SMARThealth Pregnancy: The development & evaluation of a complex intervention using mobile clinical decision support to screen, refer and manage pregnant women at high risk of future cardiometabolic disorders in rural India

Shobhana Nagraj
Green Templeton College
Nuffield Department of Women's & Reproductive Health
University of Oxford

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Dedication

For Swami, and for Amma & Appa

Abstract

India has witnessed a rapid rise in cardiometabolic diseases (CMDs), and women with high-risk pregnancy conditions including hypertensive disorders of pregnancy (HDP) and gestational diabetes mellitus (GDM) are at increased risk. In rural India, Community Health Workers (CHWs) deliver antenatal care, and are ideally placed to screen at-risk women in their villages. The aims of my thesis were to design, develop and evaluate a contextually-relevant, theory-informed complex intervention to enable CHWs to screen, refer and counsel pregnant women at high risk of future CMDs during their transition between antenatal, postnatal and ongoing healthcare services.

Guided by the MRC conceptual framework for complex interventions, my study was conducted in three phases. In phase 1, I reviewed the evidence for the associations between high-risk pregnancy conditions and CMDs; community-level interventions for high-risk pregnant women (including mobile technologies), and the integration of non-communicable disease programmes into antenatal care platforms. Qualitative methods were then used to explore the context of maternal healthcare in rural districts of two diverse States in India. In-depth interviews and focus group discussions with key stakeholders (n=71), were thematically analysed. The study revealed three local priority conditions (anaemia, HDP and GDM), the need for improving local understanding of long-term sequelae of high-risk pregnancies, and highlighted important socio-cultural practices impacting intervention design. In phase 2, using behaviour change theory (COM-B/Behaviour Change wheel and Theoretical Domains Framework), the target behaviours, intervention functions and policy categories to be addressed through a complex intervention were identified, using data from the contextual study. A total of 15 Behaviour

Change Techniques (the 'active ingredients') were embedded into intervention design, and the proposed mechanisms of action of SMARThealth Pregnancy were articulated in a logic model. The final intervention included: a) a village awareness programme; b) targeted training for CHWs to screen, refer and counsel women on the three priority high-risk pregnancy conditions and to conduct point-of-care testing for anaemia and blood pressure, and community-based GDM screening, and; c) mobile clinical decision support (App) to enable CHWs to deliver guideline-based care for women at home, at three timepoints: last trimester of pregnancy, week 1 and week 6 postpartum. In phase 3, feasibility and acceptability of the intervention was evaluated in a pilot cluster randomised controlled trial (n=4 primary health centre clusters), and a qualitative process evaluation using Normalisation Process Theory. A total of 200 pregnant women were randomised equally to the SMARThealth Pregnancy intervention or control. Recruitment was timely (4.5 months), with minimal loss to follow-up (2%). The intervention became embedded and integrated into the daily work of CHWs, who experienced increased social and professional recognition, with women perceiving improved quality of care. SMARThealth Pregnancy was feasible and acceptable as a model of task-sharing for CHWs to deliver integrated home-based care for women at high risk of future CMDs, in the context of rural India.

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I would like to say a huge thank you to Professor Krina Zondervan for all her inspiration, support and guidance during my DPhil; and to the thoughtful management team, my lovely

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Finally, I would like to thank my dearest parents, dear sister, and all my wonderful family and friends – Elke, David, Charlie, Brendon, Viv, Raju, Verena, Lucy and Carol, for their unwavering belief in me, love and support. None of this would have been possible without them. I cannot express all my heartfelt gratitude to you.

Declaration

I declare that this thesis is a presentation of my original research work and has not previously been submitted for a degree from any other university. To the best of my knowledge, this thesis does not contain any material previously published or written by another person except where duly acknowledged in the text.

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Abbreviations

ANC	Antenatal Care
ANM	Auxiliary Nurse Midwife
ANMOL	ANM Online
ASHA	Accredited Social Health Activist
BCT	Behaviour Change Technique
BP	Blood Pressure
CHW	Community Health Worker
CMDs	Cardiometabolic Diseases
COM-B	Capability, Opportunity & Motivation model of Behaviour Change
CVD	Cardiovascular Disease
FGD	Focus Group Discussion
GDM	Gestational Diabetes Mellitus
Hb	Haemoglobin
HIC	High-income country
IHD	Ischaemic Heart Disease
LMICs	Low- and Middle-Income Countries
mHealth	Mobile Health
MRC	Medical Research Council
NCDs	Non-Communicable Diseases
PCP	Primary Care Physician
PHC	Primary Health Centre
PNC	Postnatal Care
cRCT	Cluster Randomised Controlled Trial
RCT	Randomised Controlled Trial
T2DM	Type 2 Diabetes Mellitus
TDF	Theoretical Domains Framework
USD	US Dollars

Foreword: The journey to my DPhil

My first encounter with maternal health in India was as a medical student. I participated in weekly antenatal service camps in an urban slum in Chennai, South India, over the course of my summer holidays. A fantastic obstetrician, Dr Usha – taught me to auscultate for a baby's heartbeat using a plastic device – called a Pinard stethoscope, and to measure the pregnant women's abdomen with an old measuring tape to date the pregnancy. We didn't have antenatal care records and created "cards" for the mothers to take with them, gave them iron tablets, a large packet of Horlicks (malt drink) and a bag of rice, and told them to return each month for a check-up. They did return – mainly for the rice and Horlicks I think! This was my first exposure to maternal healthcare in India. The experience had a great impact on me, inspiring me to return to India year after year, to participate in medical camps and, for periods of time, I lived in rural India. India, for me, is a beautiful paradox. While I have witnessed India rapidly changing over the last 20 years – with great scientific, technological and economic progress, many women living in poverty in both rural and urban settings, still face the same issues. I didn't know it at the time, but many years later, I would be doing my DPhil at Oxford University to address the very problems I had encountered all those years ago in Chennai.

It wasn't until 2016, after participating in an NHS Hackathon, that I realised the potential of mobile technology in driving change. Soon after this, I learnt about the work of The George Institute for Global Health, and the Nuffield Department of Women's & Reproductive Health, Oxford, and contacted my (now) supervisors. By strange coincidence, they were working together in Oxford…and thus began my DPhil journey.

"India does not live in its towns but in its villages."

\- M.K. Gandhi

1 Introduction

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1.1 Background

India has experienced a rapid rise in non-communicable diseases (NCDs) over the past three decades [1]. Cardiovascular disease (CVD) is the leading cause of death in both men and women in India [1,2], presenting at an earlier age [3,4], and with high case fatality rates in the Indian population [3]. Even in less developed States of India, where the level of epidemiological transition to NCDs is lower, the prevalence of CVD risk factors such as hypertension and type 2 diabetes mellitus (T2DM) is rapidly increasing [1]. Rapid

urbanisation, together with dietary changes to include more processed foods, and more sedentary lifestyles, have contributed to this transition [4].

The rapid rise in NCDs witnessed over the last few decades, has significantly impacted the volume of early CVD deaths seen in Indian women [1,5]. For those living in rural areas, there are further challenges to accessing medical care for CVD, including low levels of awareness of CVD risk factors, health literacy, and poorer access to high-quality health services [6]. Significant gender disparities also exist for Indian women in seeking health care [7], compounded by diagnostic challenges in recognising the symptoms of CVD in women [8].

The rise in early CVD deaths in Indian women necessitates identification of strategies for prevention and management of cardiometabolic risk, particularly in rural areas. Early identification of women at risk of CVD, may offer potential opportunities for preventative measures to be put in place. One such opportunity, is during pregnancy. Pregnancy-related conditions such as Hypertensive Disorders of Pregnancy (HDP) and Gestational Diabetes Mellitus (GDM) carry independent risks for future development of cardiometabolic disorders, including CVD and risk factors such as hypertension and T2DM [9–13]. Antenatal care (ANC) is often the first encounter adult women have with the formal health sector in rural India, and is an ideal opportunity for engaging, screening, counselling, and managing women at increased cardiometabolic risk.

This thesis is a presentation of my journey, to convey the voices of pregnant women and CHWs in rural India, and embed these into the design of a complex intervention. In this first chapter, I outline the context of maternal healthcare in rural India, to provide an in-

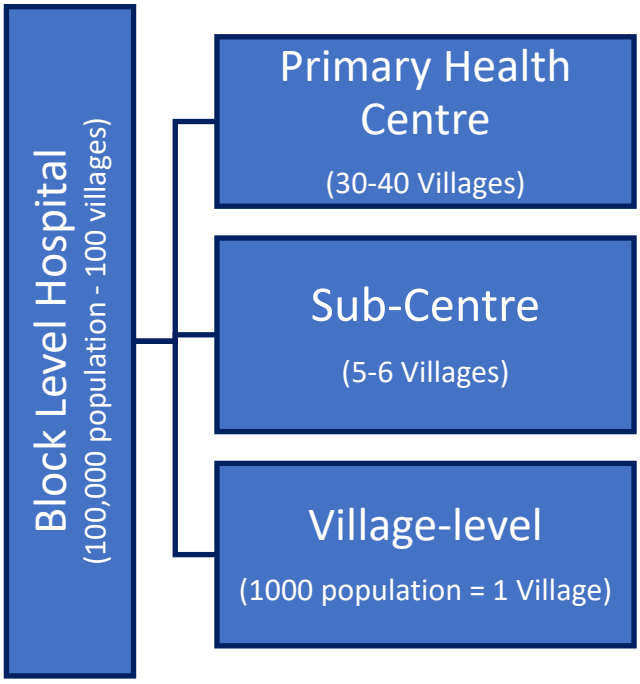
depth understanding of the health system, and introduce the two rural sites involved in my study. The chapter concludes by outlining the overall aims of my thesis and signposts the content of my thesis chapters.

1.2 The historical context of healthcare in rural India

India is the largest democracy in the world. In the last national election in 2019, over 600 million people voted in a coordinated effort across an entire sub-continent, showing potential for organised systematised infrastructure to connect with even the hardest to reach [14]. Two-thirds of the Indian population live in rural areas [15]. To serve the healthcare needs of over 800 million people in rural India [16], in 2005 the Government of India launched the National Rural Health Mission (NRHM) [17]. Its aims were to provide universal, accessible, affordable, and quality healthcare to rural populations. The scheme has now been extended to include the National Urban Health Mission (2013), under the wider umbrella of the National Health Mission [18,19].

Part of the NRHM initiative was a drive to improve primary health care provision in villages, creating a decentralised model of primary care, with governance at the village-level through village councils, known as *Gram Panchayats*. The scheme also proposed the creation of Primary Care Sub-centres (covering a group of villages), Primary Health Centres (PHCs) and Community Health Centres (CHCs) (covering a larger population). Thus, a four-tier system of healthcare serving all villages in India from the village to the CHC, was created.

Figure 1.1: Organisation of healthcare system in the National Rural Health Mission



To support this new infrastructure, flexible financing to enable local decision-making, capacity-development for healthcare management and clinical skills, accountability to quality standards, and data monitoring through engagement with District Health Authorities, NGOs, and National Health Systems Resource Centre (NHSRC), and healthcare governance, were put into place. These measures aimed to expand the availability of 24/7 primary care facilities across rural India. The expansion of rural health services was further supported with the availability of equipment and medications at each PHC, village outreach programmes through mobile medical units (MMUs), and the creation of a new rural healthcare workforce [20].

1.3 Community Health Workers in rural India

At the village level, a whole new cadre of healthcare professional was created. Working on a voluntary basis, Accredited Social Health Activists or ASHAs [19] were introduced. In addition, a more highly trained cadre of community healthcare worker (CHW) called an Auxiliary Nurse Midwife (ANM) was introduced to look after a group of villages.

ASHAs are female healthcare workers in each village in rural India that cover a population of approximately a thousand people. Their main duties are to motivate women to register their pregnancies and engage with antenatal care services [21]. They also encourage other villagers to engage with primary health services, and address their village's general health concerns. For this role, ASHAs came to be known as the "*daughter-in-law of the village*" [22]. ASHAs previously received financial incentives for ensuring that pregnant women in their village attended the recommended four antenatal visits, and conducted home-based postnatal visits. More recently, some states in India have provided ASHAs a monthly salary in recognition of their integral role in the NRHM [23].

Another cadre of CHWs known as Anganwadis (based at an Anganwadi centre), is responsible for the postnatal care of newborns until the age of 5 years [24] Anganwadis distribute free food packages (including rice, grains, and eggs) in line with government schemes for pregnant women during the antenatal period, and up to 6 months postpartum. Both ASHAs and Anganwadis report to ANMs, who cover a group of villages and work out of a primary care sub-centre (usually housed in the same building as the Anganwadi centre). ANMs undergo 2 years of training before qualifying [25] so as to perform clinical tasks such as blood pressure (BP) and blood glucose measurement. ANMs are also involved in the registration and provision of antenatal and postnatal care for their group of

villages. The work of the ASHAs, Anganwadis and ANMs is intricately linked, and hierarchical [19]. Each ANM reports to the PHC, which serves a population of approximately 30-40,000 people in most cases.

Figure 1.2: Overview of levels of healthcare provision in rural India per population

Each PHC is staffed by two primary care physicians (usually one male and one female). Primary care physicians (PCPs) are usually stationed at a rural PHC for 1-3 years as part of their postgraduate medical training. Historically, PCPs rarely worked in PHCs out of personal choice, but to improve their prospects of getting into a postgraduate speciality training programme of their choice (for which there were previously incentives for working in a rural PHC). As a result, community engagement and upliftment have not always been priorities for PHC doctors. In addition, the prospects for career development and training, as well as private income generation, are limited in rural contexts, thus reducing its appeal to most medical graduates [26]. It is rare that PCPs remain in their rural posting for longer

than the allotted time, leading to frequent changes to the delivery of primary care to the villages. In this changing landscape, it is the CHWs who provide continuity of care to village women.

1.4 Government schemes for maternal health in India

With the launch of the NRHM, numerous schemes relating to maternal child health were initiated. In response to the high levels of maternal and neonatal mortality in India [27–30], in 2005 the Government of India established a conditional cash transfer scheme for women of low socioeconomic status. The scheme, known as the Janani Suraksha Yojana (JSY) provides financial incentives to pregnant women to encourage women to have institutional deliveries [31].

The scheme also supports ASHAs to promote institutional births, and other positive health-related behaviours around pregnancy and the postpartum period [32]. Evaluations of the JSY scheme have highlighted positive improvements to antenatal care, institutional delivery, and skilled birth attendance [31,33]. After controlling for socioeconomic and demographic status, mothers who received JSY financial assistance are less likely to have perinatal and neonatal deaths [31,33].

Building on the JSY, to encourage the health and engagement with health services of pregnant women and their babies, the Janani Shishu Suraksha Karyakam (JSSK) scheme was started in 2011 [34]. The JSSK entitles pregnant women and infants (up to 1 year of age) free medications, blood products and free patient transport to and from government health facilities.

1.4.1 Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) scheme

In 2016, the Ministry of Health & Family Welfare, Government of India launched a universal programme to provide comprehensive, quality antenatal care, free of cost, delivered on the 9th day of every month at the PHC or CHC level [35]. Unique features of the scheme include private sector engagement, and encouraging the voluntary contributions of both private and public obstetricians to participate in provision of monthly antenatal care, with national recognition for both individual and team contributions. The aims of the programme are to reduce maternal mortality through improving the quality and regularity of antenatal care visits, screening, early identification, and management of high-risk pregnancies, provision of free diagnostics and medications during pregnancy. The scheme's objectives ensure that all pregnant women are seen at least once during the second or third trimester by an obstetrician; receive at least one antenatal ultrasound scan, and high-risk pregnant women are identified and flagged for regular follow-up by a specialist.

1.4.2 Financial Schemes for Universal Health Coverage: The Rashtriya Swasthya Bima Yojana (RSBY) and the Ayushman Bharat Insurance Schemes

The NRHM improved primary care healthcare infrastructure and human resources in rural India; however, significant barriers to accessing healthcare are still faced by the poorest, including high out-of-pocket spending on healthcare and inequity [36]. In 2008, a publicly financed health insurance scheme known as the RSBY, was introduced to cover hospital expenses for 'Below Poverty Line' (BPL) households in India. The scheme formed the preliminary basis for universal health coverage. In 2007, 90% of the spending on private healthcare in India (accounting for 73.5% of total health expenditure) was out-of-pocket

expenditure [37][38]. The main objectives of the RSBY scheme were to improve access to hospitalisation for the poorest households in India, and reduce out-of-pocket expenditure for the poorest. However, impact evaluations of the scheme have shown it was ineffective in reducing out-of-pocket expenditure for BPL households and reducing inequity [36,39]. Some of the reasons for this finding included poor enrolment practices, weak monitoring and supervision [40]. Each year, 60 million Indians are pushed below the poverty line due to out-of-pocket expenditure on health [41]. In response, in 2018, the Government of India launched an updated health insurance scheme to provide universal health coverage in India to 40% of the country. Known as the Ayushman Bharat scheme, it is the largest publicly funded healthcare programme in the world [42], covering approximately 100 million vulnerable families across India. Accessed by the national identity "Adhaar" card, the scheme provides free health coverage for primary, secondary and tertiary healthcare services for families, up to a cost of 500,000 Rs per family per year at both private and public providers. In order to reduce fraudulent bills and payments, the scheme has attempted to use cashless payments and has strict penalties for any evidence of corruption or fraud. It remains to be seen if the scheme will have the desired effect of reducing out-of-pocket expenditure for the poor, improving universal healthcare coverage, and addressing some of the ethical issues surrounding private healthcare providers [43].

1.5 Maternal healthcare in the villages

The majority of ANC is provided by CHWs in the villages of India. ASHAs quickly find out which women in their village are pregnant and take them to register the pregnancy with the ANM at the subcentre. After registration, they have access to the free government schemes for iron folate tablets, food packages and regular antenatal care. Women are

encouraged to attend the PHC to have their booking bloods and to see the doctor, especially if the pregnancy is high-risk. Most PHCs have facilities for normal vaginal deliveries, as well as newborn resuscitation. Women requiring blood products or Caesarean section are usually referred to secondary care. In India, there is a complex health system with regards to overlap of private and public providers, as well as healthcare provided by non-governmental and faith-based organisations [44]. The situation is further complicated as many women seek care from multiple providers during pregnancy and after birth.

1.6 The areas studied: Haryana and Andhra Pradesh, India

1.6.1 Selection of study sites

To conduct my DPhil research, I worked in collaboration with the George Institute for Global Health, India. The George Institute, India, have their main offices in New Delhi (North India) and Hyderabad (South India). The two rural study sites in Haryana in Northern India, and Andhra Pradesh in South India, were purposively selected due to familiarity of George Institute field staff with the States and their spoken languages, for their contextual diversity, and for pragmatic reasons relating to travel. The sites differed in terms of their spoken language, clothing, diet, gender issues, and health indicators (discussed below). The choice of **two** geographically and culturally diverse rural sites provided contextual richness to the study, and enabled findings to be more generalisable within the Indian context than working in one site alone. Additionally, the North India site was an accessible two-hour drive from the New Delhi office, and the South India site could be accessed by a 5-hour train journey from the Hyderabad office. The two specific districts were selected after careful consultation with local staff at the George Institute. While neither district had been involved in previous George Institute studies, they were identified

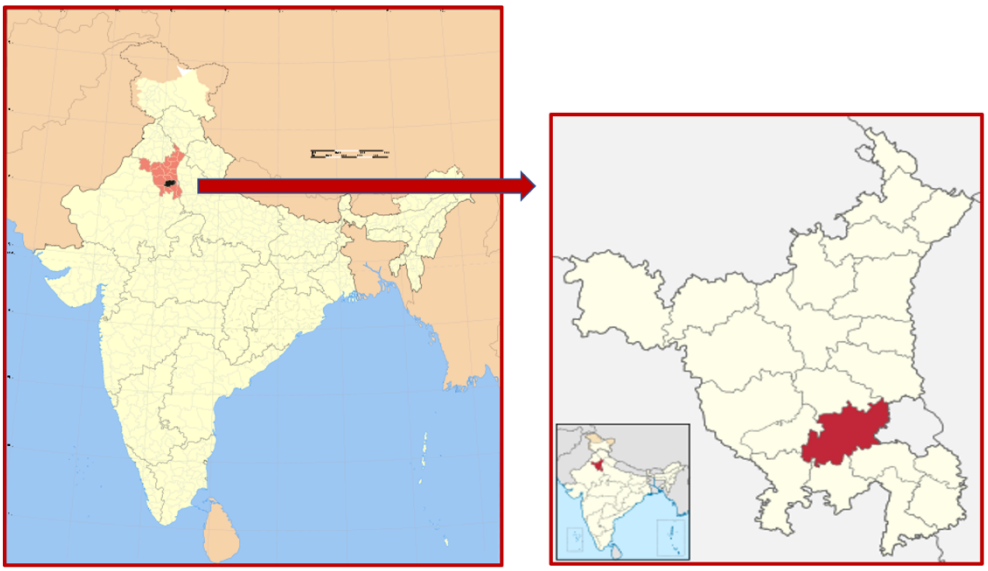
as areas that might benefit from further study. The study sites will now be discussed in more detail.

1.6.2 Haryana

Haryana is a state in Northern India, bordering the Indian capital city of New Delhi. It is one of the most prosperous States in the country [45]. Historically, Haryana has been known for its high levels of gender inequity. In 2011, Haryana had the lowest sex ratios for those aged 0-6 years of 830 girls per 1000 boys [46]. The female disadvantage extends into childhood survival, health and schooling, and is more marked in those with higher socioeconomic status [45], although the situation is improving following a number of government schemes.

Conditional cash transfer schemes for disadvantaged girls have incentivised the accrual of benefits amounting to 2000 USD for girls reaching the age of 18 and being fully immunised, studying until the age of 16, and remaining unmarried. This was extended to include second girls in all groups in 2005 [47]. In addition, the Prime Minister's National "**Beti Bachao Beti Padhao**" (Save the girl child; Educate the girl child) scheme, launched in 2015, aimed to address the issue of declining child sex ratios through promoting the value of the girl child, and bringing the issue of child sex ratios into public discourse [48]. It introduced state performance indicators, focussing on gender critical districts. National laws prohibiting sex selection abortion are also in place, and include the Prenatal Diagnostic Techniques Act, 1994 (amended in 2002) [49]. As a result of these laws and performance indicators, Haryana is now seeing an improvement in child sex ratios, although attitudinal change will take longer to take effect [50, 51].

Figure 1.3: Map of India with State of Haryana highlighted in red & map of Haryana with Jhajjar District highlighted in red [1]



The latest national statistics in India show the maternal mortality ratio in Haryana to be 101/100,000 births (with a national average of 130/100,000 births) [52]. In the last National Family Health Survey (NFHS-4) in 2015-16, in rural Haryana, 63% of mothers had an antenatal check-up during the first trimester, and 42.6% had at least four antenatal care visits [53]. Sixty-seven percent of mothers received postnatal care within 2 days of delivery in rural areas. There have been significant improvements in institutional deliveries over the last decade: in 2005-6, only 35.7% of deliveries were institutional, and this was raised to 80.3% in the 2015/16 survey [53].

[1] State images credited to CC BY SA PlaneMad/Wikimedia: https://en.wikipedia.org/wiki/List_of_districts_of_Haryana#/media/File:India_Haryana_locator_map.svg, g. District Images credited to CC BY SA: Milenioscuro: https://en.wikipedia.org/wiki/File:India_-_Haryana_-_Jhajjar.svg#/media/File:India_-_Haryana_-_Jhajjar.svg)

A number of schemes have ensured improved local services for high-risk pregnant women in Haryana, along with the wider national schemes. These include implementation of a High-Risk Pregnancy (HRP) policy and a web-based online portal to track timely care for HRP women in Haryana in 2017; the launch of a pre-conception care package in 2016, and establishing intravenous iron sucrose injections as part of the essential medicines provided at the PHC level [54]. My DPhil work is based in the Jhajjar district of Haryana, which has seen some of the greatest improvements in child sex ratios over the last decade [50]. This change is largely due to the presence of better data collection mechanisms, and local champions and local female role models [55].

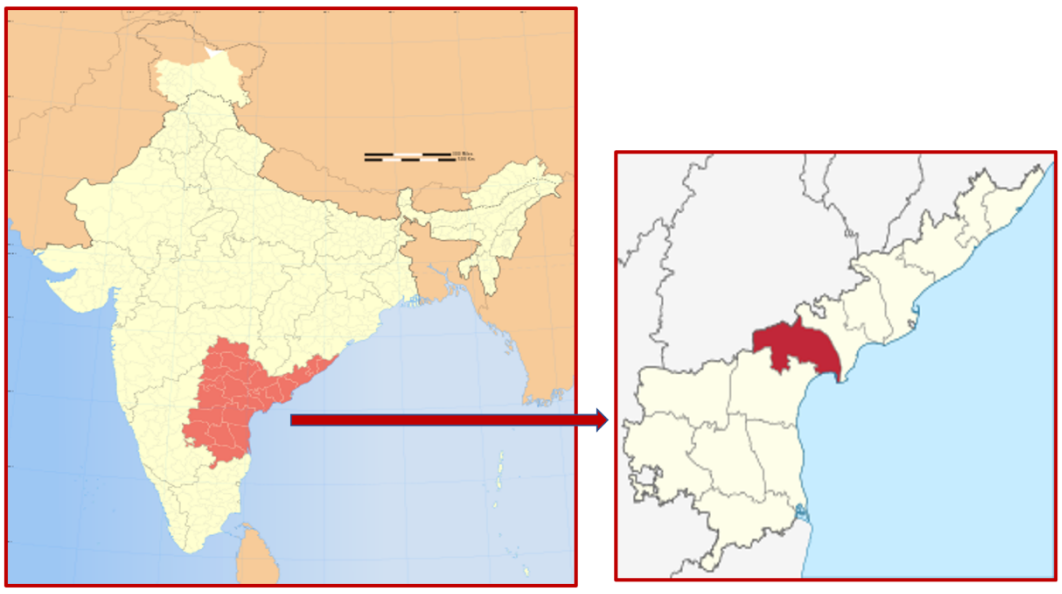
1.6.3 Andhra Pradesh

Andhra Pradesh is a large State situated in south-east India with some of the best health-related outcomes in the country. These results are due, in part, to an innovative financial assistance scheme known as the **Aarogyasri** scheme, which provides assistance to BPL families for healthcare, including surgery and post-operative care [56]. Due to rapid urbanisation and associated changes in diet towards more processed foods, the patterns of NCD prevalence in Andhra Pradesh are changing [57]. There is an increase in prevalence of hypertension and T2DM in women, often with earlier onset than in other countries [1,58–60]. In relation to maternal health indicators, in the most recent NFHS-4 survey, only 18% of women aged 15-49 had completed 12 or more years of schooling compared to 31% of men [61]. Although the child sex ratios are better than those seen in Haryana (F:M = 939:1000 in 2011), there is still a strong preference for sons in the State [61]. Two-thirds of births in Andhra Pradesh occur within 3 years of a previous birth, i.e. birth intervals, which are associated with adverse maternal and infant outcomes [62], are shortened. Andhra Pradesh's health performance indicators for maternal care are much

better than those in Haryana. The maternal mortality ratio is 74/100,000 births [63]; in 2015-16, 97% of women received ANC – 82% of whom received care during the first trimester of pregnancy [61]. Over three quarters (76%) of women received four or more ANC visits, with 92% of women having institutional deliveries, and 81% of women receiving postnatal care within 2 days of delivery [61].

The research site for my DPhil was in the Guntur district of Andhra Pradesh. The area is a mostly farming community, with 70% of the population living in rural areas. In this district 98% of births were in an institution, with a skilled birth attendant – the highest in the State [64,65].

Figure 1.4: Map of India with State of Andhra Pradesh highlighted in red & map of Andhra Pradesh with Guntur District highlighted in red [2]



[2] Images credited to CC BY SA PlaneMad/Wikimedia: https://en.wikipedia.org/wiki/Outline_of_Andhra_Pradesh#/media/File:India_Seemandhra_locator_map.sv

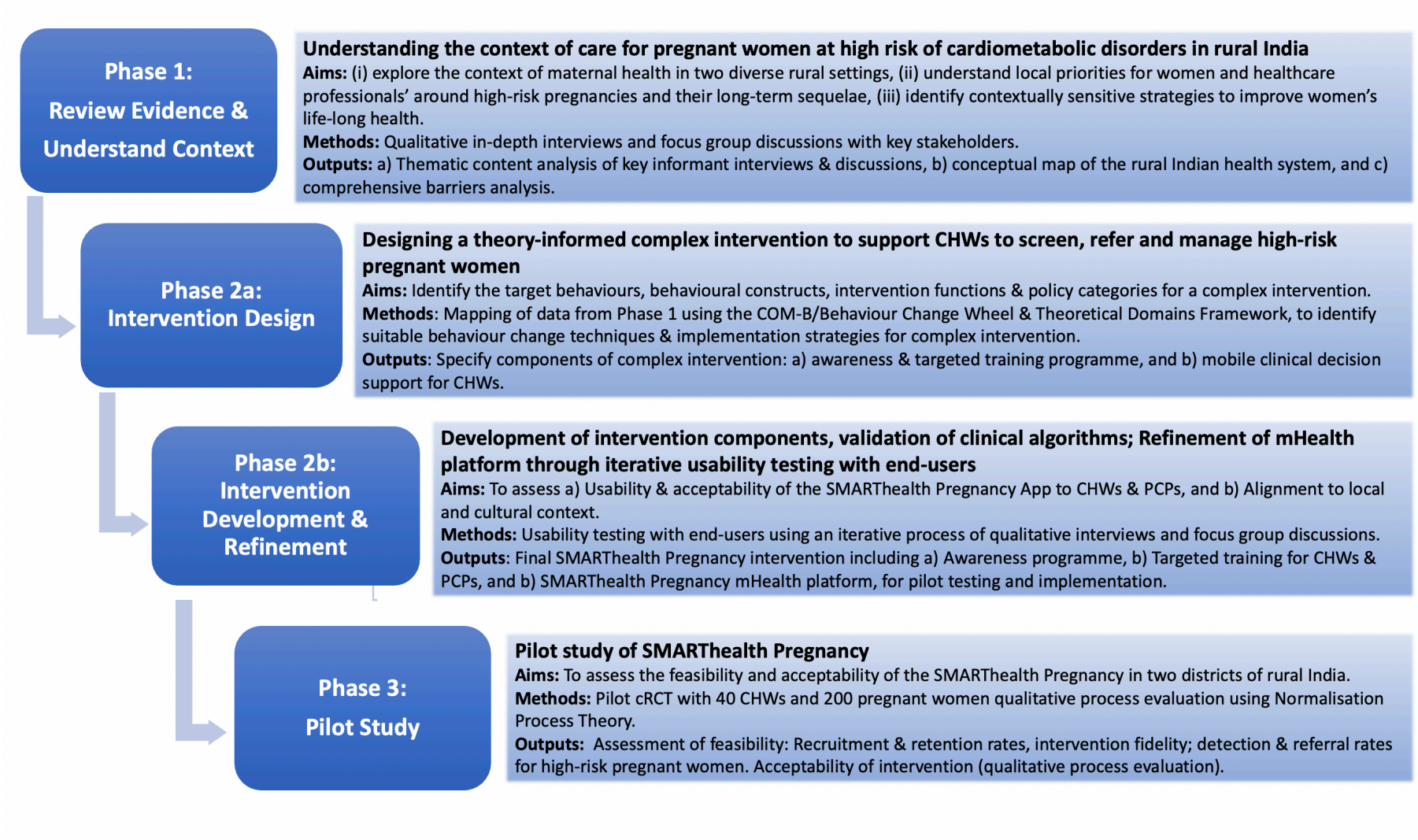
1.7 Overview of thesis chapters

My thesis is divided into three phases (Figure 1.5). **Phase 1** involves a literature review, providing the evidence base for a complex intervention (Chapter 2); outlining the theories and frameworks used within the thesis (Chapter 3); and in-depth contextual work in rural India (Chapter 4). **Phase 2** of my thesis involves the development and refinement of a complex intervention using healthcare worker training and a mobile clinical decision support system. The intervention development builds upon Phase 1, using qualitative data from the contextual work and combining this with relevant theory, and using principles of human-centred design in the creation of a theory-informed complex intervention and logic model for the intervention (Chapter 5). **Phase 3** involves the evaluation of the complex intervention: SMARThealth Pregnancy, through a pilot cluster randomised controlled clinical trial (cRCT) in rural India, using mixed methods (Chapter 6).

