescient in antenatal care, as healthcare professionals were positioning themselves as the decision makers for who should be allowed to self-manage (Chapter 5). If patient empowerment is truly a goal in maternity care, shared decision making must be part of the process; pregnant people and healthcare professionals ought to decide together whether self-management is suitable.

7.2.2.2 *Patient education*

Patient empowerment is not possible without some of the knowledge imbalance between healthcare professionals and patients being addressed. Jotterand et al suggest that "*patients are vulnerable due to their health status and lack of medical knowledge, which makes them dependent on the clinicians' expertise*"; patient education, therefore, becomes "*an important tool for clinicians*" as the goal is to ensure patients have the autonomy to make

informed decisions about their healthcare (162). The right to self-determination, "*to information about one's health condition*" and the rejection of "*the sick role*" have been the key touchstones of patient education (163) since it emerged as a concept in the 1960's and 1970's (162).

The WHO's definition of patient education includes acknowledging that "*patient education is designed to train patients in the skills of self-managing*" (164) (165). Healthcare professionals raised concerns about whether pregnant people would be able to self-manage effectively and accurately, and if self-management might make them more anxious. Patient education emerges as the perfect counter to those concerns. However, there is resistance to patient education in healthcare. Drahi outlines some of the reasons patient education has failed to be fully integrated into the healthcare system which include clinicians lacking the necessary training to be patient educators, the lack of one-on-one training available to patients, and in certain healthcare systems, a lack of time and even health insurance to cover education activities (162) (163). Integrating patient education into maternity care in the NHS, where time and resources are already stretched and rarely allow for individualised medicine, is challenging; but, as evidenced through this thesis, it is an important element for the implementation of, and adherence to, self-management.

Although some of the conceptual and cultural barriers may seem more troublesome to implementing self-management in antenatal care, the practical barriers are also important to understand and are, potentially, much easier to overcome by means of patient education. Healthcare professionals and pregnant people were concerned about interpreting a urinalysis dipstick, or being unable to contextualise the results in the bigger picture of hypertension and pre-eclampsia. Both parties often stated that these barriers were not insurmountable with correct education and instruction from healthcare professionals.

7.2.2.3 *Self-management and self-surveillance*

The final component of patient empowerment is self-management. Earlier in this thesis, the issue of self-management in relation to the medicalisation of pregnancy was discussed; whether self-management would contribute to over medicalisation, or whether it would re-define the traditional role of the clinician as the conductor of medical surveillance and the pregnant person as the subject of that surveillance. Examining the evidence in this thesis suggests that pregnant people welcome the concept of self-surveillance, seeing it as way to increase their involvement in their care, and as a potential way of ensuring a healthy birth. Johnson posits that "*maternal subjects may…embrace medicalisation as part of their desire for the best possible outcomes in reproductive, foetal and infant health*" (82). There are, of course, inherent issues in where we place the responsibility for positive birth outcomes. Johnson goes on to criticise the manner in which pregnant people are expected to engage in risk avoidance, simply due to the wealth of technology and information available to them (82). This could also be parsed as a critique of self-management – even if self-management is made available to pregnant people, the burden of that responsibility should not be underestimated.

7.2.3 Patient-centred care

In chapter 1 (Section 1.8.3) patient-centred care was depicted as sharing many of the same components as patient empowerment: shared decision making, self-management, and patient education. The key questions that drive much of the research on patient-centred care are, as Stewart poses, "*What is it? Do patients want it? Do doctors practise it? What are its benefits?"* (117). Considering these questions in relation to this thesis, a patient-centred care approach for hypertensive pregnancies involves some form of self-management, whether that be all three self-management activities (self-monitoring, self-testing, self-titrating), or pairing back the intervention to surveillance based activities (self-monitoring

and self-testing). Unsurprisingly, patients do want patient-centred care, which was already a known quantity in literature focusing on the general population (117), but was also evidenced in this thesis for pregnant people. The question of whether doctors practice patient-centred care is less known, particularly in maternity care where paternalism is more prevalent (128). However, if we interpret self-management as patient-centred care, this thesis can speak to the benefits of patient-centred care, as both healthcare professionals and pregnant people saw multiple benefits to self-management. In chapter 1, it was stated that patient-centred care leads to empowered patients (section 1.8.3). In reality, these concepts are intrinsically linked, patient-centred care cannot exist without patient empowerment, and patient empowerment cannot exist without patient-centred care.

7.2.4 Self-management: where do we go from here?

The question that now remains after examining all the data collected in this thesis is whether self-management has a future in antenatal care. Much of the data collected for this thesis reflects not on the clinical benefits of self-management, but the patient benefits. There are unique challenges for self-management in pregnancy. Firstly, maternity care is inherently more paternalistic than other areas of medicine (128). Secondly, that healthcare professionals are not unreasonably concerned with safety regarding self-titration (Chapter 6, Section 6.5.5.1). Finally, that the majority of maternity care for high risk pregnancies is based in hospital, rather than based in a GP practice (166). The first two issues of paternalism and patient safety are not easily solved. While it is clear that the NHS is moving towards a more patient-centred model of care, evidenced by the emphasis on this in the NHS Long Term Plan (46), maternity care still contends with paternalism driven by concerns over patient safety and the consequences of adverse outcomes (Chapter 6, Section 6.5.5.1). Patient safety remains a concern for many healthcare professionals when it comes to self-management. As discussed in chapter 6 (Section 6.5.5.1) these concerns are paramount in maternity care

where concerns exist the pregnant person and the baby dyad and the litigation costs are significant. Despite this, maternity safety was largely absent as a theme in the data collected for this thesis. This silence could be explained by the main focus of the data collection being self-testing, which is a relatively low risk self-management activity. As explained in chapter 3 (Section 3.5.6) urine testing is not done in isolation, other screening tests are performed (such as blood pressure monitoring). Patient safety was primarily alluded to in this thesis during discussions on self-titrating medication, a self-management activity that carries inherently more risk if done incorrectly. Perhaps, the lack of safety concerns regarding self-testing were because it is a self-management activity that feels safer and inherently less consequential than an adverse event occurring from incorrectly titrating medication. The silence around maternity safety in this data was surprising, but it remains an important consideration, and barrier, for the future implementation of self-management interventions in antenatal care. Regarding the setting of maternity care, more research is needed to understand whether the change in setting, a hospital as opposed to a GP practice, makes self-management more challenging, and whether it would hinder communication with the clinician.

7.2.4.1 *Is there a burden of treatment?*

The most salient critique of self-management, and all it entails, is the burden of treatment theory. Throughout this thesis it has remained prescient, and the question still remains – are we burdening patients with self-management? May et al's theory argues that we have placed undue burden on patients by pushing self-management and patient-centred care narratives (47). Jotterand et al grapple with patient's new role as decision makers, but remain concerned that "*with more autonomy the burden of responsibility to make the appropriate healthcare decision* [becomes] *heavier*" (162). Treatment burden is often associated with reduced adherence to management regiments (167), but whether this

burden is quite so strenuous in pregnancy, when the period of self-management would be bounded, remains to be seen. In this thesis, the burden of treatment was often represented in the theme of anxiety. Although, these data are messy and there was no consensus about whether self-management would increase or decrease anxiety, and thus, no consensus over whether self-management would be a burden. As has already been stated in this thesis, the burden of treatment theory is not equipped to account for the specific demands and challenges of pregnancy, which already involves patient work, often in form of risk mitigation (57). But, despite those shortcomings it allows space to consider whether placing the extraneous demands of self-management on pregnant people, who already face the extraneous demands of pregnancy, is acceptable. According to the views of pregnant people in this thesis, self-management *is* acceptable; perhaps because, as Mair suggests, some treatment burdens are more acceptable if they are transient and situational (154), as is the case in pregnancy.

While self-management is clearly more complex to implement in the pregnant population than the general population, there is an appetite for it in pregnancy. This thesis has demonstrated that pregnant people seek more control and agency in their antenatal care, and they view self-management as a potential route to that increased involvement.

7.3 Strengths and Limitations

The strengths and limitations of the individual studies that made up this thesis have been outlined in each chapter. Prior to this thesis, very little data has been gathered on self-management in pregnancy, particularly relating to the management of hypertension and pre-eclampsia. This thesis has attempted to piece together evidence from a variety of different sources to further our knowledge and understanding of self-management in pregnancy. The use of different research methods and the mix of both quantitative and

qualitative data presented analytical challenges, but ultimately provided a broader, more detailed range of evidence from both healthcare professionals and pregnant people.

However, there remain limitations to the scope and ability of this thesis to paint a comprehensive view of the self-management of hypertensive pregnancies. The lack of data available on self-management during pregnancy meant that much of the research, particularly the qualitative work, had little conceptual framework to inform the data collection and the analysis. Therefore, the research questions that guided the work in this thesis were broad, particularly in relation to the qualitative work. Quite simply, there was a considerable amount that was unknown about self-management in pregnancy, and this thesis aimed to address some of those knowledge gaps.

In hindsight, it would have been beneficial to have analysed some of the healthcare professional qualitative data in depth before conducting the last round of interviews and focus groups, to explore some of the concepts that have since been established in this thesis as important elements of self-management implementation. For example, space was not afforded in the interviews or focus groups to discuss shared decision making. However, the ability to collect more data with healthcare professionals was also impacted by the COVID-19 pandemic, as it was not possible to recruit any participants from Birmingham Women and Children's Hospital. The funder of this work, the NIHR, halted all research that did not pertain to COVID-19 during the first wave of the COVID-19 pandemic, when the data from Birmingham Women and Children's Hospital was due to be collected. The initial lockdown in the UK occurred as considerations were being made about additional data collection. As mentioned above (Section 7.2.1) the data collected in this thesis was captured immediately prior to the pandemic, as such, it does not capture healthcare professional's or pregnant

people's views on self-management and remote care after the real world experiment of the past 18 months.

7.4 Reflexivity

As Dodgson writes "*all qualitative research is contextual*", occurring at a specific time and place (168). In chapters 4, 5, and 6, I offered an explanation of the contextual challenges that related to each individual study; for example, the time constraints and ad hoc method of approach that affected the data collection in the qualitative studies. However, it is also important to reflect on the wider societal context that affected latter stages of this DPhil – the COVID-19 pandemic. Undeniably, this will have influenced the way I engaged with the data and affected my thinking about self-management as forms of remote care and remote work became our default way of operating. I am conscious of the fact I found our new remote way of life difficult and isolating, and I was alive to these biases as I engaged with the data analysis and I have attempted to put my own scepticism aside and, instead, remain faithful to the data.

Another important part of the research process is to reflect on the personal biases and beliefs that I may have brought into the research. I was an outsider to the experiences of all the study participants recruited for this work. I have no personal experience of pregnancy, which meant I did not have shared experiences with the pregnant people I spoke to as part of the study. I also do not have any clinical expertise, being a junior qualitative researcher, which meant I was an outsider to healthcare professionals. My lack of shared experience with pregnant people meant that while I could empathise with their concerns and worries either regarding their pregnancy or self-management, I could not fully understand them. Similarly, as a researcher without a clinical background I cannot possibly understand the challenges and burdens healthcare professional's face in their jobs. It is important to

recognise these shortcomings and how it may have affected the power dynamic in the room. It is quite possible that healthcare professionals held back and were not as honest with me as they would have been if a fellow healthcare professional was speaking to them. Likewise, if I had personal experience of pregnancy it may have given me additional insight into my interactions with pregnant people over the course of the study. On the other hand, this meant I approached the data openly, with potentially less biases based on personal experience. I am also a white, middle class woman, and I tried to remain self-aware of my own considerable privilege during the data collection and the data analysis.

7.5 Conclusions

7.5.1 Clinical Implications

This research found that self-testing for proteinuria by pregnant people appeared to be accurate compared to current in-clinic dipstick testing performed by a healthcare professional, and was acceptable to both pregnant people and healthcare professionals. Further research is needed on a potential home testing regime in pregnancy, including research on a self-testing regime that involves multiple tests, in order to capture more incidents of serious disease. While this thesis has teased out some of the potential barriers to self-testing, more research is needed on how it could be best utilised in practice, how multiple tests fit into usual care, and whether remote monitoring substantially increases the workload of healthcare professionals. This thesis has also demonstrated that healthcare professionals need to communicate in terms that focus on the health of the baby, as that is the primary motivating factor for pregnant people.

7.5.2 Research Implications

This thesis has primarily focused on the patient benefits of self-management and the cultural barriers that self-management faces in regards to implementation. This work has shed light

on the culture of paternalism in antenatal care, and this is a considerable barrier to self-management which relies on a functional, two way relationship between patient and healthcare professionals to be successful. There were concerns about self-titrating medication, and more work is needed in this area to understand if stringent, pre-approved protocols will affect healthcare professional's views about this self-management activity. For pregnant people, the benefits of self-management were palpable. There was a clear theme, throughout the thesis, of patient empowerment. Maternity care, due to the culture of paternalism, can be disempowering for many pregnant people. Self-management offers an opportunity to redistribute some of the power held by the clinician in the patient clinician relationship. However, more research is needed to understand the unique burden of treatment in pregnancy, which falls not only on pregnant people, but their wider social networks and circles. The additional actor involved in pregnancy self-management, the baby, is the primary reason pregnant people are motivated to self-manage, but it is also the reason that there are additional safety concerns. Overall, more 'real world' research is needed on self-management in pregnancy in order to understand if self-management could be safely integrated into pregnant people's lives and the everyday barriers and facilitators they may face. Self-management in pregnancy is more complex than general population self-management, which this thesis has shown, but it ought to be given full consideration in antenatal care, particularly considering the current transition towards remote care and monitoring exacerbated by the COVID-19 pandemic.

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Appendix: Chapter 2

Appendix 1.1: Prospero Registration Form

PROSPERO
International prospective register of systematic reviews

UNIVERSITY of York
Centre for Reviews and Dissemination

??? For those soon to register with PROSPERO, records may not be submitted between Thursday 1st April (5 pm) and Tuesday 6th (8 am) whilst staff are away and the university is closed for the Easter period. During this time you may still work on your record and save it for submission after Easter.

Systematic review

1. * Review title.

Give the title of the review in English

What are the current behaviours and attitudes among pregnant women regarding the self-management and self-monitoring of chronic conditions in pregnancy?

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

01/04/2019

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/12/2019

5. * Stage of review at time of this submission.

Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Beth Jakubowski

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Ms Jakubowski

7. * Named contact email.