The overall aim of my thesis is to develop and evaluate a complex intervention, embedding the voices of women and healthcare workers in the co-design of the intervention. This complex intervention aims at improving the screening, detection, referral and management of pregnant women with high risk of future cardiometabolic disorders in rural India, in order to reduce: a) maternal and perinatal mortality and morbidity in the short term, and b) the burden of pregnancy-associated cardiometabolic risk in these women, in the long-term. The SMARThealth Pregnancy intervention provides an integrated approach to women's health across the life-course, using ANC as a window of entry into the rural health system in India (Box 1.1).

g. District Images credited to CC BY SA: Milenioscuro: https://en.wikipedia.org/wiki/Guntur_district#/media/File:Guntur_in_Andhra_Pradesh_(India).svg

Figure 1.5: Phases of the thesis



Box 1.1: The SMARThealth Pregnancy intervention and components

SMARThealth Pregnancy: Intervention visits (integrated into existing visits) & rationale:		
Last Trimester Pregnancy	**Week 1 Postpartum**	**Week 6 Postpartum**
- Engage & optimise high-risk women before delivery	- Detect, refer & counsel women for early postpartum complications	- Detect, refer, engage & counsel women at persistent risk of CMDs
Intervention components related to three priority high-risk pregnancy conditions:		
1. Village Awareness Programme	To raise community awareness around three priority conditions (anaemia, HDP & GDM) & long-term sequelae	
2. Targeted Education & Training for CHWs	To provide knowledge, skills & attitudes: Enabling CHWs to deliver guideline-based, point-of-care testing for anaemia & BP to women at home, and community-based screening for GDM	
3. Mobile Clinical Decision Support	To support CHWs to deliver home-based screening, referral and counselling & link high-risk women to on-going health services	
*ASHAs remunerated for extra work in line with Government guidelines		

*CMDs = Cardiometabolic Diseases; CHWs = Community Health Workers; HDP = Hypertensive Disorders of Pregnancy; GDM = Gestational Diabetes Mellitus.

I used the conceptual framework outlined by the Medical Research Council (MRC) [66] to guide the development and evaluation of SMARThealth Pregnancy. Table 1.0 outlines my thesis chapters and how these are linked to the MRC Framework for complex interventions. In addition, I used relevant behaviour change and sociological theories in the development and evaluation of the complex intervention focusing on both: a) **individual agency** within the health system, using the Behaviour Change Wheel and Theoretical Domains Framework [67,68] and; b) **collective agency** within the health system when embedding new technologies into routine practice, using Normalisation Process Theory [69]. The overall philosophical standpoint for my thesis is one of pragmatism [70,71]. A unique feature of my DPhil thesis is that it integrates approaches from the fields of software development (human-centred design), social sciences, and implementation science. In the next chapter I review the literature relating to the cardiometabolic sequelae of high-risk pregnancy conditions, and consider the strategies for providing integrated care for women across the life course.

Table 1.1: Chapters of the DPhil project mapped to MRC framework for complex interventions

DPhil Chapter	Contents	Link to MRC Framework
Development of the SMARThealth Pregnancy complex intervention		
Chapter 2: Review of literature	Narrative literature review of: • Cardiometabolic disorders and pregnancy-related risk factors. • Community-level interventions for high-risk pregnant women and NCDs. • Integration of NCD prevention into ANC.	**1.1**:Identifying evidence base by reviewing published literature and existing systematic reviews.
Chapter 3: Overview of theory and frameworks used in thesis	• MRC Framework for complex interventions Implementation science theories & frameworks: • Behaviour Change Wheel • Theoretical Domains Framework • Normalisation Process Theory	**1.2:** Identifying & developing appropriate theory
Chapter 4: Understanding the context of maternal healthcare in rural India: a qualitative study	A qualitative study to explore: • Sociocultural context of healthcare delivery in rural India • Identify local priorities for care • Stakeholders' understanding of high-risk pregnancies and their future impact Develop a conceptual map of health system in rural India	**1.2:** Identifying & developing appropriate theory
Chapter 5: Theory-informed design and development of SMARThealth Pregnancy	• Theory-informed design of intervention components. • Development of clinical algorithms and App. • Finalising intervention & conducting usability testing with end-users. • Developing a logic model for SMARThealth Pregnancy	**1.3:** Modelling processes & outcomes
Assessing feasibility & piloting methods		
Chapter 6: Evaluation of SMARThealth Pregnancy: a pilot cluster randomised controlled trial and qualitative process evaluation	Pilot cluster randomised controlled trial to evaluate: • Feasibility: Recruitment, retention rates; fidelity to intervention practices; prevalence of high-risk conditions in pregnancy • Acceptability: through a qualitative process evaluation	**2.1:** Testing procedures for acceptability, compliance & intervention delivery

PUBLICATION FROM CHAPTER

Nagraj S, Kennedy S, Norton R, Jha V, Praveen D, Hinton L, Hirst J. Cardiometabolic risk factors in pregnancy and implications for long-term health: identifying the research priorities for low-resource settings. *Frontiers in Cardiovascular Medicine*, 2020.

2

Literature review

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2.1 Introduction

In Chapter 1, I presented the rationale for my thesis. I outlined the rapid rise in NCDs in India and the implications for women in rural areas, and presented an overview of the rural health system. In this chapter, I synthesise the evidence on high-risk pregnancies and their association with cardiometabolic disorders in later life; explore community-level interventions for high-risk pregnant women and NCD prevention, and identify models of integrated care, relevant to the rural Indian context, in a narrative literature review [72] (please see **Appendix A** for overview of methods and search strategies).

2.11 Cardiometabolic disorders & pregnancy-related risk factors

Cardiometabolic *disorders* constitute a range of metabolic risk factors including insulin-resistance, hypertension, dyslipidaemia and central obesity. These conditions contribute to an increased risk of cardiometabolic *diseases* (CMDs), including CVD and T2DM [73]. CMDs are the leading cause of death and disability in the world [74,75]. The early onset of CVD in Indian women necessitates preventative measures to be implemented earlier in their life course [1,5]. Pregnancy is one such opportunity to engage women in discussions about their cardiometabolic health. The physiological demands of pregnancy can act as a stress test, which identifies women with an underlying susceptibility to CVD [76,77]. Pregnant women with high-risk conditions, including HDP and GDM are among those at risk of future CMDs [78].

2.2 Hypertensive Disorders of Pregnancy and cardiometabolic risk

HDP complicate between 5-10% of pregnancies worldwide [79,80]. They account for 14% of the global burden of maternal mortality [81] and contribute to 76,000 deaths/year [82]. HDP include pre-existing hypertension, gestational hypertension and preeclampsia/eclampsia (which may also occur in the presence of pre-existing hypertension) [83]. In this chapter, I focus on gestational hypertension and preeclampsia. These two conditions are characterised by new onset of hypertension (BP ≥140 mmHg systolic or ≥ 90 mmHg diastolic) after 20 weeks' gestation [83]. Preeclampsia (unlike isolated gestational hypertension) is a multi-system disorder of pregnancy that can lead to eclampsia (a serious complication characterised by seizures), which is a major cause of maternal mortality worldwide [84]. Observations that preeclampsia is associated with CVD have led to the hypothesis that these conditions may share common risk factors such as dyslipidaemia, inflammation, smoking and T2DM, which contribute to the vascular dysfunction seen in women with preeclampsia [85].

In 2007, Bellamy et al conducted one of the first comprehensive systematic reviews and meta-analyses reporting an association between preeclampsia and subsequent CVD [86]. They provided data on over 3 million women from retrospective and prospective cohort studies, and showed that the relative risks of **chronic hypertension** and **ischaemic heart disease** after a pregnancy complicated by preeclampsia were **3.70** (2.70-5.05) after 14.1 years, and **2.16** (1.86 – 2.52) after 11.7 years, respectively [86]. These findings have been supported by subsequent large cohort studies, systematic reviews and meta-analyses, showing a 2 to 5-fold increased risk of developing chronic hypertension after preeclampsia;[87–91]; a 2-fold increased risk of CVD [88,92–96] and evidence of

metabolic dysfunction in the decades following pregnancy [97–99]. The inclusion of confounding factors such as body mass index (BMI) and subsequent high-risk pregnancies are, however, inconsistent across these studies, limiting the ability to make causal inferences.

2.22 Trajectory of hypertension and risk after Hypertensive Disorders of Pregnancy

Whilst the risk of post-HDP chronic hypertension is established, the trajectory of these risks, especially in LMIC settings is less clear. In a large cohort study involving 1.5 million primiparous women in Denmark followed up for 1-20 years, 14-32% of women with HDP in their first pregnancy developed hypertension in the subsequent decade, versus 4 -11% in a comparable group of normotensive women [100]. The risks of persistent hypertension in the year following a pregnancy complicated by HDP were 12 to 25-fold higher, and 10-fold higher in the decade following the pregnancy than for normotensive women, even after adjusting for smoking, diabetes and other potential confounding factors [100]. The study further highlighted the risk trajectory for developing post-HDP hypertension, which starts in the first year postpartum and persists for up to two decades - findings that are supported by subsequent studies [101–103].

Most observational studies investigating the association between HDP and future CMDs have been conducted in high-income settings [12,100,103–105]. While there are currently no comparable large cohort studies based in low- and middle-income (LMIC) settings, smaller cohort and cross-sectional studies confirm post-HDP hypertension as a clinical entity. In sub-Saharan Africa, three small cohort studies in tertiary care investigated postpartum BP trends following preeclampsia/eclampsia. In a prospective cohort study in

Cameroon, 23/54 (42.6%) women had persistently elevated BP 6 weeks after severe preeclampsia/eclampsia, reducing to 14.8% at 6 months [106]. Two prospective cohort studies in comparable hospital settings in Uganda [107], and Nigeria [108], involving 200 and 198 women respectively, found that approximately a quarter of women with preeclampsia/eclampsia had persistent hypertension at 6 weeks postpartum [107,108].

2.23 Implications of research for postpartum care of women with Hypertensive Disorders of Pregnancy

The association between HDP and CMDs is well established [86,95,109,110], and risks may start early in the postpartum period [101,102]. Evidence that preeclampsia and gestational hypertension carry independent risks for future CVD [13] has prompted professional bodies to: a) recommend asking about HDP as part of cardiovascular risk factor screening in women [111,112]; b) discuss cardiovascular risk as early as 6-8 weeks postpartum [113], and c) recommend regular follow-up for all women with HDP [102,114].

A systematic review of postpartum interventions to reduce post-HDP cardiovascular risk [115] revealed limited evidence to guide the care of such women. This was due to a lack of intervention studies, insufficiently powered trials, and the need for clinical effectiveness studies with long-term follow-up [115]. Using a cardiovascular risk prediction model, Berks *et al*, 2012, analysed pooled data from several studies, and estimated that lifestyle interventions after preeclampsia have the potential to reduce cardiovascular risk by 4-13% [116]. Further studies are, however, needed to understand the feasibility of engaging women in lifestyle interventions beyond the immediate postpartum period, and which healthcare professionals are best placed to deliver those interventions. Educating women

and healthcare professionals might be a useful first step in promoting women's long-term engagement with health services [117,118]; however, pragmatically, it is unclear what **form** postpartum interventions for women with HDP might take, and the ideal **content** and **timing** for conversations about cardiovascular risk. A systematic review by Cairns *et al,* 2017 [119], showed there was a lack of good quality evidence to guide the postpartum pharmaceutical management of HDP. Further good quality RCTs are needed to compare anti-hypertensive medications and determine the thresholds for adjusting medication in these women. Most studies included in these systematic reviews were based in high-income, tertiary care contexts, and the implications are uncertain for women living in low-resource settings, where there are significant challenges around the affordability and adherence to hypertensive medications [120].

2.3 Gestational Diabetes Mellitus and cardiometabolic risk

GDM is the new onset of hyperglycaemia during pregnancy [121]. It is one of the most common pregnancy complications, affecting approximately one in six women globally in 2019 [122]. GDM carries significant maternal and neonatal morbidity, contributing to high birthweight, increased rates of Caesarean section, instrumental delivery, birth trauma, stillbirth and congenital anomalies [123].

The global rise in GDM prevalence is reflective of the rapid economic growth and ensuing epidemiological transition seen in LMICs [124–126]. South-East Asia is one of the WHO regions with the highest prevalence of GDM, affecting 15% of pregnant women (versus 6.1% in Europe) [127]. In India, GDM prevalence is rapidly rising [128], with considerable variation between States and urban/rural settings, depending on the diagnostic

criteria used [129]. GDM prevalence is reported to lie anywhere between 3.8% in urban Kashmir [130] and 42% in Northern India [131]. A systematic review and meta-analysis of GDM prevalence in India [132] revealed considerable study heterogeneity, particularly related to diagnostic criteria.

2.31 Challenges & importance of diagnosing Gestational Diabetes Mellitus

The numerous diagnostic guidelines for GDM [121,133] reflect the lack of universal acceptance of any one screening method. The diagnostic gold standard is an oral glucose tolerance test (OGTT). This involves administrating a 50 -100g glucose drink, ideally between 24-28 weeks' gestation, followed by venous plasma glucose readings at baseline, 1 hour and/or 2 hours. The test can be performed either in a fasting or non-fasting state [134]. Testing requires laboratory services and human resources, which make diagnosis in low-resource settings challenging [135]. These practical constraints, and the lack of universally accepted guidelines, have made comparative studies of GDM prevalence across high-income country (HIC) and LMIC settings difficult [127].

Despite conflicting diagnostic criteria, screening for maternal hyperglycaemia is important to prevent pregnancy complications. In 2008, the Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) Study followed over 25,000 pregnant women in nine countries investigating the effects of maternal hyperglycaemia on neonatal outcomes [136]. After controlling for confounding factors, there remained a strong and continuous association between maternal hyperglycaemia and adverse neonatal outcomes, even with mildly raised maternal blood sugar [136]. As well as the immediate effects on the index pregnancy, screening for GDM has implications for the long-term cardiometabolic health of both

women with GDM and their offspring, who are at increased risk of future T2DM [137–139]. With no clear threshold for diagnosis, GDM diagnostic criteria have been reached by expert consensus [140,141], or based on pragmatic approaches [142–144].

2.32 Risks of Type 2 Diabetes Mellitus after Gestational Diabetes Mellitus

Women with GDM are more likely to develop ongoing dysglycaemia in the postpartum period, with many converting to T2DM in the decade following pregnancy [145]. In their systematic review and meta-analysis of cohort studies involving more than two million women, Song et al (2017) [146] found that women with a pregnancy complicated by GDM had a 7.76 fold increased risk of T2DM compared to women without GDM. The risks of conversion to T2DM were greatest in the 3-6 years immediately following the index pregnancy; however, significant risks also existed in the early postpartum period (<3 years), which persisted for at least 10 years [146]. These findings are in keeping with a prior systematic review and meta-analysis by Bellamy et al, 2008 [147]. Compared to women with normoglycaemic pregnancies, those with GDM have a 7 to 10-fold increased risk of developing T2DM [147–150]; a 3 to 4-fold increased risk of metabolic syndrome (characterised by insulin-resistance, hypertension, dyslipidaemia and central obesity) [151,152], and an approximately 2-fold increased risk of CVD [153,154].

The risks of T2DM are greater for women with GDM and a high Body Mass Index (BMI) (doubles risk) [155], and for those with concomitant HDP or who have had a preterm birth [155]. Any level of hyperglycaemia during pregnancy and the need for insulin therapy further increases the risk of conversion to T2DM [136,148,155], supporting the benefits of screening and glycaemic control for both pregnancy outcomes [136] and future risk of T2DM.

Limitations of these systematic reviews include the considerable heterogeneity of studies [150,156], the lack of LMIC representation in long-term cohort studies [156], and the paucity of community-based prevalence studies. The few cohort studies conducted in LMIC settings have shown similar associations between GDM and postpartum conversion to T2DM [157,158]. In a cross-sectional study in South Africa, following 220 women with hyperglycaemia in pregnancy for 5-6 years, almost half the women progressed to T2DM, and worryingly, almost half (47%) of these women were unaware of their diagnosis [159].

In Indian women, the risks of conversion to T2DM appear greater than in other populations [160,161], due to a complexity of factors including insulin resistance, increased adiposity and reduced skeletal muscle mass [162,163]. A retrospective review of 898 women in an urban clinical setting in South India, revealed that 58% developed T2DM, with half developing T2DM within the first 5 years postpartum, and a further third between 5-10 years postpartum. In total, 90.2% of women converted to T2DM within 10 years of the index pregnancy. A limitation of this study was the significant loss to follow-up, as only 19.3% of women provided postpartum OGTT data (mean follow-up = 4.5 years) [160]. Other studies that have followed women in urban hospital settings in India have shown that over 20% have evidence of dysglycaemia within the first year postpartum [164] and up to 72% by 5 years [161].

2.33 Implications for postpartum follow-up of women with Gestational Diabetes Mellitus

In view of the evidence, postpartum screening for women with GDM is recommended in national guidelines across the world [165–167]. In spite of these recommendations, uptake

of postpartum screening in both HIC and LMIC contexts is poor [168]. Barriers include negative perceptions about the screening process, lack of awareness of the risks of GDM [169], competing personal priorities in the postpartum period, and lack of transport [170,171]. Additionally, in low-resource settings, the availability of trained staff, equipment and laboratories for screening are all issues. To address the burden of GDM in rural India, the International Diabetes Federation (IDF) proposed a strategy for community-based screening [172]. The **W**omen in **IN**dia with **G**DM **S**trategy (**WINGS**) studies have shown it is feasible to perform an OGTT in rural areas using a capillary blood glucose (CBG) (when drawing venous blood is not possible) [173,174]. Although it has low sensitivity for detecting GDM [175], the latest Government of India guidelines recommend a non-fasting OGTT followed by a 2-hour CBG as a pragmatic solution to screening in rural areas, with repeat postpartum screening at 6 weeks for women with GDM [142].

2.34 Postpartum interventions for women with Gestational Diabetes Mellitus

The first 5 years following a pregnancy complicated by GDM offer opportunities to prevent progression to T2DM. Evidence-based postpartum interventions have focused on the lifestyle and medication strategies of the Diabetes Prevention Programme (DPP) study, which showed a 58% reduction in the development of T2DM in high-risk non-pregnant adults in the lifestyle intervention group, and 31% in the group taking metformin (an oral hypoglycaemic medication) alone [176–178]. Tailored postpartum lifestyle interventions based on the DPP are feasible [179,180], and can reduce weight gain and increase exercise levels [179]. Furthermore, intensive lifestyle interventions and metformin use in postpartum women with GDM are effective in delaying or preventing diabetes in women

with evidence of dysglycaemia and a history of GDM [181,182], although evidence for use in low-resource settings globally is limited.

2.35 What should we be doing for women with Gestational Diabetes Mellitus after pregnancy in India?

For Indian women, the risks of developing T2DM after a pregnancy with GDM appear higher than for other populations. These risks manifest in the first year postpartum [164]. Given the rapid rise in T2DM in India [183], and projected impact of GDM [122], it would be sensible to implement early screening and postpartum interventions. Numerous clinical guidelines have recommended the postpartum follow-up of women with GDM, with an OGTT at 6-12 weeks and counselling for risks of developing T2DM and CVD [165,167,173,174]. There is evidence for the use of lifestyle interventions and medications in the postpartum period to reduce the risk of progression to T2DM, but a distinct lack of intervention trials in low-resource settings globally. Considerable uncertainty also exists around community-based screening for GDM, i.e. which are the best tests, diagnostic criteria and resources to use, and what are the implications of a diagnosis for women living in rural areas, where treatment with insulin and metformin are not affordable, available or practical. Balancing pragmatic issues with the accuracy of screening tests is important. The review has highlighted the lack in LMIC settings of: a) long-term cohort studies following women with GDM; b) community-based studies for GDM screening and c) implementation trials of postpartum interventions for GDM in low-resource settings globally.

2.4 Community-level interventions for high-risk pregnant women

For women living in rural India and other low-resource settings, lack of transport, poor literacy, demands of family and work, and affordability are all factors, which make multiple visits to hospital challenging [184,185]. As an alternative, community-level interventions for high-risk pregnant women can prevent delays in seeking healthcare [186]. Such interventions include Community Health Worker (CHW) programmes, point of care testing (POCT), and use of mobile Health (mHealth) technologies.

2.41 Task-sharing and the role of Community Health Workers

CHWs are individuals from the communities they serve, trained to address health issues affecting their community [187]. In both HIC and LMIC contexts, CHWs advocate for their population, facilitate the modification of health behaviours and improve health literacy [188]. In many contexts, CHWs are recognised as part of the formal health system and as key to achieving universal health coverage (UHC) [189,190].

In low-resource settings, task-sharing of clinical work to CHWs has been used as a strategy to meet physician shortages [191,192]. Task-sharing involves increasing the types of healthcare worker trained to deliver a certain service, and differs from transferring medical tasks normally reserved for nurses and physicians to less-specialised healthcare workers, such as CHWs (task-shifting). Recognising the unique skills of CHWs in healthcare delivery, task-sharing involves redistribution of tasks to enable collaborative teamworking as a cost-effective strategy for improving healthcare efficiency and delivery in low-resource settings [193]. Global CHW programmes across urban and rural settings have

been shown to improve healthcare delivery in the fields of maternal-child health [194,195], communicable disease management [196], and primary and secondary prevention of NCDs [197–201].

In a multi-country, cRCT involving 2645 adults >40 years old with hypertension in rural South Asia, (Bangladesh, Sri Lanka and Pakistan), CHWs were trained to measure and monitor BP and provide home health education in their villages [202]. The cRCT lasted 2 years, with BP monitoring and home-based education visits every 3 months. In addition to the CHW component of the intervention, local physicians were trained to manage hypertension using a checklist approach. A hypertension triage reception was started in government clinics and CHWs were remunerated by local district health offices. A 5.2 mmHg reduction in systolic BP in the intervention group compared to the control group was seen at 24 months. Additionally, the intervention group showed improved prescribing behaviours and adherence to anti-hypertensive medication, at minimal cost (<$11USD per patient). The cRCT was well designed and conducted, with minimal loss to follow-up, and high levels of fidelity to intervention practices (>90% per protocol).

Further community-level studies in both rural and urban LMIC settings globally have used technology to assist CHWs in BP management, and demonstrated significant improvements in cardiovascular risk reduction, medication adherence and healthy lifestyle behaviours [203,204]. These trials demonstrate the value of multi-component CHW-led programmes for NCD management in rural LMIC areas. Involving primary care physicians and CHWs in NCD management, enhances the level of cardiovascular risk reduction and contributes to health system strengthening through integration of NCD programmes within multiple levels of the health system [203,205].

2.42 The role of Community Health Workers in early detection of women with high-risk pregnancies

In low-resource settings, CHWs have been involved in identifying and monitoring high-risk pregnant women. Most trials have focused on preeclampsia as a leading cause of maternal mortality worldwide; for example, using POCT to screen for high BP [206–211]. BP measurement using traditional devices can be daunting for unskilled CHWs. In response, a low-cost ($25 USD per unit) semi-automated BP device with a traffic light triage system – the Cradle Vital signs alert (VSA) was designed for use by minimally trained health professionals in any setting. Feasibility studies using the Cradle device in sub-Saharan Africa and India showed high levels of CHW acceptability [209,212]; a subsequent multi-country stepped-wedged, cRCT failed to impact the primary outcomes of maternal mortality and morbidity [210]. These results may have been due to a combination of the uni-faceted approach, focused on one high-risk condition, insufficient sample size, and lack of in-depth contextual understanding of the factors leading to maternal morbidity and mortality from preeclampsia in the areas studied.

2.43 The role Community Health Workers & mobile technology

Mobile Health (mHealth) refers to the use of mobile wireless technology for healthcare provision [213], i.e. standard mobile phones, smartphones and iPad-like tablet devices [214]. Rapid advances in the reach and functionality of mobile technology in LMICs have allowed the development of low-cost interventions, which can be delivered at scale [215], with implications for healthcare equity. These advances have led to the use of mobile technology for health-related behaviour change [214,216], provision of clinical decision

support [217], reminder-recall systems [218,219], and to improve data collection to enable health systems planning and surveillance [220].

The rapid expansion of mobile technology has impacted healthcare provision in the fields of maternal-child health [221], and NCD prevention and management [222]. A systematic review of 51 RCTs in maternal-child health, concluded that mHealth interventions could improve delivery of ANC and uptake of early breastfeeding [221]. Further studies have shown positive applications in screening and monitoring of HDP, improving efficiency and service delivery [223], and reducing delays in accessing medical care for pregnant women [224].

In spite of these advances, to date, there are very few examples of robust, large-scale mHealth intervention studies in LMIC settings. A cRCT of a smartphone-based mHealth intervention (ImTECHO) for pregnant women, involving a population of almost half a million in rural India, demonstrated the value of multi-faceted applications of mobile technology in the supportive supervision and mentoring of CHWs, and as a job-aid to improve uptake of standardised ANC [225]. The mHealth intervention did not, however, impact clinical endpoints of maternal and neonatal mortality and morbidity.

Another large-scale trial using mHealth, focused on preeclampsia, was the Community-Level Interventions for Preeclampsia (CLIP) trial [226] . The cRCT was conducted in Mozambique, Pakistan and India, and studied a CHW-led intervention to screen, triage and manage women with preeclampsia, supported by a mobile Health (mHealth) risk stratification tool. The full **P**re-eclampsia **I**ntegrated **E**stimate of **RiS**k model (fullPIERS) was developed in a HIC setting to predict adverse maternal outcomes in women with

preeclampsia, using a combination of clinical history, signs and symptoms, and laboratory tests [227,228]. Due to the lack of laboratory support in low-resource settings, the fullPIERS prediction model was modified, integrated into an mHealth platform (PIERS-on-the-Move: POM), and found to be acceptable and feasible, with moderate utility in predicting adverse pregnancy outcomes in women with HDP [229–231]. CHWs in the CLIP cRCT were trained to measure BP using a digital device, and received risk-stratification and management support through the POM mHealth tool. The trial gave CHWs duties outside of their traditional tasks, including administration of medication. An individual participant-level meta-analysis of over 60,000 pregnant women revealed that the CLIP intervention did not reduce the primary endpoints of adverse pregnancy outcomes [226]. This may be the result of the focus on one health condition and a need to address wider health system barriers influencing the implementation of community-level interventions for high-risk pregnant women.

In NCD prevention and management, mHealth has been shown to be an effective strategy for improving medication adherence [232], and for secondary prevention of CVD [222]. A review of mHealth in the self-management of BP also demonstrated clinical effectiveness [233]. Multi-faceted mHealth strategies (e.g. tailored messages and interactive communication) had additional impact [233]. Reviews of mHealth in delivering care for high-risk pregnant women, and in NCD prevention and management, have highlighted that multi-faceted mHealth interventions incorporating several strategies both within the mHealth platform and in its implementation within the health system, are more efficacious than disease-specific strategies targeting one area of the health system [220–222,226,233,234]. There is however, a lack of robust clinical trials beyond small-scale pilot studies of mHealth in LMIC settings [235,236]. This has limited the ability to

draw conclusions about the clinical effectiveness of mHealth interventions in these clinical areas [235].

2.44 Implications for high-risk pregnant women and non-communicable disease prevention

The overall evidence to support clinical effectiveness of mHealth technology is, to date, inconclusive [214,237]. Although there are examples of clinical effectiveness in the fields of SMS-messaging for smoking cessation, and multi-faceted interventions to improve adherence to HIV medication in LMICs [238], most large-scale trials evaluating mHealth interventions have, to date, been conducted in HICs [214]. Further robust implementation trials of mHealth interventions are needed to show evidence for efficacy, clinical and cost-effectiveness, particularly in LMICs [214,235].

Use of mobile technology in low-resource settings has further implications for health systems. Challenges to integrating mHealth interventions into a health system include lack of digital literacy of healthcare workers [239], and readiness of the health system infrastructure to integrate digital technology into the daily work of healthcare workers [240,241]. Introduction of complex interventions such as mHealth into a health system may lead to a variety of unintended consequences, which are not always acknowledged or discussed. Such unintended effects reported in the literature include increased workload [211,212,219], frustration and resistance of healthcare workers to new ways of working [219], and disruptions to the of focus of activities for healthcare workers from traditionally allocated tasks in order to incorporate the new intervention [211]. Complex interventions may also have wider impacts outside of the intended beneficiaries or intended outcomes. For example, Namazzi *et al* [211] found that husbands of the women receiving a CHW-

led intervention for maternal health, reported frustration that their wives did not inform them of their pregnancy. Furthermore, Nathan *et al* [212] developed the CRADLE BP device primarily to address the delays for women in reaching the healthcare facility and delays at the facility, but found that the intervention additionally impacted care-seeking behaviour amongst women *before* they decided to reach the healthcare facility. Systems-level thinking considers the broader impacts of introducing a complex intervention beyond its immediate beneficiaries, recognising these system-wide effects [223].

2.5 Health systems strengthening for women's life-long health

Health systems are complex, dynamic and interactive [242]. Strengthening such systems may be achieved through vertical and horizontal integration between the community, primary and secondary care, and a shift to more patient-centred approaches [243,244]. Integrated care is the provision of healthcare with the aim of improving the patient experience, whilst achieving greater value and efficiency. It has been shown to improve uptake, earlier initiation of treatment and lower loss-to-follow up for pregnant women requiring antiretroviral treatment for HIV [244]. Integrated programmes may also provide opportunities for family members and partners to engage with health services [244]. In low-resource settings, using healthcare encounters such as ANC, might offer opportunities to engage women and their families in discussions about their future cardiometabolic health.

A systematic review of the integration of ANC services with health programmes in LMICs found there was limited evidence to support policy changes in this area [244]. This was mainly due to the studies' limited generalisability, and lack of RCT evidence. Most (9/12)

of the studies included in the review focused on the integration of HIV-related services with ANC. A further two looked at the integration of syphilis screening with ANC and only one described the integration of postnatal care for chronic conditions with ANC services [244] .

There are very few examples of integration of NCD prevention strategies into maternity services in LMIC settings. Existing studies have focused on using ANC as an opportunity to screen and counsel women about breast cancer [245], and perinatal mental health [246–248]. Although, an integrated approach to managing GDM in primary care in Pakistan has been advocated [249], its implementation has not yet been studied. Examples from programmes to prevent maternal to child transmission of HIV in sub-Saharan Africa do, however, show how integrated care across the continuum of women's health might be designed and implemented to respond to the needs of women throughout their lives, at scale, in low-resource settings [250]. Currently, in many low-resource contexts, the postnatal period (critical for preventing neonatal and maternal morbidity and mortality), is a neglected area of service delivery, fragmented from routine ANC, and presents a missed opportunity for providing integrated care for women during their transition from pregnancy to post-reproductive women's NCD services [251].

2.6 Discussion

Pregnancy represents a unique physiological event in the life course of a woman, which may unmask a woman's susceptibility to future CMDs [252]. There is good quality evidence for both early postpartum and life-long follow-up of women with HDP and GDM, to reduce their future risk of CMDs. The form which this postpartum follow-up should

take in low-resource settings is less clear, although some guidance exists [83,142,172,253]. Tackling the rise in NCDs and reducing maternal mortality are both key objectives of the Sustainable Development Goals [82], and there have been calls for integrating NCD prevention into the existing continuum of women's healthcare programmes globally [254]. Strategies and interventions to address high-risk pregnancy conditions in low-resource settings have, to date, focused on pregnancy, delivery, and the immediate postpartum period alone, rather than integrating NCD prevention into postpartum care. In rural areas of India, where there is limited access to health services, integrated, life-long, community-based strategies are required to address the rising burden of NCDs in women.

This literature review highlights the need for more robust RCTs of interventions (both digital health and other complex interventions) targeting antenatal and postnatal care in LMICs. Of the RCTs of community-based interventions that have been conducted, most have failed to show any impact on hard clinical outcomes [225,226], but have improved process and quality of care measures [225,226]. The reasons are multifactorial. Firstly, it is unclear if the hard clinical outcomes studied are truly reflective of the change processes that have occurred, as in many of the studies the theory of change is not clearly articulated. Transparent reporting of the mechanisms of impact of an intervention are central to evaluating and understanding how an intervention has its effects [255]. Secondly, the studies have usually focused on a single condition and strategy for improving maternal health outcomes. A multi-faceted approach to intervention design might be best suited to address maternal mortality in areas where HDP are just one of many high-risk conditions facing pregnant women. Lastly, there may be a need to move beyond targeted community-level interventions to include wider health systems strengthening, through provision of

integrated models of care involving primary and secondary care, and throughout a woman's life course.

In rural India, there are still significant challenges in screening and diagnosing HDP and GDM, which require innovative and creative problem-solving. Antenatal and postnatal care in rural India is delivered by CHWs, who are ideally placed to deliver community-based interventions to identify and counsel pregnant women at high-risk of future CMDs. This review has highlighted that interventions targeting high-risk pregnant women and NCDs, need to consider multiple strategies, applicable to the context, to articulate a theory of change, and integrate effectively within the health system to deliver patient-centred care throughout the life-course. With this in mind, I set out to explore the following research questions [Table 2] in designing a complex intervention to address the detection, referral and management of pregnant women at high-risk of future CMDs in rural India.

2.7 Primary & secondary research questions

Table 2.1: Summary of primary & secondary research questions of thesis

Primary Research Question (addressed through whole thesis)	
Is it feasible and acceptable for CHWs in rural India to screen, refer and manage high-risk pregnant women during antenatal and postnatal care using a complex intervention, including mobile clinical decision support?	
Secondary Research Questions	**Addressed in:**
What contextual factors are important in developing a conceptual map of the healthcare system for pregnant and postpartum women in rural India?	*Chapter 4*
How can theory be used to inform the design and development of a complex intervention and refine this for testing?	*Chapter 5*
What are the important factors in the design and delivery of the complex intervention that can explain its acceptability, feasibility, and likelihood of scalability outside of a pilot study?	*Chapter 6*

"Nothing is as practical as a good theory"

– KURT LEWIN

3

Theoretical frameworks & Methods

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3.1 Introduction

In the previous chapter, the literature relating to the long-term cardiometabolic sequelae of high-risk pregnancy conditions, including HDP and GDM, was explored and community-level strategies to address these issues were discussed. This literature review provided an evidence base and rationale for the development of a multi-faceted intervention to screen, refer and manage women with high-risk pregnancies in rural India. In this chapter, I outline the theoretical frameworks and methods used in the process of intervention development and evaluation, and explain why these particular frameworks and theories were chosen for my research.

3.2 The MRC Framework for complex interventions

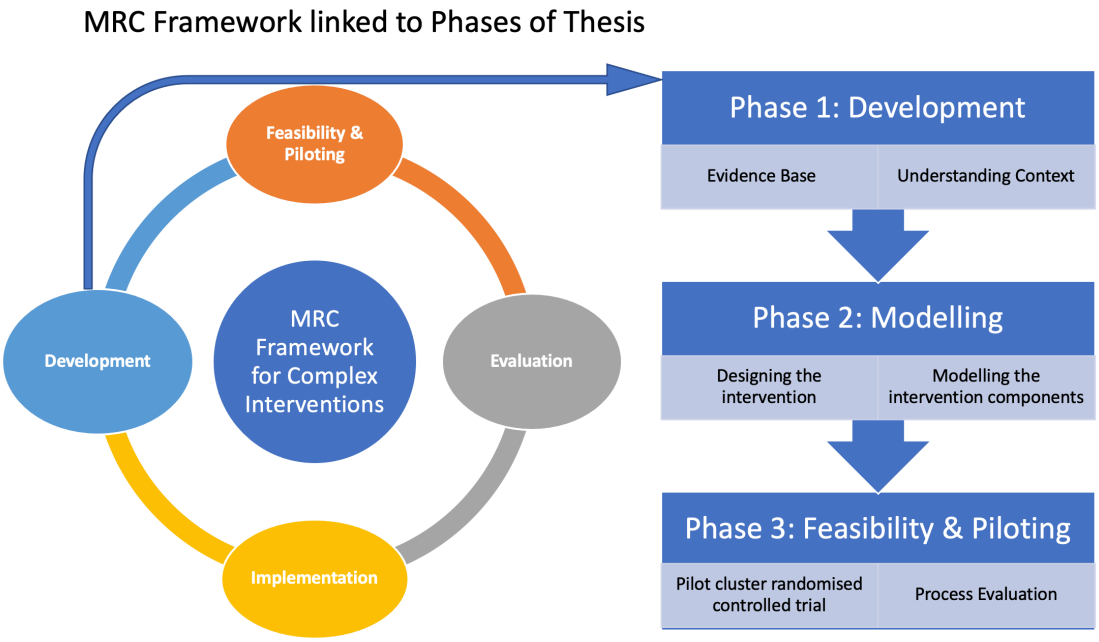
A complex intervention is one that contains several interacting components, which may operate at various levels within a dynamic health system. Complex interventions require an array of behaviours to be enacted by healthcare workers and other key stakeholders within the health system [66]. Additional complexity may include wider social and environmental influences and human-system interactions [256, 257]. These factors can make the effects of the components of a complex intervention hard to anticipate or measure, and lead to unintended consequences. In the face of these uncertainties, guidance and theoretical frameworks can aid the systematic development and evaluation of such interventions [258].

The MRC framework for complex interventions [66] outlines the process of development, evaluation and implementation of complex interventions in four key stages:

- **Development:** Identification of the evidence base, identifying and developing relevant theory and modelling processes and outcomes.
- **Feasibility/Piloting**: Testing intervention procedures, determining recruitment and retention rates, and facilitating estimation of sample sizes for future effectiveness studies through conducting a feasibility or pilot study.
- **Evaluation:** Assessing effectiveness, understanding the change process, assessing cost-effectiveness.
- **Implementation:** Dissemination, surveillance and monitoring and long-term follow-up (including post-evaluation scale-up).

The MRC framework allows for flexibility between these four stages, moving iteratively between development, feasibility and evaluation until implementation is possible and optimised. The framework further enables researchers to consider factors involved in the **causal mechanisms** of complex interventions, and gives scope to understanding the real-world effectiveness of the intervention. In this thesis, I have focused primarily on the stages of **development** and **feasibility & piloting** of a complex intervention, whilst considering implementation issues throughout the research process. Figure 3.1 outlines the MRC Framework and its links to my research.

Figure 3.1: Medical Research Council Framework for complex interventions and phases of thesis



Developing and using theory to model a complex intervention is integral to the development phase of the MRC framework for complex interventions. However, structured advice on how to embed theory into intervention design has, historically, been scarce, which has led to many interventions being designed without explicit use of theory [257].

The MRC guidance on **process evaluation** emphasises use of theory in the evaluation of complex interventions, providing examples of how theory may be used to explain the causal mechanisms and guide the evaluation of a complex intervention [259]. The guidance highlights the importance of understanding **why** a complex intervention worked or not, and **how** the intervention had its intended (and unintended) effects. Unlike the 2008 framework for complex interventions, the MRC guidance on process evaluation [259] recognises the importance of having a good understanding of the **context** in which complex

interventions occur. This is a move away from traditional biomedical models in clinical research, which have focused on a linear progression from the development of a research concept into evidence of clinical effectiveness, for the overall goal of public health impact [260]. Complex interventions, however, are rarely linear in their outcomes, and are influenced by the wider social and political contexts in which they are situated [261]. Recognising the importance of context in the adoption of complex interventions into routine healthcare practices is a key focus of implementation research [262]. Implementation research sits under the wider umbrella of implementation science [262]; a field of science which started in the late 1990's following the observation that evidence of clinical effectiveness provided through robust clinical trials did not always guarantee adoption of an intervention into routine care for patient and public health benefit [263][264].

3.3 Implementation science: Theories & Frameworks

Implementation science focuses **beyond** establishing the clinical efficacy and effectiveness of an intervention. It aims to understand the contextual factors that improve or obstruct the adoption of evidence-based interventions into routine healthcare in real world settings [265]. Implementation research has been advocated to address the global rise in NCDs, to improve smooth and timely adoption of evidence-based practices into global settings, and accelerate policy action [266].

3.31 Why use theory in intervention development and evaluation?

Although there is evidence to support the efficacy [267] and effectiveness [268] of theory-informed interventions in small-scale clinical trials, evidence of population-level impact in real world settings is scarce [269].

A systematic review of reviews by Dalgetty *et al*, 2019, showed limited evidence that theory-informed interventions are any better than those developed because '*it seemed like a good idea'* [270]. These findings may be due to in part to the lack of theory being explicitly stated within studies, or due to limitations in the way the theories were used, or could signal wider implementation problems. This then begs the question – *why use theory to inform the design of complex interventions?*

Theory, theoretical models and frameworks can be important in understanding the relationships between phenomena within a complex system, and modelling how these phenomena interact. Theories are based on empirical evidence, and can be used to both describe and *explain* phenomena through the use of analytical statements and principles, and predict what is likely to happen in a given situation. Theory may be simplified into a model, which offers a more narrow and descriptive way of understanding phenomena. Theoretical models may be separate to, or embedded within a larger theoretical framework. Theoretical frameworks use a wider set of categories, constructs and variables, and outline the relationships between these categories, thereby providing structure when approaching or evaluating a research area.

Embedding implementation theories and frameworks into the development and feasibility stages of the MRC Framework might help to address implementation issues at the start of

the research process. Theories and frameworks can help to both **explain** the causal mechanisms of the intervention and **optimise** its implementation. Furthermore, implementation science theories and frameworks have the potential to build the views of local communities into the heart of the design of a complex intervention and thereby improve the chances of local adoption and improvement of service delivery [271,272]. The use of theory in the development and evaluation of complex interventions also enables **comparison** between interventions, thereby providing opportunities to **test** the theory, and facilitate its further development [257]. Several examples of theory-informed interventions have been published in a diverse range of fields from back pain [273] to stroke medicine [274].

Implementation theories and frameworks are specifically developed by implementation researchers, either through adapting existing theories and concepts or *de novo*, in order to provide understanding and explanation of the process of implementation. Nilsen, 2015, summarises the aims of implementation theories, models and frameworks into three areas: 1) Those that describe the **process** of translating research into practice; 2) Those that aim to **understand and explain** what influences implementation outcomes (through either determinant frameworks, classic theories and implementation theories), and 3) Those that **evaluate** implementation [275]. In this thesis, I will be using the COM-B/Behaviour Change Wheel (BCW) framework [67] and Theoretical Domains Framework (TDF) [68,276] for behaviour change, to design the intervention, and to understand and explain the implementation process and outcomes of SMARThealth Pregnancy. In addition, I will be using Normalisation Process Theory [69,277,278] as a lens to conduct the qualitative process evaluation of the intervention, and to explore how the intervention was embedded into routine healthcare practice to provide clues as to its future sustainability. These

theories and frameworks sit within the second aim of Nilsen's [275] categorisation, and will now be discussed.

3.32 Behaviour Change Frameworks used for intervention development

Complex interventions attempt to change the dynamics of social systems, through influencing the behaviours of agents within those systems [279]. Effective models for behaviour change take into account behavioural theory of both the internal and external factors impacting behaviour, and further consider an understanding of the **contexts** in which interventions are effective, and **how** the theory might inform the design and evaluation of such implementation interventions.

Michie's COM-B/BCW is an integrative framework, which captures the diverse influences on behaviour in a structured and methodological way to design and implement interventions [67]. The framework was developed through a systematic review and synthesis of 19 existing behaviour change frameworks and provides a coherent and systematic method for: a) identifying and organising potential barriers to behaviour change; b) selecting barriers that, if modified, are most likely to lead to behaviour change in a given context, and c) choosing evidence-based behaviour change techniques most likely to be effective in overcoming targeted barriers.

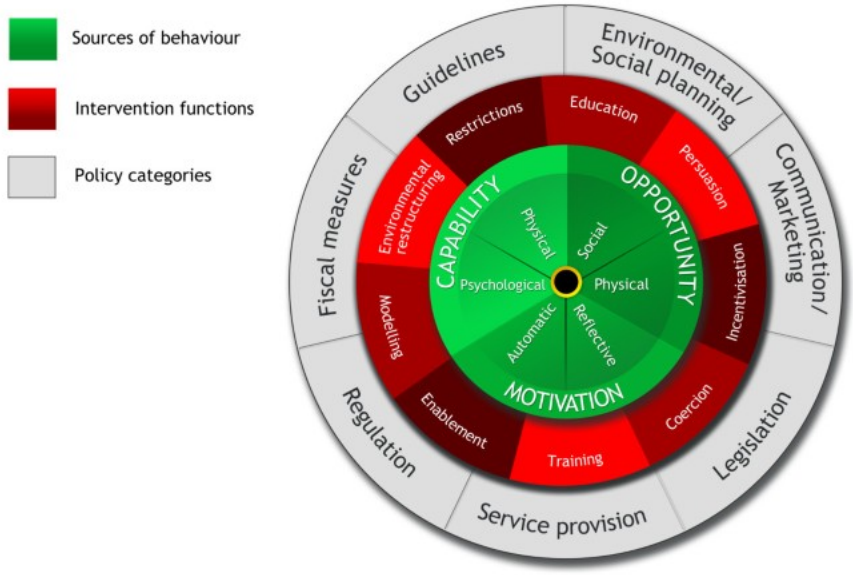
At the 'heart' of the BCW are three main domains of behaviour: Capabilities, Opportunities and Motivations (COM), which interact to effect behaviour change (COM-B). These domains are further subdivided as outlined in Table 3.1 below.

Table 3.1: Domains of the COM-B model of behaviour change. Adapted from Michie et al, 2011 [67]

Domain of Behaviour Change Wheel	Sub-Domain	Description examples
Capabilities	Physical	Physical abilities to perform behaviour
	Psychological	Psychological abilities: reasoning, comprehension
Opportunities	Physical	Physical environment and its impact on behaviour
	Social	Social and cultural context which may influence behaviour
Motivations	Automatic	Emotions and impulses that lead to enacting or inhibiting behaviour
	Reflective	Abilities to evaluate and plan behaviour

The COM-B/BCW approach to intervention design considers **which aspects** of the motivational system outlined by the capabilities, opportunities and motivations of key actors in a health system can be targeted, and **how** these might most effectively be targeted (using **intervention functions**), in order to achieve a **target behaviour**. The COM-B domains provide the basis or sources of behaviour to align to intervention functions within a complex intervention. The second 'layer' of the BCW outlines the intervention functions which can be employed to achieve a desired behavioural response. Intervention functions include: Education, Persuasion, Incentivisation, Coercion, Training, Restriction, Environmental restructuring, Modelling and Enablement. These functions are further linked to **policy-level strategies** (the third 'layer' of the BCW), which impact behaviour change including: Communication/marketing, Guidelines, Fiscal, Regulation, Legislation, Environmental/Social planning, and Service provision. The COM-B/BCW can be used to identify relevant intervention functions that might influence the capabilities, opportunities and motivations of agents within a health system, and thereby lead to a change in behaviour.

Figure 3.2: The domains of the Behaviour Change Wheel [3]



The "active ingredients" within the intervention functions are known as Behaviour Change Techniques (BCTs). BCTs are observable and replicable components of behaviour change interventions, and have been categorised in an extensive taxonomy of BCTs [280]. Specifying BCTs within the intervention functions used in a complex intervention, can help researchers understand the precise components of the intervention and which of these had the most impact as part of the development of a logic model or programme theory. By considering which target behaviours are important to address for agents within the health system, and mapping these desired behaviours within COM-B domains to the relevant intervention functions and policy categories, a complex intervention, using single or multiple intervention functions can be designed to target specific behaviours using a range of BCTs. The end-point of any behavioural intervention is a change in **behaviour**, rather than the clinical outcome (the consequence of the change in behaviour) [281].

[3] Reproduced from Michie *et al*. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* 2011 6:42 published under CC BY 2.0.

3.33 Theoretical Domains Framework

The Theoretical Domains Framework (TDF) [68] is another integrative framework of behaviour change, complementary to COM-B/BCW. The TDF synthesised 128 theoretical constructs from 33 behavioural theories (judged to be most relevant to implementation questions) [68]. It consists of domains primarily relating to individual capabilities and motivations, and also takes into account wider physical and social factors within the environment. The TDF domains give a more granular understanding of the **psychological capabilities** and **reflective motivation** domains of the COM-B model as illustrated in Table 3.3. In designing interventions, the TDF fits well with the COM-B/BCW [68] and they can be used synergistically [282].

Table 3.2: Constructs of the Theoretical Domains Framework mapped onto the Capabilities, Opportunities and Motivations of the COM-B framework

COM-B domains	Associated TDF domains
Physical capability	Physical skills
Psychological capability	Knowledge; Cognitive and interpersonal skills; Memory, attention & decision processes; Behavioural regulation.
Social opportunity	Social influences
Physical opportunity	Environmental context and resources
Automatic motivation	Reinforcement; Emotion
Reflective motivation	Social/Professional role and identity; Beliefs about capabilities; Optimism; Intentions; Goals; Beliefs about consequences.

In Chapter 5, I outline how the COM/BCW and TDF have been used to design the SMARThealth Pregnancy intervention components and implementation strategies.

3.34 Normalisation Process Theory

Normalisation Process Theory (NPT) is a mid-range theory, which addresses the concept of community-based action and the different types of work stakeholders ***do*** when implementing a new practice. NPT was developed by iteratively synthesising generic theories of implementation [69,277,278]. Capturing important elements of the implementation process, NPT assists health services researchers to understand how complex adaptive social systems (such as the maternal health system in rural India) function, and the roles of **individual** and **collective** behaviours that interact to implement a complex intervention within this system. NPT can be used to help understand how complex interventions become embedded into the day-to-day work of key players in the health system after implementation. NPT has also been highlighted as an approach to understanding the real-world implementation of an intervention and its future scalability and sustainability [272].

NPT focuses on four key constructs, each with further sub-domains (in brackets) [283]:

1. **Coherence**: Refers to the work individuals and groups do to **make sense** of an intervention. Understanding how the intervention differs to existing practices (**differentiation**), how people make sense of the intervention collectively and individually (**communal and individual specification**), and how people come to understand its value and benefits (**internalisation**).

2. **Cognitive participation**: This is the **relational work** required to build and sustain intervention practices. For example; how people work to drive forward a new intervention (**initiation**); how they reorganise their relationships to contribute to new practices (**enrolment**); if people believe it is correct for them to be involved

in intervention delivery (**legitimation**), and how the relationships to deliver the intervention are sustained (**activation**).

3. **Collective action:** Refers to the **operational work** done by individuals and teams to implement a new intervention. Operationalisation of a new intervention may: require new interactions between people in the health system, both with each other and with the intervention (**interactional workability**); require people to build accountability, trust and confidence in the new ways of working (**relational integration**); require division of labour to deliver the intervention (**skill set workability**), and involve reallocation of resources to deliver new practices (**contextual integration**).

4. **Reflexive monitoring:** This is the formal and informal **appraisal** of how the new intervention affects individuals and the wider health system. This may involve evaluation of the worth of a new set of intervention practices (**systemisation**); through formation of informal or formal groups (**communal appraisal**) or individually (**individual appraisal**), and result in further refinement of intervention practices, creating change, reorganisation and embedding of the intervention within the health system (**reconfiguration**).

NPT is flexible and can be used in multiple ways at the discretion of the researcher [personal communication with author - Professor Carl May]. These include to a) support intervention design; b) describe the context of a trial within the process evaluation of randomised controlled trials, and c) explore forms of collaborative care [278]. The main uses of NPT have, to date, been in feasibility studies and process evaluations. The ways

in which NPT has been integrated into research methods has included deductive analysis of qualitative data using framework or directed content analysis [278]. NPT has also been used to include both **deductive and inductive elements** in a theory-led analysis, without the need to force data to fit within a rigid framework, and for inductive analysis of qualitative data in light of NPT constructs [284,285]. In my thesis, I will be using NPT as a lens for conducting a framework analysis in the qualitative process evaluation of SMARThealth Pregnancy (Chapter 6).

3.4 The need for mixed methods

Mixed methods research is a form of research design with its own philosophical assumptions and methods of inquiry [286]. As outlined by Creswell & Clark [287] the central premise of mixed methods research is that:

"The use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone."

A combination of research methods is often needed to address diverse research questions arising as a result of the complexities of healthcare research [272,288]. O'Caithan *et al*, 2019, in their 'Guidance on how to develop complex interventions to improve health and healthcare' acknowledge the use of mixed methods in the development of complex interventions [272]. For example, understanding the context, priorities and values of stakeholders using qualitative approaches to data collection might permit more socially located responses [289]. Outcome evaluation of a healthcare program might, however, require quantitative methods. Use of mixed methods is compatible with the MRC

framework, which acknowledges the variety of research questions arising during each of its four stages, and the range of methods required to address these questions.

The dominant methodology used within my thesis is qualitative, as outlined in detail in the relevant methods sections of the contextual study (Chapter 4) and the qualitative process evaluation of the pilot study (Chapter 6). In the design phase (Phase 1) of the SMARThealth Pregnancy intervention, qualitative methods are used in an inductive and exploratory way, to inform the design of the intervention and its components (Chapter 4). A qualitative synthesis of the barriers to the provision of integrated antenatal and postnatal care of high-risk pregnant women identified during the contextual work, informs the design of the complex intervention (Chapter 5). Intervention development focuses on the four principles of human-centred design: a) ensuring solutions to core or root issues, rather than surface level issues; b) focusing on people; c) taking a systems-perspective (acknowledging the complex and interdependent parts of the health system), and d) involving iterative refinement to ensure the intervention meets the needs of the people [290]. During the SMARThealth Pregnancy intervention development (Phase 2), a combination of qualitative and quantitative data were collected in parallel during usability testing to refine the intervention before the pilot study, as part of a human-centred approach to intervention design and development [272,290].

During the final phase (Phase 3), in a pilot cRCT of SMARThealth Pregnancy, both quantitative and qualitative data were collected in parallel. These data were then integrated using a narrative approach to answer the primary research question relating to feasibility and acceptability of the intervention (Chapter 6).

Addressing bias and trustworthiness of data

The use of mixed methods in the pilot study enables triangulation of data to answer the primary research question. Triangulation refers to the use of multiple data sources, methods of data collection and analysis, and combining and comparing these different sources to help reduce subjectivity and bias within the research process. Use of conceptual frameworks to outline the research process can help establish validity and reliability, and thereby trustworthiness of research findings. As part of the qualitative methods used in this thesis, I consider Guba's four key criteria for establishing trustworthiness: credibility, dependability, confirmability and transferability of the research methods and analysis, to appraise the validity of qualitative research [291]. O'Caithan *et al*, further outline the importance of providing adequate justification for using mixed methods and clear descriptions of the methods and insights gained from integrating methods in the Good Reporting of A Mixed Methods Study (GRAMMS) [292]. At the heart of my research process, are the concepts of positionality, reflexivity and self-awareness as a researcher, now discussed.

3.5 Positionality and Reflexivity in the research process

Positionality refers to the way in which a researcher interacts and engages with the social, cultural, and political context of the study [293]. Reflexivity allows the researcher to identify assumptions and preconceptions they may have entering the research. It is an essential component of high-quality qualitative research [288,293,294]. An element of trustworthiness of my DPhil research, particularly for the qualitative aspects of the thesis, includes acknowledging my background and values as the primary researcher and their impact on *how* the research was conducted, analysed and interpreted. Here, I reflect on the impact of being both an outsider and a doctor has had on my doctoral research.

I am a female medical doctor, with a professional background in paediatric surgery and primary care. I was born in India, and raised in the UK since the age of 2. Over the last 15 years, I have spent a great deal of my time living and working in rural India, both on short-term projects and longer term stays of up to a year. This background and knowledge of the country and its society, the way I looked and dressed enabled me to integrate rapidly in both study settings, build trust with local healthcare workers, and be accepted into the communities. While I felt very at home in rural India, I was aware that my accent, education, and mannerisms may have also been interpreted by others as being an 'outsider', and affected the way I was perceived.

Although I tried my best to be introduced as a researcher to women in the study, participants often found out that I was a doctor. I was aware that this might affect the dynamics of the interviews and being a 'doctor from London', meant that I was often put on a pedestal – particularly by other healthcare workers who, I quickly reassured, knew much more about rural India and the challenges they face as healthcare workers than myself – and that **they** were the experts in this field. Due to the way I looked and dressed (in Indian traditional dress) and my awareness of the customs and traditions of India, the women and healthcare workers felt at ease, and were happy to share their experiences unreservedly in all cases. Although I had worked and lived in rural India in the past, I was unfamiliar with the two areas involved in my DPhil study.

My familiarity with the Indian context, and rural India in particular, added credibility to the research and the development of this complex intervention. While I was mostly able to understand the languages in both areas I worked in, I was not able to speak the local

languages and translators were required. These language barriers may have impacted the data collection and analysis. However, these barriers were minimised by briefing the field team and translators on the content of interviews and focus groups and by sharing thoughts and notes after each interview with the wider team, to check understanding and nuances.

At each stage of the DPhil research, I consciously stepped back from the work, and reflected on my feelings, any preconceptions, and tried to come to each stage of the process with a fresh outlook as a DPhil student. This approach helped me to step out of traditional positivist paradigms used in medical research.

In this chapter, I have outlined the theoretical lenses used within the thesis in the process of intervention development and evaluation, and the key considerations given to my positionality and reflexivity during the research process. In the next chapter, I outline a contextual study of maternal care in two diverse districts of rural India to address my secondary research question: *What contextual factors are important in developing a conceptual map of the healthcare system for pregnant and postpartum women in rural India?*

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4

Understanding the context of care for pregnant women at high risk of cardiometabolic disorders in rural India

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4.1 Introduction

In this chapter, I outline a qualitative study undertaken in the Jhajjar district of Haryana and the Guntur district of Andhra Pradesh (described in Chapter 1). The aims of this study were to **explore the context** of maternal health in two diverse rural settings, **understand local priorities** for women and healthcare professionals around high-risk pregnancies and their long-term sequelae, in order to inform the development of **contextually sensitive strategies** to improve women's life-long health. The study was designed to answer the secondary research question of my thesis: *What contextual factors are important in developing a conceptual map of the healthcare system for pregnant and postpartum women in rural India?*

Local beliefs and practices relating to high-risk pregnancy conditions do not always align with traditional biomedical models of disease [295]. High-risk conditions such as preeclampsia are conceptualised in a variety of ways by different populations globally [295,296]. This may impact the health-seeking behaviours of women. Women's and healthcare professionals' understanding of the long-term health risks following a pregnancy complicated by HDP or GDM have not (to date) been explored in a rural Indian context. Awareness of the contextual factors relating to a pregnant woman's journey through the rural health system, is integral to developing empathy and understanding for the needs and priorities of key actors within the health system. Although integral to maternal healthcare, the views of CHWs and women, are not often included in planning women's health services in India [297][298,299]. This study was conducted to gain greater contextual understanding, and engage key stakeholders early in the intervention development process. Community engagement and involvement is key to the successful design, integration and future sustainability of complex interventions [272], and at the

heart of human-centred design methods [300]. I conducted a qualitative study to explore: a) the context of maternal and women's healthcare in two diverse districts of rural India; b) women's and healthcare professionals' understanding of high-risk pregnancy conditions, and their associated long-term health risks; c) the pathways for detection, referral, management and follow-up of high-risk pregnant women in rural India, and d) CHWs engagement with mobile technologies, and how these may be integrated effectively within the health system.

The objectives of the study were to:

- Document perspectives of key stakeholders within the health system in rural India regarding the detection, referral and life-long management of high-risk pregnant women.
- Develop a conceptual map of the health system with regards to the provision of integrated antenatal and postnatal care for women with high-risk pregnancies.
- Explore the modifiable barriers to providing integrated antenatal and postnatal care within the local health system to inform the development of a complex intervention (see Chapter 5).

4.2 Methods

4.21 Sampling & participant recruitment

A purposive sample of key stakeholders including: government representatives from the Health Department of Haryana and the Commissionerate of Health and Family Welfare, Andhra Pradesh, (responsible for commissioning maternal health services to rural populations), obstetricians, Primary Care Physicians (PCPs), CHWs, and

pregnant/postpartum women in both districts, were identified through local contacts at the George Institute for Global Health, India. Further theoretical sampling of laboratory technicians (responsible for conducting all antenatal screening blood tests in their communities) and health officials resulted from initial interviews with stakeholders. Study participants were chosen due to their direct relationship and impact upon the pregnant woman's journey from the village to secondary care, during and after pregnancy. Collecting data from a range of key stakeholders, through use of both interviews and focus groups, enabled exploration of areas of convergence and complementarity, whilst also identifying outlying cases. This was important in the process of triangulation during data analysis.

Sample Size

Guidance on sample size for qualitative studies was sought from the relevant literature [301, 302, 303]. The sample size aimed to provide adequate representation of the participant groups, whilst also ensuring the study was pragmatic, and that theoretical saturation was likely to be achieved [304]. With this in mind, the aim was to include up to a maximum of 90 participants, including eight FGDs of up to ten people, and ten in-depth interviews, across both study sites.

4.22 Conducting interviews & focus groups

Semi-structured in-depth interviews (IDIs) were conducted with government representatives, local obstetricians, PCPs and laboratory technicians. Focus Group Discussions (FGDs) were held with CHWs, and pregnant and postpartum women. From prior experience in rural India, I felt CHWs and local women were more likely to open up and converse in a group setting with their peers. Due to professional hierarchies and the

ensuing power dynamic between different cadres of CHWs, separate focus groups were held for ANMs, and ASHAs/Anganwadis. Both ASHAs and Anganwadis report (as a group) to one ANM. Focus groups with ASHAs and Anganwadis were conducted separately to ANMs, to enable them to express their views freely. FGDs started with introductions and an ice-breaker exercise to relax the group and stimulate discussion and engagement. Participants were invited to share their experiences of: 1) detecting, referring and managing high-risk pregnant women in the community; 2) the follow-up care the women receive; 3) their awareness of the long-term cardiometabolic risks associated with pregnancies complicated by HDP and/or GDM, and 4) the role of technology in the course of their work.

FGDs were also held with a mixture of pregnant women, and women (with both high-risk and uncomplicated pregnancies), who had delivered a baby within the last 2 years. The women were invited to discuss their experiences of antenatal and postnatal care in their villages, and their awareness of future health risks associated with pregnancies complicated by HDP and GDM. Interviews and FGDs were held in the CHWs' local villages, and at the place of work for government officials, obstetricians and PCPs, to minimise inconvenience. Each FGD had between six to ten participants, and lasted between 30-60 minutes.

Topic guides for each participant group were developed, and reviewed by the research team prior to use. Although topic guides were not piloted, they were iterated as the fieldwork progressed (**Appendix B**). Interviews and FGDs were conducted by myself (SN), with help of a field team assistant from the George Institute for Global Health, India, fluent in the local language. Participant information sheets and informed consent forms

were developed and translated into Hindi (Haryana) and Telugu (Andhra Pradesh). Both written and verbal information was conveyed in the local language, and each participant was asked to sign and date the latest approved version of the ICF before each IDI/FGD. Written informed consent was obtained from all participants.

Each IDI/FGD was conducted in English when possible or in the local languages of Haryanvi (Haryana) and Telugu (Andhra Pradesh), with simultaneous translation by the field team assistant. Interviews and FGDs were audio-recorded with participant consent, transcribed and back-translated from Hindi (Haryana) and Telugu (Andhra Pradesh) into English by a professional transcription company based in India. For the interviews conducted in English, I self-transcribed the interviews, all transcripts were anonymised.

Reflexivity

The importance of reflexivity in qualitative research was outlined in Chapter 3. To be transparent in my thinking processes and analysis of data, I made field notes and diary entries during and immediately after the interviews or FGDs to document my thoughts following each of the interviews and discussions. I used these notes during data analysis, comparing my initial thoughts with objective evidence from the interview/FGD transcripts. Additionally, I held debrief meetings with the field team assistant from the George Institute, India immediately following each IDI/FGD, and further discussions with my supervisor (LH) during the process of data analysis.

4.23 Ethical approval

Ethical approval was obtained from the Oxford Tropical Research & Ethics Committee (OxTREC ref: 506-18), and The George Institute Ethics Committee, India (ref: 004/2018) (**Appendix C**).