Give the electronic email address of the named contact.

bethany.jakubowski@phc.ox.ac.uk

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

01865 617961

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of Oxford

Organisation web address:

https://www.phc.ox.ac.uk/

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record.**

Ms Bethany Jakubowski. University of Oxford
Ms Jaspreet Khaira. University of Oxford
Professor Richard McManus. University of Oxford
Dr Katherine Tucker. University of Oxford
Dr Lisa Hinton. University of Cambridge

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

CLAHRC Oxford

Grant number(s)

State the funder, grant or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

What are the current behaviours and attitudes among pregnant women regarding the self-management and self-monitoring of chronic conditions in pregnancy?

16. * Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

The search terms used to find articles in PubMed

- Pregnant women MeSH

- Pregnan* OR gestational OR maternal

- Decision making MeSH

- Self-care MeSH

- Shared decision making OR self manag* OR self-monitor

The search terms used for CINAHL

- Pregnancy OR Expectant Mothers

- Pregnan* OR gestational OR maternal

- Self-care

- Shared decision making OR self-manag* OR self-monitor

There was also a broad secondary search using the search term 'pregnancy self-management' in PubMed

17. URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search **results**.

https://www.crd.york.ac.uk/PROSPEROFILES/136681_STRATEGY_20200916.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

This review is on the self-management of chronic conditions in pregnancy i.e. hypertension, diabetes, kidney disease. The scope of the review is to look at the feasibility and acceptability of women self-managing, and how they regard this new burden of treatment.

19. * Participants/population.

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

The population being studied is pregnant women with a chronic condition, there are no further restrictions on the study population.

Inclusion Criteria

1. Chronic condition: diabetes (gestational or chronic), hypertension (gestational or chronic), obesity, kidney disease, others to be reviewed as they come up

2. Pregnancy

3. Self-management: self-monitoring, self-weighing, self-care, others to be reviewed as they come up

4. Qualitative.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The

preferred format includes details of both inclusion and exclusion criteria.

This review is looking at the self-management of chronic conditions in pregnancy. Self-management can be defined as self-monitoring (i.e. of blood glucose or blood pressure), or as action on the basis of self-monitoring (i.e. diet management, self-care, weight management).

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Usual care if appropriate.

22. * Types of study to be included.

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

Qualitative studies are eligible for inclusion, including secondary analysis of previous qualitative research.

Inclusion Criteria

1. Chronic condition: diabetes (gestational or chronic), hypertension (gestational or chronic), obesity, kidney disease, others to be reviewed as they come up

2. Pregnancy

3. Self-management: self-monitoring, self-weighing, self-care

4. Qualitative

23. Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

Chronic conditions in pregnancy are under researched, so the aim of this review is to examine the current qualitative evidence of the behaviours and attitudes towards the self-management of chronic conditions in pregnancy. It is important to determine what, if any, self-management currently takes place and whether women find it acceptable and feasible to self-manage. Therefore the inclusion criteria for this review is for the participant to have a chronic condition (i.e. hypertension, diabetes) during pregnancy (this can be defined as gestational or chronic), and for some form of self-management to be taking place. This self-management can either be self-monitoring (i.e. of blood glucose or blood pressure), or action on the basis of self-monitoring (i.e. diet management, self-care, weight management).

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

The study aims to explore whether self-management of chronic conditions in pregnancy is acceptable and

feasible to pregnant women. It also aims to explore current practice and the current evidence base of chronic disease management in pregnancy.

Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Not applicable.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

None.

Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Not applicable.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

All of the studies identified in the search were screened independently by two reviewers (title and abstract) who then came together to agree on which articles should get a full text review. Both reviewers then independently completed the full text review and met again to agree on which articles should be included in the final review. Discrepancies were resolved by reviewing the definition of self-management and chronic condition as these were often the causes of uncertainty. The first author will then use a data extraction spreadsheet to list the key themes and findings from the papers. 10% of the included articles will be screened by another member of the study team, measuring the 10% of articles against the inclusion criteria and the COREQ quality assessment guidelines. The included studies will then be put into NVivo 12 and a thematic analysis, using the guidelines produced by Braun and Clarke (2006), will be carried out by the first author. A theoretical lens will be used to reflect the themes that emerge during data analysis.

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

Two researchers carried out the screening of articles, and met after the title and abstract screening to feed back results and decide which articles required a full text review. They met again following this screening to decide which articles should be included in the final review. To determine the quality of the studies, the COREQ guidelines will be used, which is a standard set of guidelines to determine the quality of qualitative work. The quality of the studies will be acknowledged in the write up, in order to be transparent about the

quality of the work in this field to date.

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This **must not be generic text** but should be **specific to your review** and describe how the proposed approach will be applied to your data. If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

Using NVivo 12, an initial thematic analysis will be conducted by the first author to create a coding framework of themes and sub themes. A theoretical lens will be used to develop the coding framework further. Discrepancies will be discussed with the wider study team and feedback will be incorporated into the framework.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

Not currently planned

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review

Cost effectiveness
No

Diagnostic
No

Epidemiologic
No

Individual patient data (IPD) meta-analysis
No

Intervention
No

Meta-analysis
No

Methodology
No

Narrative synthesis
No

Network meta-analysis
No

Pre-clinical
No

Prevention
No

Prognostic

No

Prospective meta-analysis (PMA)
No

Review of reviews
No

Service delivery
No

Synthesis of qualitative studies
Yes

Systematic review
Yes

Other
No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
No

Care of the elderly
No

Child health
No

Complementary therapies
No

COVID-19
No

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
No

Nursing
No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
No

Pregnancy and childbirth
Yes

Public health (including social determinants of health)
No

Rehabilitation
No

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care

No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

England

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

We will aim to publish the review in a high impact scientific journal.

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Pregnancy; maternal health; chronic conditions; self-management

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published.New registrations must be ongoing so this field is not editable for initial submission.
Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission). List authors, title and journal details preferably in Vancouver format.

Give the link to the published review or preprint.

Appendix 1.2: PRISMA statement submitted for systematic review publication

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2, 3, 4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5, 6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5, 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7, 8, 10, 25, 26
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7, 8, 10, 25, 26
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7, 8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	N/A
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9, 10, 11

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	10 - 14
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	10
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	15, 16, 17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	17, 18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	18, 19
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19, 20

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Appendix 1.3: Search strategy for systematic review

Two databases were searched, CINAHL and Pub Med. The search terms used to find articles in Pub Med (n=107) were MeSH terms 'pregnancy,' 'pregnant women', 'decision making', 'self-care', and 'pregnan* OR gestational OR maternal', and 'shared decision making OR self manag* OR self-monitor'. There was also a broad secondary search in Pub Med using the search term 'pregnancy self-management' which identified a further 1,931 articles for review. The search terms used for CINAHL (n=707) were 'pregnancy OR expectant mothers', 'pregnan* OR gestational OR maternal', 'self-care', and 'shared decision making OR self-manag* OR self-monitor'. This identified a total of 2,745 articles, which when controlled for duplicates left 2,695 for review. 25 articles were identified for full text review, of which 16 were selected for the systematic review.

Appendix 1.4: COREQ quality assessment spreadsheet

Title	Self-monitoring lifestyle behaviour in overweight and obese pregnant women: qualitative findings	"I was tired of all the sticking and poking" : Identifying Barriers to Diabetes Self-Care Among Low-Income Pregnant Women	The maternal experience of having diabetes in pregnancy	Women's experiences of gestational diabetes self-management: a qualitative study	Factors promoting diabetes self-care among low-income, minority pregnant women	Socio-cultural aspects of self-management in gestational diabetes	Women's experiences of factors that facilitate or inhibit gestational diabetes self-management	Lived experience of blood glucose self-monitoring among pregnant women with gestational diabetes mellitus: a phenomenological research	Living with gestational diabetes in a rural community	"Is gestational diabetes a severe illness?" Exploring beliefs and self-care behaviour among women with gestational diabetes living in a rural area of the south east of China	Experiences, perceptions and self management of gestational diabetes in a group of overweight multiparous women	Ethnic Differences in Dietary Management of Gestational Diabetes Mellitus: A Mixed Methods Study Comparing Ethnic Chinese Immigrants and Australian Women	Self-management of gestational diabetes among Chinese migrants: A qualitative study	The experience of gestational diabetes for Indigenous Māori women living in rural New Zealand: qualitative research informing the development of decolonising interventions	"Diabetes Just Tends to Take Over Everything" : Experiences of Support and Barriers to Diabetes Management for Pregnancy in Women With Type 1 Diabetes	Barriers to Gestational Diabetes Management and Preferred Interventions for Women With Gestational Diabetes in Singapore: Mixed Methods Study
Interviewer/Facilitator	First author	Author 1 and 2	Not reported by coder/analyser was present for all interviews and focus groups	Not reported	Author 1 and 2	Author 1	Author 1	Not reported	Not reported	Author 1	Not reported	Not reported	Chief investigator	Not reported	Not reported	First and second author
Credentials	Author 1: DNSc, MPH, RNC-OB, FAAN. Author 2: PhD, RN, FAAN	Author 1: MD, MPH, Author 2: MD, MPH, Author 3: MPH, Author 4: APN, CDE, Author 5: MD, MPH	Author 1: MD, Author 2: PhD, RN, PMHCNS-BC, Author 3: PhD, RN, IBCLC	Author 1: PhD	Author 1: MD, MPH, Author 2: MD, MPH, Author 3: MPH, Author 4: APN, CDE, Author 5: MD, MPH	Author 1: PhD student. Author 2: Assistant Professor	Not reported	Author 1: PhD, RN, Assistant Professor of Nursing. Author 2: PhD, RN, Associate Professor of Nursing	Author 1: DNP, APRN-C. Author 2: DNS, WHNP-C	Author 1: M, Msc. Author 2: RN, PhD. Author 3: RN, PhD	Not reported	Author 1: MN, APD Author 2: PhD Author 3: MD Author 4: PhD	Not reported	Not reported	Not reported	Author 1, PhD, Author 2 MPH, Author 3 MPH, Author 4 MBBS, MD, Author 5, MBBS, Author 6, PhD
Occupation	Author 1: Associate Professor. Author 2: Researcher	Author 1: Fellow in Maternal-Fetal Medicine. Author 2: Resident in OBGYN at Northwestern. Author 3: Senior Research Coordinator at Northwestern. Author 4: Advance Practice Nurse in Maternal-Fetal Medicine. Author 5: Professor of OBGYN at Northwestern	Not reported	Associate Professor Midwifery	Author 1: Fellow in Maternal-Fetal Medicine. Author 2: Resident in OBGYN at Northwestern. Author 3: Senior Research Coordinator at Northwestern. Author 4: Advance Practice Nurse in Maternal-Fetal Medicine. Author 5: Professor of OBGYN at Northwestern	Author 1: PhD student. Author 2: Assistant Professor Nursing	Not reported	Author 1: Assistant Professor. Author 2: Associate Professor	Author 1: Visiting Assistant Professor of Nursing. Author 2: Visiting Assistant Professor	Author 1 a teacher of maternal care and bilingual	Not reported	Not reported	Faculties reported	Faculties reported	Not reported	Faculties reported
Experience and training	First author: Expert in prenatal health promotion and content analysis. Second author: PhD. Doctoral studen: carrying out analysis: undergraduate degree in exercise science, experience in a home visitation programme for low-income pregnant women	Extensive expertise in maternal-fetal medicine and research	Extensive expertise judging by credentials	Not reported but has a PhD in a related field	Members of the research team reported to have prior qualitative research experience and extensive interviewing training	PhD student	Not reported	Not reported	Not reported	Not reported	Interviews conducted by experts in anthropology and social psychology	Not reported	CI was fluent in English, Mandarin and Cantonese	Not reported	The main interviewer had a background in health psychology and skills in motivational interviewing.	Not reported
Relationship established	First author called or e-mailed each woman 3 - 7 days before a scheduled interview	Not mentioned	Not mentioned	Approached by researcher prior to interview to confirm interest	Not mentioned	Not mentioned - secondary analysis	Access to women facilitated by diabetes co-ordinator, no relationship pre-established with researcher	Prolonged engagement was carried out by researchers to build a rapport with participants before interviews	Established through recruitment	Not mentioned	Established through recruitment and screening process	No	Participants had interviewer's contact details	Lead researcher spoke to participants ahead of the interviewer	Potential participants could indicate interest by contacting the investigator. Study procedures and the consent process reviewed with them.	Established through recruitment

Participant knowledge of the interviewer/interview	Not mentioned - assumed through recruitment	Were identified because they had GDM so knew why the research was being conducted	Recruitment flyers provided some knowledge of subject matter	Recruited from diabetes clinic fitting criteria	Were identified because they had GDM and at their first clinic visit so knew why the research was being conducted	Not mentioned - secondary analysis	Recruited through diabetes clinic and by diabetes co-ordinator so would have been told what the study was about	Participants approached by staff nurses so knew about what the study was about prior to taking part	Had diagnosis of the disease which was being explored in interviews, and recruited via study posters	Interviewer did not know participants prior to study, was not part of the clinical care team.	Women were given a health questionnaire prior to recruitment	Were identified because they had GDM so knew why the research was being conducted	Interested participants were provided with written information that explained the background of the study and provided the contact details of the researchers. All participants were recruited after they had received diabetes education from a diabetes educator and had at least two weeks of self-management experience.	The contact details of all consenting participants were then provided to the lead researcher, who contacted participants via phone or home visits (when no phone service was available). The lead Investigator provided detailed information about the research, answered any questions from women and obtained written informed consent and confidentiality agreements (including accessing their diabetes-related health data from the clinic) for each participant.	Potential participants were informed that the purpose of the study was to identify barriers to and supports for blood glucose management around pregnancy	Recruited from diabetes clinic fitting criteria, participants had previously participated in a survey on the same subject.
Interviewer characteristics	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	Not mentioned - secondary analysis	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported	No bias reported
Methodological orientation and theory	Self-monitoring theory, behavioural and lifestyle change theories	Cognitive load theory	Phonomenology	Phonomenology	Cognitive load theory	Phenomenology	Interpretative phenomenology	Phenomenology	Phenomenology	No specific theoretical framework reported	Phenomenology	Symbolic interactionist framework and grounded theory	Thematic analysis	Kaupapa Maoris Methodology	Thematic analysis	Thematic analysis
Sampling	Purposive	Purposive	Convenience	Purposive (blinded for review)	Purposive	Purposive	Purposive	Purposive	Purposive and snowball	Purposive	Purposive	Purposive	Purposive	Purposive - a sub sample of a larger study	Purposive	Purposive
Method of approach	Interview explained to trial participants and informed consent sought	At a clinic serving public assisted low-income women. Informed consent sought.	Flyers dicributed in healthcare provider offices	Women invited to participate if fitted criteria, approached by researcher if Diabetes Coordinator confirmed their interest.	Recruited at their first clinic visit for diabetes care	Women being treated for GD were recruited	Diabetes coordinator approached women, participants were recruited after they attended GDM education and had at least 3 weeks self management of condition	Approached at ancenatal care clinics and informed consent obtained	Information about study posted in obstetric and health care provider officers in New York State	Women purposefully recruited from obstetric clinics and wards at a specific hospital.	Women recruited through department of diabetes, given questionnaire and selected based on the questionnaire results	Women recruited through GDM clinics	Between August and October 2016, participants were purposively recruited from the antenatal clinic at the RPAH in the inner West Region of Sydney, Australia. Billingual flyers about the study were distributed at the clinic. Interested participants were provided with written information that explained the background of the study and provided the contact details of the researchers.	The ten participants advised that they either had a clinical history of GDM (n = 8) or had been exposed to diabetes in utero (n= 2). Eligible participants were recruited via the local primary care clinic between September and December of 2015.	Participants were recruited using advertisement flyers that were sent for distribution to diabetes specific clinics around the United States. Adult U.S. women (≥18 years of age) with type 1 diabetes who were fluent in English and were either pregnant, planning pregnancy for the immediate future, or had experienced a previous pregnancy were invited to participate in a phone interview.	Potential participants for the survey (this is a mixed methods study and interview participants were recruited from survey participants) were approached in the waiting room of the GDM clinic. The study team refrained from approaching women who seemed tired or anxious. After getting informed consent, women were given a self-administered survey. For pregnant women who were willing to participate in prenatal interviews, sessions were scheduled based on their convenience. In the second phase, to increase survey completion, the