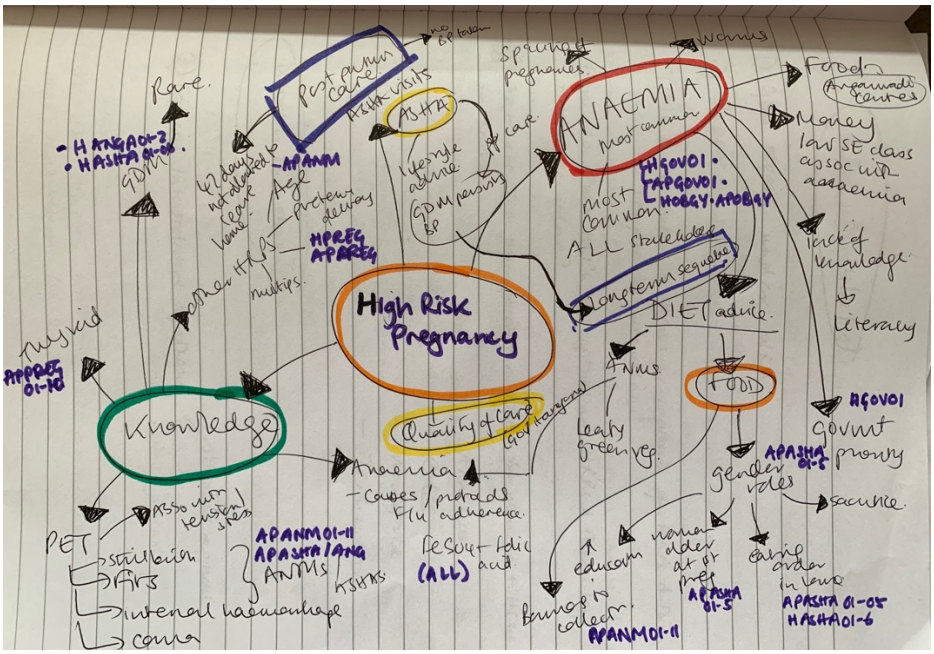
4.24 Data analysis

Qualitative studies can give rise to vast amounts of empirical data. Theoretical approaches have developed to enable systematic organisation of data, to distil the essence of these data into themes and concepts by providing structure to the process of data analysis [305]. I conducted a thematic analysis to organise, describe and interpret the data arising from the interviews and focus groups. Thematic analysis is a qualitative analytic method which can be used flexibly across a range of theoretical and epistemological approaches [306].

Firstly, I familiarised myself with the data. This was achieved by listening repeatedly to the interviews and FGDS, transcribing these data (when conducted in English), and iteratively reading and re-reading interview transcripts, meeting debriefing notes and personal diary entries. During the process of familiarisation, I started to generate initial codes within the data. Coding data is the fundamental analytical process used by the researcher in the analysis of qualitative data [307]. I was careful to maintain reflexivity and not to impose any preconceived ideas or frameworks on the data; hence, in these initial stages, I coded the data in as many ways as possible that fitted with the data. Emphasis was given to the words, language and the implied meanings within the data. I read through the transcripts repeatedly, revisiting the original transcripts several times during the process of coding, constantly comparing the codes generated to the data [308, 309] and ensuring that all perspectives were represented within the coding. I then organised these

data into themes by looking at the properties and relationships between codes. A theme captures a pattern of response and/or meaning within the data, and requires the researcher to be actively engaged and immersed in the data. To maintain theoretical sensitivity (the ability to acknowledge, examine and remain conscious of any underlying assumptions I might have brought to the research process), I was mindful of my own involvement in the process of data analysis, whilst also immersing myself in the data. Where possible, I maintained an inductive approach to data analysis; however, as well as looking for *emergent* themes within the data, I also looked for *anticipated* themes linked to the study objectives, using the approach outlined by Ziebland and McPherson (2006) [310], which acknowledges the value of exploring new areas of interest raised by respondents in addition to issues the researcher felt were significant at the start of the research process. I then reviewed the themes to check if they made sense with respect to the coded data and across the entire data set, linking codes and considering the relationship between codes, and generating a thematic 'map' using a One Sheet of Paper approach (OSOP) [310].

Figure 4.1: One Sheet of Paper Approach picture for high-risk pregnancy



During this process, I considered the phenomenon of interest and the conditions in which this occurred; for example, testing for GDM in the community. I then considered the actions or interactions of people in delivering GDM screening, whilst thinking about the key players in the health system and the complex ways in which they interact [311]. Finally, I refined the themes to reflect the overall narrative and present the results of this thematic analysis below.

Table 4.1: The steps of thematic analysis adapted from Braun and Clarke, 2006 [306]

Steps in Thematic Analysis	Actions
Familiarisation	Transcription, reading, re-reading, noting initial thoughts
Coding	Generating initial codes. Systematically collating data relevant to each code across the full data set
Searching for themes	Collating the codes into themes, and curating data into these initial themes
Reviewing themes	Creating a thematic 'map' of the analysis, checking if themes and coded extracts fit together well and explain the findings
Naming & defining themes	Refining the themes through ongoing analysis, developing the overall story of the analysis. Clearly defining and naming each theme.
Producing a report	Final analysis, relate findings back to research questions and literature, producing a report with examples to support findings.

4.3 Results

In total, 71 participants took part in seven FGDs and 11 IDIs. Participants included: three government officials; four obstetricians; four PCPs; 33 CHWs (aged 29-54); 24 pregnant/postpartum women (aged 20-35), and three laboratory technicians (see **Appendix B** for coding of IDI and FGD participants).

Table 4.2: Summary of participants in qualitative study

	Focus Groups = 7 (no: of participants)			In-Depth Interviews = 11 (no: of participants)				Total
Participant Category *	**PW**	**ASHAs/ AWW**	**ANM**	**PCP**	**OBGY**	**LAB**	**GOV**	
Haryana	1 (4)	1 (8)	1 (4)	1 (2)	1 (2)	1 (2)	2 (2)	
Andhra Pradesh	2 (20)	1 (10)	1 (11)	2 (2)	2 (2)	1 (1)	1 (1)	
No: of participants	**24**	**18**	**15**	**4**	**4**	**3**	**3**	**71**

* PW = Pregnant women; ASHA = Accredited Social Health Activist; AWW = Anganwadi Worker; ANM = Auxiliary Nurse Midwife; PCP = Primary Care Physician; OBGY = Obstetrician; LAB = Laboratory technician; GOV = Government official.

Themes and sub-themes arising from the thematic analysis are outlined in Table 4.3. In this results section, I have interwoven between themes to unfold the narrative of each of the three high-risk pregnancy conditions mentioned by stakeholders during IDIs/FGDs.

Table 4.3: Table of Themes

Themes	Sub-Themes
Priorities of care	Anaemia; Serious nature of HDP; Low prevalence of GDM.
Socio-cultural influences	Household hierarchies; Diet & alcohol; Gender roles; Cultural practices; Frustrations of healthcare professionals.
Detection & Management of HDP & GDM	Variations in screening for GDM; Lack of awareness & knowledge of GDM guidelines; Challenges to screening for GDM.
Expectations for maternity care	Routinisation of BP measurement; GDM screening and postpartum care not embedded into maternity care.
Postpartum management of HDP & GDM	Postpartum cultural practices; Responsibilities of CHWs; Lack of postpartum follow-up of high-risk women.
Professional hierarchies	Professional roles; Division of labour; Power dynamics.
Trust	Trust in healthcare professionals; Trust in health system; Trust in technology.
Long-term sequelae of high-risk pregnancy conditions	Knowledge & empowerment of women; Chronic disease management; Women's health not seen as a priority in postpartum.
Strategies to improve integrated care	Training; Task-sharing; Technology.
Quality of Care	Resources; Workforce; Dignity; Trust.

4.31 Priorities for care for high-risk pregnant women

All healthcare workers in both study sites expressed good understanding of the range of high-risk conditions seen in pregnant women in their areas, and referral pathways for further management.

"If a woman has high blood pressure or she is multigravida or she is elderly pregnancy, if she is anaemic, if she underwent previous C-section, she is considered as high risk, and she should be taken care of, and she'll be referred to a senior doctor so that the mother and child doesn't have any problems."

-ANM, Haryana

This finding was due, in part, to recent government initiatives focusing on high-risk pregnant women, and education and training programmes for CHWs. In Haryana, the government had recently established high-risk pregnancy units in every government hospital, with clear referral pathways for women from community settings to secondary care. These system-level initiatives had resulted in improvements in healthcare workers' knowledge of high-risk conditions and the need for specialist services.

"*Since the last four years…before that, there was no high risk pregnancy unit. Now we have made the different high-risk pregnancy units in which the high-risk pregnancy patients come and we give them treatment as early as possible, and they are labelled as a high risk pregnancy….So ASHAs and ANMs - they know that in our village, this is a high-risk pregnancy patient and this is a normal patient, so they get treated very early and diagnosed and they send [the women] to the higher institutes*."

- Obstetrician, Haryana

The most important high-risk pregnancy conditions identified by stakeholders in both study sites were anaemia and HDP. Due to the high prevalence of anaemia amongst pregnant women, all stakeholders acknowledged anaemia as the highest priority.

"*Antenatal cases facing anaemia is the MOST common problem…severe anaemia, moderate anaemia…MOST common problem…"*

- Government official, Haryana

Socio-cultural factors contributing to high prevalence of anaemia in women

Healthcare workers were aware of the causes of anaemia in their communities, and understood it to be preventable and treatable. The high prevalence of anaemia was intrinsically linked to wider socio-cultural factors influencing women within the communities. Government officials, doctors and CHWs in both study sites acknowledged that most cases of severe anaemia were found amongst women from households of brick factory workers (Haryana) and agricultural labourers (Andhra Pradesh), who lived on a meagre daily wage.

"Most of the anaemic patients are among those doing daily labour"

- ANM, Andhra Pradesh

CHWs reported the most common causes of anaemia were diet, poverty, and intestinal worms; however, important associations were also made between the presence of anaemia, household income, and alcohol consumption.

"Along with this alcohol consumption… if it is there in the family.. the family members do not take care of the pregnant women after consuming alcohol….whatever 200 or 300 Rupees that they earn, they spend for alcohol and do not bring much money home."

- ANM, Andhra Pradesh

Anaemia was intimately associated with household dietary beliefs and practices. In spite of frequent counselling by health professionals on diet, there was a cultural perception in

both regions that consumption of dairy products such as milk and ghee (clarified butter) would help correct anaemia.

"Patients didn't take anything related to treat their anaemia. In the villages there is plenty of milk - they think "We take milk, so we will not be having the anaemia". When the patients come and they find out their Hb [haemoglobin] is low – they say "..but I drank so much milk, so much!". They do not know that anaemia is due to iron deficiency."

- Obstetrician, Haryana

Government officials and healthcare workers reported free government schemes to provide iron folate tablets and nutritious meals to women in the antenatal and postnatal periods (up to 6 months postpartum) to address the high prevalence of anaemia. Additionally, treatments for iron deficiency anaemia, including iron sucrose injections and blood transfusions were freely available at local government hospitals. In spite of good knowledge of these initiatives amongst healthcare workers, health behaviours of pregnant women were intrinsically linked to their immediate family and household.

"They will be given food in Anganwadi centres but some of them do not take it because their husbands do not let them take… such things happen!"

- ANM Andhra Pradesh

Healthcare workers reported repeatedly counselling women in their communities to adhere to taking oral iron folate tablets both prophylactically and to treat anaemia, throughout their pregnancy and into the postpartum period. CHWs were aware of the side-effects of oral iron and had developed subtle ways of checking for medication compliance amongst women in their villages.

"They are giving reasons like they start getting pain in the limbs after using the [iron] tablets, and they feel dull.. and when we ask them how they had passed the stool they say it was normal, and then we say that they had not taken the medication.. because if they take that tablet that [their stool] would be dark in colour."

- ASHA, Andhra Pradesh

Importance of household influences on anaemia in women

Long-standing cultural and dietary practices, and the presence of household hierarchies, prevented pregnant and postpartum women from following the advice of healthcare workers. Their perceived lack of empowerment to challenge existing household dietary practices was acknowledged by healthcare staff.

"We keep telling them what food they should take, but still they should be able to know in their in-laws houses, so we should also tell the mother-in-law."

- ASHA, Andhra Pradesh

CHWs recognised the limitations of an approach recommended by the government and doctors, which targeted individual women, when most of the dietary habits and issues of medication compliance were controlled at the household-level. They acknowledged the importance of family support to guide the health-related behaviours of women.

"*We definitely call the mother-in-law and instruct her about what type of food should be given to the women and also counsel them…previously they [mother-in-law and husbands] used to not concentrate much [on the pregnant women], but these days they are looking after the pregnant women."*

- ASHA, Andhra Pradesh

The situation was further complicated by migration of pregnant women to their mother's village during the last trimester of pregnancy. Unless the pregnant woman re-registered

for ANC in her mother's village or saw a private doctor, haemoglobin (Hb) would not be routinely measured in the last trimester of pregnancy. Anaemia would also worsen with each subsequent pregnancy. This complex combination of factors led to women presenting with severe anaemia at the hospital, which had implications for maternal mortality and morbidity.

"The patient gets pregnant multiple times…anaemia will increase….sometimes the patients are such stubborn patients that even ASHA workers say: "Please come to the hospital and I will go with you to be treated",…No… The patient will not come,… She will come with Hb 3 [3g/dL]*…when she is going to die...then she will come."*

- Obstetrician, Haryana

Awareness of the serious consequences of anaemia

There was a mismatch between the importance and serious nature of anaemia expressed by government officials and healthcare workers involved in maternal health, and the perceived dangers attributed to moderate and severe anaemia in pregnancy expressed by the pregnant women themselves. This lack of understanding by pregnant women around the serious nature of anaemia in pregnancy, led to frustration amongst healthcare workers, and a sense of despondency.

"We have given them the facility; we give free transport - everything is free from the first day the patient gets pregnant to the six weeks after birth. This period is absolutely free for EVERY pregnant patient…Even transport, even medicines, each and every check-up, test, ultrasound, everything…but they...they don't use it…contraception – in spite of our repeated counselling... when they conceive, they come bleeding with 3 Hb [haemoglobin of 3g/dL]."

- Obstetrician, Haryana

Compliance with iron tablets was particularly problematic in the postpartum period. A shift to caring responsibilities for a new baby, coupled with a lack of awareness of the

impact of anaemia on their babies' growth, and ability to breast feed; resulted in women deprioritising their own health, and not taking iron tablets.

"*We'll give iron tablets till six months [postpartum] but they don't take it.*"

- ANM, Haryana

It was not an expectation or routine practice for women to have their Hb measured in the postpartum period, and as a result, women were unaware of their anaemia status after delivery.

Trust and the role of the ASHA in promoting women's health

ASHAs were uniquely positioned by virtue of the trust and rapport they had built with families within their villages to offer guidance to households on diet, lifestyle modifications and adherence to medications.

"We trust ASHA…We get a lot of benefits from ASHA."

- Pregnant woman, Haryana

ASHAs held authority in the community through influence at the household level. They expressed their ability to motivate not only pregnant women, but also their extended families.

"*We talk to them and we go on daily house visits…at some point of the day or after school, for one hour in the evening… we go to visit them and when we frequently keep checking …we keep knowing who are growing healthy and who are losing weight, and we keep visiting their houses and motivate their families…..at the time of house visit we speak to the family members who are available there mother-in-law father-in-law or any other persons and motivate them.*"

- ASHA, Haryana

4.32 The serious nature of Hypertensive Disorders of Pregnancy

All stakeholders identified HDP as an important cause of maternal and neonatal mortality and morbidity in their areas. Due to the serious complications associated with HDP, it was considered the second leading priority for pregnant women in the areas studied. Knowledge of HDP (including preeclampsia) was embedded into the education and training of all healthcare workers. CHWs demonstrated good working knowledge of the clinical signs and symptoms of preeclampsia, its complications, and the need for referral of high-risk women to an obstetrician.

ANM 1: "If the BP raises there maybe brain haemorrhage [stroke], there is a chance of patient's death."
ANM 2: "..and the baby may be a stillbirth."

- ANM focus group, Andhra Pradesh

"Even the baby might suffer if mother has high BP…the sac may dry up."

- ANM, Haryana

As a result of healthcare professionals' and women's good knowledge of HDP and its complications, measurement of BP had become routinely embedded into ANC. It was both an expectation and an experience of pregnant women, to have their BP measured at least monthly during the antenatal period at the primary health centre (PHC), either by the ANM or the doctor.

All healthcare workers recognised raised BP could be detected for the first time during labour, with serious consequences. Although there was good intellectual understanding of the serious complications of HDP, with some healthcare workers having witnessed fatal complications of HDP in women and their babies; there was a paradoxical tendency amongst doctors to normalise high peripartum BP as a sign of the "stress" of giving birth, rather than a pathology that required medical attention and follow-up.

"….at the time of delivery, there will be increase in BP in most of them [the women] and that too due to apprehension, stress….all of the women will have that"

- Obstetrician, Haryana

Similarly, CHWs recognised HDP could affect women in subsequent pregnancies, but they attributed this finding to stress rather than a pathology associated with pregnancy.

"*It not compulsory that she should get high BP in the next pregnancy too [if woman has high BP in pregnancy],.. it comes only with the mentality of the patient, depending upon their tensions..*"

- ASHA, Andhra Pradesh

Health professionals' roles in relation to Hypertensive Disorders of Pregnancy

Government officials, obstetricians and PCPs felt it was the role of ANMs and doctors to detect HDP and measure BP during and after pregnancy, rather than ASHAs. They saw the role of the ASHA to be limited to motivating and counselling women about their BP and lifestyle modification.

"*Because ANM - they do the courses – they have a 2-3 year course. And ASHAs are just 10th plus [secondary school education]. They don't have that type of training.*"

- Obstetrician, Haryana

Whilst the majority of home visits to pregnant and postpartum women, were conducted by ASHAs, and ASHAs expressed a willingness to learn new skills, home-based BP measurement was not performed. Pregnant women and other types of healthcare professionals rationalised this by concluding that "*ASHAs don't take BP*". Obstetricians saw their main role in the management of HDP to be centred around prescribing antihypertensive medication, managing labour and delivery, and providing advice on when to stop antihypertensives.

Postpartum cultural practices and care for women with hypertensive disorders

In both study sites, following birth, women were not permitted to leave their house (except for medical emergencies), for at least 40 days. Home visits by the ASHA were the only contact with health services that most women had in the postpartum period. They reported that they derived a great deal of benefit from these visits. If the ASHA felt there was an emergency requiring hospital care, the woman would attend based on her advice.

"I came home on the third day, then on seventh day ASHA came to me. She used to come every week and check baby's weight, temperature. She used to do check-up for me and also she used to give necessary advice."

- Pregnant woman, Haryana

Although, obstetricians and PCPs understood that it was the responsibility of ANMs to deliver postpartum care to women, in practice, ASHAs delivered the majority of postpartum care.

"They might have some problems [after delivery], the ASHA worker does six visits, we usually do one visit, but for high risk cases, we do more visits."

- ANM, Haryana

Postpartum care for women with hypertensive disorders

Some pregnant women reported that, despite having had normal BP during pregnancy, they had raised BP during labour and were discharged with medications. While they were told by obstetricians to take medication until their BP normalised, women from more rural areas, particularly those who delivered at government hospitals, were not routinely followed up in the postpartum period, sometimes with serious consequences.

"Even patient having eclampsia, she went home even having eclampsia and when she came, she was no more. We can't do anything for such patients."

- Obstetrician, Haryana

Whilst healthcare workers recognised the potentially serious consequences of preeclampsia in the postpartum period, women were less aware. In contrast to the antenatal period, women did not have the same level of expectation for having their BP measured postpartum, nor did they express a sense of urgency after being diagnosed with HDP.

" *I delivered on Friday evening at 8pm. They planned to discharge me on Monday but my BP raised, so they didn't discharge me…so I came home against their advice on Monday…now they are not giving birth certificate to my child."*
"Did they give you medicine for BP?"
"Yes…for 7 days…I didn't go for another check-up."
"*Did you get your BP checked after that?*"
"*No… I didn't have any problem.*"

- Pregnant women focus group, Haryana

4.33 Low prevalence of Gestational Diabetes Mellitus

Women with GDM were recognised as high-risk by all stakeholders. In spite of screening for GDM, the condition was rarely seen in either study site, although both primary and

secondary care doctors acknowledged that the landscape for GDM was changing within their communities, with more women choosing to have babies at a later age, and a trend towards overweight and metabolic problems earlier in a woman's life.

"*The scenario will change in a few years or so because of the fast food and PCOS [polycystic ovarian syndrome] types…. now there are so many of gestational diabetes-type patients coming."*

- Obstetrician, Andhra Pradesh

The screening procedures for GDM differed both within and between the study sites. The most frequent screening method was a random, non-fasting, capillary blood glucose, performed by the laboratory technicians at the PHC. The lack of consistent screening practices for GDM, coupled with a lack of awareness of the serious consequences of GDM amongst women and healthcare professionals, resulted in tragic narratives amongst those few women who were eventually diagnosed with GDM.

"*During my first pregnancy I did not have any gestational diabetes.. my second pregnancy was delayed…suddenly doctor has seen and said that the baby had died within the womb…I did not understand anything…I was shocked thinking why did this happen to me?.. then I knew that baby dies within the womb if the pregnant woman is diabetic..."*

"…Next time when I was pregnant I underwent sugar test and then was found out to be diabetic during fourth month of pregnancy…and the baby had neural tube defect…even this is also because of sugar... baby did not have spine at all and there are many gaps in the spine…even if the baby is born how can he sit?...Then [in next pregnancy], the doctor advised me to use metformin from the beginning…I lost hope after the second baby…I conceived after three months and my blood sugar was normal… and the baby was fine.. all these things happened just because of sugar."

- Postpartum woman, Andhra Pradesh

In contrast to screening for HDP, GDM screening had not become embedded into maternal health services. Most women were aware of testing for "high sugar", but were unaware of the consequences of raised blood glucose levels for their pregnancy and baby. Women did not expect to be screened for GDM. As a result, inconsistent screening practices had not been questioned by pregnant women.

"*I was tested twice before food and after food… in seventh month… Lab tech has done the test."* . I: "*Did they give you any sugar drink*?". "*No…I ate the roti which I've brought from home*." I: "*Did they do sugar tests for [all of] you?"*. PW2: "*No"*
PW3: "*I had my Hb test done here [at PHC] but not sugar test. I had blood sugar tests done at Rohtak [Government hospital] at 3-4 months*."

- Pregnant women focus group, Haryana

The gold standard test for GDM screening, the Oral Glucose Tolerance Test (OGTT), was not commonly performed in primary care, and was limited to secondary care settings. However, even within secondary care settings, testing for GDM was not always conducted.

"Every woman isn't tested for blood sugar. Every woman is sent to the GH [General Hospital], *but even there, blood sugar isn't tested."*

- ASHA, Andhra Pradesh

There were several barriers to performing OGTTs in rural areas. CHWs reported that women in rural areas, particularly labourers, were unlikely to be able to wait for two hours for an OGTT and have repeated venous blood tests, due to demands on their time.

"*We can do [the OGTT]…but it will take time…Those two hours of waiting, taking a sample again… and all that.. I've seen a patient tested there… it takes two hours for each patient….. waiting for hours is difficult in villages… There will be people who go to work."*

- ANM, Andhra Pradesh

Further barriers to GDM screening with an OGTT, included lack of laboratory staff and infrastructure to check venous blood glucose at specific timings (0, 1 and 2 hours), and a lack of availability of oral glucose solution and drinking water in rural community settings to administer tests. The sheer volume of pregnant women attending for ANC in both districts and the need to screen every woman, also had considerable implications for the healthcare workforce.

"OGTT is very useful in pregnancy but we don't have that because this is a rural area and we don't have that glucose and all… and we have to do that hourly [blood test] and then 60 minutes after that.."

- Obstetrician, Andhra Pradesh

In response to these challenges, locally developed GDM screening practices were being implemented by laboratory technicians. For example, women were asked to attend the PHC with a roti (a type of Indian bread), and the laboratory technician would take their capillary or venous blood sample before and after eating the bread. While these practices did not follow evidence-based guidelines for the diagnosis of GDM, they were acceptable to local women, and helped identify outlying cases.

Healthcare workers were not all aware of the 2018 Government of India guidelines for GDM screening in rural India, using a non-fasting OGTT and 2-hour capillary blood glucose. Obstetricians and PCPs could see the value of conducting community-based

screening for GDM, but felt that ANMs (rather than ASHAs) would be the best people to conduct these tests, as they had been trained in capillary blood glucose measurement and could conduct the test at the sub-centre. They viewed the role of the ASHA as motivating women to have the tests completed, and questioned their legitimacy and ability to conduct screening tests and interpret results.

"…because it's like… they [ASHAs] don't have much knowledge about the subject and all and er… that can be misused also … the level of accuracy, that can also be doubted."

- Primary Care Physician, Haryana

In contrast, ASHAs were eager to improve their knowledge and clinical skills, with readiness to take on additional duties, particularly if these would help elevate their knowledge, status or financial standing.

"We can do the blood pressure checking in the digital apparatus. We don't have experience in checking blood sugar levels." I: "Is it something you want to learn?" ASHA: "Yes mam."

- ASHA, Haryana

Factors impacting the medical management of Gestational Diabetes Mellitus

Decisions about medical management of women with GDM were made by obstetricians, who subsequently led their care and follow-up. There were regional variations in prescribing insulin for GDM, largely dependent upon the presence of refrigerators and ability to conduct glucose monitoring within villages. In Andhra Pradesh, particularly in the more affluent villages, where villagers could afford fridges, insulin therapy was prescribed by obstetricians.

"There is a lot of awareness here.. this is a rich village.. there is no one who doesn't have a fridge…. Already older patients have glucometers with them.. most of them have relatives staying in America."

- Laboratory technician, Andhra Pradesh

Prescribing insulin was not based on an individual woman's wealth, but on the collective affluence of the village in which she lived. In south India, it was customary to share village resources amongst households and, even when village women did not own a fridge of their own, obstetricians still prescribed insulin to women with GDM.

"*Actually…they [women with GDM] should keep that [insulin] in refrigerator…so if at all they are not having refrigerator, they will be using whoever nearby has the refrigerator in the nearby houses…they will be preserving that [insulin] in their houses*".

- Obstetrician, Andhra Pradesh

In contrast, in Haryana, the treatment of choice for GDM was metformin, because it was available free of charge at government healthcare facilities, and did not require the same intensity of blood glucose monitoring as insulin.

"Metformin is free of cost here for patients…The patients are poor, first they want to come here [government hospital] as the services are free. If the doctor is not available, or the medicine she has to take, then she goes to private sector…otherwise the patient comes here."

- Obstetrician, Haryana

Postpartum care for women with Gestational Diabetes Mellitus

Due to the low prevalence of GDM reported at both sites, standardised postpartum follow-up was not being practised at either site. There was a lack of awareness amongst women and healthcare workers of the need for routine postpartum blood glucose testing. Women

without GDM explained their lack of awareness by saying "*None of us have sugar so we do not know what will happen later*" and, those with experience of GDM, reported they did not engage with long-term follow-up after their blood glucose returned to normal after delivery.

"*I stopped that [medicine] because it [GDM] was cured…after I delivered they have done sugar test two to three times and there was no sugar detected in those tests."*

- Pregnant woman, Andhra Pradesh

Health professionals involved in screening for GDM asked women to return to have their blood sugar checked, but this was at the woman's discretion.

"*They come to me after delivery…at most two to three people [with GDM] came to me after delivery…they come to me one and half months after delivery…we advise them to come every month for the [blood sugar] test but it is their wish*."

- Laboratory technician, Andhra Pradesh

4.34 Knowledge of long-term sequelae of high-risk pregnancies

Whilst the prevalence of HDP and GDM was low in the areas studied, all types of healthcare worker acknowledged a trend towards chronic diseases, such as hypertension and T2DM, in women over the age of 30-40 within their communities.

"Now-a-days, blood pressure and diabetes have become so common that we check their BP and sugar compulsorily [in adulthood]."

- ANM, Haryana

Healthcare workers and government officials attributed the increase in chronic diseases in women to prioritisation of other aspects of family and work life, and a failure to attend to their own health.

"*They got so busy in their family life, taking care of the kids and the family and even in the rural background…they work in the fields also… and the health is the secondary thing for them, and slowly the things start getting bigger [worse] for them and they don't even go to the hospitals*."

- Primary Care Physician, Haryana

Obstetricians, PCPs and ANMs were able to associate the presence of HDP and GDM with an increased likelihood of recurrence of these conditions in subsequent pregnancies. They acknowledged that, for most women, these issues resolved soon after delivery. Only one obstetrician observed a link between these high-risk conditions and early onset of hypertension and diabetes.

"*Those who are having pregnancy induced hypertension or gestational diabetes after delivery, their BP and all sugar levels will be reduced for some of them…but in some of them they may continue…only few of them will continue.. but the thing is they get the diabetes and hypertension early in the life not at the older age but a bit earlier they are more prone to get those this is a bit earlier.*"

- Obstetrician, Andhra Pradesh

However, ASHAs, by virtue of living within their communities and having continuity of care throughout a woman's life, noticed links between high-risk conditions in pregnancy and the life-long health of women in their villages, even taking the practical step of offering health counselling to affected women.

"*There are chances she might have problems later in her life.. like heart attack, brain stroke. BP keeps on coming on and off."…. "We can advise yoga, regular usage of medicines, proper diet."*

- ASHA, Haryana

Women were unaware of the associations between high-risk conditions in pregnancy and their long-term health. Whilst women expressed a desire to feel more empowered and educated about high-risk pregnancy conditions that might affect their baby, they were less concerned about the impacts of these conditions on their own health.

PCPs reported offering repeated counselling to women in their communities about chronic diseases, the need for adherence to medication and regular follow-up care for anaemia, hypertension and diabetes; however, women often ignored their advice, presenting to health services as an emergency.

"They come to us [in primary care] and they say "just give something" and just symptomatic…and we keep on saying - you need to go to the civil hospital and you get yourself investigated for the this thing [diabetes]… but they keep on delaying the things until it becomes an emergency. That is a habit here."

- Primary Care Physician, Haryana

The need for improved chronic disease detection and management for women was acknowledged by all stakeholders, and had become the focus of a new NCD programme launched by the Government of India. Obstetricians and PCPs outlined the scheme, which was being operationalised at the level of the PHC, targeting women after the age of 30 years.

"This NCD scheme is for all women 30 plus [years].. now 27 plus [27 years] people are also included in this program...it is really concerned about diabetes, hypertension, breast cancer, cervical cancer…whatever it may be...there, in the PHC, medical officer will give the treatment...in case it is high risk [patient] they [primary care doctors] refer to the secondary or tertiary care units."

- Government official, Andhra Pradesh

The role of traditional healers in women's health

The desire for "quick fix" remedies for chronic diseases, and a reluctance to take life-long medication (even if free of charge from government hospitals), resulted in women exploring traditional healing modalities. PCPs expressed their frustrations with this approach, viewing traditional healers as "quacks", rather than fellow health practitioners having a place in the health system.

"They do not want to take anymore medicine – they are cured. Otherwise, there is quackery – they go to quacks….like the advertisements, like miracles will happen….and nowadays on TV you might see a whole campaign is running…"Use this, you can get relief from diabetes and use this and you get relief from….". Quackery is also adding onto our burden of this diabetes and chronic diseases."

- Primary Care Physician, Haryana

4.35 Impact of quality of care on women's health-related choices

Quality of maternal health services was an important factor influencing decision-making of pregnant women, and recognised by CHWs to be central to women's compliance with medications and their health-seeking behaviours. The issue of **quality** was intimately connected to **trust** in the health system; for example, it was a common perception that iron tablets provided by the government were not as effective as those purchased from private hospitals/pharmacies.

"*They don't take most of them [tablets] saying it doesn't taste good…especially the women who are anaemic…the tablets look exactly like the tablets that has been given in the private hospital…even if we explain to them that both are same, they don't take."*

- ASHA, Haryana

Women also viewed giving birth in a government hospital as problematic, due to perceived low quality care, overcrowding and lack of dignity. This often resulted in out-of-pocket expenditure to attend a private hospital, placing further burden upon household economies. Once admitted, women, being unable to tolerate the government hospital environment, self-discharged before it was medically safe.