																women were given an incentive of $25 (US $17.5). In the first phase, 50 patients participated in the survey.
Sample size	13	10	8	15	10	12	15	30	10	17	5	83	18	10	15	15
Non-participation	22 women enrolled in the intervention, 9 refused interview	46 women identified, 22 ineligible, 12 declined participation	Not reported	Not reported	46 women identified, 22 ineligible, 12 declined participation	Not mentioned - secondary analysis	30 women met inclusion criteria, 20 agreed to participate, 15 available on day of interview	Not reported	Not reported	Not reported	Not reported	11 declined to participate and reasons were given	Not reported	Reported in the larger study (6 withdrew)	27 indicated interest	Of the 50 patients who completed the survey, 35 gave verbal consent to participate in the interviews and 15 participated in the interviews
Setting of data selection	10 interviewed in clinic private rooms, 3 over phone	Conducted in private	Over the phone or in person	10 phone interviews, one in interviewee's home, one focus group at the hospital clinic	Conducted in private	Not mentioned - secondary analysis	Focus group in private room in clinic, phone interviews, face to face interview at one woman's home	Interviewed at the antenatal clinic, diabetes clinic or obstetric ward	Interviewed in person or at phone	Interviewed in a room at the hospital	Not reported	Not reported but some on the phone (others in person)	The interviews were conducted by the chief investigator in either a staff meeting room or a waiting room at the hospital, according to the participant's preference.	Interviews undertaken in participants' homes or the health centre, or a mutually agreed venue.	Decided to conduct the interviews over the phone unless participants were local to the study site and wished to come to the study office	Most interviews were conducted at the health care facility or at the participants' homes, in a private space conducive for the participant to share thoughts effectively.
Presence of non-participants	No	No	Yes, additional investigator to take field notes	No	No	Not mentioned - secondary analysis	No	No	No	No	No	No	Yes, participant's partner present in two interviews	No	No	No

Description of sample	Mean age 29.5 years, majority obese, majority were African American (77%), unmarried (69%), previous pregnancy (77%), third trimester (69%)	Mean age 28.5, African American (4), Latina (4), Native American (1), Asian (1). Most educated to high school degree level, most multiparous, all diabetic	Average age 35, mostly highly educated, no demographics reported	Variety of ethnic backgrounds, 23 - 40, majority high school educated, majority primiparous	Mean age 28.5, African American (4), Latina (4), Native American (1), Asian (1). Most educated to high school degree level, most multiparous, all diabetic	Aged between 23 - 38, most worked outside the home, most were married, mix of first pregnancy and second pregnancies	Age range 23 - 40, education level lower than population average, mix of ethnic backgrounds, majority of women primiparous	The mean age of participants 32.5 years, 17 women were Buddhists, 13 women were Muslims. Majority multiparous and employed.	All women Caucasian between 25-49. All had history of GDM.	27.5 median age, six women high educational level, five middle educational level, six low educational level	Reported in table	Reported in table	Reported in table: The mean age of participants was 34 years (SD = 3.6; range 29–41). The majority of participants came from China, Hong Kong or Taiwan and held a university degree	10 Māori women aged between 30 and 69 years. Outlined in full table, participants had diverse pregnancy experiences and current diabetes-related health conditions	All participants were married, with a mean age of 34 years and a mean duration of type 1 diabetes of 21 years. Ten participants used a continuous glucose monitoring (CGM) system, and 13 used an insulin pump to manage their diabetes. Ten women had previously been pregnant, three were pregnant at the time of the interview, and five were trying for or contemplating pregnancy in the immediate future (within 3–4 months from the time of their interview).	The women who participated in interviews had a demographic profile similar to that of the survey questionnaire participants. Half of the 15 participants in the age group of 31 to 35 years were primiparous or had a family history of T2DM, and most of them were Chinese or Indian, employed full time, with a degree, and attending a private prenatal clinic.
Interview guide	Yes	Yes	Yes	Not reported	Yes, provided in article	Yes	Not reported	Yes	Yes	Yes and provided in paper	Yes	Yes	Yes	Yes	Yes	Yes
Repeat interviews	No	Three interviews per person	No - these were focus groups	No	Three interviews per person	Two interviews conducted per person	No	Two interviews conducted per person	Follow up interviews conducted with four participants	No	No	No	No	No	No	No
Audio/visual recording	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio	Audio
Field notes	No	No	Yes	No	No	Not mentioned -	No	No	No	No	Yes	Yes	No	No	Yes - notes and reflections	No

						secondary analysis									recorded by interviewer	
Duration	30 minutes	30-60 minutes	Not reported	Not reported	30-60 minutes	Not mentioned - secondary analysis	Not reported	30 - 45 minutes	15 - 30 minutes, second interviews 15 - 30 minutes	40 - 60 minutes	90 minutes	45 - 90 minutes	Not reported	Not reported	Between 30 and 50 minutes	Not reported
Data saturation	Not discussed	Reached at 29 interviews	Not discussed	Not discussed	Reached at 29 interviews	Not mentioned - secondary analysis	Not mentioned	Data were collected until saturation (after six months)	Checked by sharing core themes with participants	Not mentioned	Not mentioned	Not mentioned but large sample size so assumed there was saturation	Not reported	Not discussed	To achieve data saturation, 10–15 people were recruited, with the possibility of conducting additional interviews, if necessary	Reported at 15 interviews
Transcripts returned	No	No	Some were to check participants views were represented correctly	No	No	Not mentioned - secondary analysis	No	No	Transcripts of first interview provided to participants doing a second interview for verification	No	No	No	No	Participants were invited to review, edit or change their transcript prior to data analysis.	No	No
Number of data coders	2	2	1 but checked informally by members of research team	1	2	1	1	1	Not reported	Not reported	Not reported	At least 2	2	The lead researcher independently coded the data, and discussed the codes and themes with two experienced Kaupapa Māori researchers, who had access to the interview data	Each transcript reviewed and coded independently by two researchers	1
Description of coding tree	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Yes
Derivation of themes	Themes derived from data	Themes derived from data	Themes derived from data and then refined based on existing evidence of topic	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data	Themes derived from data

Software	N/A	ATLAS.ti 6	N/A	N/A	ATLAS.ti 6	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	ATLAS.ti V.5	Nvivo 11	Not mentioned	Not mentioned	Not mentioned	Atlas Ti
Participant checking	No	No	Yes	No	No	Not mentioned - secondary analysis	No	No	Yes participants were informed of core themes for member checking and saturation verification	No	No	No	No	Participants were invited to review, edit or change their transcript prior to data analysis.	No	No - but transcripts checked by an author for accuracy
Quotations presented	Yes in full quote tables by theme and sub theme	Yes in full quote tables by theme and sub theme	Some reported, no quote table	Yes with a quote table	Yes in full quote tables by theme and sub theme	No quote table, in text quotes included	No quote table, in text quotes included	No quote table, in text quotes included	No quote table, in text quotes included	No quote table, in text quotes included	No quote table, in text quotes included	Yes and quote tables included	Yes, embedded in article	Yes, embedded in article	Yes, embedded in article	Yes but quote tables not included
Data and findings consistent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Clarity of major themes	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear
Clarity of minor themes	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear
Quality Assessment	Medium	High	Medium	High	High	Medium	High	High	Medium	Medium	Low	High	High	Medium	High	Medium
	Small sample size, short interviews, however themes were clear and recruitment process was transparent	Despite small sample size, multiple interviews allowed for a richer dataset.	Small sample size, even though focus groups tend to be better with a smaller sample size, this was still quite low and does not allow for a rich data set and exploration of themes	Good sample size, clear discussion of themes and recruitment	Despite small sample size, multiple interviews allowed for a richer dataset.	A good sample size for a secondary analysis, but more information on primary data collection needed for transparency	Good sample size and mixed qualitative methods, leading to an apparently rich dataset. Paper was clear.	Good sample size , rich dataset and exploration of themes. Clear paper.	Small sample size, but the discussion of themes was nuanced and rich. The interviews were also reported as being quite short.	Good sample size with rich, longer form interviews. Clear paper and recruitment process clearly explained.	Very small sample size, potentially too low to make any assumptions about experiences of self-management	Very large sample size, very rich dataset, clear paper and all processes communicated well	Good sample size, clear paper and clear recruitment and analysis processes described	Small sample size, but an exploratory study and acknowledged it was a sub set of women who are rarely interviewed about their experiences.	Good sample size, clear description of analysis process and themes very clear and supplemented with quotes	Based on the qualitative interviews alone the sample size is small. However, there was a rich discussion of themes and analysis was rigorous.

Appendix 1.5: Papers for the full text assessment

Author	Title	Year	Journal	Included/Excluded	Reason for Exclusion
M. Carolan	Women's experiences of gestational diabetes self-management: A qualitative study	2013	Midwifery	Included	N/A
M. Carolan, G. K. Gill and C. Steele	Women's experiences of factors that facilitate or inhibit gestational diabetes self-management	2012	BMC Pregnancy and Childbirth	Included	N/A
M. C. Carolan-Olah	Educational and intervention programmes for gestational diabetes mellitus (GDM) management: An integrative review	2016	Collegian	Excluded	No qualitative methods
M. Chavez-Courtois, C. Graham, I. Romero-Perez, G. Sanchez-Miranda, B. Sanchez-Jimenez and O. Perichart-Perera	Experiences, perceptions and self-management of gestational diabetes in a group of overweight multiparous women	2014	Cien Saude Colet	Included	
C. A. G. de Castillo and M. L. Vásquez	Self-care of diabetic pregnant women, a way of ensuring a healthy baby	2006	Texto and contexto enfermagem	Excluded	No self-management
L. Ge, K. Wikby and M. Rask	'Is gestational diabetes a severe illness?' exploring beliefs and self-care behaviour among women with gestational diabetes living in a rural area of the south east of China	2016	Australian journal of rural health	Included	
J. E. Hirst, L. Mackillop, L. Loerup, D. A. Kevat, K. Bartlett, O. Gibson, et al.	Acceptability and user satisfaction of a smartphone-based, interactive blood glucose management system in women with gestational diabetes mellitus	2015	Journal of diabetes, science and technology	Excluded	No qualitative methods
C. J. Homko, W. P. Santamore, V. Whiteman, M. Bower, P. Berger, O. Geifman-Holtzman, et al.	Use of an internet-based telemedicine system to manage underserved women with gestational diabetes mellitus	2007	Diabetes, technology, and therapeutics	Excluded	No qualitative methods
J. M. Kendrick, C. Wilson, R. F. Elder and C. S. Smith	Reliability of reporting of self-monitoring of blood glucose in pregnant women	2005	Journal of obstetrics, gynaecology and neonatal nursing	Excluded	No qualitative methods
E. Manabe	Production of a self-monitoring check sheet for pregnant women	2005	Journal of Japan academy of midwifery	Excluded	No qualitative methods

Author	Title	Year	Journal	Included/Excluded	Reason for Exclusion
W. K. Nicholson, A. J. Beckham, K. Hatley, M. Diamond, L. S. Johnson, S. L. Green, et al.	The Gestational Diabetes Management System (GooDMomS): development, feasibility and lessons learned from a patient-informed, web-based pregnancy and postpartum lifestyle intervention	2016	BMC Pregnancy and Childbirth	Excluded	No qualitative methods
J. A. Nolan, S. McCrone and I. R. A. Chertok	The maternal experience of having diabetes in pregnancy	2011	Journal of the American Academy of Nurse Practitioners	Included	
J. Reid, A. Anderson, D. Cormack, P. Reid and M. Harwood	The experience of gestational diabetes for indigenous Māori women living in rural New Zealand: qualitative research informing the development of decolonising interventions	2018	BMC Pregnancy and Childbirth	Included	
C. Shieh and C. B. Draucker	Self-monitoring Lifestyle Behavior in Overweight and Obese Pregnant Women: Qualitative Findings	2018	Clinical Nurse Specialist	Included	
VE. Murphy, PG. Gibson, PI Talbot, CG Kessell, VL Clifton	Asthma self-management skills and the use of asthma education during pregnancy	2005	European Respiratory Society	Excluded	No qualitative methods
Y. Y. E. Wah, M. McGill, J. Wong, G. P. Ross, A. J. Harding and I. Krass	Self-management of gestational diabetes among Chinese migrants: A qualitative study	2019	Women and Birth	Included	
C. S. Wan, H. Teede, A. Nankervis and R. Aroni	Ethnic Differences in Dietary Management of Gestational Diabetes Mellitus: A Mixed Methods Study Comparing Ethnic Chinese Immigrants and Australian Women	2020	Journal of the Academy of Nutrition and Dietetics	Included	
D. Wazqar, M. Evans	Socio-cultural aspects of self-management in gestational diabetes	2021	Diabetes and Nursing	Included	
L. M. Yee, J. M. McGuire, S. M. Taylor, C. M. Niznik and M. A. Simon	"I Was Tired of All the Sticking and Poking": Identifying Barriers to Diabetes Self-Care Among Low-Income Pregnant Women	2015	Journal of Healthcare for the Poor and Underserved	Included	
L. M. Yee, J. M. McGuire, S. M. Taylor, C. M. Niznik and M. A. Simon	Factors promoting diabetes self-care among low-income, minority pregnant women	2016	Journal of Perinatology	Included	
S. Youngwanichsetha and S. Phumdoung	Lived experience of blood glucose self-monitoring among pregnant women with gestational diabetes mellitus: a phenomenological research	2017	Journal of Clinical Nursing	Included	

Appendix: Chapter 3

Appendix 2.1: Protocol for UDIP study

PROTOCOL: Accuracy of self-testing for proteinuria during Hypertensive pregnancy

A diagnostic accuracy study testing the ability of hypertensive pregnant women to detect proteinuria in comparison to midwives, automated readers and a laboratory reference standard.