" I didn't feel good in the hospital…..there were so many people around me. I felt uneasy and discomfort...so I came home….there were many toilets, but there were 20-25 women who have delivered in the same ward. I didn't feel good."

- Pregnant woman, Haryana

The lack of staff and resources in government hospitals were acknowledged by Government officials and obstetricians. Acute shortages of obstetricians in rural areas, added significant pressure on the few dedicated obstetricians continually serving in rural district hospitals, creating a palpable sense of helplessness.

"*I want my patients [to be] admitted here for eclampsia – I can treat here, but if I am alone…I…We can't do – I can give the service.. but with my access…if the baby dies, this is my fault, not the patient, and that I can't do [tolerate]…Manpower is less."*

- Obstetrician, Haryana

Severe workforce shortages of obstetricians in government hospitals, affected the ability to provide high-quality, 24-hour obstetric services, particularly in Haryana. In spite of both district and national-level schemes to incentivise working in rural areas, there were still many unfilled positions for obstetricians. This was due, in part, to the rural locality, and the lack of good schools and facilities for the families of doctors serving these areas.

"Actually at some facilities we have a shortage of staff nurses…on the other side gynaecologists are very short – ACUTE shortage of gynaecologists. Especially at district hospitals – we have only one gynaecologist. So chances of 24/7 caesarean services , tertiary services, crucial care – that is really a big challenge to manage with one gynaec."

- Government official, Haryana

4.36 Strategies for improving care for pregnant women at high-risk of future cardiometabolic disorders

Acknowledging workforce shortages affecting obstetricians, national and regional strategies were being implemented to share responsibilities for providing women's health services between the community-level and secondary care. These strategies included early identification of high-risk pregnant women at the time of registration for ANC; use of a national online portal for ANMs to record key performance indicators relating to ANC and PNC provision - known as 'ANM Online' (ANMOL), and provision of mobile tablets (iPad-like devices) to ANMs to enable more effective community-level data collection related to ANC.

Tablets were viewed as a symbol of status and power in the professional hierarchy of the rural health system, and while ANMs valued having one, they expressed their frustrations maintaining up-to-date paper-based records at their sub-centres in addition to completing online data entry.

"It feels good [using a mobile tablet]….*but now it is burden to us because we have to enter in the tablet and also in the physical register. It is a double work."*

- ANM, Andhra Pradesh

Although ANMs acknowledged the negative impact of data entry on their perceived workload, some (but not all) ANMs felt uneasy about providing ASHAs with tablets, and the potential impact of task-sharing duties on their professional relationship. Others felt it would help reduce their workload, and were open to task-sharing.

"*If the ASHA is provided a tablet, would that help ANM?*
ANM 1*: It is our work, so we should do it.*
ANM 2*: If ASHA does that, we might lose our job.*
ANM 3*: It will reduce our work. It will help us."*

- ANM focus group, Haryana

In contrast, PCPs recognised the value of sharing data entry tasks with ASHAs, using tablets. They felt increased administrative duties associated with data entry, had reduced their ability to provide patient-facing services in women's health. For example, in Haryana, PCPs had been given tablets to complete data entry for a national tuberculosis programme, a role, they felt could be more suitably conducted by other members of the healthcare team.

"*This system has even increased more our work...now we have to make the data entry for each and every patient, then we have to do computer maintenance…because everything is responsibility of the doctor. If we will not do the data entry, then that will be our fault that you have not done this…We see the patients also…Otherwise one or another operator, ASHA worker, or other person should be there to do the data entry - so we can see the patient and give the treatment.*"

- Primary Care Physician, Haryana

ASHAs were keen to engage with technology, saw its value in reducing workload for both themselves and others, and felt confident of their ability to use tablets.

"We will take some time in the beginning, but we will enjoy using it [mobile tablets] *later."… "It would be less work…because in case we forget something we can immediately refer to it…"If we do everything online it will be easier."*

- ASHA, Andhra Pradesh

4.37 The role of technology in healthcare provision in rural India

All stakeholders acknowledged the important role of technology for identifying and targeting problems in maternity services, improving information flow, and capturing trends in maternal mortality, thereby strengthening the maternal health system.

"Actually technology really helps to find out the problems – and if we find out the problems THEN we get the solutions for that."

- Government official, Haryana

Government officials recognised the importance of collecting real-time, community-level data from ASHAs, who knew what was happening on the ground, in order to improve high-risk pregnancy outcomes.

"*Actually, ASHAs and ANMS are participating in all services and we need to contact them regularly – especially ANMS. Because they have contact with ground workers – the ASHAs*."

- Government official, Haryana

Government officials and PCPs saw the importance of having information systems which enabled data capture and were interoperable within existing systems, but also enabled communication with the CHWs on the ground to allow them to target high-risk women.

Stakeholders accepted there were limitations to using mobile technology in rural settings. Government officials, doctors and CHWs felt that future strategies utilising mobile technology, should take into account health professionals' workloads, availability of mobile signal and electricity (to charge the mobile devices), interoperability of the new technology within the existing health system, with PCPs expressing their interest in being involved in the design of future interventions.

"If there is a coherence and everything is done digitally, it shouldn't double our work."

- ANM, Haryana

"No we feel open to it…technology should be used…and…it should be used according to us [with our input]."

- Primary Care Physician, Haryana

4.38 Building a conceptual map of priorities & strategies for high-risk pregnant women

This qualitative study helped me develop an in-depth understanding of the context of care for high-risk pregnant women in rural India. Understanding the priorities of care for key stakeholders and drawing upon the findings of this study, I was able to identify strategies and areas for intervention for the provision of integrated life-long healthcare for high-risk pregnant women. With this in mind, I created a conceptual map of the maternal health system in rural India, focusing on the three priority conditions identified in the study

(Figure 4.2). As an extension of the conceptual map, I identified barriers and facilitators at different levels in the health system for each of the three priority areas (Table 4.4).

Figure 4.2: A conceptual map of health system priorities for high-risk pregnant women in rural India

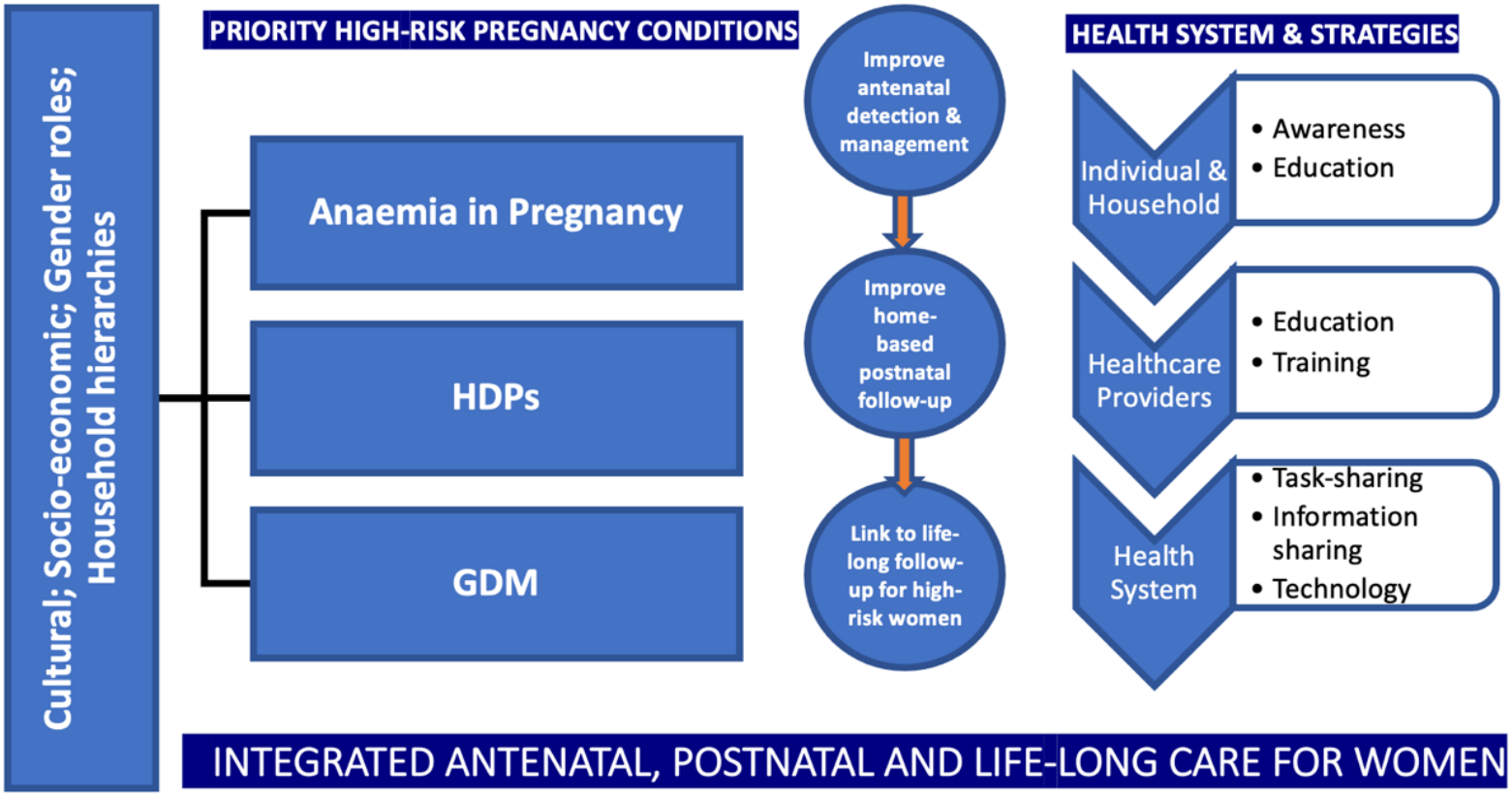


Table 4.4: Barriers & facilitators to provision of integrated care for women

Priority area	Level of Health System	Barriers	Facilitators
Anaemia	Individual/ household-level	Lack of awareness of serious nature of anaemia/non-compliance with iron tablets	ASHAs have influence at household level, providing guidance on dietary practices and compliance to iron tablets
	Provider-level	Need for improved detection & management of anaemia in last trimester (as pregnant women move location)	ASHAs visit all pregnant women in their village throughout pregnancy and postpartum, even after migration
	Provider-level System-level	ASHAs unable to detect anaemia or advise woman on referral if needed in the postpartum period	ASHAs conduct postpartum visits & are confident in their ability to learn new skills
HDP	Provider-level, System-level	Lack of postpartum BP measurement; ASHAs not trained to measure & interpret BP	Antenatal BP measurement is routinely embedded in practice & is expectation of pregnant women ASHAs conduct postpartum visits and are confident in their ability to learn new skills
	Individual/ household-level	Lack of knowledge of long-term cardiometabolic sequelae of high-risk pregnancies	Healthcare workers & women keen to educate & empower themselves about high-risk conditions
GDM	Provider-level	Lack of knowledge of Government of India GDM guidelines	Willingness for healthcare workers to learn and operationalise Government's guidance
	System-level	Lack of standardised testing for GDM; Lack of equipment/resources	Government of India have launched GDM guidelines & willingness to operationalise GDM screening in rural areas

The conceptual map and the barriers and facilitators to providing integrated care to high-risk pregnant women, identified through the contextual study, were used as the basis to design a complex intervention for pregnant and postpartum women in rural India (Chapter 5).

4.4 Discussion

This qualitative study explored the views of key stakeholders involved in maternal health in two diverse rural districts of India. In both regions, stakeholders unanimously agreed that due to its high prevalence and impact upon maternal mortality, anaemia was the highest priority condition affecting pregnant women. These findings are supported by several studies highlighting the high prevalence of anaemia amongst Indian women of reproductive age [312–316], and in alignment with national government priorities [317]. Detection and referral pathways for pregnant women with moderate to severe anaemia were well established in the districts studied, and known to healthcare workers. The national Anaemia Mukt Bharat (an Anaemia-free India) campaign has further highlighted the importance of strengthening pathways for early detection, monitoring, referral and management of anaemia in rural areas, and provided free resources and medications to meet a set of key performance indicators relating to anaemia in pregnancy across India [317].

This study revealed healthcare workers were aware of the complex social, economic and cultural issues impacting the high prevalence of anaemia. CHWs, in particular recognised that health-related behaviours of pregnant women were influenced by their households and wider community, and acknowledged the limitations of government strategies which

targeted individual behaviour change in pregnant women. These findings reinforce the need to move away from exclusive and individualised health counselling of pregnant women, towards more holistic behaviour change interventions involving the household and embracing the wider community. This study highlights that strategies to address anaemia in pregnancy need to acknowledge the complex socio-cultural and gendered influences impacting the condition in women. This in agreement with the findings of Chatterjee and Fernandes [318], who recognised the importance of adopting anaemia awareness programmes that reached the family, and communities of pregnant women [318]. Similarly, a quantitative evaluation of a large national data set found that factors affecting prevalence of anaemia in women of reproductive age in Ethiopia clustered around the individual factors, as well as household and community-level influences [319].

Cultural practices highlighted during this study significantly impacted on continuity of care and engagement of women with health services, particularly in the postpartum period. Migration of pregnant women during the last trimester resulted in gaps when identifying and treating anaemia prior to labour. The practice of staying indoors for 40 days after delivery, further prevented women from engaging with health services during a critical time for both mother and baby. A constant 'health service presence' throughout this period were ASHAs, who visited all pregnant women within their village, regardless of migration or postpartum practices, and had inspired trust within their communities. However, as ASHAs were not trained to identify anaemia or measure BP, and unable to triage women in the home environment, there were still significant barriers to early detection and management of high-risk women in villages. Models of CHW-led home-based care are feasible and acceptable both within the context of pregnancy [212,231,320–325] and chronic disease management [202,326–328]. While home-based, CHW-led interventions

would require adequate education, training and support; task-sharing with CHWs was identified by doctors as a potential strategy to address workforce shortages in women's health. From the findings of this study, ASHAs seem well placed to deliver such interventions (particularly in the postpartum period), and to offer health-related counselling at the household level.

Several knowledge-practice gaps were identified in this study. Practices relating to antenatal screening for GDM were inconsistent both within the districts, as well as across study sites. The Government of India launched their national guidelines for antenatal and postnatal management of GDM in 2018 [329]. Whilst this guidance offers a pragmatic solution to community-based testing for GDM, it had not been fully operationalised in the study settings. There were still significant barriers to GDM screening in the community, including incomplete knowledge amongst healthcare staff about the clinical guidelines and diagnostic criteria for GDM, inadequate postpartum follow-up for women with GDM, and lack of awareness of the long-term consequences of GDM. Women, who were unaware of the significance of GDM on their pregnancies and future health, did not have the level of knowledge to question variations in practice. There were several practical and logistic issues associated with performance of OGTTs in the community, including waiting times and lack of lab staff to measure blood glucose. This study revealed that operationalisation of the Government of India GDM guidelines would require health system strengthening through provision of training, diagnostics, workforce and medications for GDM and investment at the level of the primary health centre. GDM has been a key focus of research and funding in the Indian sub-continent [330–332]; however, most prior research has been conducted in urban hospital settings [333–338]. This study revealed that GDM is a low priority in rural areas studies due to its low prevalence. Whilst inconsistencies in screening

might account for some of these findings, it is clear that rural women differ from urban and semi-urban populations in characteristics such as BMI, nature of their work and socio-economic status [339]. Undernutrition and its association with anaemia, was identified as a key issue affecting pregnant women in this study, rather than overweight (associated with GDM), seen in urban and semi-urban settings [340].

With few exceptions, healthcare professionals and government officials were unaware of the links between high-risk pregnancy conditions such as HDP and future CMDs. This contrasts with findings of a study of health worker's knowledge of the links between preeclampsia and future CVD in a Nigerian teaching hospital, which revealed good knowledge of future cardiovascular risk amongst doctors, with lower levels of knowledge amongst nurses, midwives and CHWs [341]. However, in keeping with the findings of this study, the need for risk-reduction training for health workers to counsel women with HDP about their long-term cardiovascular risk, was advocated.

Workforce constraints were identified as a significant issue affecting in particular obstetricians, but also PCPs. Workforce shortages in secondary care impacted provision of 24 hour obstetric services, and pregnant women's perceived quality of care at government hospitals. In primary care, doctors felt overwhelmed with administrative tasks. Task-sharing with CHWs was identified as one strategy to free the time of doctors. All key stakeholders saw the value of mobile technologies for collecting community-level data relating to high-risk pregnant women and providing a means of communicating and sharing information between the ground-level to government offices, and enable timely response to local emergencies. Stakeholders however, raised concerns that such technologies would need to ease rather than increase workloads of CHWs, designed in

partnership with local doctors, be interoperable within the existing health system and free the time of doctors for patient-facing duties.

4.41 Strengths and limitations

Strengths of this study include the rigorous approach to the design and methodology. Trustworthiness of data analysis was achieved through using well established research methods. In addition, I spent time (one month) immersed within the research environments over the course of the study, getting to know the communities and living and working alongside CHWs and doctors in the areas studied. I conducted peer debriefing meetings with study staff following each IDI and FGD and triangulated my findings by collecting data from a variety of sources, in a variety of ways and discussing findings with colleagues during debriefing meetings and comparing these to my field notes. Conducting interviews in two diverse states in India, enabled greater generalisability of findings across rural areas of India. Different stakeholders participated in the study, which provided a wide range of opinions and sources of data from which to form a conceptual model of the health system for women in rural India. Data saturation was achieved at both study sites, due to the more than adequate number of study participants.

While I used elements of theoretical sampling and constant comparison in my approach, I was not completely naïve to the context, which prevented a purely inductive approach to data analysis. I practised reflexivity by being mindful of my thoughts and documenting them in my field notes, which enabled me to gain distance from my original ideas and the data. Most IDIs were conducted individually; however, in Haryana, PCPs, obstetricians and laboratory technicians requested to be interviewed in pairs.

4.5 Conclusion

The key priorities for care, and the experiences of women and healthcare workers in both rural areas were similar. This study supports the need for strengthening community-level strategies to address the escalating burden of high-risk conditions in pregnancy and their long-term sequalae, by targeting important knowledge to practice gaps in the provision of integrated care throughout a woman's life-course. At the individual and household-level, greater awareness of long-term risks associated with high-risk pregnancy conditions is needed. Further education and training for healthcare workers is required to meet the newly operationalised guidelines for GDM, and to screen, detect, refer and counsel high-risk pregnant women both during and after pregnancy. The study further highlighted task-sharing with CHWs and use of mobile technologies, as potential strategies for health systems strengthening. In the contexts studied, a complex intervention for pregnant women at high-risk of future cardiometabolic disorders, would also need to take into account the community's priorities relating to the high prevalence of anaemia in pregnancy in order to be acceptable and sustainable.

This study has highlighted the important contextual factors influencing the provision of integrated antenatal, postnatal and life-long care for women in rural India. The study culminating in a conceptual map of the health system, and by outlining the barriers and facilitators in the health system that would need to be addressed by a complex intervention, which will be discussed in the next chapter.

"Behaviour precedes belief - that is, most people must engage in a behaviour before they accept that it is beneficial; then they see the results, and then they believe that it is the right thing to do...implementation precedes buy-in; it does not follow it."

- **Douglas B. Reeves**

5

Theory-informed design & development of a complex intervention

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5.1 Introduction

Chapter 4 explored the views of key stakeholders relating to high-risk pregnancies and their long-term sequelae in two diverse districts of rural India, concluding with a conceptual map of the rural maternal health system. Three high-risk pregnancy conditions that would benefit from a complex intervention, were prioritised by stakeholders for different reasons: anaemia (due to its high prevalence), HDP (due to their serious nature), and GDM (due to the need for improved screening and follow-up practices and to operationalise new government guidelines). The next stage of the MRC Framework for the development of complex interventions includes identifying relevant theory and modelling processes and outcomes [66].

For new practices around the three priority conditions to be implemented in the health system, individual and collaborative behaviours of key stakeholders would require change. For this to occur, three preconditions must be met: a) actors in the health system must have the **psychological and physical ability (Capability)** to enact the behaviour; b) they must have the **reflective and automatic mechanisms (Motivation)** that activate or inhibit the behaviour, and c) they must have the **physical and social environment** that enables or restricts the behaviour **(Opportunity)** to occur [67][342]. For example, in relation to improving home-based, postpartum anaemia screening, ASHAs must understand the causes of anaemia, counsel women on their diet and medication adherence (psychological capability), have the skills to measure Hb in a woman's home (psychological and physical capabilities), have belief in their ability to perform the home-based reading within their professional role (reflective motivation), and the equipment and support to enable the

delivery of postpartum care (social and physical opportunities). These three components of behaviour change are at the heart of the COM-B/Behaviour Change Wheel (BCW) framework [67,343]. The COM-B/BCW framework was formulated to enable systematic embedding of behaviour change theory into the process of intervention design [67], and can be used synergistically with the Theoretical Domains Framework (TDF) [68,282,344], as outlined in Chapter 3. These frameworks have been used to design interventions successfully and systematically in a wide range of health and policy areas [345–347].

Interventions that change behaviour within a health system involve many interacting components which can have potentially complex implications [348]. The contextual study revealed several modifiable health system barriers to providing integrated antenatal and postnatal care, and ongoing follow-up for high-risk pregnant women. In this chapter, using relevant theory, I explore these modifiable barriers influencing individual and collective behaviours of actors within the rural health system, using qualitative data from the contextual study (Chapter 4). The aim of this chapter was to design and develop a theory-informed complex intervention and a model of care that could be implemented and evaluated, adopted for other contexts, and potentially extended into the years following pregnancy, to answer the secondary research question of my thesis: *How can theory be used to inform the design and development of a complex intervention and refine this for testing?*

5.2 Methods

The stages of theory-informed intervention design start with behavioural analysis of the problem(s) to be addressed by an intervention, and progress to selecting appropriate behaviour change techniques and implementation strategies to bring about the desired

behaviour change. Following a systematic, theoretically-guided process for intervention development, ensures transparency in the development process, provides clarity regarding intervention components, and enables development of programme theory and a logic model (outlined at the end of this chapter) [272]. Use of theory further assists in effective evaluation of the intervention (Chapter 6), by providing a deeper understanding of the underlying mechanisms through which the intervention has its effect.

In the first stage of intervention design, I formulated a 'behavioural diagnosis' by conducting a barriers analysis (barriers and facilitators to providing integrated and continuous antenatal, postnatal, and on-going follow-up care for high-risk pregnant women in rural India), using data from the contextual study (Chapter 4). Modifiable barriers for each of the three priority conditions, were mapped to the COM-B/TDF domains to identify **theoretical constructs for behaviour change** within the health system. From this exercise, **target behaviours** for each priority condition were identified. The TDF was used to illustrate more precisely the behavioural constructs to be targeted within the COM-B model [349] (Table 5.1).

Table 5.1: Theoretical Domains Framework (TDF) mapped onto the Capabilities, Opportunities and Motivations (COM-B) model

COM-B components	Associated TDF domains
Capability: Physical	Physical skills
Capability: Psychological	Knowledge; Cognitive and interpersonal skills; Memory, attention & decision processes; Behavioural regulation.
Opportunity: Social	Social influences
Opportunity: Physical	Environmental context and resources
Motivation: Automatic	Reinforcement; Emotion
Motivation: Reflective	Social/Professional role and identity; Beliefs about capabilities; Optimism; Intentions; Goals; Beliefs about consequences.

In the second stage, I selected intervention functions and policy categories pertaining to each target behaviour and the associated theoretical constructs, using the COM-B/BCW framework, in a process guided by Michie *et al*, 2014 [349].

In stage 3, behaviour change techniques (BCTs) were selected from the taxonomy of 93 BCTs [280], to pinpoint the **behavioural content** of the selected implementation strategies and policy categories for SMARThealth Pregnancy. The final components of the SMARThealth Pregnancy intervention were then decided, together with their timing and mode of delivery, using the APEASE criteria [350], which consider the contextual relevance and sustainability of intervention strategies. This process was guided by Michie *et al,* 2014 [349].

Following the process of intervention design, I **developed and refined** the intervention, through an iterative process of usability testing and feedback with end-users, including CHWs and PCPs. Usability testing is a method in software development which measures how easily a new digital technology can be operated, understood and improved to enhance satisfaction for end users. Comprehensive guidelines on usability testing are outlined by the International Organization for Standardization (ISO) standards (ISO standard 9241) [351]. Usability testing is particularly helpful in the design of medical applications which involve end-users in refining interventions as part of user-or human-centred design [352] and is recommended as part of the development of digital technologies in medicine by regulatory authorities including the U.S Food & Drug Administration (FDA) [353] and the National Institute for health & Care Excellence (NICE) [354]. The aims of iterative usability testing were to obtain feedback on the **ease** of using the SMARThealth Pregnancy platform; ascertain **satisfaction** with the design; assess the **time to completion** of two

mock clinical scenarios, and assess **correct completion** of each clinical scenario, especially if any errors were made (human error rate).

Ethical approval

Ethical approval for the usability study was obtained from the Oxford Tropical Research & Ethics Committee (OxTREC ref: 501-19), and The George Institute Ethics Committee, India (ref: 03/2019) [**Appendix C**]. The process of intervention design is summarised in Table 5.2.

Table 5.2: Stages in designing a theory-informed behaviour change intervention

[349]

Stage	Components of theory-informed intervention design
1	**Formulating the Behavioural Diagnosis:** **Understanding the behaviour that needs to be changed**
	a) Define problems identified by the contextual work in behavioural terms b) Select **target behaviours** related to the three priority areas identified c) Specify target behaviours in detail (enacted by whom, when, where, how)
2	**Mapping target behaviours to domains of the COM-B & TDF:** **Consider the full range of options for behaviour change (using COM-B & TDF)**
	a) Map modifiable barriers associated with the three priority areas to COM-B & TDF b) Identify **intervention functions and policy categories** in the frameworks, that could be used to enable implementation of high-quality integrated antenatal, postnatal, and life-long care for women in rural India
3	**Select appropriate Behaviour Change Techniques for the context:** **Use a systematic method for selecting behaviour change techniques (APEASE)**
	a) Articulate precise **behaviour change techniques** (BCTs) within the intervention functions and policy categories identified in step 2 b) Consider which BCTs and modes of delivery would be most useful in the context of rural India c) Use APEASE criteria [350] to decide if the BCT be: **A**ffordable; **P**racticable; **E**ffective/Cost effective; **A**cceptable to stakeholders; **S**afe; **E**quitable in rural India

The results of each of the stages of intervention design are now outlined, building upon the findings of the qualitative study and conceptual model outlined in Chapter 4. This is followed by the process of intervention development and iterative testing with end-users.

5.3 Results: Defining the problem in behavioural terms

For each of the three priority conditions, modifiable barriers were mapped onto COM-B/TDF theoretical constructs to decide the target behaviours pertaining to different levels within the health system.

5.31 Selecting target behaviours: Anaemia in Pregnancy

The contextual work (Chapter 4) identified that pregnant women, unaware of the serious consequences of anaemia, were often non-compliant with iron tablets, migrated to their mother's home in the last trimester of pregnancy, and presented to the hospital in labour with severe anaemia. Solutions to optimise Hb levels before delivery, would include screening and treatment for anaemia during the last trimester of pregnancy. Severe anaemia during labour might be prevented through improved compliance with iron folate tablets during antenatal care, and management of moderate/severe anaemia with intravenous iron sucrose or blood transfusions. Addressing the modifiable barriers to providing continuity of care for women with anaemia in pregnancy, has potential to reduce complications of postpartum haemorrhage and maternal mortality [355]. Further barriers were identified in the postpartum period: women were not routinely screened for anaemia and women's health was not prioritised, resulting in worsening anaemia between pregnancies. The contextual study also identified that the high prevalence of anaemia in pregnant women was influenced by a complex interaction of factors, including diet,

cultural practices, socio-economic status, and gender issues, impacting upon non-adherence to iron tablets. Table 5.3 presents an overview of the modifiable barriers relating to anaemia in pregnancy, together with the evidence from the contextual study, mapped onto COM-B/TDF domains.

Table 5.3: Modifiable barriers relating to anaemia in pregnancy & associated theoretical constructs

Modifiable barriers	Quotes from contextual study	COM-B & TDF domains/constructs
Anaemia		
Lack of awareness of serious impacts of anaemia. **(Individual/household-level)**	"*Basically education is the most important part. Second part is our eating habits. We have to eat healthy, and we have to educate our kids to eat healthy."* – Government official, Haryana.	Capability: Psychological TDF: Knowledge
Long-standing household practices and cultural beliefs impacting anaemia prevalence. **(Individual/household-level)**	"*Patients didn't take anything related to treat their anaemia. In the villages there is plenty of milk - they think "we take milk, so we will not be having the anaemia."* – Obstetrician, Haryana.	Opportunity: Physical TDF: Environmental context (person-environment interaction) Opportunity: Social TDF: Social influences (social norms, group identity)
Lack of compliance with iron folate tablets particularly in postpartum period. **(Individual/household-level)**	"*There are family members who don't allow them to take iron tablets."* – ASHA, Andhra Pradesh	Motivation: Automatic TDF: Emotion (impulse & emotion of women regarding taking iron tablets) Opportunity: Social TDF: Social influences (wider cultural factors and pressures from household)
Lack of continuity of care between pregnancy and postpartum period – need for improved detection and management of anaemia in third trimester of pregnancy **(Health provider-level and health system-level)**	*"Actually they [pregnant women] go for periodical [Hb] investigation.. some of them know they are anaemic…as per Indian customs, the first and second delivery, they go to their parental home…she may not carry her entire medical report to that area and there is some other doctor, and they may not take proper precautions…some gap is*	Opportunity: Physical TDF: Environmental context & Resources (to measure Hb in third trimester after women migrate)

Modifiable barriers	Quotes from contextual study	COM-B & TDF domains/constructs
	there…and that might be the cause of anaemia..” – Government official, Andhra Pradesh	
Lack of postpartum screening for anaemia **(Health provider-level and health system-level)**	“*Until 40 days women are not allowed out of house, so they don’t come [to the PHC] till that time. After 40 days, if we call them to check the baby’s weight or for immunization then they come.”* – ASHA, Andhra Pradesh	Capability: Physical TDF: Skills (to measure Hb) Opportunity: Social TDF: Social influences (women don’t leave homes for 40 days & unable to engage in postpartum Hb check
ASHA unable to screen for anaemia or advise woman on referral if needed in the postpartum period. **(Health provider-level)**	“*ASHAs are just 10th plus (education). They don’t have that type of training.*” – Obstetrician, Andhra Pradesh	Opportunity: Social TDF: Social influences (perceptions of ASHAs & their skills) Capability: Physical TDF: Skills (to perform Hb test) Capability: Psychological TDF: Memory, Attention & Decision processes (decision-making - to interpret Hb & refer)

The behavioural diagnosis was a need to **improve the detection and management of moderate/severe anaemia in the last trimester of pregnancy and postpartum period** by addressing the theoretical constructs identified in Table 5.3. Based on these findings, the following target behaviours relating to anaemia in pregnancy were identified:

a. Improve awareness of anaemia and its serious impacts upon women and their babies: (individual/household-level).
b. Need for postpartum detection, referral, and management of moderate to severe anaemia: (health provider-level and health system-level).
c. Improve adherence to iron folate tablets during pregnancy/postpartum: (individual/household-level, health provider-level).

Specifying target behaviours relating to anaemia

From the contextual work, it was apparent that ASHAs were trusted by pregnant women and the entire household, and ideally placed to improve awareness of the serious nature of anaemia and the importance of taking iron folate tablets at the household-level, in addition to improving delivery of wider awareness programmes at the community-level.

"ASHA workers can influence villagers…because they are local people…They are part of the community…they are local people….they can influence…Doctors don't have time.. it is too busy schedule.... it is not possible for us to give some health education."

- Obstetrician, Andhra Pradesh

As women did not leave their homes for 40 days postpartum, and the only regular healthcare encounters during this time were with ASHAs, for the target behaviour of postpartum Hb measurement to be performed, ASHAs (*who*) would need to learn to perform the skill of using a Hb meter (*how*), at home (*where*), in the postpartum period (*when*). They would further need the skills or support to interpret the result, and refer the woman to the doctor if needed for further management of moderate or severe anaemia. ASHAs would also need to provide standardised, guideline-based advice on the importance of adherence to iron folate medication for the immediate and ongoing health of women.