Short title/acronym: Proteinuria Detection In Pregnancy (U-DIP)

U-DIP

Ethics Ref: 18/YH/0208
Date and Version No: 17/05/2018

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Signatures:

Richard McManus **Katherine Tucker** **Richard Stevens**





The research team declare no conflicts of interest.

Confidentiality Statement: This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	Accuracy of self-testing for proteinuria during hypertensive Pregnancy	
short title	Proteinuria Detection in Pregnancy (U-DIP)	
Study Design	Diagnostic accuracy study	
Study Participants	Pregnant women, 18-50 years, with chronic or gestational hypertension or pre-eclampsia, at greater than 20 weeks gestation, and health care professionals involved in the appointments.	
Planned Sample Size	Total sample size between 275 and 733 women. Recruitment will stop when 110 women with proteinuria have been enrolled. Around 15 health care professionals will be recruited for the qualitative interviews. Around 50 healthcare professionals will be recruited for the focus groups.	
Planned Study Period	24 Months	
Research Questions	Can pregnant women with hypertension accurately self-monitor for proteinuria?	
	Objectives	**Outcome Measures**
Primary	To determine accuracy of self-testing for proteinuria	Participant and health professional tested readings will be compared to laboratory proteinuria testing results. **Reference test for primary analysis:** laboratory urinary protein-creatinine ratio (uPCR), (Additional reference test for sensitivity analyses: laboratory albumin/creatinine ratio (ACR)) **Primary Index test**: dipstick self-testing by study participants. **Secondary Index tests**: 1) visual dipstick test by healthcare professional 2) testing using an automated reader
Secondary	1) To determine the acceptability of self-testing in this group 2) Assess feasibility of self-reporting via return of photographs, for use in future development of an app.	1) Analysis of free text responses from postcards, and transcripts from interviews and focus groups with healthcare professionals and study participants. 2) Successful return of photographs of dipstick test taken using a mobile phone.

2. ABBREVIATIONS

ACR	Albumin Creatinine Ratio
CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HP	Healthcare Professional
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure
UPCR	Urine Protein to Creatinine Ratio

3. Lay summary

Proteinuria testing and blood pressure monitoring are the most commonly performed antenatal screening tests: they are carried out at every antenatal visit and are central to the diagnosis of pre-eclampsia (raised blood pressure plus protein in the urine, a potentially serious condition for both mother and baby).

A number of women in the UK develop pre-eclampsia within the interval between antenatal visits. It is possible that self-testing using urine dipsticks could improve the detection of pre-eclampsia. The most likely group to benefit from home testing would be those with raised blood pressure.

Previous work has suggested that self-testing of urine during pregnancy may have a similar accuracy to health care professional testing, that self-testing could be easily implemented during an antenatal appointment, and that most women would find self-testing acceptable.

In this study, we wish to determine the accuracy of visual proteinuria testing by pregnant women with raised blood pressure compared to laboratory testing, visual testing by a healthcare professional, and testing using an automated reader.

We will recruit women with raised blood pressure from 20 weeks into their pregnancy as they attend routine antenatal care appointments. Women who agree to take part will be asked to test their own urine and provide this sample for further testing. Women may also be asked to take a photograph of their test results and transfer them by email to a dedicated research email address using their phone in order to create a database of images for the development of an app to aid at home self-testing, and to look at the feasibility of implementing an app into antenatal care (such an app would require use of a smartphone camera). Women and healthcare professionals will also complete a free text postcard about self-testing to answer questions about acceptability and feasibility. Interviews and focus groups with healthcare professionals and women who took part in the study will be conducted at the end of the study to discuss their experiences of the study.

4. BACKGROUND AND RATIONALE

This research is part of a wider programme of work to explore the use of self-monitoring of blood pressure and self-testing of urine during pregnancy. The overall aim is to improve the detection and management of raised blood pressure (hypertension) and pre-eclampsia in the higher risk and hypertensive population.

Proteinuria analysis and blood pressure monitoring are the most commonly performed antenatal screening tests and are central to the diagnosis of pre-eclampsia.

Proteinuria testing is routinely carried out by midwives or doctors at routine antenatal visits. (1) Standard reagent strips are used with further testing in the case of positive results: spot testing urine protein:creatinine ratio (uPCR) (and in a minority of units 24 hour sample testing) as per NICE and PRECOG guidelines.

A substantial number of women in the UK develop pre-eclampsia within the interval between antenatal visits.(2) Furthermore a significant proportion of deaths from pre-eclampsia also had serious disease present between normal antenatal visits.(3) Regular home testing for proteinuria could improve detection of pre-eclampsia in women with hypertension, as well as reducing the time, money, stress and inconvenience of frequent appointments without compromising the ability to detect and monitor a potentially serious disease.

Self-testing using urine dipsticks is inexpensive, convenient, easy to use, and provides a rapid result. Self-testing of urine for glucose or albuminuria is becoming increasingly common in diabetic care. (4, 5) However, there are surprisingly little data on self-testing of proteinuria in the pregnant population. Our literature review of proteinuria detection in pregnancy suggests that there is a very limited amount of

work published in this area. Several studies describe providing pregnant women with urine dipsticks to periodically check for protein along-side self-monitoring blood pressure, but have not formally evaluated test performance, effect on frequency of visits to clinics, and pregnancy outcome. (Tucker 2014)

An Australian study from 2002 examined proteinuria testing in pregnancy by asking women to test their own urine for protein in a clinic, the sample was then re-tested by the midwife. The study did not compare the results to a laboratory standard (such as UPCR) or automated testing but suggested that self-testing of urine during pregnancy can be practical and easily implemented by teaching women during an antenatal visit.(6) There was no data presented on patient satisfaction or acceptability, however, no women declined to take part.

Our own pilot work in the area has shown that pregnant women are willing and able to monitor their own urine alongside blood pressure monitoring and can test accurately with minimal training. Linked qualitative work has shown that pregnant women and health professionals are generally positive about the utility of self-testing for protein during pregnancy. (8)

This study will determine the accuracy of proteinuria self-testing by pregnant women with raised blood pressure in comparison to visual health care professional testing, testing using an automated reader, and a laboratory reference standard uPCR and ACR test. The secondary aim of this study is to assess the views and study experiences of women and healthcare professionals who took part.

5. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures
Primary Objective Determine accuracy of self-testing for proteinuria	Participant and health professional tested readings will be compared to laboratory proteinuria testing results. **Reference test for primary analysis:** laboratory urinary protein-creatinine ratio (uPCR), (Additional reference test for sensitivity analyses: laboratory albumin/creatinine ratio (ACR)) **Primary Index test**: dipstick self-testing by study participants. **Secondary Index tests**: 1) visual dipstick test by healthcare professional 2) testing using an automated reader
Secondary Objectives: 1) To determine the acceptability of self-testing in this group 2) Assess feasibility of self-reporting via return of photographs, for use in future development of an app.	1) Analysis of free text responses from postcards, and transcripts from interviews and focus groups with healthcare professionals and study participants. 2) Successful return of photographs of dipstick test taken using a mobile phone.

6. STUDY DESIGN

This is a diagnostic accuracy study. Pregnant women with hypertension (gestational or chronic) will be asked to test their urine for protein alongside one of their routine antenatal care visits. This study will be completed in a single visit. The study will recruit participants until 110 cases of proteinuria are obtained.

The sample will be tested by:

- The participant (primary index test)
- A health care professional (using a visual check)
- An automated reader
- Laboratory uPCR (reference test)
- Laboratory ACR (alternate reference test for sensitivity analyses)

A subset of women may also be asked to take a photo of their test results using their phone, and email the photo to a secure NHS e-mail server. The purpose of this is to test the feasibility of this method of self-reporting, and the photos will be used in the future development of an App

At the end of their visit, participating women will be provided with an opportunity to provide feedback about their thoughts and feelings about self-testing on a free text postcard. A sample of women who have consented during the study will also be asked to undertake a follow up interview. Their healthcare professional will also be interviewed or asked to participate in a focus group at the end of the patients visit, and their feedback on the study will also be sought on a free text postcard.

6.1. Study Participants

The study population will comprise of pregnant women aged 18 to 50 years with a diagnosis of gestational or chronic hypertension or pre-eclampsia at greater than 20 weeks' gestation attending antenatal clinics. Around 15 health care professionals involved in antenatal care will be recruited for qualitative interviews, and 50 will be recruited for the focus groups.

6.2. Eligibility Criteria

Inclusion Criteria

The participant is eligible for the study if ALL of the following apply:

- Participant is willing and able to give informed consent for participation in the study.
- Pregnant ≥20 weeks' gestation
- Aged 18 to 50 years
- Chronic or gestational hypertension or pre-eclampsia (defined by criteria of International Society for Study of Hypertension in Pregnancy).

Inclusion Criteria for sub-set of women participating in the photo study

- Own a smartphone capable of taking a photo and sending an e-mail directly from the phone

Exclusion Criteria

- The study participant is unable to read and write in English
- The usual care team consider it inappropriate to approach the participant, for example if they are acutely unwell.

Inclusion Criteria Healthcare Professionals

- They are part of the patients usual care team
- Have had patients who participated in the study

- Has experience of managing women who self-monitor BP during pregnancy or is in a role where this could be the case: midwife (both hospital and community), obstetrician or obstetric physician.
- Is willing and able to give informed consent for participation in the study.
- Works at a participating NHS Trust

Exclusion Criteria Healthcare Professionals

- There are no exclusion criteria for Healthcare Professionals

7. STUDY PROCEDURES

Eligible women will be provided with study information and invited to take part in the study. Those consenting will have basic demographic (i.e. age, ethnicity, parity, risk factors for pre-eclampsia) and medical history data collected and be trained in study procedures including urinalysis dipstick use.

Participating women will be asked to self-test alongside their antenatal clinic visit, and their urine sample will be retained for (a) visual dipstick test by the health care professional (b) testing with an automated reader and (c) laboratory uPCR and ACR testing. This is a routine antenatal test that is completed at antenatal care appointment. An automated reader will be provided to sites if they do not have one, using an automated reader is in the NICE antenatal care guidelines and staff will have prior knowledge of how to use one.

A subset of women may also be asked to take a photograph of the test results using their phone and send this to the study team via a secure email address.

Finally, participants and health care professionals will be given the opportunity to provide a free text comment about self-testing during pregnancy on a postcard. Women and health care professionals who have consented will also be asked to give a follow up interview or participate in a focus group. These will take place during the study.

7.1. Recruitment

The study will take place across multiple sites, anticipated sites include the John Radcliffe Hospital and Guy's and St Thomas's Hospital, and posters explaining the study will be placed in waiting rooms where we are hoping to recruit on days when the study team are at the hospital.

Potential participants will be identified by the usual care team (trained practice/hospital doctors and midwives) at usual antenatal care appointments (including from hypertension clinics), and provided with

study information. If they are interested in participating, they will contact the research team, will be invited to attend a study visit ideally alongside usual care. At this visit a member of the research team will explain the study, the eligibility criteria will be checked and they will be invited to consent to the study on the same day.

We aim to recruit women over a period of 24 months (approximately 3-6 per week). Women will complete the study on the same day as they consent to take part. Purposive sampling will be used to include women from both hospital settings, a range of ages, socio-economic and ethnic background, and parity.

The healthcare professionals who take part will be members of the participant's usual care team. They will be approached by a member of the research team during or prior to the start of the study at their hospital site. If they are interested, they will be provided with a participant information sheet about taking part in the qualitative interviews and focus groups.

7.2. Screening and Eligibility

The usual care team at each site will identify potentially eligible women for the study, and eligibility criteria will be confirmed by the researcher. Written consent will be obtained from all study participants, and no study procedures will be undertaken before gaining written consent. Consent will be obtained by the research midwife or researcher present.

7.3. Informed Consent

Written Participant Information and Informed Consent will be presented to the participants detailing: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as she wishes to consider the information and the opportunity to question the researchers, their midwife, other health care professional or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed.

The person who obtains consent must be suitably qualified (GCP trained) and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant and the original will be kept on site.

7.4. Study visit

At the participant's routine antenatal clinic visit, the research team will collect information including basic demographics and pregnancy medical history and any other relevant medical history. Further to this, training in self-testing for proteinuria will be provided. This training has been developed by our team using experience from previous projects and/or clinical work and will be delivered to participants by the research team.

Women will then be asked to test their own urine sample in an appropriate space on site and provide the same sample for analysis by laboratory testing as well as to their healthcare professional for routine testing. They will be given a brief explanation and a guidance sheet to explain this process. The health care professional's results will be obtained by the researcher from the participants medical notes. Participants may also be asked to take photos of their results using a photo sheet, and e-mail them to the study team. This will be used to test the feasibility of developing of an app that will enable women to test their urine at home with the benefits of an automated reader. The photos will be deposited in a database, to be used in a future project to develop and validate the app.

At the end of their antenatal visit, they will be offered the opportunity to make comments about their experience of self-testing for proteinuria on a free text postcard, which will be handed back to the study team during the same appointment or provided with a free post envelope.

7.5. Sample Handling

Participants will be asked to provide urine samples at standard antenatal appointments; these will be re-tested by their health care professional and sent for testing via automated reader and laboratory uPCR and ACR testing according to standard operating procedures in the clinical laboratories.

The samples will be not be stored following testing and will be disposed of after testing according to the usual procedures for the hospital laboratories.

8. QUALITATIVE COMPONENT

Qualitative sub-study

This aims to understand how proteinuria self-testing in pregnancy is implemented and acceptable in daily life and routine clinical practice and will include women and healthcare professionals who took part in the accuracy testing part of the study, and explore facilitators and barriers to successful implementation lie. Data will also be collected on whether the inclusion of this kind of app in antenatal care is likely to be feasible during the qualitative interviews and focus groups.

Interviews with participating women: Women who have consented to be contacted for a follow up interview will be contacted by a member of the research team by phone/email/in person. We aim to conduct interviews with around 30 women across the two sites. The semi-structured interviews will be, according to preference, conducted in their own homes, at one of the study sites (alongside part of a usual care antenatal appointment), or over the phone. The timing of the interviews will be after the data is collected for the dipstick testing portion of the study. Interviews will last approximately 15-30 minutes and will be audio-recorded for transcription and analysis. During the interviews the researcher may also make research notes that will also be anonymised during the transcription process.

Semi-structured interviews/focus groups with healthcare professionals: interviews will be conducted with around 15 health care professionals involved in the study across the two sites. The aim will be to understand how self-testing was operationalised in practice and provide key information on the acceptability among health care professionals. These interviews will occur on the site the healthcare professionals work at, or over the phone after the completion of the dipstick testing portion of the study. They will last approximately 15-30 minutes and will be audio-recorded for transcription and analysis. During the interviews the researcher may also make research notes that will also be anonymised during the transcription process. Around 50 healthcare professionals will be recruited to take part in a focus group. These will be approximately 30-45 minutes long and groups will consist of between 2 – 8 healthcare professionals. The focus groups will also take part on the site the healthcare professionals work at, and the session will be audio-recorded for transcription and analysis. The focus group will be led by a researcher, who will be present for the entire session and take research notes. The focus groups will take place during the course of the study.

Postcards: All healthcare professionals and participating pregnant women will be issued with a free text postcard to complete either at the study visit or given the opportunity to post them back after the study visit. The emphasis will be on participants' experiences of taking part in and satisfaction with testing. This approach is useful for capturing aspects of a participant's experience of a study or an intervention which may otherwise not be documented. (7)

8.1. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements
- Withdrawal of Consent

Withdrawn participants will not be replaced. When possible the reason for withdrawal will be recorded in the study file. The data from these participants will be kept unless specifically requested not to.

8.2. Definition of End of Study

The study will end when all data has been obtained and data checking has taken place to ensure a complete data set.

9. STATISTICS AND ANALYSIS

9.1. Description of Statistical Methods

Analyses will include test performance (i.e. positive / negative predictive value, sensitivity and specificity) of each index test compared to the reference standard(s): see 9.3.

There is no planned interim analysis; full analysis will be carried out at the end of the study when all data have been collected.

9.2. The Number of Participants

In a previous study using synthetic urine samples, sensitivity of dipstick measurement for proteinuria was approximately 80% for both pregnant women and healthcare professionals, rising to above 90% when using an automated dipstick reader.

100 complete cases of proteinuria would give sufficient numbers to estimate sensitivity of 80% with a standard error of 4%, or a sensitivity of 90% with a standard error of 3%. To ensure sufficient case numbers, allowing for possible missing data, we will recruit until 110 cases of proteinuria are obtained. Projected total recruitment is therefore between 275 and 733 pregnant women, assuming case rates between 15% and 40% in our high-risk hypertensive population.

We will monitor our recruitment by entry criteria to ensure that there are participants with a spread of gestational stage and that women with both chronic and gestational hypertension are represented. This is to ensure that our study population is representative of the likely users if self-testing were to be put into practice.

All pregnant women participants will be asked to take photos for the app development.

Approximately 30 women and 15 healthcare professionals will be interviewed as part of the qualitative interviews component of the study. Approximately 50 healthcare professionals will take part in the qualitative focus groups.

9.3. Analysis of Outcome Measures

Where possible data will be used from all participants to perform a complete case analysis.

DIAGNOSTIC ACCURACY

Primary analysis: Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of primary index test (self-tested urinary dipstick) will be compared to reference test (laboratory uPCR testing).

Secondary analyses: Sensitivity, specificity, PPV and NPV of the following compared to reference test:

- Visual dipstick test by healthcare professional
- Testing with an automated reader

Sensitivity analyses: each of the above primary and secondary analyses will be repeated using the alternate reference test (laboratory ACR).

Qualitative analysis: The interviews and focus groups will be audio-recorded and transcribed. Transcripts and free text responses will be separately coded in NVivo and will be separately analysed thematically using the modified Framework approach and NVivo software. Provisional analytic categories will be iteratively refined using the constant comparative method as new data emerge with continued interviewing.

PHOTOGRAPH COLLECTION

Rate and quality of return of photographs of dipstick test taken using a mobile phone will be used in order to indicate the feasibility of using s self-reporting app in antenatal care

10. DATA MANAGEMENT

10.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

10.2. Data Recording and Record Keeping

Data will be recorded onto a combination of electronic and paper case record forms. In the case of electronic forms, underlying data will be stored in password protected files on University of Oxford computers. The Case Report Forms will not include identifiable information but will include a unique study identification number for each participant. Keys linking participant identifiers to study ID number will be kept separately from the rest of the data. All patient identifiable information (consent forms and contact details) will be collected in paper form and will be held securely in a locked filing cabinet in a restricted access secure room at the department of Primary Care Health Sciences. Contact information will be destroyed at the end of the study, unless participants have agreed to be contacted for potential involvement in future research, in which case contact details will be held in a secure locked cupboard separate to any study information for a maximum of five years. Only the research team will have access to this confidential data. This information will be held separately from any study data. The study will follow the NHS Code of Confidentiality.

Photographs emailed to the study team, via a secure e-mail address, will be saved onto a secure database, and will be labelled with the study ID number. The email, and sender email address, will then be deleted. Qualitative data (postcards and interview transcripts) will be transcribed, then placed into electronic files for analysis and stored on secure University of Oxford computers. Audio recordings of interviews, focus groups and postcards will be deleted after being transcribed, checked and transferred

to electronic data. The researchers conducting the study will perform the transcription, and all identifying information will be removed during the transcription process.

The investigators will facilitate any study-related monitoring or regulatory inspection(s), providing direct access to source data/documents as necessary.

The anonymised data will be kept for ten years after publication.

11. QUALITY ASSURANCE PROCEDURES

Data for this study will be entered onto an electronic database which will have built in safeguards regarding data quality. All research staff and practice staff involved in the study will be subject to quality control checks by the Primary Care Clinical Trials Unit.

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

12.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and Health Research Authority (HRA) for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

12.5. Expenses

Participation in this study will happen on the day of the participant's usual antenatal appointment. If participants are asked to participate in a follow up interview and opt to come back to the hospital to this, outside of their usual antenatal appointment, reasonable travel expenses will be paid back upon production of receipts, or a mileage allowance provided as appropriate.

12.6. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, this is with the exception of the consent form and contact details which will be kept separately in a secure facility. All documents will be stored securely and only accessible by study staff and authorised personnel. Photos and participant emails will be deleted from the study e-mail address once they have been logged and stored on the secure study drive. During the transcription process for the interviews and focus groups, all identifying information will be removed by the researcher. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

12.7. Other Ethical Considerations

It is possible that self-testing for proteinuria may increase anxiety in participants but previous work by our team has not found this to be common. We will consult with women who have had (or are undergoing) hypertensive pregnancies about the protocol and the information provided to participants to ensure this is reasonable and acceptable. We are aware of a need not to worry participants unduly and will consider whether we have achieved this in the qualitative parts of this pilot study. If it becomes apparent during this study that the questionnaires, information provided or protocol are not acceptable then these will be changed accordingly. Should an individual feel excessively anxious due to study procedures then they will be free to withdraw.

A Freephone helpline will be available should participants or clinical staff require advice over and above that provided in the guideline (0800 9150045). This number will be included in the PIS.

13. FINANCE AND INSURANCE

13.1. Funding

This work is funded by a National Institute for Health Research (NIHR) Programme Grant: RP-PG-0614-20005.

13.2. Insurance

Study insurance to cover negligent harm will be provided by the sponsors, the University of Oxford. The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

14. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the National Institute for Health Research (NIHR). Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. The research will be displayed on the Nuffield Department of Primary Care website: https://www.phc.ox.ac.uk/publications

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15. APPENDIX A: SCHEDULE OF STUDY PROCEDURES

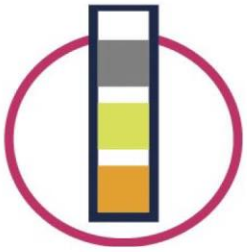
Procedures: Patients	**Visit timing Day 1**		**Within in duration of study**
	Screening	**Study visit**	**Follow up**
Eligibility assessment *(accuracy study)*	Y		
Informed consent	Y		
Demographics		Y	
Medical history		Y	
Trained to self-test for proteinuria		Y	
Dipstick self-testing		Y	
Photographs of results for app development		Y	
Free text postcard		Y	
Qualitative interview			Y
Focus groups			Y

Procedures: Health Care Professionals	**Visit timing Day 1**	
	Screening	**Study visit**
Eligibility assessment *(qualitative sub study)*	Y	
Informed consent	Y	
Free text postcard		Y
Qualitative interview		Y

16. APPENDIX B: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	2	23/07/2018	Bethany Jakubowski Kath Tucker Richard McManus	**The secondary index tests were clarified as:** 1) visual dipstick test by healthcare professional 2) testing using an automated reader Previously the visual test by a health care professional was missing. Grammatical and spelling errors have also been corrected.

Appendix 2.2: Patient information sheet for the UDIP study



UDIP: Proteinuria Detection In Pregnancy (U-DIP)

Can you help?

A Summary of the Study

This study is testing whether women can accurately test their urine for the presence of protein (proteinuria). Protein in the urine and high blood pressure can indicate pre-eclampsia, a potentially serious condition for the mother and the baby that requires careful monitoring. We would like to determine the accuracy of urine self-testing compared to health professional testing, an automated reader, and laboratory testing. We will seek feedback from you and your healthcare professionals after the study. In the future we hope this study will be used to reduce the detection time to pre-eclampsia.

If you take part in the study

You will be asked to self-test your own urine, on the day of one of your antenatal visits. You will be given guidance on how to do this. The sample will also be used for:

- Testing by a health care professional
- Testing using an automated reader
- A laboratory test

You will also be asked to take a photo of your results and provide feedback on your views and experiences of self-testing. Your sample will be disposed of after the laboratory test analysis.

1 Why are we doing this study?

Urine testing is a common antenatal screening test which is important in the diagnosis of pre-eclampsia. We would like to find out if self-testing urine for protein is accurate. We are recruiting between 275 and 733 women to test their urine at an antenatal visit to determine the accuracy of self-testing. We are also asking women to take photos of their results, so that we can assess the feasibility of developing an app in the future. The acceptability of self-testing will be determined by seeking feedback on participants experiences in the study, as well as the views of up to 15 antenatal healthcare professionals.

2 Why am I being asked to take part?

You are being asked to take part because you have chronic or gestational hypertension or pre-eclampsia, and you are 20 weeks pregnant or greater. Taking part is entirely optional, and you can withdraw at any point without having to give a reason and with no consequence to your clinical care.

3 What will I need to do if I want to take part?

Your first step would be to contact the research team who will arrange to talk to you about the study. You can contact them on **0207 188 3570** or via your antenatal clinic.

4 What will happen if I take part?

You will be asked to self-test your own urine, on the day of one of your antenatal visits. You will be given guidance on how to do this. Your sample will also tested by a health care professional, an automated reader, and a laboratory test, so that we can compare results between methods. You will also be asked to complete a free text postcard to feedback your view on your experience of self-testing. You will also be asked to take a photo of your self-testing results and e-mail them to bump@phc.ox.ac.uk so we can look at the potential feasibility of using an app to aid self-testing. If you agree, you may also be asked to complete a follow up interview, which will be conducted by staff and can take place at a location convenient to you (over the phone, at your home, or at a routine antenatal visit).

5 Possible advantages and disadvantages

While there will be no direct benefit to you, we hope that the information from this study will lead to improvements in the diagnosis of pre-eclampsia during pregnancy. Participating in this study will add some extra time to your routine antenatal appointment.

6 More information about taking part

Will my expenses be paid?
Your participation in this study will happen on the day of your usual antenatal appointment and we will only be asking you to self-test your urine once, at this appointment. If you are asked to participate in a follow up interview and opt to come to the hospital for this we will pay back any additional travel expenses, but only if this is surplus to your regular antenatal appointment.

Will my taking part in this study be kept confidential?

Yes. You will only be identified by a unique study number so that your sample and any additional information you give us is kept confidential. We will keep your contact details if you consent to a follow up interview, but these details will be destroyed at the end of the study. Any personal information will be removed from the interview transcripts. All data will be kept securely according to the Data Protection Act 1998. Responsible members of the University of Oxford and the relevant NHS trusts may be given access to data for monitoring and/or audit the study to ensure that the research is complying with regulations.

The University of Oxford_is the sponsor for this study based in the United Kingdom

We will be using informationfrom you and your medical records in order to undertake this study and will act as the data controller for this study.
This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for up to ten years after study publication. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting bump@phc.ox.ac.uk

St Guy's and St Thomas' Hospital will keep your name, NHS number and contact details confidential and will not pass this information to the University of Oxford. St Guy's and St Thomas' Hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from The University of Oxford and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

The University of Oxford will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, or contact details.

St Guy's and St Thomas' Hospital will keep identifiable information about you from this study for up to ten years after the study has finished.

7 Who is paying for and running the study?

The research is being funded by the National Institute for Health Research. Funds have been allocated to the Nuffield Department of Primary Care. The sponsor of the study is the University of Oxford. The chief investigator is Professor Richard McManus.

8 Participation in future research

If you think you might be interested in participating in future research, the research team will collect your contact details and keep them securely for a maximum of 5 years. This is entirely optional, and being contacted does not oblige you to participate in future research.