Table 5.4: Specification of target behaviours: Anaemia in Pregnancy

Target Behaviour	Behavioural specifications			
Anaemia	**Who?**	**How?**	**Where?**	**When?**
Improving awareness of serious nature of anaemia	ASHA – due to the trust and respect they hold within the community	Provision of household-level counselling	Home-based	Standard antenatal and postnatal visits as well as opportunistic
Postpartum detection, referral, and management of anaemia	ASHA – due to women not leaving homes and ASHA conducting postpartum home visits	Use of handheld haemoglobinometer to measure Hb. Use of mobile clinical decision support to interpret readings and refer/counsel women.	Home-based	Standard postnatal visits: **Week 1-2** (to check for anaemia resulting from labour) and; **Week 6** (to check for persistent anaemia)
Improved advice and adherence to iron folate tablets	ASHA – due to the trust and respect they hold within the community	Provision of household-level counselling	Home-based	Standard antenatal and postnatal visits

5.32 Selecting target behaviours: Hypertensive Disorders of Pregnancy

The literature review (Chapter 2) presented evidence that women with HDP are at increased risk of developing chronic hypertension and CVD [85,86,97,356]. From the contextual study (Chapter 4), most women and healthcare workers were unaware of this, and subsequently, women with HDP had not been counselled regarding their future risk of CVD. As it was cultural practice not to leave home in the postpartum period, women discharged from hospital with antihypertensive medications did not routinely have their postpartum BP measured. The majority of complications following HDP occur in the postpartum period [357,358]; however, women with HDP in the contextual study had no means of knowing how to titrate any antihypertensive medication and when to stop, due to lack of postpartum follow-up. Although not previously used in rural India, home-based BP measurement and self-management of BP following HDP has been shown to be feasible in high-income settings [359–362].

Table 5.5: Modifiable barriers relating to Hypertensive Disorders of Pregnancy & associated theoretical constructs

Modifiable barriers	Quotes from contextual study	COM-B & TDF domains/constructs
HDP		
Lack of awareness of long term cardiometabolic sequelae of HDP and barriers to women's lifestyle modification. **(Individual/household-level; health provider-level)**	"*Actually if a young female starts focussing on herself – doing exercise and all – then it is thought here in this rural background that it is a wastage of time. That she is much into herself and not taking care of herself or her family*." – Primary Care Physician, Haryana	Capability: Psychological TDF: Knowledge (improving awareness & education of women and healthcare professionals)
Lack of postpartum screening for high BP **(Health provider-level and health system-level)**	"*Post-delivery we don't check their BP. If someone has any problem, then we'll check their BP.*" – ANM, Andhra Pradesh	Capability: Physical TDF: Skills (lack of home-based BP measurement)
ASHA unable to measure BP or advise woman on referral if needed in the postpartum period **(Health provider-level)**	"*ANM will check the blood pressure, staff nurse also does blood pressure checking. Lab technician does the sugar test*." – ASHA worker, Andhra Pradesh	Opportunity: Social TDF: Social influences (perceptions of ASHAs' abilities) Capability: Physical TDF: Skills (to conduct home BP) Capability: Psychological TDF: Memory, Attention & Decision processes (decision-making)

Based on these findings, the behavioural diagnosis was a need to **improve the postpartum detection and management of women with HDP**. This could be achieved by addressing the physical and psychological capabilities (physical skills, knowledge, decision-making) of ASHAs to measure and interpret BP values at home, improving psychological capabilities (knowledge, awareness,) of women and healthcare workers about the long-term risks associated with HDP, and creating social opportunities (to change perceptions of ASHAs) and enable home-based BP measurements.

The following target behaviours were identified:

a) Improve awareness of HDP and the impact on future CMDs in women (individual/household-level).

b) Need for postpartum BP measurement in high-risk women and referral of women with persistently raised BP to national NCD programme for ongoing follow-up (health provider-level and health system-level).

Table 5.6: Specification of target behaviours: Hypertensive Disorders of Pregnancy

Target Behaviour	**Behavioural specifications**			
HDP	**Who?**	**How?**	**Where?**	**When?**
Improving awareness of long-term cardiometabolic sequelae of HDP	ASHA – due to the trust and respect they hold within the community	Provision of household-level counselling	Home-based	Antenatal and postnatal visits as well as opportunistic
	All healthcare professionals	Provision of education & training for healthcare professionals	During continuing professional development classes for CHWs/Drs	During healthcare professionals' monthly training
Postpartum detection, referral, and management of high BP	ASHA – due to women not leaving homes and ASHA conducting postpartum home visits	Use of validated digital BP apparatus to measure BP at home. Use of mobile clinical decision support to interpret BP and refer/counsel women.	Home-based	Standard postnatal visits: **Week 1-2** (to check BP in women with HDP and counsel/refer for follow-up; **Week 6** (to check for persistent high BP & counsel about long-term risks for CVD)

5.33 Selecting target behaviours: Gestational Diabetes Mellitus

The contextual study revealed that although GDM was rare, its prevalence, and that of T2DM in older women, had been rising in both study settings in recent years. The latest Government of India guidelines for GDM [329] advocated universal screening in pregnancy; however, these guidelines had not yet been operationalised in the community settings studied. As a result, antenatal screening practices for GDM were inconsistent and not guideline-based. Several logistic challenges to conducting the recommended OGTT screening in the context of rural Indian villages, and a lack of knowledge and training for CHWs to implement the latest Government guidelines, were identified. While stakeholders recognised that many women in their 40's and beyond had T2DM, they were not aware of the links between GDM and future risk of T2DM and CVD. Women diagnosed with GDM did not routinely undergo the recommended postpartum follow-up [329], nor receive counselling about their significantly heightened risk of T2DM [363,364].

Table 5.7: Modifiable barriers relating to Gestational Diabetes Mellitus & associated theoretical constructs

Modifiable barriers	Quotes from contextual study	COM-B & TDF domains/constructs
GDM		
Lack of knowledge of Government of India guidelines for community-based GDM screening **(Health provider-level)**	*"We are told to do RBS [Random Blood Sugar], so we do RBS and not glucose tolerance test"* – ANM, Andhra Pradesh	Capability: Psychological TDF: Knowledge
Need for routine and standardised screening for GDM **(Health provider-level and health system-level)**	"*Every woman isn't tested for blood sugar. Every woman is sent to the Government Hospital, but even their blood sugar isn't tested.*" – ASHA worker, Haryana	Capability: Physical TDF: Skills Capability: Psychological TDF: Knowledge

Modifiable barriers	Quotes from contextual study	COM-B & TDF domains/constructs
	"*Second one [fetal death] was full-term, third one [fetal death] was at fifth month…I don't want anybody to suffer like me…"* -Postpartum woman, Andhra Pradesh: Screened for GDM after two fetal deaths	
Lack of time and resources to perform OGTT **(Health provider-level and health system-level)**	"*OGTT is very useful in pregnancy, but we don't have that because this is a rural area, and we don't have that glucose and all and we have to do that hourly and 20 minutes after that.."* - Obstetrician, Andhra Pradesh	Capability: Physical; TDF: Skills Opportunity: Physical TDF: Environmental context & Resources Capability: Psychological TDF: Memory, Attention & Decision processes Motivation: Reflective TDF: Social/professional role & identity; Beliefs about capabilities (for ASHAs and ANMs to conduct & interpret OGTT)
Lack of awareness of long-term consequences of GDM **(Individual/household-level; health provider-level)**	"*I did not go for OGTT [postpartum]…as it [blood sugar] was normal now…random sugar is normal…only [I do] exercise that's it."* – Postpartum woman with GDM, Andhra Pradesh	Capability: Psychological TDF: Knowledge

The behavioural diagnosis identified was a need to **improve the antenatal and postnatal screening of all pregnant women for GDM using the Government of India guidelines.** For this behaviour to be enacted, the psychological (knowledge and decision-making) and physical capabilities (to perform and interpret an OGTT), and physical opportunities (resources) provided to healthcare workers to conduct OGTT, would need to be addressed. CHWs would also need to work in different ways (professional roles, beliefs about capabilities) and require adequate motivation to operationalise the new Government of India GDM guidelines, and follow-up and counsel women with GDM in the postpartum period about their risks of T2DM.

The following target behaviours were identified:

a) Improve knowledge and implementation of Government of India guidelines for screening GDM.

b) Provide training and resources for CHWs to perform OGTT in the community.

c) Build awareness of the links between GDM and future T2DM and CMDs.

Table 5.8: Specification of target behaviours: Gestational Diabetes Mellitus

Target Behaviour	Behavioural specifications			
GDM	**Who?**	**How?**	**Where?**	**When?**
Improving knowledge and implementation of Government of India GDM guidelines	Healthcare workers (ASHAs, ANMs, PCPs)	Education and training	During continuing professional development classes for CHWs/Drs	During healthcare professionals' monthly training
Provision of training and resources for CHWs to perform OGTT in the community		Education and training, provision of resources to conduct OGTT	During continuing professional development classes for CHWs/Drs	During healthcare professionals' monthly training
Building awareness of the links between GDM and future T2DM and CMDs	ASHA – due to the trust and respect they hold within the community	Provision of household-level counselling	Home-based	Antenatal and postnatal visits as well as opportunistic
	All healthcare professionals	Provision of education & training for healthcare professionals	During continuing professional development classes for CHWs/Drs	During healthcare professionals' monthly training

5.4 Selecting intervention functions, policy categories and behavioural components

The domains of COM-B/TDF identified as key determinants of behaviour change within the health system included: improving knowledge (psychological capability), clinical skills (physical capability), and providing resources (physical opportunity) for addressing high-

risk pregnancies and their long-term sequelae at all levels of the health system; addressing decision-making (psychological capability), beliefs about capabilities, professional roles (reflective motivation) of healthcare workers, and addressing wider social influences upon health (social opportunity) at the community-level.

To address the physical capabilities of healthcare workers, **training** and **enablement** were identified as key intervention functions to empower ASHAs with the skills, equipment, and resources to conduct home-based Hb (haemoglobinometer) and BP (validated semi-automated BP device) measurement, interpret readings and refer women (through provision of mobile clinical decision support), and for ASHAs and ANMs to conduct community-based screening for GDM. To address improvement of psychological capabilities, **education** and **training** were identified as important intervention functions, alongside policy categories of **guidelines** (guideline-based care) and **service provision** (operationalising Government of India GDM guidelines and postnatal follow-up of high-risk pregnant women). To raise awareness of the serious nature of anaemia and encourage compliance with iron tablets (automatic and reflective motivation), **persuasion** was identified as an important component of home-based counselling to be provided by ASHAs to pregnant women and their household, and the wider community. To improve the physical and social opportunities for ASHAs to deliver a new model of home-based care for pregnant women, **environmental restructuring** was identified as a function to address community perceptions of ASHAs' abilities. ASHAs (at the time of this study) worked on an incentive-basis. In order to provide ASHAs with adequate motivation (both automatic and reflective) to deliver intervention practices, they would need to be adequately remunerated, by providing **incentives** (both social and financial). Intervention functions and policy categories most suited to addressing these COM-B/TDF domains were

identified using the BCW, evidence from the literature review (Chapter 2), and contextual work (Chapter 4), highlighted below in Table 5.9.

Table 5.9: The Behaviour Change Wheel intervention functions and policy categories (adapted from Michie *et al* [349])

Intervention functions	**Description**
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability or opportunity
Policy categories	**Description**
Communication/ marketing	Using print, electronic, telephonic, or broadcast media
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision
Fiscal	Using the tax system to reduce or increase the financial cost
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental/ social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

Identifying Behaviour Change Techniques to target health system change

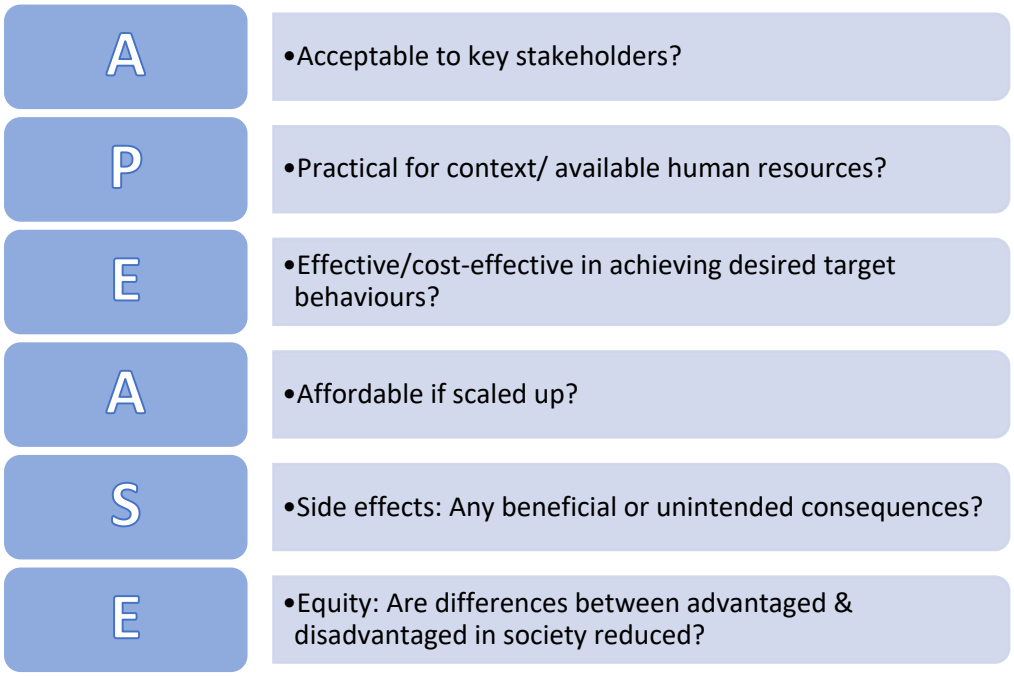
BCTs represent the most basic, irreducible, observable, and replicable components of behaviour change interventions [281]. The behavioural content of SMARThealth Pregnancy was decided by looking at the full range of BCTs using the BCT Taxonomy [280], and consulting previous literature on BCTs that have worked for interventions in

similar fields [365, 366]. A total of 15 BCTs were identified to target the related COM-B/TDF constructs (Figure 5.2).

Mode of delivery of SMARThealth Pregnancy

I then considered the most appropriate modes of delivery for the SMARThealth Pregnancy intervention to address the target behaviours and theoretical constructs identified in the behavioural analysis, building upon the evidence base and the conceptual model of the health system and strategies identified in the contextual study (Chapter 4). The chosen modes of delivery, intervention functions, policy categories and BCTs were reviewed against the APEASE criteria [350] (Figure 5.1) to determine their local relevance, feasibility, and likely sustainability in rural Indian settings, based on evidence from the literature review (Chapter 2) and contextual study (Chapter 4).

Figure 5.1: APEASE criteria (adapted from Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions; 2014. p. 329 [350]**)**



Timing of the intervention components for delivery of a model of care

Three important time points were identified from the evidence-base and contextual study for intervention delivery practices. These time points were chosen in consultation with local doctors and CHWs to enable: a) the intervention to be fully integrated into existing ASHA home visits and b) pragmatic evaluation of the feasibility of the model of care (Chapter 6).

The third trimester of pregnancy (28 – 36 weeks' gestation) was chosen as a window to engage, identify and optimise the health of high-risk pregnant women before delivery, and to ensure those who had migrated to their mother's homes in the last trimester of pregnancy, were registered for ANC and linked to local health services for ongoing postpartum care. The next critical time when most maternal and neonatal deaths occur is

during the early postpartum period (weeks 1 & 2), [367]. I used this as an opportunity for ASHAs to measure BP and Hb, identify serious postpartum complications requiring referral, and offer counselling to women and their families on breastfeeding, diet, and compliance with oral iron, as part of the second intervention visit. The third intervention visit at the time of the 6-week postpartum check was chosen to identify high-risk women with persistently raised blood glucose and/or BP. Such women are at increased risk of future CMDs [368–374] and could be referred to primary care and linked to the national NCD programme for regular, ongoing, life-long follow-up. ASHAs were remunerated in line with local government guidance, and given 500 Indian Rupees (INR) per month and an additional 150 INR per intervention visit in both States.

Building upon the strategies identified in the conceptual model of the health system presented in Chapter 4, the final components of SMARThealth Pregnancy included:

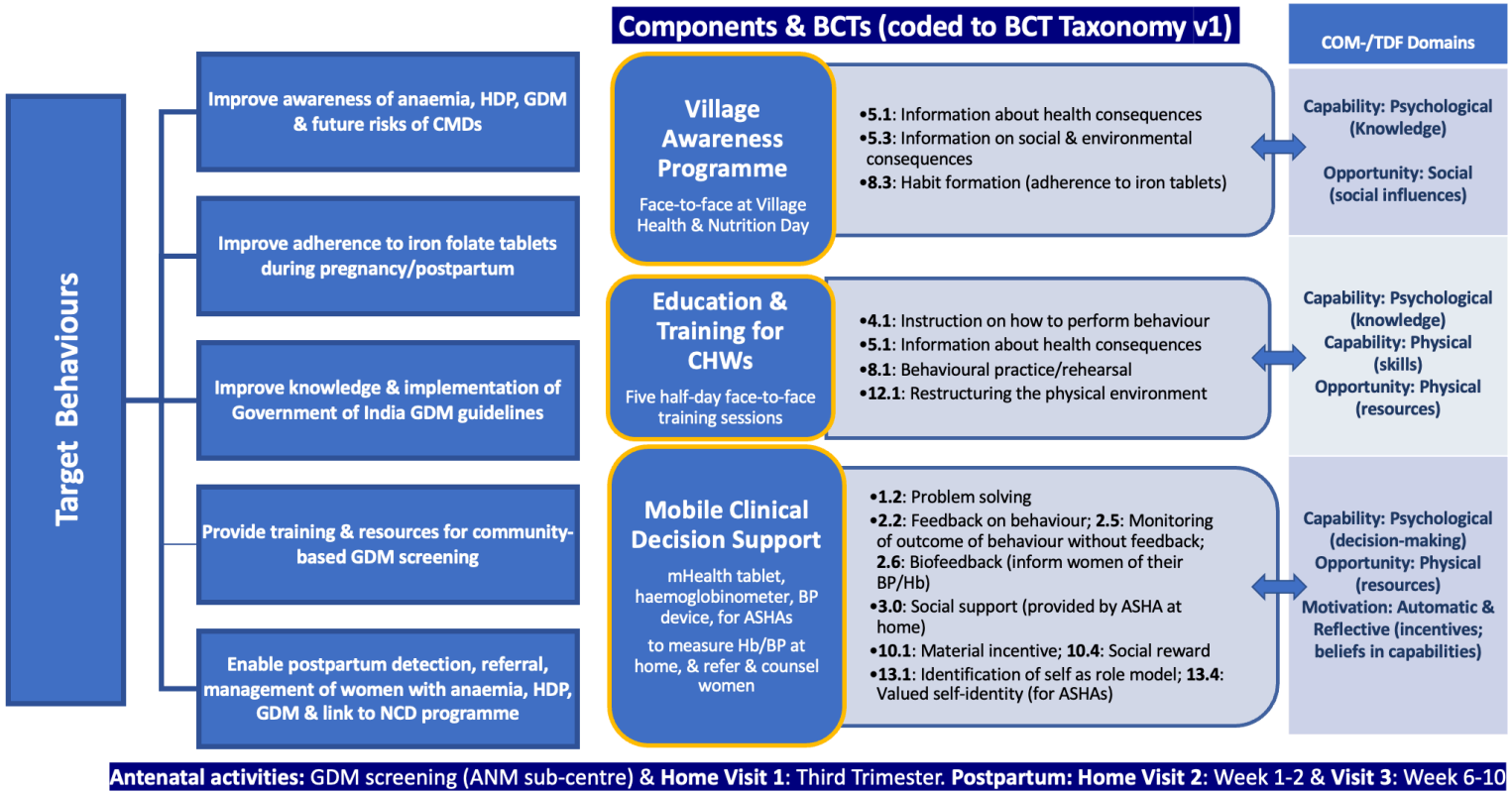
1) An awareness programme about anaemia, HDP and GDM and their immediate and long-term consequences (individual/household/community-level);

2) Targeted education and skills training covering the detection, referral, and management of anaemia in pregnancy, HDP and GDM (health provider-level) and;

3) A mobile Health (mHealth) platform for ASHAs and PCPs; providing mobile clinical decision support to enable home-based screening, referral, counselling, and lifestyle advice for pregnant women at high-risk of future CMDs (health system-level & health provider-level).

The intervention components linked to theoretical constructs and BCTs are summarised in Figure 5.2.

Figure 5.2 Intervention components linked to behavioural constructs, behaviour change techniques and target behaviour[4]



1. Coding from BCT taxonomy v1.0 by Michie S, Richardson M, Johnston M, *et al*.(2013). The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions, Annals of Behavioral Medicine, 2013; 46(1): 81-95.

5.5 Development & refinement of SMARThealth Pregnancy

Identifying clinical guidelines and measurement devices to inform the intervention

The components of the SMARThealth Pregnancy intervention were then developed. I systematically searched the literature to identify relevant clinical guidelines and validated point-of-care BP and Hb measurement devices, and the findings were discussed with local obstetricians in rural India and the wider study team (including my DPhil supervisors) until consensus was reached. Guidelines and devices most relevant to the rural Indian context were selected [142,317,375,376].

The CRADLE device (APEC, UK) is a low-cost ($20 USD each), semi-automated BP device, validated for pregnant women, and designed for low-resource settings (charged using an android phone charger)[375] . The CRADLE device was chosen for ASHAs to measure BP as it has been evaluated and shown to be usable by CHWs in rural India [209,212,323,377], and its recommendations align with the Federation of Obstetric and Gynaecological Societies of India (FOGSI) and WHO guidelines for management of HDP, ideal for the rural Indian context [378,379].

The Government of India recommendations for point-of-care Hb testing devices for use in rural community settings [317] include the TrueHb Hemometer© (Wrig nanosystems Pvt.Ltd, 2020) [380], made in India at relatively low cost (4000 INR per device with test strips) and tested for diagnostic accuracy in an Indian population [381]. These factors made it a suitable choice to ensure the sustainability and scalability of the SMARThealth Pregnancy intervention in India in the future.

Developing the Awareness, Education & Skills Training components

As identified in the contextual study, health awareness programmes within villages in rural India are delivered by CHWs and PCPs during local village health and nutrition days (held monthly at each village affiliated to the PHC). The content of the awareness programme covering the three priority conditions was nested within the CHW and PCP education and training sessions. This was to enable the awareness components of the intervention to be fully integrated into the daily work of CHWs and PCPs, and embedded into their intervention visits and village health and nutrition days (**see Appendix D**).

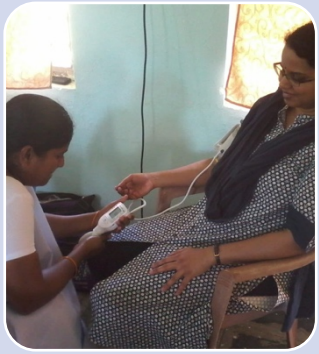
Targeted Education & Skills Training

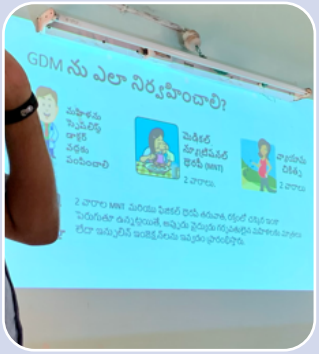
The targeted training component of SMARThealth Pregnancy was designed to build upon existing knowledge of high-risk pregnancy conditions known to CHWs and PCPs, following a spiral approach to learning [382], and for them to develop mastery in intervention delivery practices, including measurement of Hb and BP and the mHealth platform. The curriculum design of the training component used the pedagogical concept of experiential learning [383] at its basis to promote skill acquisition and retention. Use of role play, simulation and hand-holding in the real world provided a supportive educational environment [384], where performance and feedback could be delivered in a personal and targeted way. This approach has been successful in other empirical studies [385,386].

The curriculum was designed to be delivered over two and a half days, as a series of five participatory learning sessions, each of 3 hours duration for CHWs (Figure 5.3), with a one-day face-to-face 'refresher' training session after 4 weeks. In addition, 'hand-holding' in the field by the local study field team following the initial training, was incorporated into the curriculum design to ensure that ASHAs felt confident using the BP device,

haemoglobinometer and the tablet in a real-world context. The curriculum for PCPs covered the same areas as for CHWs, but was designed to be delivered as a half-day, one-to-one training session, assuming a higher degree of baseline knowledge on both educational and skills training components, and in response to feedback from doctors regarding their availability.

Figure 5.3: Overview of Education & Training Sessions





Session 1:

Introduction & Anaemia and TrueHb© meter

- Part 1: Theory and Knowledge of Anaemia in Pregnancy and Anaemia Mukt Bharat guidelines
- Part 2: Skills: Use of the TrueHb© meter: demonstration, role play and skills practice

Session 2:

HDP & CRADLE device

- Part 1: Theory and knowledge of HDP and CRADLE device recommendations
- Part 2: Skills: Use of CRADLE device: demonstration, role play and skills practice

Session 3:

GDM & OGTT testing

- Part 1: Theory and knowledge of GDM and Governemnt of India GDM Guidelines
- Part 2: Skills: Administering an OGTT, checking two-hour capillary blood sugar: demonstration, role play and skills practice.

Session 4: mHealth platform & visits

- Part 1: Knowledge of intervention visits, timings and the corresponding mHealth platform screens.
- Part 2: Skills: Use of SMARThealth pregnancy mHealth platform: demonstration, role play and simulated home visits with peer-feedback.

Session 5: Summary of Learning

- Wrap up, questions & answers, trouble shooting and end of training quiz

Development of the SMARThealth Pregnancy mHealth platform

The George Institute for Global Health has previously developed the SMARThealth system (smartphone-based application) using an android operating system, on a seven-inch tablet to aid screening for cardiovascular risk [326] and mental health [387] in adults in rural India. Building upon the SMARThealth programme, I developed the content and user interface of the SMARThealth Pregnancy Application (App).

The process of App development involved creation of the **'back-end'** content: creating the clinical algorithms for the App, converting these to code, and clinically and statistically validating the algorithms. This was followed by development of the **'front-end'** content of the App: developing the user interface, including colour schemes and screen layout to ensure ease of usability for CHWs and PCPs. I used the findings from the literature review (Chapter 2), contextual study (Chapter 4) and the BCTs and clinical guidelines identified in this chapter, to inform the content, embed behavioural theoretical constructs and inform the nuances of App design. For example, understanding the context (Chapters 1 & 4) and knowing that gender issues (including sex-selection practices) were prevalent in rural India, I used gender neutral colours (e.g. purple, yellow) throughout the App design.

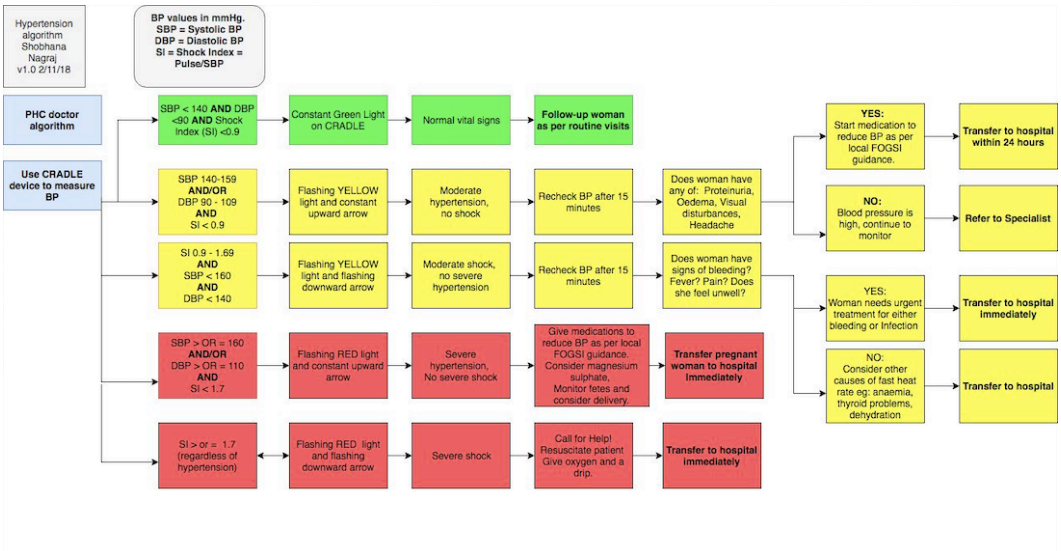
I worked with The George Institute for Global Health Digital Technologies teams in Australia and The George Institute for Global Health software developers in India, to create the back- and front-ends of the SMARThealth Pregnancy mHealth platform. I led and was involved in each stage of this process, as outlined below.

Technology & architecture of the SMARThealth Pregnancy mHealth platform

Formation of Clinical Algorithms

The algorithm development and validation processes were guided by the established methods used for developing the previous SMARThealth mHealth platforms by The George Institute for Global Health [234,326]. In the first stage of content creation, I used the clinical guidelines identified in the earlier review and condensed these into flow charts, using 'io draw©' flowchart software [388] (Figure 5.4). The clinical guideline flowcharts were cross-checked with the original guideline documents by an independent member of the digital technology team.

Figure 5.4: Example of flowchart created using *io draw* flowchart software



The guideline flowcharts were then used to determine:

- **Input variables** e.g. Patient ID, Date of Birth, Weight, Height, Last Menstrual Period, Haemoglobin.
- **Calculated variables** e.g. Age, BMI, Estimated Date of Delivery.

- **Output Recommendations** e.g. *This woman has evidence of severe hypertension. Call ambulance and refer patient to hospital urgently.*

I then transferred the variables and output recommendation text to an Excel spreadsheet, and with the guidance of an algorithm administrator at the George Institute, Sydney, converted the clinical guideline flowcharts into **pseudocode**, using '**If→Then**' rules, as illustrated here:

*"**IF** the BP is > or = to 140/90, **THEN** follow recommendation output **2B**".*

The algorithm administrator at the George Institute for Global Health independently converted the pseudocode into **code**, which was entered by the algorithm administrator into the George Institute for Global Health's rules engine. This is a software database for the algorithm rules, which stores clinical algorithms in a 'rules set' on the George Institute for Global Health servers in Australia, India and China, respectively. The algorithms are mirrored across each of the three servers and can be modified as necessary. They are also available in an offline mode for work in the field when there may be issues regarding Internet connectivity (such as in rural India). This enables the SMARThealth Pregnancy App to communicate with the locally stored version of the rules engine if there is no Internet connection, and automatically update the set of rules when it is connected to the Internet, if or when there are any changes made to the rules set. The rules engine administrator based at the George Institute, Sydney was responsible for instituting any changes to the rules engine.

Clinical and Statistical validation of clinical algorithms

SMARThealth Pregnancy algorithms were based on existing evidence-based clinical guidelines. The clinical and statistical validation of the SMARThealth Pregnancy algorithms were performed by the George Institute, Sydney, Digital Technologies team, in accordance with their established protocol for validation of mHealth platforms [326], as described below.

Clinical validation

For clinical validation of the algorithms, a de-identified data set of 200 pregnant women's BP values and pulse and Hb values, covering a range of clinical scenarios, was created. An independent senior PCP then looked through all 200 cases and made expert recommendations based on the clinical guideline algorithms provided. There was a 100% fit between the clinician and the rules engine outputs for the data set.