9 What if there are any problems?

If there are any problems or you have any concerns, you can contact the study coordinator (see section 10). The University of Oxford, as sponsor, has appropriate insurance in place in the unlikely event you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment with which you are provided. If you wish to complain about any aspect of the way in which you have been approached or treated in this study, you should contact Katherine Tucker (details below) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480. You can also contact the head of CTRG by e-mailing ctrg@admin.ox.ac.uk. The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please use **020 7188 8801**

10 Study co-ordinator contact details

For more information about the study please contact the trial manager, Katherine Tucker, at Katherine.tucker@phc.ox.ac.uk

Appendix 2.3: Consent form for the UDIP study

UNIVERSITY OF OXFORD

NHS National Institute for Health Research | NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Site logo

U-DIP

Participant ID ☐

Contact number: 0207 188 3570

Consent Form

Proteinuria Detection in Pregnancy (U-DIP)

Name of Chief Investigator: Professor Richard McManus

	Please initial each box
1. I confirm that I have read and understood the information sheet for participants, dated 17.05.18 version 1, for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Oxford, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4. I agree to donate urine as part of this study. I consider these samples as a gift to the University of Oxford and I understand I will not gain any direct personal or financial benefit from them.	☐
5. I understand that if I provide a photograph of my urine test, this may be used for in future research for the development of an App. It will not be possible for me to be identified by it.	☐
6. I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it.	☐
7. I agree to participate in this study.	☐
OPTIONAL (please circle)	
8. I agree to be contacted for a follow up interview about my experience of self-testing. I understand that this interview will be audio recorded, and agree to the use of anonymised quotes in research reports and publications.	Yes No
9. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes No

Name of participant (please print)	Date	Signature
Name of person taking consent (Please print)	Date	Signature

When completed, top copy for participant, bottom copy kept in site file

UDIP consent form version 1 Date: 17.05.2018 IRAS ID: 238483 REC: 18/YH/0208

Appendix 2.4: Case report form for the UDIP study

ID

Proteinuria Detection In Pregnancy (U-DIP)
Participant Visual Dipstick Reading
Instructions

U-DIP

1. How many weeks pregnant are you? _____

2. How old are you? _____

3. Is this your first pregnancy? (circle) YES / NO

4. Have you been diagnosed with high blood pressure during this pregnancy? (circle) YES / NO

5. Please indicate your ethnic group

- ☐ Asian or Asian British
- ☐ Black or Black British
- ☐ Chinese
- ☐ Mixed
- ☐ White British
- ☐ White Irish
- ☐ Other (please specify _____

6. Please provide the first four digits of the postcode of your home address (this will be used to look at the demographic distribution of participants)

___ ___ ___ ___

Using the test strip:

1. Dip the test pad of the strip into the sample and remove immediately.

2. Drag the edge of the strip against the container rim to remove excess liquid.

3. Compare each test pad to the colour blocks on the bottle label and note the result straight away on this form (ignore colour changes that occur after 2 minutes).

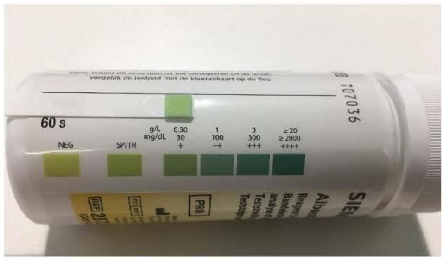
1



2



3



Please read your dipstick according to the bottle

The sample is (please tick one box):

☐	☐	☐	☐	☐	☐
Negative	**SP/TR** **Trace**	**0.3** **30 (1+)**	**1** **100 (2+)**	**3** **300 (3+)**	**>20** **>2000 (4+)**

NHS National Institute for Health Research

Site Logo

UNIVERSITY OF OXFORD

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Appendix 2.5: Statistical analysis plan for the UDIP study

Statistical Analysis Plan for UDIP 2018

Richard Stevens, Beth Jakubowski, Kath Tucker, Lucy Chappell, Richard McManus

1. Background

See protocol.

2. Objectives

2.1. Primary Objective

Determine accuracy of self-testing for proteinuria

2.2. Secondary Objectives

The secondary objectives listed in the protocol (determine acceptability, feasibility of self-reporting for app development) are not addressed by this statistical analysis plan.

3. Study population

See protocol for inclusion criteria.

4. Reference tests

4.1. Primary reference test

Laboratory uPCR (reference test): continuous measure.

Values ≥30 [units] will be considered disease-positive.

4.2. Secondary reference test

Laboratory ACR: continuous measure.

Values ≥8 will be considered disease-positive, following Waugh et al.

5. Index tests

5.1. Primary index test

Dipstick result when read visually by participant: ordinal measure, with outcomes as follows:

- negative
- trace
- 1+
- 2+
- 3+

- 4+

Categories 1+ and up will be considered index test positive and categories 'negative' and 'trace' will be considered index test negative.

5.2. Secondary index tests

- Dipstick result read visually by health professional: ordinal measure as above.
- Dipstick result read by health professional using automated device: ordinal measure categorised as negative, trace, 1+, 2+, 3+.

These ordinal measures will be classes positive and negative as described in Section 5.1 above.

6. Analyses

6.1. Descriptive analyses

Number and characteristics of recruited patients will be summarized, using median and quartiles for continuous measures and n(%) for dichotomous. Categorical and ordinal measures will be tabulated as n(%).

Number completing study and number with non-missing outcomes will be reported.

6.2. Primary analysis

The following outcome measures will be calculated for the primary index test compared to primary reference test, and reported with 95% confidence intervals:

- Sensitivity
- Specificity
- PPV
- NPV
- Likelihood Ratio's
- ROC curve

6.3. Secondary analyses

The outcome measures of 6.2 will be calculated for each secondary index test against the primary reference test.

The outcome measures of 6.2 will be calculated for the primary index test, and for each secondary index test, against the secondary reference test.

The secondary reference test will be compared to the primary reference test using a scatterplot and a Bland-Altman difference plot with mean difference and 1.96-standard-deviation limits of agreement (Bland and Altman, Lancet 1995; 346:1085-7).

6.4. Missing data

6.4.1. Missing data for index tests

The number of missing test results will be reported for each index test, stratified by primary reference test result.

6.4.2. Missing data for reference tests

The primary analysis will use complete case analysis (i.e. exclude participants with missing reference test result).

Sensitivity analyses will be carried out (i) assuming all missing tests were disease positive and (ii) assuming all missing tests were disease negative, to bracket the uncertainty around results.

6.5. Pre-specified sensitivity analyses

As described above, analyses of index tests will be repeated using a secondary reference test.

Motivated by previous data suggesting automated readers are over-sensitive, the analyses of the automated reader secondary index test will be repeated using a threshold of 2+ instead of 1+.

7. Sample size

See protocol.

8. Interim reporting strategy.

There are no pre-specified interim analyses, except for monthly reporting of total recruits and total number index-test-positive.

The study will be closed to recruitment after the first monthly report at which the target number of index-test-positives has been reached or exceeded.

Appendix 2.6: Sponsor approval for the study





Clinical Trials and
Research Governance

RESEARCH SERVICES
Clinical Trials and Research Governance
Joint Research Office
Boundary Brook House
Churchill Drive
Headington, Oxford
OXON
OX3 7LQ

To whom it may concern

Date: 03/05/2018

Dear Sir/Madam,

Title: Accuracy of Self-testing for Proteinuria during Hypertensive Pregnancy

PID: 13285

Protocol Date/Version: 26.04.2018 Version 1

The above study has been designed by Prof Richard McManus and colleagues at the University of Oxford and funded by the National Institute for Health Research {NIHR). I confirm that the University will accept the role of Research Sponsor of this Study and will comply with the requirements of the UK Policy Framework for Health and Social Care Research October 2017, insofar as these apply in the United Kingdom.

Insurance-provided indemnity arrangements are in place for the project:
Newline Underwriting Management Ltd., at Lloyd's of London.

Sponsorship is confirmed subject to the condition that the following are sent to Clinical Trials and Research Governance for review prior to submission to the Research Ethics Committee . Failure to do so may compromise insurance cover for the project.

- Any minor or substantial amendments
- Any extension to the study end date
- Addition of any new research site or patient identification centre

In addition, annual progress reports, the end of study notification and final report must be copied to Clinical Trials and Research Governance.

Lastly, where they exist, University Core SOPs must be followed by default for all clinical research sponsored by the University. Further information can be found here: https://www.admin.ox.ac.uk/researchsupport/ctrg/resources/

Any communications relating to Research Sponsorship should be directed to the undersigned, whose contact details are given in this letter.

Yours faithfully
Elaine Chick
Deputy Head of Clinical Trials and Research Governance

Tel: +44 {0)1865 616480 · Web: www.admin.ox.ac.uk/researchsupport/ctrg/
Email: Heather.house@admin.ox.ac.uk or Elaine.Chick@admin.ox.ac.uk

Appendix 2.7: REC and HRA approval for the UDIP study

NHS
Health Research Authority
Yorkshire & The Humber - Leeds East Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8081

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

21 May 2018

Professor Richard McManus
Professor of Primary Care
University of Oxford
Nuffield Department of Primary Care
University of Oxford
Radcliffe Observatory Quarter
OX2 6GG

Dear Professor McManus

Study title:	**Accuracy of self-testing for proteinuria during hypertensive pregnancy**
REC reference:	**18/YH/0208**
Protocol number:	**1**
IRAS project ID:	**238483**

The Proportionate Review Sub-committee of the Yorkshire & The Humber - Leeds East Research Ethics Committee reviewed the above application on 25 May 2018.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

- **Recruitment arrangements and access to health information, and fair participant selection**

The Sub-Committee noted that it was assumed that all participants had a mobile telephone capable of taking photographs. Members determined that most would, but maybe not all, and asked that this was included in the inclusion criteria.

Key Investigator Miss Bethany Jakubowski advised that this had been included in the inclusion criteria for the sub-set of women who took part in the photo study, but was not in the inclusion criteria for women who took part in the primary study, as they did not need a phone.

The Sub-Committee was satisfied by the response given.

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

Members asked what time the interview would take place relative to the testing, and whether it was possible that the participant could have lost the baby.

Miss Jakubowski explained that there was no specific timeline for the interviews to take place, but in general it would be within 3 months of their initial participation in the study. This could mean that some women were interviewed after the birth of their baby, depending on their gestational age when they participated in the study. In order to ensure that they did not contact a woman inappropriately following an adverse pregnancy outcome, they would check with the direct care team whether there was any reason not to approach the woman for an interview prior to the approach to arrange timing. Only women who agreed to an interview in theory at the time of the original participation were approached.

The researchers obtained the participant's e-mail addresses when they e-mailed the photograph. Members queried how this would be stored.

Miss Jakubowski explained that the photographs were emailed to the study team, via a secure e-mail address, and were saved onto a secure database, and also labelled with the study ID number. She confirmed that the participants' e-mails and their e-mail address were then deleted.

The Sub-Committee asked why the ethnicity and postcode of participants was needed.

Miss Jakubowski advised that they were interested in whether there were any cultural barriers to urine testing. The ethnicity of participants was obtained so that the researchers would know which women they could discuss this with during the interviews and prepare accordingly. They would ensure that the questions were asked sensitively and without causing any offense to the participant. The postcode data would help the researchers to understand the population each hospital is serving, and this can be used to discuss barriers with the healthcare professionals as well.

The Sub-Committee asked who carried out the interviews and focus groups.

The interviews and focus groups were carried out by appropriate members of the research team who were trained in qualitative research.

The Sub-Committee was satisfied by the responses given.

- **Informed consent process and the adequacy and completeness of participant information**

The Sub-Committee considered whether the poster needed to mention that the researchers were conducting a study on urine testing. Members noted that not all potential participants would know what proteinuria or pre-eclampsia was. If a reason was added, members asked that this was given in simple terms. The Sub-Committee asked that the study poster was amended to state that the researchers were conducting a study on urine testing.

Miss Jakubowski advised that the study poster already used simple terms such as 'urine testing', and did not use the words 'proteinuria' or 'pre-eclampsia'. The study title was included on the poster for reference, but the description below used simple terminology. She advised that if the Sub-Committee would like further details in the description they were happy to amend. The language used in the Participant Information Sheet had been amended to reflect comments made by the Sub-Committee.

The Sub-Committee noted that the Participant Information Sheet for patients was well done.

Members noted some errors and amendments required to the Participant Information Sheets and Consent Forms. Revised documents were submitted, which were reviewed and approved by the Sub-Committee.

Members noted that the topic guides were brief. Members asked that more detail about the interview questions and topic guides was given.

Miss Jakubowski advised that the topic guides had been updated to include further details. Women were asked about cultural barriers, as appropriate. The researchers intended to discuss whether self-testing was acceptable to all populations, and how it might work alongside current antenatal care, current practices, and potential barriers.

The Sub-Committee were satisfied by the responses given.

- **Other general comments**

The Sub-Committee noted that the trial could be registered on www.researchregistry.com

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster for Participants]	1	02 May 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance Letter]	1	01 August 2017
Interview schedules or topic guides for participants [Topic Guide Focus Groups]	1	17 May 2018
Interview schedules or topic guides for participants [Topic Guide Interviews Women and HCP]	1	17 May 2018
IRAS Application Form [IRAS_Form_04052018]		04 May 2018
Letter from sponsor [Letter from sponsor]	1	03 May 2018
Other [Postcard for Healthcare Professionals]	1	02 May 2018
Other [Postcard for Participants]	1	02 May 2018
Other [Photo Sheet for Participant]	1	02 May 2018
Other [Participant Visual Read Form]	1	02 May 2018
Other [Covering Letter for Sub Committee]	1	17 May 2018
Participant consent form [Consent Form Healthcare Professionals]	1	17 May 2018
Participant consent form [Consent Form Participants]	1	17 May 2018
Participant information sheet (PIS) [Healthcare Professional Participant Information Sheet]	1	02 May 2018
Participant information sheet (PIS) [Participant Information Sheet Healthcare Professionals]	1	17 May 2018
Participant information sheet (PIS) [Participant Information Sheet]	1	17 May 2018
Research protocol or project proposal [Protocol]	1	17 May 2018
Summary CV for Chief Investigator (CI) [Prof Richard McManus CV]	1	13 May 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

18/YH/0208	**Please quote this number on all correspondence**

Yours sincerely

pp

Dr Rhona Bratt
Chair

Email: nrescommittee.yorkandhumber-leedseast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Dr Heather House, Oxford University Hospitals NHS Trust*

A Research Ethics Committee established by the Health Research Authority

Yorkshire & The Humber - Leeds East Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 25 May 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rhona Bratt	Retired Multimedia Project Manager	Yes	
Professor Kenneth Brodlie	Retired Professor of Visualization	Yes	
Dr Nicky Kime	Senior Research Fellow	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	REC Manager

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Richard McManus
Professor of Primary Care
University of Oxford
Nuffield Department of Primary Care
University of Oxford
Radcliffe Observatory Quarter
OX2 6GG

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

21 May 2018

Dear Professor McManus

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Accuracy of self-testing for proteinuria during hypertensive pregnancy**
IRAS project ID:	**238483**
Protocol number:	**1**
REC reference:	**18/YH/0208**
Sponsor	**University of Oxford**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr Heather House
Email: ouhtma@ouh.nhs.net

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **238483**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Heather House, Oxford University Hospitals NHS Trust, (Sponsor Contact and Lead NHS R&D Contact)*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster for Participants]	1	02 May 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance Letter]	1	01 August 2017
HRA Schedule of Events [Schedule of Events]	1.0	11 May 2018
HRA Statement of Activities [Statement of Activities]	1.0	11 May 2018
Interview schedules or topic guides for participants [Topic Guide Focus Groups]	1	17 May 2018
Interview schedules or topic guides for participants [Topic Guide Interviews Women and HCP]	1	17 May 2018
IRAS Application Form [IRAS_Form_04052018]		04 May 2018
Letter from sponsor [Letter from sponsor]	1	03 May 2018
Other [Postcard for Healthcare Professionals]	1	02 May 2018
Other [Postcard for Participants]	1	02 May 2018
Other [Photo Sheet for Participant]	1	02 May 2018
Other [Participant Visual Read Form]	1	02 May 2018
Other [Covering Letter for Sub Committee]	1	17 May 2018
Participant consent form [Consent Form Healthcare Professionals]	1	17 May 2018
Participant consent form [Consent Form Participants]	1	17 May 2018
Participant information sheet (PIS) [Healthcare Professional Participant Information Sheet]	1	02 May 2018
Participant information sheet (PIS) [Participant Information Sheet]	1	02 May 2018
Participant information sheet (PIS) [Participant Information Sheet Healthcare Professionals]	1	17 May 2018
Participant information sheet (PIS) [Participant Information Sheet]	1	17 May 2018
Research protocol or project proposal [Protocol]	1	17 May 2018
Summary CV for Chief Investigator (CI) [Prof Richard McManus CV]	1	13 May 2016

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	External study funding has been secured from as part of a programme grant from National Institute for Health Research. Material study support will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.