Statistical validation

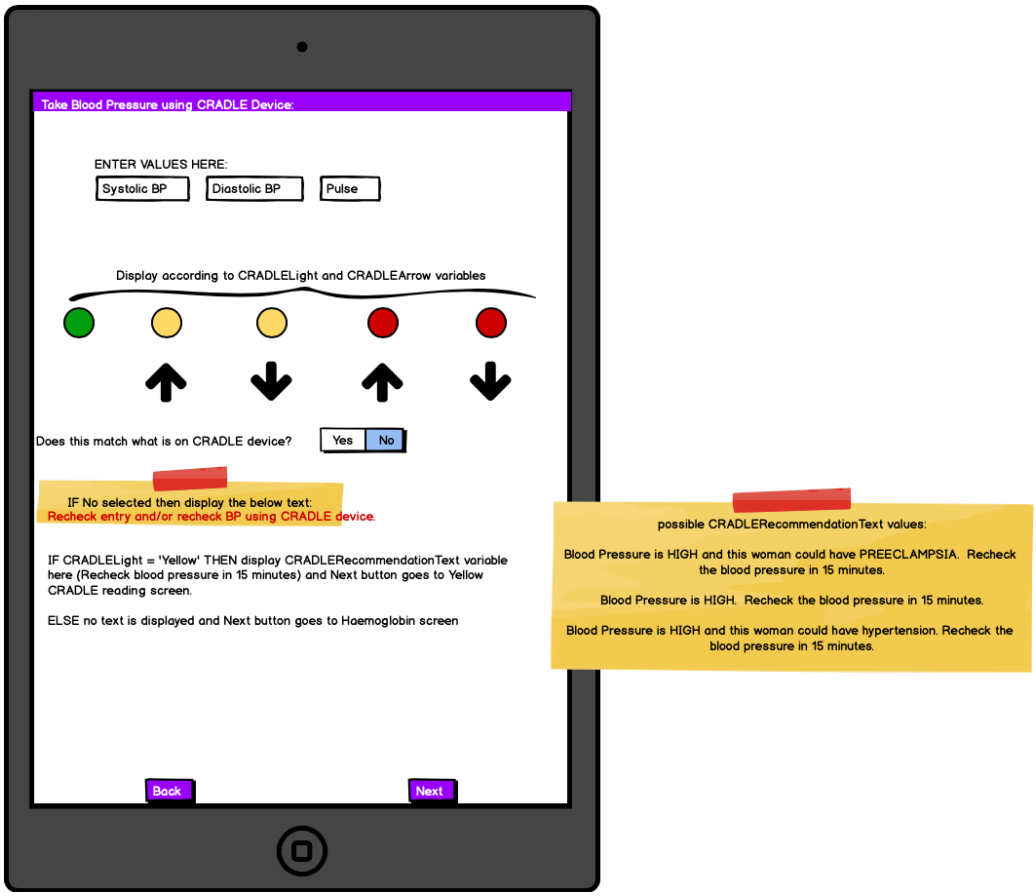
The algorithms for SMARThealth Pregnancy were sent to the statistical programmer at the George Institute for Global Health. Statistical validation was carried out using a 10,000 patient data set, randomly generated using Excel's random formula for all the input variables contained within the algorithms, to include a wide range of case scenarios. The programmer coded the algorithms and data set into SAS software© (version 9.4) and generated output variables (the **Calculated_Expected** output). The input and expected output variables were then transferred into the rules engine, which generated its own output variables (**Calculated_Actual**) and then compared these with the **Calculated_Expected** outputs. Discrepancies between **Calculated_Expected** and **Calculated_Actual** variables were identified and resolved by the statistical programmer and algorithms administrator.

Once the amendments were made, the new expected output was uploaded and compared again using the rules engine. This process was repeated until there was a 100% match between **Calculated_Expected** and **Calculated_Actual** outputs. The final prototype App had a 100% match between the expected and actual output data.

Front-end development of the SMARThealth Pregnancy platform

The user design software Balsalmiq Cloud © [389] was used to create screens (known as **wireframes**) for the SMARThealth Pregnancy applications for each user (CHW and PCP) and for each of the three visits (Third Trimester; Postpartum Week 1; Postpartum Week 6). These wireframes were annotated with the relevant coding instructions required for the software developers (Figure 5.5), who used these wireframes to create the front-end screens of the SMARThealth Pregnancy App.

Figure 5.5: Example of wireframe using Balsalmiq© software for SMARThealth Pregnancy user interface



Project management

The teams from Sydney and Hyderabad then worked together to integrate the back- and front-ends using the Application Programming Interface (API). The API is a set of rules, protocols and tools that allow integration of the code from the algorithms with the user interface of the application [390]. I coordinated the teams across Sydney and Hyderabad to develop a prototype SMARThealth Pregnancy application, using an Agile approach [391]; a type of software development project management methodology, involving iterative cycles in the development of an application to refine the prototype, make it more efficient, usable and to share learning within the team. I led the App development team (consisting of software developers, algorithm developers and clinicians), and was

responsible for organising and coordinating weekly virtual meetings, across all three sites (UK, India & Sydney).

5.6 Iterative testing of SMARThealth Pregnancy mHealth component with end-users

After finalising the SMARThealth Pregnancy prototype App, I conducted iterative testing with end-users (CHWs and PCPs) to model and refine the mHealth component of the intervention, as recommended [66,272]. I conducted four rounds (iterations) of usability testing: two in the Guntur District of Andhra Pradesh, and two in the Jhajjar district of Haryana, India. A purposive sample of five ASHAs and two PCPS (at each study site) was used to hold a total of five in-depth interviews and three FGDs for the three rounds of usability testing across both study sites (n=14 participants). The sample size was guided by previous research in this field [392]. As the user interface and content of the SMARThealth Pregnancy platform differed between CHWs and PCPs, FGDs/interviews with CHWs/PCPs were held separately at each site to encourage more open discussion and provide profession-specific feedback. Interviews and FGDs were conducted by myself, with the help of a local research assistant from the George Institute, Hyderabad (for Guntur) and the George Institute, New Delhi (for Haryana). Participant Information Sheets (PIS) were shared with participants ahead of the interviews and FGDs, and written informed consent was obtained from all participants. All discussions were audio recorded and transcribed.

Content and outcome of usability testing

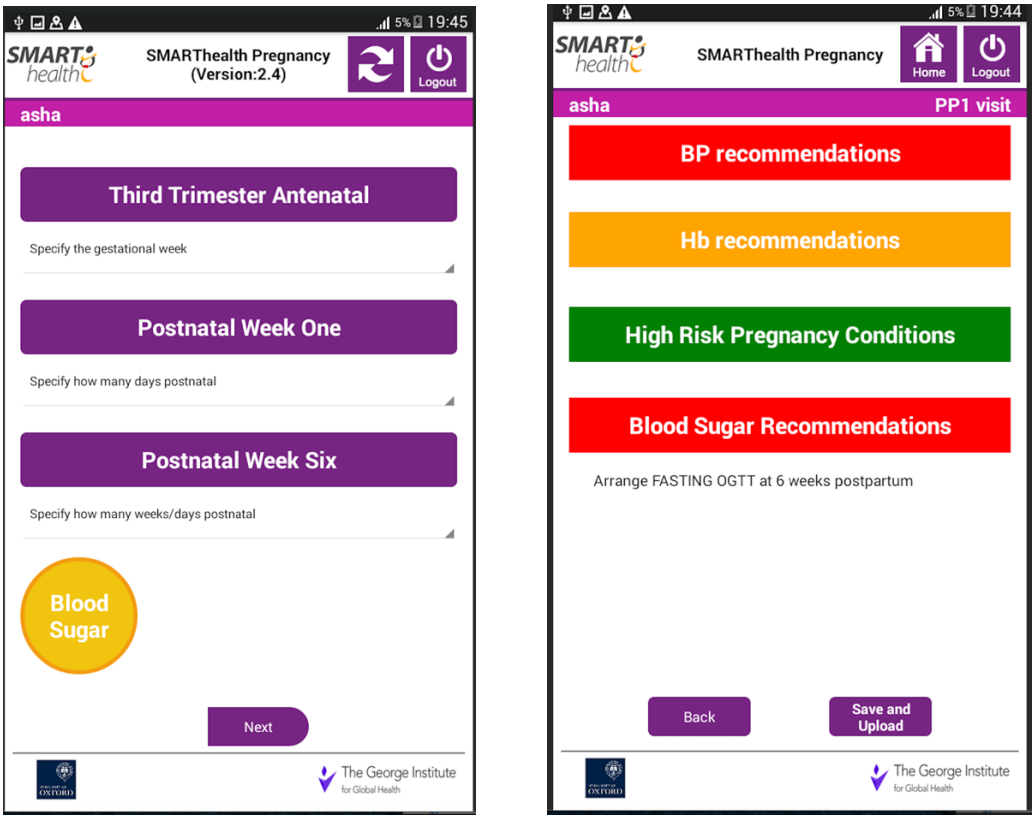
I created two clinical case scenarios based on real-life events prior to the FGDs and interviews. The mock patient clinical details and investigation results were entered into the local ANC hand-held patient record booklet for each mock scenario. Each participant had access to an individual SMARThealth Pregnancy mHealth tablet and a mock clinical case record. Participants worked independently through the scenarios using the SMARThealth Pregnancy App on the tablet provided. A local research assistant and myself observed as they completed the tasks. Completion times and 'clicks' to completion were measured and stored within the tablet. Feedback and discussions were completed as a group for CHWs, and individually with PCPs. Each interview/FGD lasted up to 60 minutes (**Appendix D**).

Following each cycle of usability testing, feedback and changes were incorporated into a document (Appendix D), using a traffic-light system to highlight bugs and fixes that were high (red), moderate (yellow), and low priority (green), based on clinical safety and usability. This document was shared with software developers and the App was regularly updated until no further bugs or fixes were required, and all usability testing was completed. The final SMARThealth Pregnancy App was thereby developed (Figure 5.6).

The final mHealth platform and implementation practices

The SMARThealth Pregnancy mHealth platform enables ASHAs to input measures and generate recommendations based on the woman's history, BP, Hb and blood glucose readings. These can be confidentially uploaded to a patient record using Open MRS software (34) and synchronised to a sister-tablet held by the PCP at the local PHC.

Figure 5.6: Final SMARThealth Pregnancy screens



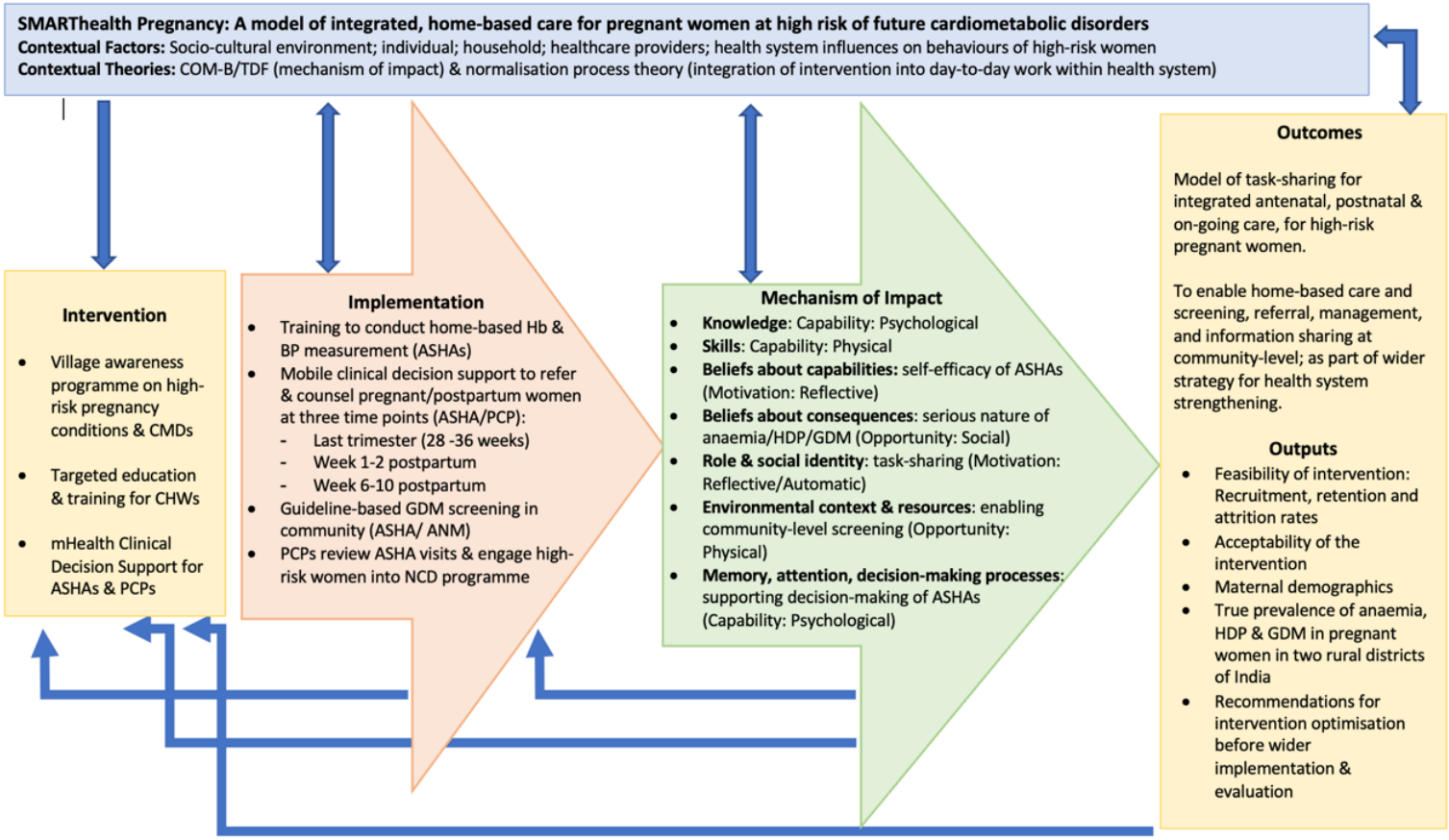
As per current standard practice, ASHAs accompany women to both primary and secondary care visits; however, women cannot be compelled to see the local PCP, although they will be encouraged to do so after each ASHA visit. High-risk pregnant/postpartum women are referred to the doctor at the local PHC via the mHealth platform, and are also provided with a paper referral card completed by the ASHA (in case they seek private services or by-pass primary care). Through the SMARThealth Pregnancy mHealth platform, the PCP can see if the woman is anaemic (and the severity), hypertensive, and/or screen-positive for GDM. If the patient attends the PHC, the PCP can repeat these readings, with access to guideline-based decision support for anaemia, hypertension and GDM as to the next steps in management/and or referral to secondary care. Based on the contextual study, it is anticipated that many women will not attend primary care, and seek

private health services from obstetricians directly, and therefore, a hand-held referral card is also completed by the ASHA. Postnatal visits involve the same Hb and BP measurements as the antenatal visit, except history-taking involves details of the birth and labour (Postpartum: Week 1 visit), and any further complications (Postpartum: Week 6 visit). The final intervention is outlined in the Template for Intervention Description and Replication (TiDieR) checklist (**Appendix D**).

5.7 Developing a logic model for SMARThealth Pregnancy

As recommended by the MRC in their guidance for developing and evaluating complex interventions [66], I developed a logic model for SMARThealth Pregnancy, outlining the components of the intervention, the proposed mechanisms for impact and outcomes following implementation (Figure 5.7). Complex interventions function in dynamic environments, and can effect change within social contexts and health systems [393]. I used relevant theory to explain how the components of SMARThealth Pregnancy might lead to change and integration within the health system in the logic model, and modelled how contextual factors might interact with intervention delivery. By lending transparency to the proposed change mechanisms, the logic model provided the basis for the qualitative process evaluation of SMARThealth Pregnancy (Chapter 6), whilst also recognising its dynamic nature, and the need for further refinement following implementation of intervention components in the real world.

Figure 5.7: Logic model of SMARThealth Pregnancy



5.8 Discussion

This chapter has explored how behaviour change theory can be used to inform the design, development and refinement of a complex intervention, addressing the secondary research question of my thesis. The methods and outputs of the systematic process of intervention development, resulted in the creation of a contextually-based, theory-informed complex intervention. Several discussion points arose during this process, which will now be discussed with reference to the relevant literature.

The centrality of context in intervention design

The systematic process, outlined in this chapter, highlighted the importance of **context** in intervention development. Evidence from the contextual study viewed through the theoretical lens of behaviour change, was used to identify the target behaviours and behavioural constructs at the heart of SMARThealth Pregnancy. The contextual study further informed the practical aspects of intervention delivery, highlighting important socio-cultural practices within rural communities and the need for home-based postpartum care, and identified healthcare workforce constraints amenable to technology and task-sharing.

By starting with the needs and priorities of the community and key stakeholders, their voices came to be embedded into the intervention design. This approach is at the heart of human-centred design, which also highlights the importance of context and prioritises being empathetic to the needs and abilities of the community [290,300]. Involving communities in intervention design has advantages of improving adoption and future sustainability of the intervention in those communities [394]. The design of SMARThealth

Pregnancy used the principles of human-centred design [290] and combined this with behaviour change theory [67,68,281]. It has been hypothesised that combining human-centred approaches with theory can inspire trust within health systems, and address context-specific implementation and sustainability issues [394]. SMARThealth Pregnancy was designed with the aim of co-creating an intervention with the community to ensure future sustainability.

Importance of transparency in reporting behavioural content of interventions

Few interventional studies have specifically addressed the use of BCTs in maternal health interventions and categorised these using a published taxonomy [366,395,396]. The lack of consistent reporting of the active 'ingredients' of maternal health interventions (BCTs), has made comparability across studies, and replicability across contexts, challenging. With this in mind, I used a systematic process highlighting the behavioural constructs and BCTs within each intervention component (using an established taxonomy), and specifying the proposed change mechanisms of SMARThealth Pregnancy in a logic model. Making the proposed mechanisms of impact of SMARThealth pregnancy implicit and providing transparency around the intervention design and implementation process, enables effective evaluation and comparability with similar interventions. Outlining specific BCTs using an established taxonomy further contributes to the evidence-base for behaviour change interventions, and identifies which BCTs may be effective for women's health.

There is evidence to suggest that use of more BCTs may increase intervention effectiveness [397, 398]; however, for health outcomes with a complex aetiology (such as anaemia in pregnancy), there is limited understanding of how intervention functions should be chosen,

which behaviours to prioritise, and how many BCTs to promote [399]. SMARThealth Pregnancy aimed to achieve a balance between the number of intervention components, behavioural constructs and BCTs to be implemented, recognising that targeting too many behaviours might negatively impact programme delivery and create information overload. The intervention components of SMARThealth Pregnancy were simplified to address the behavioural constructs associated with three areas: education (including awareness), training and mHealth (decision support). This pragmatic approach was decided in partnership with the community and key stakeholders (outlined in the conceptual map of health system in Chapter 4), and using established criteria [350].

Complexity and integration of SMARThealth Pregnancy within the health system

The design of SMARThealth Pregnancy acknowledged the complexity and inter-dependence of different actors functioning at different levels of the health system (individual/household-level, provider-level, and system-level), functioning across different levels of the health system, and delivering guideline-based care to high-risk pregnant women in their homes. Previous studies using mHealth to deliver guideline-based care to pregnant/postpartum women have focused on the community-level alone, without considering integration of community-level services within primary and secondary care [320–322,400]. By taking a health systems lens, SMARThealth Pregnancy attempted to address different levels within the health system. This approach is similar to the multi-level framework proposed by Chaudoir *et al* [401], which highlights the importance of identifying predictors influencing implementation outcomes across different levels of the health system.

Social influences upon behaviour change in rural India

The choice of intervention components, strategies and delivery practices of SMARThealth Pregnancy was based on theory, evidence and pragmatic considerations, as supported by French *et al,* 2012 [273]. There were, however, some limitations to this approach. The COM-B/BCW and TDF frameworks, whilst recognising 'social opportunities' influencing behaviour of individuals within a health system, are based on behaviour change theories that focus on individual agency. In rural India, however, pregnant women rarely have the level of autonomy to make independent decisions about their own health. Health-related behaviours of women and practices of healthcare professionals in rural India are intimately connected to other household members, professional hierarchies within the health system, and wider socio-cultural influences. This finding is supported by the work of Blankenship *et al* [402], who acknowledges the wider social and environmental influences affecting individual health-related behaviours and choices. These authors refer to interventions functioning in such contexts as **structural interventions** - which attempt to promote health by altering the structural context of the health system, rather than targeting individual health-related behaviours [402]. The term 'structural intervention' recognises that individual agency in the health system may be constrained and/or shaped by wider influences (structures) within the social, political and cultural environment [402]. Anaemia in pregnancy is one example of a condition addressed by SMARThealth Pregnancy, which encompasses such 'structural' determinants. Behaviour change theory may not encompass the full range of social influences influencing behaviour change. Sociological theories, such as Normalisation Process Theory [69] (Chapter 6) may, therefore, be required to explain the complexities of creating lasting behaviour change through routine embedding of interventions in the context of rural India.

Strengths & Limitations

The strengths of the approach taken for the development of SMARThealth Pregnancy include the use of systematic and well-established methods, outlined by Michie *et al* [349]. Transparency in the intervention design and development process has the potential to enable future replication and comparison with other interventions addressing women's health, and will add empirical evidence to the currently limited knowledge-base of BCTs that might be effective in similar settings. The intervention was designed considering the needs, priorities and advice of key local stakeholders. A unique feature of SMARThealth Pregnancy is that it has embedded the voices of local stakeholders and combined this with a theory-informed approach. Adam *et al*, 2020 highlight this approach as integral to the successful establishment of trust amongst healthcare workers implementing an intervention and intrinsically connected to an intervention's success and sustainability [394].

Limitations of the approach taken for intervention design include the properties of the behaviour change theories themselves. Theories with more of a socio-centric focus might be required to explain the mechanisms of impact fully (as outlined above). Furthermore, the COM-B/BCW and TDF models adopt a linear, stepwise approach to intervention design, but in practice, it is likely that further iterations will be required following implementation and evaluation of SMARThealth Pregnancy. The dynamic nature of complex interventions is, however, acknowledged and incorporated into the cyclical framework for complex interventions outlined by the MRC, which both allows for, and recommends, iterative movement between the four stages [66].

5.9 Conclusion

This chapter has presented a theory-informed approach to intervention design and development, building upon the findings of the contextual study in Chapter 4, and answering the secondary research question of my thesis. I have used relevant theory from the behavioural sciences to explain how the intervention components are likely to impact the implementation of the SMARThealth Pregnancy, and presented the process of mHealth App development and usability testing. The systematic process and logic model outlined in this chapter can be used to guide further refinement and adaptation of SMARThealth Pregnancy following implementation, and provide a basis for future studies. To date, this unique combination of the human-centred design approaches with theory has not been used to guide development of interventions addressing life-course approaches to women's health.

In the next chapter, to answer the primary research question of my thesis, I outline the pilot cRCT of SMARThealth Pregnancy, focusing on the qualitative process evaluation, and theorising the mechanisms of impact in relation to the logic model presented in this chapter.

PUBLICATIONS FROM CHAPTER:

1. **Nagraj S**, Kennedy SH, Jha V, Norton R, Hinton L, Rajan E, Arora V, Praveen D, Hirst JE. SMARThealth Pregnancy: The development & evaluation of a complex intervention for pregnant women at high risk of future cardiometabolic disorders in rural India (RCOG conference abstract). *BJOG: An International Journal of Obstetrics & Gynaecology*. *In press* 2021.

2. **Nagraj S**, Kennedy SH, Jha V, Norton R, Hinton L, Rajan E, Arora V, Praveen D, Hirst JE. SMARThealth Pregnancy: Feasibility and acceptability of a complex intervention for high-risk pregnant women in rural India: Protocol for a pilot cluster randomised controlled trial. *Frontiers in Global Women's Health* 2021; 2: 620759.

6

A pilot cluster randomised controlled trial of SMARThealth Pregnancy

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6.1 Introduction: why a pilot study is needed

Feasibility and piloting are an integral stage of the MRC framework for complex interventions [66]. A pilot study is a type of feasibility study which is intended to model study practices ahead of a definitive trial [403]. Pilot studies can be either external to, or embedded within (and progress to), a larger trial and help identify feasibility and implementation issues ahead of conducting a larger clinical trial [403]. Following intervention development, I designed and conducted an experimental study to evaluate SMARThealth Pregnancy.

As a newly designed complex intervention, there were several areas of uncertainty to be addressed regarding implementation of SMARThealth Pregnancy. Firstly, in rural areas, high-risk pregnancy conditions were not always consistently documented. Consequently, the true prevalence of anaemia in pregnancy, HDP and GDM in the contextual study settings were unknown. Secondly, at the time of the pilot study, the Government of India had launched new guidelines for universal GDM screening [329]. However, there were still uncertainties around operationalisation of these guidelines and the most suitable implementation strategies in rural settings. Finally, as part of the intervention delivery of SMARThealth Pregnancy, ASHAs were provided with mobile clinical decision support

and trained to measure Hb and BP in women's homes. It was unclear if these practices would be acceptable to ASHAs and pregnant women, and the unintentional and intentional impacts of these intervention practices on the health system. These areas of uncertainty gave rise to clinical equipoise [404] between existing maternity care and the new integrated model of task-sharing offered by SMARThealth Pregnancy.

Intervention studies include clinical trials (which focus on clinical effectiveness), and implementation trials (which test implementation strategies). Implementation trials typically work at the provider-level and involve the health system, with randomisation and analysis at the provider-level (cluster-level). I designed the SMARThealth Pregnancy pilot study as a cRCT to compare current maternity care with SMARThealth Pregnancy. I chose a randomised study design to reduce the systematic bias arising from external influences that may affect maternity care, e.g. the impact of state-wide and local elections on rural health services, so that study outcomes could be attributable to the intervention rather than confounding factors. Outcomes of implementation trials look beyond clinical outcomes, to understand adoption of complex interventions, and process and quality measures. The pilot cRCT of SMARThealth Pregnancy was conducted to focus on implementation and address the primary research question of my thesis, and explore one of the secondary research questions:

Is it feasible and acceptable for CHWs in rural India to screen, refer and manage high-risk pregnant women during antenatal and postnatal care using a complex intervention including mobile clinical decision support?

What are the important factors in the design and delivery of the complex intervention that can explain its feasibility, acceptability, and likelihood of scalability outside of a pilot study?

In this chapter, I present the methods and results of the pilot study of SMARThealth Pregnancy, including descriptive statistics relating to the feasibility of the intervention and a qualitative process evaluation using Normalisation Process Theory (NPT) [69] (Chapter 3) as a theoretical lens to understand the acceptability and integration of the intervention implementation into the daily work of ASHAs. Although clinical outcome data will not be discussed in this chapter, these data will be used by the wider study team to inform intraclass correlation coefficient (ICC) calculations for a larger cRCT of SMARThealth Pregnancy in the future.

6.2 Methods

6.21 Study objectives

The objectives of the pilot study were to **evaluate the feasibility and acceptability** of the intervention components to enable further refinement and modification, to explore the **mechanisms of impact** and address **implementation issues** in a real-world setting.

Feasibility of the intervention was determined in terms of: (i) how many PHCs approached accepted the invitation to participate in the trial; (ii) participant recruitment rates; (iii) retention of pregnant women in the trial to 6 weeks postpartum, and (iv) intervention fidelity (i.e. if the intervention was delivered as planned by ASHAs). Acceptability of the

intervention was evaluated through qualitative interviews and FGDs with end-users (including CHWs and pregnant women). The study also evaluated whether the intervention would integrate within the existing health system and any potential unintended consequences. In addition, the prevalence of the three key conditions: anaemia, HDP and GDM was collected.

6.22 Study setting & design

The pilot study was conducted in the same two sites as the contextual work (Chapter 4): the Jhajjar district of Haryana and the Guntur District of Andhra Pradesh. It was designed as a prospective, parallel, unblinded, cRCT, guided by the CONSORT 2010 statement extension for randomised pilot and feasibility trials [405], and registered with ClinicalTrials.gov (NCT03968952) [406]. Ethical approval for the study was obtained from the Oxford Tropical Research Ethics Committee (OxTREC reference: 22-19) and the George Institute India Ethics Committee (Reference: 010/2019 – see **Appendix C**). Trial oversight was conducted by a steering committee consisting of my DPhil supervisors and senior staff at the George Institute for Global Health, India.

6.23 Sample size

Whilst no formal sample size calculation was undertaken, a pragmatic approach was used, combining published guidance on sample size for pilot studies with an in-depth discussion with the team statistician [407–409]. A sample size of four PHC clusters, recruiting a total of 200 pregnant women was chosen to provide rich feasibility data ahead of a definitive trial, whilst also being achievable in the context of a pilot study.

6.24 Randomisation

A list of PHCs in the Jhajjar district of Haryana (n=27) and the Guntur district of Andhra Pradesh (n=48) was compiled using data from the Government of India website [410,411]. Each PHC was assessed for eligibility and stratified by geographical region and population size. To avoid contamination between intervention and control groups, the villages selected under each intervention and control PHC were non-contiguous. Four PHCs (two from each study site) were randomised to either SMARThealth Pregnancy or control (enhanced standard care). Individual randomisation of pregnant women was not possible due to contamination of the intervention practices within villages; therefore, cluster randomisation of PHCs was conducted. An independent, blinded statistician at the George Institute for Global Health randomised four PHCs using a random number generator. Two PHCs (one in each study district) were allocated to the SMARThealth Pregnancy intervention, and two to the control group (enhanced standard care).

6.25 Consent

Informed consent was obtained at the cluster-level and the individual-level. In rural India, PHCs are led administratively by a senior medical officer, who has overall responsibility for all affiliated staff (including PCPs and CHWs) and for providing care to women in the PHC villages. Consent for the four eligible PHCs was obtained from the administrative lead prior to randomisation. Additionally, staff (PCPs and CHWs) affiliated to the study PHCs were approached to participate.

Participant Information Sheets (PIS) and Informed Consent Forms (ICF) were developed for pregnant women, healthcare workers and the PHC administrative lead. These were

conveyed both verbally and in written form in the local language to all study participants prior to obtaining written informed consent.

Eligible pregnant women in the third trimester of pregnancy (28-36 weeks' gestation) were identified through the ANM during their standard ANC visits and recruited to the study. A total of 200 pregnant women (50 in each of the four PHC clusters) were recruited to the study. Informed consent was obtained from the intervention group to share their antenatal handheld record, demographic details, medical and obstetric history, and have their BP and Hb measured by an ASHA at each of the intervention visits: a) the last trimester of pregnancy (between 28-36 weeks' gestation); b) week 1 postpartum and c) week 6 postpartum. Informed consent was also obtained from the control group to share their antenatal handheld record, demographic details, medical and obstetric history, and have their BP and Hb measured by an independent member of the research team at baseline and after their routine 6-week postpartum visit (end line). Individual consent was obtained from CHWs and women prior to interviews and FGDs as part of the qualitative process evaluation.