Section	Assessment Criteria	Compliant with Standards	Comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS or on the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net, or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

A

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 2.8: Susbtantial amendment REC and HRA approval for the UDIP study

NHS
Health Research Authority

Yorkshire & The Humber - Leeds East Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Tel: 0207 1048 088

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

20 August 2018

Beth Jakubowski
Researcher in Pregnancy Health Care
Nuffield Department of Primary Care Health Sciences
University of Oxford Radcliffe Observatory Quarter
Woodstock Road
Oxford
OX2 6GG

Dear Ms Jakubowski

Study title:	**Accuracy of self-testing for proteinuria during hypertensive pregnancy**
REC reference:	**18/YH/0208**
Protocol number:	**1**
Amendment number:	**Substantial Amendment 1, 25/07/18**
Amendment date:	**09 August 2018**
IRAS project ID:	**238483**

The above amendment was reviewed at the meeting of the Sub-Committee held by correspondence.

Summary of amendment

This amendment was submitted with relation to the analysis of the study in order to differentiate between an automated reading of a dipstick and a visual reading by a healthcare professional, which had not been previously specified in the study protocol. For clarity, it has now been stated in the protocol that the laboratory test for ACR is an alternate secondary reference test, and the visual dipstick test by a health care professional is included as a separate secondary index test.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable** ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 1, 25/07/18	09 August 2018
Research protocol or project proposal	2 - clean	25 July 2018
Research protocol or project proposal	2 - tracked	25 July 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/YH/0208:	**Please quote this number on all correspondence**

Yours sincerely
pp

Sarah Brothers

Dr Rhona Bratt
Chair

E-mail: nrescommittee.yorkandhumber-leedseast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Heather House, Oxford University Hospitals NHS Trust*

Professor Richard McManus, University of Oxford

A Research Ethics Committee established by the Health Research Authority

Yorkshire & The Humber - Leeds East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 20 August 2018

Committee Members:

Name	*Profession*	*Present*
Dr Rhona Bratt (Chair)	Retired Multimedia Project Manager	Yes
Dr Andrew Pollard	Consultant Anaesthetist	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Miss Sarah Prothero	REC Assistant

Appendix 2.9: Minor amendment 1 HRA and sponsor approval for the UDIP study

Ignore
Delete
Junk
Reply
Reply All
Forward
Meeting
More
Move
Rules
OneNote
Actions
More
Mark Unread
Categorize
Follow Up
Tags
Translate
Find
Related
Select
Editing
Zoom
Send to OneNote
OneNote

Mon 28/01/2019 15:27

Karl Shepherd

RE: UDIP amendment (IRAS: 238483)

To Bethany Jakubowski

Cc rpm@oxfordgfs.org

You replied to this message on 28/01/2019 15:27.

Dear Beth,

RE: Minor amendment 1 (dated 21.01.2019) IRAS ID: 238483 , approved by study sponsor.

Thank you for accepting the changes. I can confirm that the amendment has now been approved by the sponsor. Feel free to now submit the documentation and amendment form to the HRA as follows.

Send the amendment into their generic account: hra.amendments@nhs.net .

It is necessary to include:

- IRAS Project ID and "Notification of Amendment" in the subject line
- Contact details (email and phone number) in the email.

Please also include a copy of this email as proof it has been approved by the study sponsor. We do not have the capacity to wet-ink sign the sponsor declaration.

Kind regards

Karl

PID13285-A002-SP001-AC001

Mr Karl Shepherd
Clinical Research Advisor
Clinical Trials & Research Governance | Research Services
University of Oxford
Joint Research Office, Boundary Brook House
Headington, Oxford, OX3 7GB
Office: +44 01865 (2)89885
Email: Karl.Shepherd@admin.ox.ac.uk

CTRG Clinical Trials and Research Governance

UNIVERSITY OF OXFORD

Joint Research Office enabling successful research through collaboration

Fri 01/02/2019 08:19

hra.amendments@nh.snet <noreply@harp.org.uk>

IRAS PROJECT ID 238483 , REC Reference 18/YH/0208 : Amendment acknowledgement and implementation information

To: Richard McManus; mcmhra@mcmhra.net; Bethany Jakobsen

Cc: mcmhra@mcmhra.net

You forwarded this message on 05/02/2019 10:19.

If there are problems with how this message is displayed, click here to view it in a web browser.

New Site Amendment, Implementation Information

Dear Professor McManus

IRAS Project ID:	238483
Short Study Title:	Proteinuria Detection in Pregnancy (U-DIP)
Date complete amendment submission received:	28 December 2019
Sponsor Amendment Reference Number:	Minor Amendment 1
Sponsor Amendment Date:	21 February 2019
Amendment Type:	Non-substantial
For new sites in Northern Ireland and/or Scotland:	Please start to set up your new sites. Sites may not open until NHS management permission is in place.
For new sites in England and/or Wales:	For studies which already have HRA and HCRW Approval: **This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.** Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).
	For studies which do not yet have HRA and HCRW Approval: **HRA and HCRW Approval for the initial application is pending.** You can start the process of setting up the new site but cannot open the study at the site until HRA and HCRW Approval is in place and the site has confirmed capacity and capability (where applicable).
	For studies with HRA Approval adding Welsh NHS organisations for the first time. Please take this email to confirm your original HRA Approval letter is now extended to cover NHS organisations in Wales. You now have HRA and HCRW Approval. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).

Thank you for submitting an amendment to add one or more new sites to your project. This amendment relates solely to the addition of **new sites.**

What should I do next ?

Please set up the new site(s) as per the guidance found within IRAS. **Please note** that processes change from time to time so please use the most up to date guidance about site set up.

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

If you have listed new sites in any other UK nations **we will** forward the information to the national coordinating function(s) for nations where the new site(s) are being added. In Northern Ireland and Scotland, NHS/HSC R&D offices will be informed by the national coordinating function.

Note: you may only implement changes described in the amendment notice.

Who should I contact if I have further questions about this amendment?

If you have any questions about this amendment please contact the relevant national coordinating centre for advice:

- England - hra.amendments@nhs.net
  Northern Ireland - research.gateway@hscni.net
  Scotland - phso.NRSPCC@nhs.net
  Wales - research-permissions@wales.nhs.uk

Additional information on the management of amendments can be found in the IRAS guidance.

Appendix 2.10: Minor amendment 2 HRA and sponsor approval for the UDIP study

Karl Shepherd

Wed 10/04/2019 14:35

To:Bethany Jakubowski <bethany.jakubowski@phc.ox.ac.uk>;

Cc:rpm@oxfordjro.org <rpm@oxfordjro.org>;

Dear Beth,

RE: Minor amendment 2 (dated 09.04.2019) IRAS ID:238483, approved by study sponsor.

Thank you for sending back the form with the revisions accepted. I can confirm that the amendment has now been approved by the sponsor. Feel free to now submit the documentation and amendment form to the HRA as follows.

Send the amendment into their generic account: hra.amendments@nhs.net .

It is necessary to include:

- IRAS Project ID and "Notification of Amendment" in the subject line
- Contact details (email and phone number) in the email.

Please also include a copy of this email as proof it has been approved by the study sponsor. We do not have the capacity to wet-ink sign the sponsor declaration.

Kind regards
Karl

PID13285-A003-SP001-AC001

Mr Karl Shepherd
Clinical Research Advisor
Clinical Trials & Research Governance | Research Services https://researchsupport.admin.ox.ac.uk/ctrg
University of Oxford
Joint Research Office, Boundary Brook House
Headington, Oxford, OX3 7GB
Office: +44 01865 (2)89885
Email: Karl.Shepherd@admin.ox.ac.uk

From: Bethany Jakubowski
Sent: 10 April 2019 14:30
To: Karl Shepherd <karl.shepherd@admin.ox.ac.uk>
Subject: Re: Minor amendment 2 UDIP study

Health Research Authority
Yorkshire & The Humber - Leeds East Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Tel: 02071048026

16 April 2019

Professor Richard McManus
Professor of Primary Care
University of Oxford
Nuffield Department of Primary Care
University of Oxford
Radcliffe Observatory Quarter
OX2 6GG

Dear Professor McManus

Study title:	**Accuracy of self-testing for proteinuria during hypertensive pregnancy**
REC reference:	**18/YH/0208**
Protocol number:	**1**
Amendment number:	**3**
Amendment date:	**11 April 2019**
IRAS project ID:	**238483**

Thank you for your letter of 11 April 2019, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

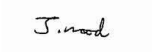
Document	*Version*	*Date*
Notice of Non Substantial Amendment		11 April 2019

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

18/YH/0208:	Please quote this number on all correspondence

Yours sincerely



Mr Jacob Wood
Approvals administrator

Email: nrescommittee.yorkandhumber-leedseast@nhs.net

Copy to: *Dr Heather House, Oxford University Hospitals NHS Trust*

Appendix 2.11: Minor amendment 3 sponsor approval for UDIP study

RE: Minor amendment 3 COVID-19 (dated 15.04.2020) IRAS ID:238483, approved by study sponsor. - Message (HTML)

File Message Tell me what you want to do...

Thu 16/04/2020 12:40

Karl Shepherd

RE: Minor amendment 3 COVID-19 (dated 15.04.2020) IRAS ID:238483, approved by study sponsor.

To Bethany Jakubowski

Cc rpmi@oxfordjro.org

Dear Beth,

RE: Minor amendment 3 COVID-19 (dated 15.04.2020) IRAS ID:238483, approved by study sponsor.

Thank you for making those changes to the protocol and amendment form. I can confirm that the amendment has now been approved by the sponsor.

Please submit the documentation to your site(s) directly, as per HRA guidance Section 3.1 (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/) .

This amendment does not require HRA assessment and is categorised as 'C':
No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However, the amendment should still be provided for information.

Please also include a copy of this email as evidence of sponsor approval.

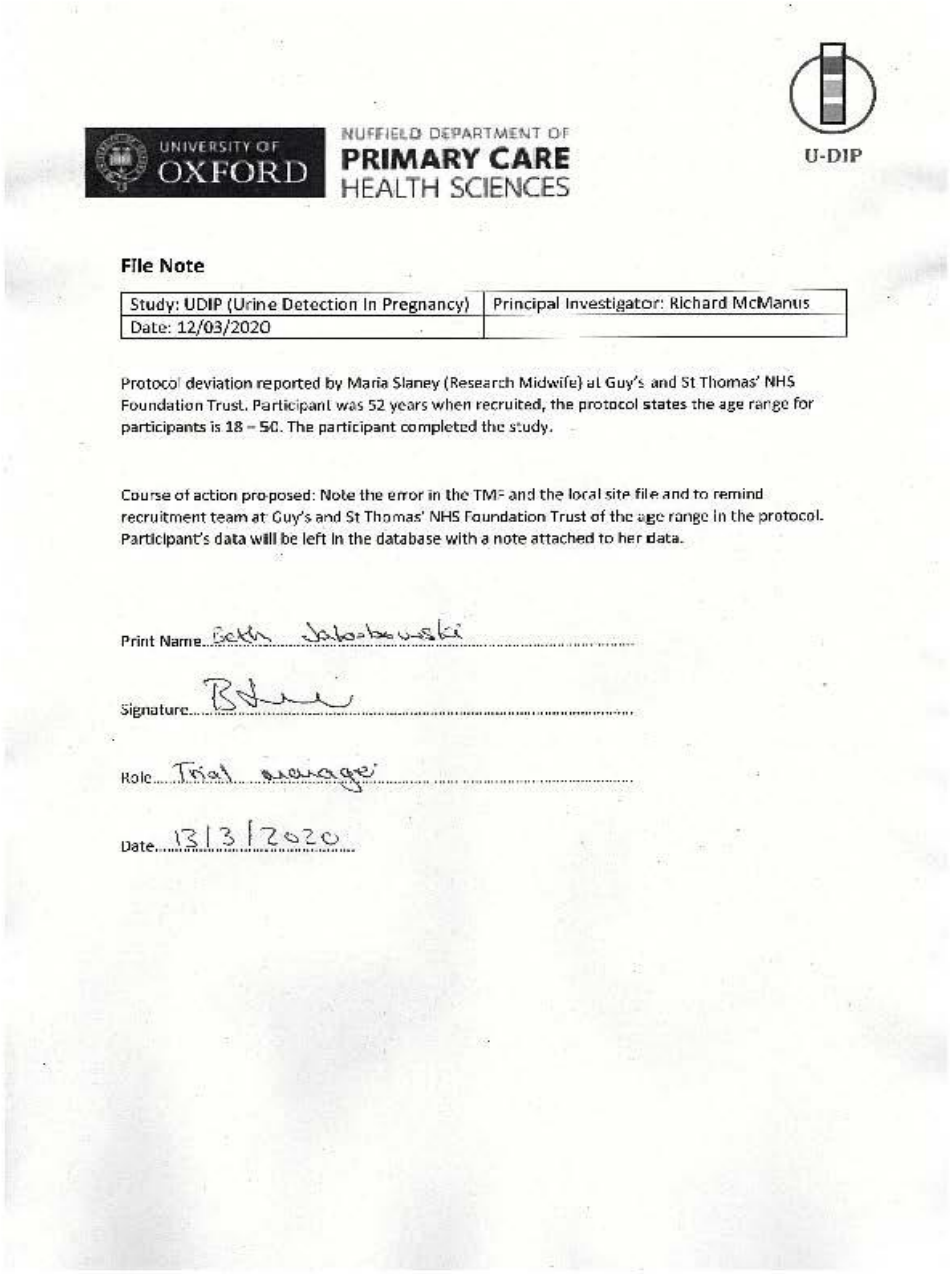
In light of remote working, please note:
Any processing of participant data should not include storage of personal data on private devices. Access to online databases should be appropriately secure, including use of VPN, encryption and anti-virus software as appropriate. University guidance on secure remote working is available here: https://infosec.ox.ac.uk/article/working-from-home-advice .

Kind regards
Karl
PID13285-A004-SP001-AC001

Appendix 2.12: STARD checklist for UDIP publication submission

Section & Topic	No	Item	Reported on page #
TITLE OR ABSTRACT			
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	1 and 2
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2, 3
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	4, 5
	4	Study objectives and hypotheses	4, 5
METHODS			
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	7
Participants	6	Eligibility criteria	6
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	6
	8	Where and when potentially eligible participants were identified (setting, location and dates)	6
	9	Whether participants formed a consecutive, random or convenience series	6 and Figure 1
Test methods	10a	Index test, in sufficient detail to allow replication	7 and 8
	10b	Reference standard, in sufficient detail to allow replication	7 and 8
	11	Rationale for choosing the reference standard (if alternatives exist)	7
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	7 and 8
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	7 and 8
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	6
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	6
Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	8
	15	How indeterminate index test or reference standard results were handled	8
	16	How missing data on the index test and reference standard were handled	8 and 9
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	8
	18	Intended sample size and how it was determined	7, 8
RESULTS			
Participants	19	Flow of participants, using a diagram	Figure 1
	20	Baseline demographic and clinical characteristics of participants	9 and Table 1
	21a	Distribution of severity of disease in those with the target condition	N/A
	21b	Distribution of alternative diagnoses in those without the target condition	N/A
	22	Time interval and any clinical interventions between index test and reference standard	N/A
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	9, 10, Table 2
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	9, 10, Table 2
	25	Any adverse events from performing the index test or the reference standard	N/A
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	12, 13
	27	Implications for practice, including the intended use and clinical role of the index test	11, 12, 13, 14, 15
OTHER INFORMATION			
	28	Registration number and name of registry	N/A
	29	Where the full study protocol can be accessed	N/A – contact authors
	30	Sources of funding and other support; role of funders	3, 16

Appendix 2.13: Protocol deviation file note for the UDIP stud



UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

U-DIP

File Note

Study: UDIP (Urine Detection In Pregnancy)	Principal Investigator: Richard McManus
Date: 12/03/2020	

Protocol deviation reported by Maria Slaney (Research Midwife) at Guy's and St Thomas' NHS Foundation Trust. Participant was 52 years when recruited, the protocol states the age range for participants is 18 – 50. The participant completed the study.

Course of action proposed: Note the error in the TMF and the local site file and to remind recruitment team at Guy's and St Thomas' NHS Foundation Trust of the age range in the protocol. Participant's data will be left in the database with a note attached to her data.

Print Name Beth Jakubowski

Signature

Role Trial manager

Date 13/3/2020

Appendix 2.14: Sensitivity analysis excluding participants who were recruited despite not meeting inclusion criteria

Threshold 1+ PCR (protein:creatinine ratio)	Participants (Albustix) n=322	Healthcare professionals (Albustix) n=322	Automated Reader (Clinitek Status + Analyser, URISTIX) n=335
Sensitivity **n/N**	0.71 (0.62 - 0.80) 81/113	0.74 (0.64 – 0.81) 83/113	0.80 (0.71 – 0.87) 90/113
Specificity **n/N**	0.89 (0.83 – 0.93) 185/209	0.88 (0.82 – 0.92) 183/209	0.83 (0.78 – 0.88) 174/209
Positive predictive value **n/N**	0.77 (0.68 – 0.85) 81/105	0.76 (0.67 – 0.84) 83/109	0.72 (0.63 – 0.80) 90/125
Negative predictive value **n/N**	0.85 (80.0 – 0.90) 185/217	0.86 (0.81 – 0.90) 183/213	0.88 (0.83 – 0.93) 174/197
Positive likelihood ratio	6.2	5.9	4.7
Negative likelihood ratio	0.3	0.3	0.3
*Threshold 1+ ACR (albumin:creatinine ratio)**	Participants (Albustix) n=335	Healthcare professionals (Albustix) n=335	Automated Reader (Clinitek Status + Analyser, URISTIX) n=335
Sensitivity **n/N**	0.68 (0.58 – 0.76) 79/117	0.71 (0.62 – 0.79) 83/117	0.75 (0.66 – 0.83) 88/117
Specificity **n/N**	0.87 (0.82 – 0.92) 179/205	0.87 (0.82 – 0.92) 179/205	0.82 (0.76 – 0.87) 168/205
Positive predictive value **n/N**	0.75 (0.66 – 0.83) 79/109	0.76 (0.67 – 0.84) 83/109	0.70 (0.62 – 0.78) 88/125
Negative predictive value **n/N**	0.83 (0.77 – 0.87) 179/217	0.84 (0.78 – 0.89) 179/213	0.85 (0.80 – 0.90) 168/197
Positive likelihood ratio	5.3	5.6	4.2
Negative likelihood ratio	0.4	0.3	0.3

Appendix: Chapter 4

Appendix 3.1: Topic guides for UDIP participants

Topic Guide: Women

UDIP

1. In your own words, could you tell me a bit about your pregnancy journey so far?
2. Did you know anything about proteinuria before the UDIP study?
    - Where did you find this out from?
3. What did you think of the UDIP study?
4. Did you have any problems with the study?
5. Would you be happy to self-test your urine at home?
6. What do you think the benefits of self-testing would be for you?
7. Do you think there would be any barriers to you self-testing at home?
8. Do you think self-testing would change anything about your relationship with your clinician?

Self-management

1. Have you come across home blood pressure monitoring before?
2. How do you feel about monitoring your blood pressure at home?
3. What do you think the benefits of self-monitoring would be for you?
4. Do you think there would be any barriers to you monitoring your blood pressure at home?
5. Do you think monitoring your blood pressure would change anything about your relationship with your clinician?
6. What do you think about titrating your own blood pressure medication? (explain titration if necessary)

OFFER SELF-MANAGEMENT EXPLANATION: Self-management in pregnancy is the self-testing of urine using a visual read dipstick for the presence of proteinuria, home blood pressure monitoring, and self-titrating of blood pressure medication following an approved protocol.

1. What do you think about self-management?
2. Do you have any concerns about self-management?
3. What do you think the benefits of self-management would be for you?

Appendix 3.2: Free text postcard distributed to UDIP participants



Postal Address: Department of Primary Care Health Sciences,

Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG
Website: http://www.phc.ox.ac.uk/

ID

Accuracy of self-testing for proteinuria during hypertensive pregnancy

During usual antenatal care midwives will test for protein in your urine to check for symptoms of pre-eclampsia. We are interested in your opinions on participating in this study and self-testing for protein in urine during pregnancy – where pregnant women themselves carry out urine dipstick testing from home in addition to usual antenatal care. Please use the space below to write any thoughts or comments you might have about your experiences in this study. If you have participated in the photo part of the study (taking a photo of your results and sending these to the study e-mail), please also share your thoughts on this experience.

Your feedback will be treated as confidential, and any responses will be anonymised. When the results of the study are published they will be accessible via the Departmental website detailed above.

Please return to your midwife before leaving the clinic, or use the stamped addressed envelope provided and place in a post box convenient to you.

NHS National Institute for Health Research | Site Logo | University of Oxford | Nuffield Department of Primary Care Health Sciences

Participants Postcard v1 Date: 17.05.2018 IRAS ID: 238483 REC: 18/YH/0208

Appendix: Chapter 5

Appendix 4.1: Patient Information Sheet for healthcare professionals in the UDIP study



Proteinuria detection in pregnancy (U-DIP)

PARTICIPANT INFORMATION SHEET for Health Care Professionals

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of this study?

This study is testing whether pregnant women can accurately self-test urine for proteinuria. In the future, we hope this will be used to reduce the detection time to pre-eclampsia. We would also like to find out how health care staff experienced incorporating the women's self-testing into their antenatal visit, and health care staff's thoughts and opinions on including self-testing in routine care pathways.

Why have I been invited?

You have been invited because you are a member of the health care team involved in antenatal care, and your patient(s) have taken part in our study. We are aiming to recruit approximately 15 health care professionals for the interview part of the study, and approximately 50 for the focus groups.

Do I have to take part?

No. This is a voluntary study and it is your decision whether or not you wish to take part. You are free to withdraw from the study at any time without giving a reason, with no personal or professional consequences.

A quick summary of the study

- You are invited to tell us what you think about the use of self-testing of proteinuria during pregnancy and your participation in the study
- This will take place in-person (or over the phone) at a time and place convenient to you, and will occur after your participating patient has completed their antenatal visit
- The study is being led by the University of Oxford and is funded by the National Institute for Health Research.

If you have any questions about the study, please contact Katherine Tucker:

Email: Katherine.tucker@phc.ox.ac.uk **Tel:** 08009150045

What will happen to me if I take part and what do I have to do?

If you would like to take part, we will arrange to do an interview or focus group after one of your antenatal clinics. This will be done at your workplace, or if you are participating in an interview, over the phone if you prefer. The interview will last no longer than an half an hour and will be audio recorded. The focus group will last between 30 and 45 minutes and will be audio recorded. Both interviews and focus groups will be transcribed and anonymised, and the original recording will be deleted after transcription. We will ask you questions about your experiences of self-testing proteinuria in pregnancy. If you are participating in a focus group between 2 to 8 other health care professionals will also be taking part.

What are the possible advantages and disadvantages of taking part?

While there will be no direct benefit to you, we hope that information from this study will help in the development of interventions to improve the self-monitoring of proteinuria in pregnancy. In the long term, we hope that this will improve the diagnosis of pre-eclampsia during pregnancy.
Participation will require about an hour of your time.

Will my taking part in this study be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for up to ten years after study publication.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your informationby contacting **bump@phc.ox.ac.uk**.

All of the information collected from you will be made anonymous. The information you provide will be coded with a number so you cannot be identified from it. The interview and focus group transcripts will have all identifying information removed, and the original recordings will be destroyed once transcription is completed. We may use your quotes in publications and presentations but it will not be possible to identify you from these. The anonymised data may be used in future, ethically approved research. The research team have a duty of confidentiality to you as a research participant. All data will be kept securely according to Data Protection legislation. Responsible members of the Universityof Oxford or the NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with applicable regulations.

St Guy's and St Thomas' Hospital will keep your name, and contact details confidential and will not pass this information to The University of Oxford. St Guy's and St Thomas' Hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from The University of Oxford and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The University of Oxford will only receive

information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

St Guy's and St Thomas' Hospital will keep identifiable information about you from this studyfor up to ten years after the study has finished.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without giving a reason, but the data you have already given may still be included in the study unless you specifically request us not to include it. If you decide you no longer wish to take part in our study, you can phone, write to, or e-mail the study co-ordinator.

What will happen to the results of the study?
The results will be published in a scientific journal/s and summarised on our website (http://www.primarycare.ox.ac.uk/) for you to read. It will not be possible to identify you in any of these reports.

What if there are any problems?
If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Katherine Tucker on 08009150045, or email bump@phc.ox.ac.uk. You may also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or for the head of CTRG, email ctrg@admin.ox.ac.uk. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

Who is organising and funding the research?
The research is being financed by the National Institute for Health Research (NIHR). The sponsor of the study is the University of Oxford.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Yorkshire and The Humber Leeds East Research Ethics Committee.

Participation in future research:

We may wish to contact you in future to ask if you would like to participate in other research. This is optional, and agreeing to be contacted does not oblige you to take part in future research. We would keep your contact details in a secure location at the Department of Primary Health Care, Oxford University for a maximum of five years, and only the research team will have access to this confidential data.

What do I do now?
If you would like to take part, please contact the research team**:** Department of Primary Health Care, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG. **Email: bump@phc.ox.ac.uk**

Appendix 4.2: Consent form for healthcare professional in the UDIP study

Monitoring in Pregnancy

UNIVERSITY OF OXFORD

NHS National Institute for Health Research

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Site logo

U-DIP

Participant ID _____

Contact number: 0207 188 3570

Consent Form for Health Care Professionals
Proteinuria Testing in Pregnancy (U-DIP)

Name of Chief Investigator: Professor Richard McManus

	Please initial each box
1. I confirm that I have read and understood the information sheet for Health Care Professionals, dated 17.05.18 version 1, for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.	☐
3. I agree to participate in a study interview or focus group, which will be audio recorded, transcribed and anonymised.	☐
4. I understand that direct quotations from my interview or focus group may be included in research reports and publications, but that it will not be possible to identify me.	☐
5. I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it.	☐
6. I understand that data collected during the study may be looked at by responsible individuals from the University of Oxford, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research.	☐
7. I agree to take part in this study	☐
8. OPTIONAL CONSENT (please circle): I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes No

Name of participant (please print)	Date	Signature

Name of person taking consent (Please print)	Date	Signature

When completed, <u>top copy</u> for participant, <u>bottom copy</u> kept in site file

Appendix 4.3: Topic guide for healthcare professionals in the UDIP study

Topic Guide: Health Care Professionals

UDIP

1. What are your thoughts on the UDIP study?
2. Have you come across self-testing before the UDIP study?
3. What do you think of home based self-testing?
    - Do you think women are capable of testing at home?
4. Do you think women testing at home will change the patient/clinician relationship?
5. Do you see any barriers to women self-testing?
6. Who do you think will benefit most from self-testing?

Self-management

- Considering our discussion about self-testing, what does self-management in pregnancy look like to you?

IF UNSURE:

Option 1: Explore blood pressure monitoring and self-titration separately

Option 2: Offer self-management explanation

Option 1:

1. Have you come across home blood pressure monitoring before?
2. Do you think women are capable of monitoring their blood pressure at home?
3. Do you think women monitoring their blood pressure at home will change the patient/clinician relationship?
4. Do you see any barriers to women self-monitoring?
5. Who do you think will benefit most from self-monitoring?
6. What do you think about women self-titrating their own blood pressure medication?
7. What do you think about women doing all three (self-testing, self-monitoring, self-titration) at home?
8. Who do you think would benefit from self-management?
9. What kind of protocol do you think is necessary for self-management?
10. Are there women you think would not be suitable for self-management?
11. What would the benefits of self-management be for clinicians?

12. How would you like the home results to be fed back to clinicians?

Option 2:

Self-management in pregnancy is the self-testing of urine using a visual read dipstick for the presence of proteinuria, home blood pressure monitoring, and self-titrating of blood pressure medication following an approved protocol.

1. Who do you think would benefit from self-management?
2. What kind of protocol do you think is necessary for self-management?
3. Are there women you think would not be suitable for self-management?
4. What would the benefits of self-management be for clinicians?
5. How would you like the home results to be fed back to clinicians?