Table 6.1 Summary of inclusion and exclusion criteria for the study

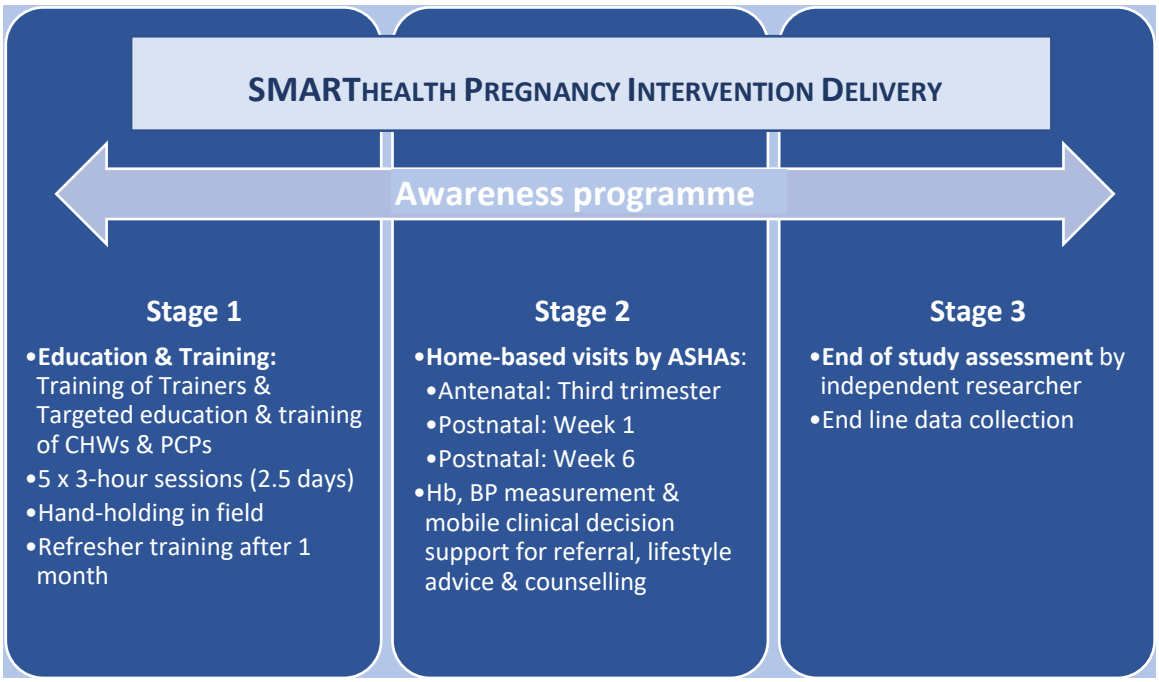
Participants	Inclusion criteria	Exclusion criteria
Primary Health Centres	- Serving population of 30,000 people or more, in either: - a) Jhajjar district, Haryana - b) Guntur district, Andhra Pradesh - PHC doctor (administrative lead) consents for the PHC to participate in the study	- Serving population of <30,000 people - Not in Jhajjar/Guntur districts - PHC doctor (administrative lead) does not give consent for the PHC to participate in the study
Primary Care Physicians	- Working at participating PHCs in either: - a) Jhajjar district, Haryana	- Not affiliated to the study PHCs in Jhajjar/Guntur

Participants	Inclusion criteria	Exclusion criteria
	- b) Guntur district, Andhra Pradesh	- PCPs not working with pregnant and postpartum women
Community Health Workers (ANMs/ ASHAs)	- Working at participating PHCs in either: - a) Jhajjar district, Haryana - b) Guntur district, Andhra Pradesh	- Not affiliated to the study PHCs in Jhajjar/Guntur
Pregnant women	- Age 18 years or above - 28 -36 weeks' gestation - Living within villages in the PHC catchment area, in either: - a) Jhajjar district, Haryana or - b) Guntur district, Andhra Pradesh	- Women < 18 years of age - Women not 28-36 weeks' gestation

Intervention group practices

The intervention components (outlined in Chapter 5) were delivered in three stages: 1) Education & Training, 2) Delivery of the home-based mHealth intervention visits, and 3) End of study assessment (Figure 6.1). Awareness programmes were delivered by ASHAs and ANMs during regular monthly village health and nutrition days in their respective villages throughout the study.

Figure 6.1: Intervention group practices



For quality assurance of intervention practices, regular field visits and observations of ASHAs were made by myself and local members of the research team at intervals during the study to ensure compliance to study procedures. In addition, data collected through the mHealth tablets were used to monitor fidelity to intervention practices.

Control group practices

The control PHCs received **enhanced standard care**. In addition to routine antenatal and postnatal care delivered by CHWs, an awareness programme was delivered to women, CHWs and PCPs at the control PHCs outlining the importance of attending ANC, identifying high-risk pregnancies, compliance with iron folate tablets and need for long-term follow-up of women with high-risk conditions such as HDP and GDM. Leaflets were also designed in local languages to convey this information and distributed to women and partners at the PHCs **(Appendix D).**

End of study visit

I developed a case report form to collect baseline and end line data. In addition to collecting baseline data, an independent researcher from the local field team (not blinded to the intervention) completed an end of study questionnaire and recorded BP and Hb readings independently in both the intervention and control groups.

6.26 Study Outcomes

In addition to collecting descriptive data relating to the prevalence and follow-up of pregnant women with anaemia, HDP and GDM in the intervention group, a qualitative process evaluation was conducted to evaluate the acceptability and integration of SMARThealth Pregnancy into the health system. End of study BP and Hb clinical outcome data were collected primarily with the aim of assessing the feasibility of collecting these measures as potential clinical endpoints in a larger trial, and to provide the confidence intervals around these continuous variables for the ICC calculation ahead of a definitive trial [409]. These are not reported here. The primary and secondary outcomes of the pilot study are outlined in Table 6.2.

Table 6.2: Primary and Secondary outcomes

Primary outcomes	
Feasibility outcomes	Determine feasibility of recruiting PHCs Feasibility of recruitment & retention of pregnant women to the study by determining: -Recruitment rates of pregnant participants per cluster per month -Retention rates of participants at six weeks postpartum
Acceptability outcomes	Evaluate acceptability of intervention to end-users using a qualitative process evaluation

Secondary outcomes	
Prevalence rates	Determine true prevalence of moderate to severe anaemia, HDP and GDM at study sites Determine proportion of pregnant women detected, referred and followed-up for moderate to severe anaemia, HDP or GDM
Intervention fidelity	Assess extent to which SMARThealth Pregnancy was delivered as planned (fidelity) by looking at: -Proportion of visits completed by ASHA in line with intervention protocol (completeness & timing of the entries onto mHealth tablet)
Clinical outcomes	Mean Hb and mean BP at six-week postpartum visit (to calculate ICC)

6.3 Statistical analysis

Descriptive statistics addressing the feasibility of the intervention (recruitment strategy and the retention of participants), referral of high-risk women and prevalence of high-risk conditions were compiled using the Statistical Programme for Social Sciences version 27 (SPSS v27©). These data were used to understand patterns of recruitment and feasibility of conducting a larger cRCT. No formal hypothesis testing was undertaken.

6.4 Qualitative Process evaluation

A qualitative process evaluation was conducted to explore the acceptability of SMARThealth Pregnancy, mechanisms of impact; understand how the intervention integrated into the daily work of ASHAs, and determine whether there were any unintended consequences.

A purposive sample of study participants (pregnant/postpartum women and CHWs) from the intervention groups at each site were invited to share their experiences of SMARThealth Pregnancy. Interviews and FGDs were conducted at intervals throughout the duration of the study following antenatal (visit 1) and postnatal intervention visits

(visits 2 and 3), to assess the acceptability of each visit as the study progressed. End of study in-depth interviews (IDIs) were planned with PCPs upon completion of the pilot study (to minimise inconvenience resulting from workforce constraints affecting them in rural areas). However, due to the Covid-19 pandemic, I was unable to return to India to conduct these interviews.

6.41 Conducting interviews and focus groups

I developed topic guides for IDIs and FGDs with pregnant/ postpartum women and CHWs. These were reviewed by my DPhil supervisors and piloted on members of the field team. Interviews/focus groups were conducted at the local PHC/subcentre for CHWs and at the pregnant/postpartum women's homes. All interviews and discussions were audio-recorded with informed consent. FGDs and IDIs were conducted by myself, together with a local research assistant trained in qualitative methods from The George Institute for Global Health, India, who provided translation into the local language when necessary. All interviews and discussions were audio-recorded with consent and transcribed from local languages into English by a professional transcription company in India.

6.42 Theoretical framework for process evaluation

Normalisation Process Theory (NPT) was chosen as a theoretical lens for the qualitative process evaluation (Chapter 3). Implementation and integration of a complex intervention into the health system require both the collective and individual actions of workers within the health system. Unlike behaviour change theory, NPT focuses on the **actions** of people within the health system to deliver a new intervention, rather than their **intentions and attitudes** towards the intervention [69,277,278]. NPT further explains how complex interventions become routinely embedded into the professional and organisational context

of the health system [278]. I felt NPT would complement behaviour change theory used to inform intervention design and provide insight into the degree of integration of SMARThealth Pregnancy into the daily work of ASHAs and the health system in rural India. The four constructs of NPT [283] (Table 6.7) were used as an analytic framework for the qualitative process evaluation.

6.43 Data analysis of qualitative process evaluation

I used a framework approach [412] and followed the seven-step process outlined by Gale *et al* : data **transcription**, data **familiarisation**, data **coding**, **development** of an analytical framework, **application** of this framework and **charting** data into a framework matrix, and **interpretation** of the findings [412]. Data were charted into a framework matrix using MS Word, with the four NPT constructs (themes) as columns and the cases (IDI/FGD source) as rows (**Appendix E**). The matrix enabled comparative analysis between cases and the data to be viewed as a 'whole', thereby facilitating data interpretation.

Whilst NPT provided a structure for the framework analysis, the topic guides were not based on NPT constructs and included open-ended questions to stimulate discussion. Therefore, I used a combination of inductive and deductive coding to discover those aspects of participant's experience that were not explained fully by NPT. NVivo QSR© software was used to organise the data.

Maintaining trustworthiness and consistency in data analysis

To maintain consistency and trustworthiness in the process of data analysis, I followed established steps outlined by Gale *et al* [412]. I also conducted team-debriefs after each IDI/FGD to triangulate the main discussion points with other members of the study team,

and practised reflexivity throughout. After conducting the initial data analysis and coding, these steps were discussed and reviewed with my supervisor (LH), an experienced qualitative researcher, to ensure consistency.

6.5 My involvement in the study design and implementation

After conducting the initial contextual work and intervention design, I designed the study, wrote and registered the pilot study protocol, which was discussed with members of the team at the George Institute for Global Health, India, and my DPhil supervisors, who agreed with the design and implementation. I worked with a team from the George Institute for Global Health, India, comprising of a programme manager, and six field team members (three at each study site). I led and was involved in each step of the implementation of the trial including seeking permissions from Government officials in rural India, writing and submitting the ethics applications in Oxford and in India, delivering the SMARThealth Pregnancy Training of Trainers sessions in India, and delivering training to CHWs at both study sites. I conducted the qualitative process evaluation of the study, and designed the topic guides and conducted interviews and FGDs with pregnant women and CHWs.

6.6 The impact of Covid-19 on the pilot study

The pilot study of SMARThealth Pregnancy started before the global pandemic with the first participant recruited in Haryana on October 22nd, 2019. In India, a national lockdown started on March 24th, 2020, lasting a period of 2 months. The lockdown delayed recruitment of participants at the control site in Andhra Pradesh and prevented end line data collection of Hb and BP measures in Haryana during April and May 2020.

As screening for high-risk pregnancy was deemed an essential service in India during the pandemic, ASHAs were still permitted to conduct ANC and postnatal follow-up visits during the pandemic [413]. In Haryana, the format of these visits was limited to either socially distanced home visits (ASHAs were not permitted to measure Hb and BP), or telephone follow-up of postpartum women. This prevented end line clinical outcome data from being collected in Haryana for some participants; however, feasibility and acceptability data relating to the primary study outcomes were still collected. In a personal communication with ASHAs and the senior medical officer in Haryana following the start of the pandemic, the SMARThealth Pregnancy mHealth platform provided structure and consistency to the postnatal visits at a time of considerable uncertainty. In Andhra Pradesh, ASHAs were permitted to perform home visits and measure Hb and BP during antenatal and postnatal home visits with personal protective equipment provided by the Government and social distancing precautions, and subsequently all data were collected per study protocol.

6.7 Results: Recruitment & descriptive statistics

6.71 Recruitment of study participants

The feasibility of the SMARThealth Pregnancy intervention was ascertained by measuring recruitment rates at each study site, fidelity to intervention practices by ASHAs, and retention of study participants at each study site. All approached PHC administrative leads agreed to participate in the study. Recruitment of 50 participants was completed in approximately 4 months or less at each study site (Table 6.3). Recruitment of eligible women at the control site in Andhra Pradesh was affected by a national lockdown during

the Covid-19 pandemic, suggesting that under 'normal' circumstances recruitment is likely to be faster.

Table 6.3: Recruitment rates of eligible pregnant women

Study Site	Intervention n=50	Recruitment rate per PHC population	Control n=50	Recruitment rate per PHC population
Haryana	94 days	12.5 women/month	50 days	16.7 women/month
Andhra Pradesh	73 days	12.5 women/month	128 days*	10 women/month

* Recruitment was affected by a two-month national lockdown due to Covid-19

All eligible women who were approached to participate were willing to give their informed consent to have their baseline and end line Hb and BP measured as part of the study. Possible reasons for this high uptake are discussed later in this chapter.

6.72 Descriptive statistics

The mean age, BMI and years of schooling of participants in the study were comparable across the intervention and control groups (Table 6.4). Whilst most women had completed secondary school education, the range of years of schooling was wide, with some women not having attended school. The average number of people in the household was five in both groups, often with only one source of income for the entire family. Baseline data relating to study participants are presented in Table 6.4.

Table 6.4: Baseline demographic data & end line visit data

	Intervention group n=100		Control n=100	
	Mean (SD)	**Range**	**Mean (SD)**	**Range**
Age (years)	23.5 (3.5)	18 - 33	24.0 (3.6)	18 - 33
Body Mass Index (BMI)	22.6 (4.0)	11 - 36	22.1 (4.1)	14 - 35
Years of schooling (years)	12.2 (3.7)	0 - 18	12.4 (4.0)	0 -20
Number of people in household	4.9 (2.1)	2 - 13	4.8 (1.9)	2 - 11
Hb at booking visit (g/dL)	9.6 (1.4)	5.8 – 14.4	9.4 (1.4)	5.8 – 14.0
Baseline visit Hb (g/dL)	9.9 (1.7)	4 – 13.1	9.6 (1.7)	5.3 – 13.1
Baseline Systolic BP	108 (11.3)	83-131	108 (12.4)	83 - 151
Baseline Diastolic BP	70 (8.5)	47-90	70 (9.0)	47 - 94
Moderate to Severe Anaemia (Hb <10) at baseline visit	**47/100 47%**		**58/100 58%**	
End line visit Hb (g/dL)	11.1 (1.7)	7.4 -14.5	10.3 (1.7)	7 – 16.7
End line Systolic BP	110 (11.6)	88 - 142	112 (13.4)	84 - 147
End line Diastolic BP	72 (8.2)	57 - 101	73 (11.9)	50 - 118

***SD = Standard Deviation**

Fidelity to intervention practices

At both study sites ASHAs completed the first and second study visits per protocol. Data entry into the mHealth tablet was complete and appropriately entered at both intervention sites, suggesting high fidelity to intervention practices by ASHAs. Before the global pandemic and national lockdown in India, the final (week 6) postpartum ASHA visits at both study sites were completed in line with the study protocol. During the national lockdown in Haryana, the district health officer did not permit home-based measurement of Hb and BP by ASHAs. End line Hb and BP data were, therefore, missing for 19/100 participants in the intervention group and 24/100 participants in the control group (Table 6.5). Home-visits by ASHAs to pregnant/postpartum women did, however, continue during the pandemic, and history-taking, provision of social support and counselling (provided through the SMARThealth Pregnancy mHealth platform) continued to be implemented by ASHAs in the intervention group.

In Andhra Pradesh, due to the availability of personal protective equipment (PPE), ASHAs were permitted by the local health authorities to perform Hb and BP measurements at home, and the local government appreciated ASHAs being able to provide these enhanced services to high-risk pregnant women at home during the pandemic. End line data were available for 47/50 participants in the intervention group in Andhra Pradesh. The three outstanding participants were followed up remotely by telephone after lockdown; however, their Hb and BP were not measured. All participants in the control group in Andhra Pradesh had end line Hb and BP measured.

Table 6.5: Fidelity to intervention practices

SMARThealth Pregnancy Visits	Haryana Number of Participants (n=50 in each group)		Andhra Pradesh Number of Participants (n=50 in each group)	
	Intervention	Control	Intervention	Control
Baseline questionnaire: Hb & BP	50	50	50	50
ASHA Visit 1: History	50	N/A	50	N/A
Hb & BP measurements per protocol	50	N/A	50	N/A
ASHA Visit 2: History	50	N/A	50	N/A
Hb & BP measurements per protocol	50	N/A	50	N/A
ASHA Visit 3: History	50 (100%)	N/A	50 (100%)	N/A
End line Hb & BP measurements	31/50 (62%)	14/48* (29%)	47/50 (94%)	48/48* (100%)

***Loss to follow up of four participants: two at each control site (2%).**

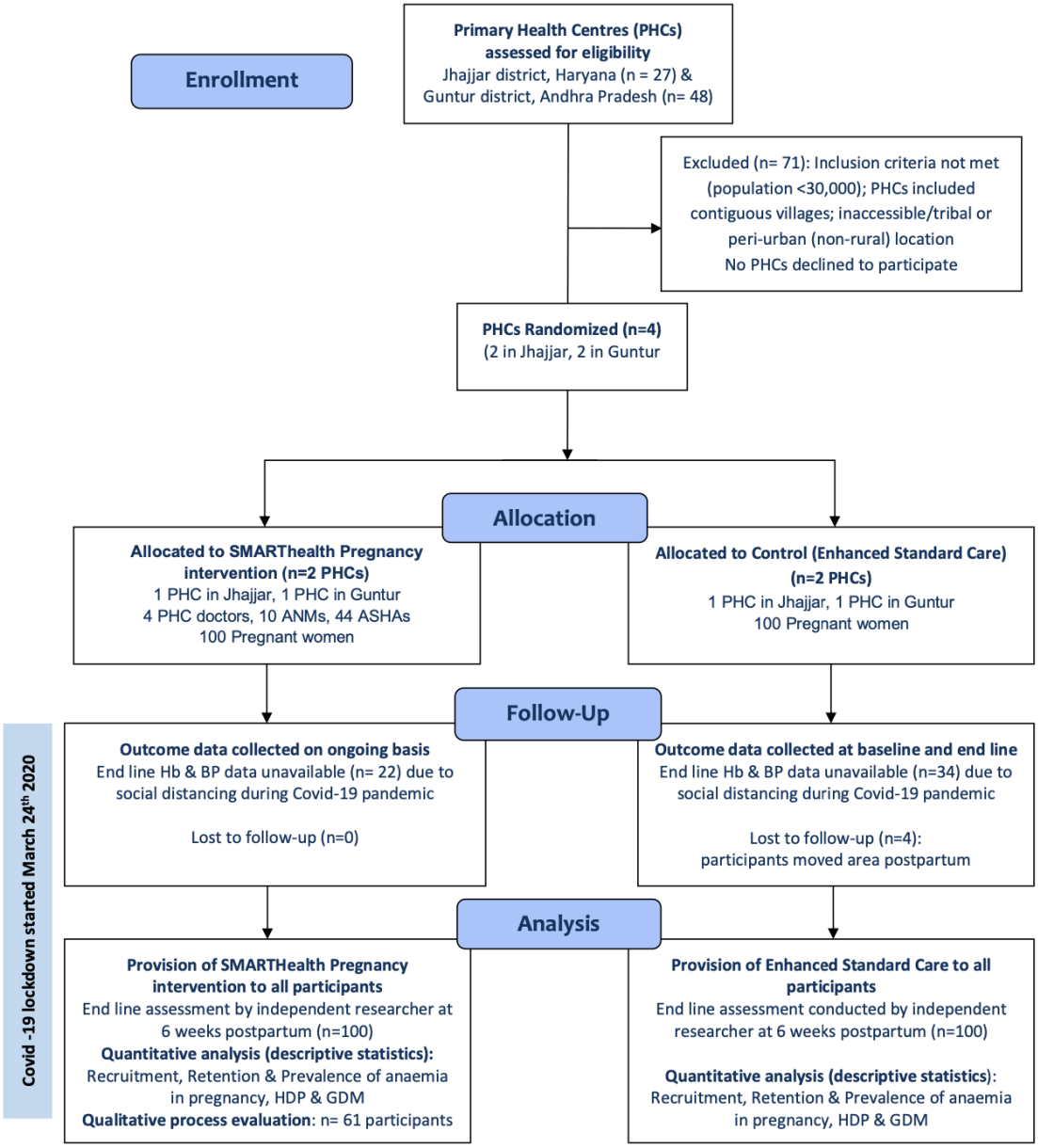
Loss to follow-up

A total of 4/200 (2%) participants were lost to follow-up (two at each site). In all four cases this was due to the women moving out of area to their mother's village in the postpartum period. In all four cases the local field teams attempted to contact the women by phone on at least three different occasions but were unsuccessful.

Postpartum engagement with primary and secondary care services

Although participants were advised to see the doctor at the PHC after each intervention visit, ASHAs were not permitted to force women to do so. Most women saw the PHC doctor or a private/government obstetrician antenatally; however, few women saw a government doctor after delivery (both before and during the pandemic). In Andhra Pradesh, 22/50 (44%) women in the intervention group saw an obstetrician privately following the ASHA intervention visit in the first 2 weeks postpartum. Most of these women (21/22) attended to have stitches removed following a Caesarean-section, and one woman attended following a stillbirth. In Haryana, only 17/50 (34%) women saw a doctor either privately or through government services in the first 2 weeks postpartum. No women in either intervention group saw a doctor (privately or at the PHC) after 6 weeks postpartum in the study.

Figure 6.2: Participant flowchart of pilot study



Prevalence of high-risk conditions in pregnancy

At baseline, mean systolic and diastolic BP in both intervention and control groups was similar (Table 6.4), with only one woman with a baseline BP above 140/90 in the third trimester. The prevalence of moderate to severe anaemia (Hb < 10g/dL), taken using the TrueHb© meter was 47% in the intervention group, and 58% in the control group at baseline (third trimester). Baseline TrueHb© readings revealed that the prevalence of severe anaemia (Hb < 7g/dL) was 3% in the intervention group, and 8% in the control group. The prevalence of HDP (5/200) and GDM (4/200) across all study sites was 2.5% and 2% respectively.

Referral rates & maternal and neonatal morbidity & mortality

Nine women (9%) in the intervention group were referred to a specialist for high-risk pregnancy. Most (4/9) were referred to a general physician for thyroid problems; a further two women were referred to an obstetrician for iron sucrose injections, and one woman for a blood transfusion. The remaining two women were referred to an obstetrician for unknown reasons. A further five women received iron sucrose injections at the PHC for moderate anaemia and were not referred to a specialist.

In the control group, twelve women (12%) were referred to an obstetrician for high-risk pregnancy conditions, including thyroid problems (n=6); twin pregnancy (n=1); iron sucrose injections (n=1); vomiting (n=1); GDM (n=1); HDP (n=1) and epilepsy (n=1). One woman in the control group in Andhra Pradesh was hospitalised for Covid-19 for 20 days and had a Caesarean-section at a private hospital. She was discharged home after delivery, with no postnatal complications. One neonatal death was reported in the

intervention group in Haryana. The baby who was born with congenital abnormalities and required resuscitation at birth, died soon after delivery. There were no maternal deaths.

Screening for Gestational Diabetes Mellitus

A total of 82% (163/200) of women in the study had been screened for GDM before 28 weeks' gestation, mainly by providing either capillary (60%) and/or venous blood samples (53%). Less than a quarter of women (19%) reported having an OGTT, the majority of which were non-fasting (Table 6.6). All women who had not had an OGTT were offered one after being recruited into the study (in line with Government of India GDM guidance). Even with this extra measure, only 4/200 (2%) women were diagnosed with GDM. Those with GDM were all already under the care of a private obstetrician in their respective areas. Although ASHAs counselled these women about the long-term implications of GDM, advised them to undergo postpartum OGTT screening and to be linked to the local NCD programme, the advice was not reinforced by local obstetricians. Women with GDM were counselled about lifestyle advice, but not offered further screening or ongoing medication by obstetricians after their blood sugar normalised post-delivery.

Table 6.6: Antenatal screening practices for Gestational Diabetes Mellitus

	Intervention		Control	
Blood sugar testing done < 28 weeks	80/100	**80%**	83/100	**83%**
Capillary blood sample	51/100	**51%**	68/100	**68%**
Venous blood sample	61/100	**61%**	44/100	**44%**
OGTT	14/100	**14%**	23/100	**23%**
Fasting OGTT (of those who had OGTT)	6/14	**43%**	3/23	**13%**

6.8 Results of qualitative process evaluation

A total of five FGDs (CHWs) and seven IDIs (CHWs and pregnant/postpartum women) were conducted with 61 participants (see **Appendix E**). Qualitative data from interviews and focus groups were organised using the four NPT constructs (Table 6.7) into a framework matrix (**Appendix E**) to explore how SMARThealth Pregnancy became integrated, embedded and routinised into the daily work of ASHAs.

Table 6.7: Normalisation Process Theory (NPT) core constructs in relation to qualitative process evaluation

Coherence	**Sense-making** work done by ASHAs to build an individual and shared understanding of SMARThealth Pregnancy *How did ASHAs and women understand the intervention & the value, impact and importance of a new set of practices?*
Cognitive Participation	**Relational work** done to build & sustain a community of practice around SMARThealth Pregnancy *How did ASHAs, ANMs and the wider community enrol and engage with SMARThealth Pregnancy to **initiate, engage, organise & sustain** intervention practices?*
Collective Action	**Operational work** ASHAs did to **enact** intervention practices *How did ASHAs and ANMs **work together** within the health system to deliver the intervention?*
Reflexive Monitoring	**Appraisal work** done by ASHAs both individually & collectively to assess SMARThealth Pregnancy *How did ASHAs & ANMs **reflect** upon their progress and appraise their work when delivering the intervention?*

6.81 Coherence: Conceptualising value of SMARThealth Pregnancy

ASHAs were able to distinguish the new set of practices associated with SMARThealth Pregnancy from their established work and understand the benefits and importance of these new ways of working. Two features of SMARThealth Pregnancy were particularly valued by ASHAs. Firstly, the visibility and accessibility of patient data through the mHealth

tablet, which enabled ASHAs to recall women's demographic and past medical history easily. ASHAs were further able to provide ANMs with these data, creating a shared understanding of the benefits of the intervention between CHW cadres.

"There are lot of uses with the Tab [mHealth tablet]. It is very good. Even if miss putting down anything in the book, if we take a look at the tab, we will get to see all the information. When we visit the pregnant woman, if you check the info on the Tab, it gives their name…"

- ASHA, Andhra Pradesh.

Secondly, the clinical decision support and traffic light system provided by the SMARThealth Pregnancy mHealth platform educated ASHAs about the significance of Hb and BP values. ASHAs felt this had improved their knowledge and transformed the nature of their home visits, improving the content and quality of care for pregnant/postpartum women.

"It has been very good. Earlier…we took their temperature...and now it is like in addition, we do BP and Hb, so they [the women] get to know a little more…that her Hb is low or BP is ok or not. So this much difference is there." *…"Like, your Hb percentage is low, you should eat well…you should get yourself checked at the hospital…Now we are able to explain things like that* ."

- ASHA, Haryana.

Impact of intervention on self-efficacy

ASHAs reported an improvement in their knowledge, skills and confidence. At the start of the study, ASHAs found the clinical skills of measuring Hb and BP challenging; however, with training and support, they quickly adapted to new ways of working to deliver the intervention. As a result, ASHAs felt more confident in their abilities and a sense of self-satisfaction with the quality of care they now were able to provide.

"Earlier we did not about tests madam, how to do them. Now we know how to do them ourselves…Now we do ourselves! We got to learn new things...our trainers were so good…they taught us so nicely that we understood very quickly…We knew earlier..but now we know more than before. We got learn a lot of new things…We got to be more confident now."

- ASHA, Andhra Pradesh

The diffusion of knowledge resulting from ASHAs engaging with the intervention impacted pregnant/postpartum women, who also valued the traffic light system and advice from ASHAs conveyed through the mHealth tablet. Through the SMARThealth Pregnancy home visits, women's awareness of high-risk pregnancy conditions, including HDP, improved.

"High blood pressure is harmful for the baby. During low blood pressure we get headaches problems in the pregnancy, like it is not good for health and it is not good for the child, that's why I know about it."

- Pregnant woman, Haryana

6.82 Cognitive participation: Negotiating relationships with other healthcare professionals & the community

The SMARThealth Pregnancy intervention changed many of the relational aspects of work with the wider health system and community. During the initiation phase of the intervention, the legitimacy of ASHAs to deliver intervention practices was questioned by healthcare workers and the community.

"ANMs also feel why are ASHA workers conducting a BP test...They are like, we have this technician who are trained for this, ASHA workers are workers."

- ASHA, Andhra Pradesh

Similarly, whilst conducting home visits, extended family members of the pregnant woman questioned ASHAs about their abilities.

"*Why was it given to you? Are you eligible to this? Why should you perform this? Are you being trained for this?" Some of them say such things."*

- ASHAs, Andhra Pradesh

However, as the pregnant women and their extended families experienced the benefits of the skills ASHAs had mastered as part of SMARThealth Pregnancy, their attitudes towards ASHAs' abilities changed **(legitimation)** [283]. ANMs also noticed improvements in the knowledge, skills and motivation of ASHAs to deliver ANC and postnatal care (PNC), recognising the value of SMARThealth Pregnancy to their own working relationships with ASHAs.

"*We noticed the difference….in the past we used to tell them that the woman is 20 weeks pregnant now, so call them. They used to call them when we asked them to…Now they know that OGTT should be done at below 28 weeks…that the woman should be present here for delivery.. whoever is under me, I have to conduct the OGTT, we should check BP for them…They have the interest to do [these things] now*."

- ANM, Andhra Pradesh

Pregnant and postpartum women also acknowledged the important contribution of ASHAs in intervention delivery with extended family members even asking the ASHAs to check their own BP. In addition, pregnant women felt well managed by ASHAs, and empowered to engage with the health system and take responsibility for their health.

"Many things I learnt many things about pregnancy phases…she tell me about all things like tablets - iron and calcium tablets and also gave me, like that…and the most important thing is involvement [with health system]…the ASHA worker is helpful for me - like glucose test, sugar test, and blood test it is very good for me…Before pregnancy I didn't know about the ASHA workers. After pregnancy I know them…Seriously…the facilities here are very good."

- Postpartum woman, Haryana

Social recognition and value of ASHAs

The perceived social status and value of ASHAs in the eyes of the women, ANMs and doctors increased during the study. Significantly, this was translated into improved trust in the ASHA's abilities, with tangible clinical benefits experienced by women.

"Sister (ASHA) is there, she's doing blood test or BP check"… Q: "Then do you trust her?"… "Yes completely, completely trust her." …. "Yes, there has been an improvement in my blood (levels). First, I had seven [Hb of 7g/dL], then….it was 9.5…then after that reached 9.8 [g/dL]. After that at the time of delivery it was 10. (smiling)"

- Postpartum woman, Haryana

ASHAs could also see the impact of the intervention on the way they were seen within their communities, experiencing an increase in respect and perceived worth.

"*Now we have some value in the village…We never used to do it before…There was no recognition for ASHAs before. Now, people at least recognise us in our area."*

- ASHA, Andhra Pradesh

Impact of SMARThealth Pregnancy on community and professional relations

ASHAs, ANMs and study participants were very supportive of the intervention and its continuation in their communities. ASHAs did not want to give up the new practices they had started in the pilot study. The increased trust and value given to ASHAs further translated into an improved sense of cohesion within the communities they served.

"Mostly people respect us more. The bonding between people and us is much closer."

- ASHA, Andhra Pradesh

ASHAs were able to recognise the impact of the new intervention practices on their ability to follow up women in the postpartum period and provide continuity of care during a time when women were not permitted to leave their homes.

"…also the family members - they are happy because they are getting it [the care] at home…and like some people are hesitant to go outside after delivery…so they get home services, so the other people are also happy and family members are also happy."

- ASHA, Haryana

6.83 Collective action: Changing the nature of work for ASHAs

To operationalise SMARThealth Pregnancy, ASHAs enacted new practices and discovered novel ways of working with ANMs and their communities. This was particularly seen in relation to the introduction of community-based GDM screening, which required ASHAs and ANMs to develop a new skill-set (**skill-set workability**), work in partnership with each other (**interactional workability**) and with pregnant women in their villages (**contextual integration**) [283]. Reconfiguration of ASHA's and ANM's workload as part of the intervention required the two cadres of CHW to create a new set of processes within their communities. For example, ASHAs gave women the OGTT solution to drink at home and accompanied them to see the ANM at the subcentre to have their blood sugar tested after 2 hours. Clinical decision support was provided through the SMARThealth mHealth platform to interpret results and provide guidance to ASHAs and ANMs regarding referral and health counselling for women with GDM. ASHAs and

ANMs both recognised the impact of these new practices on their knowledge of GDM and its future risks.

"We got to know about OGTT only because of this training…we did not know about this in the past. Ma'am, we never asked about diabetes. That is the truth…Yes, we got to know only after you came in. We used to know about Hb and BP but we never used to ask about diabetes."

- ASHA, Andhra Pradesh

ANMs further expressed their gratitude for the intervention, and the difference it had made to their ability to deliver gold standard care to their communities, providing a service previously only offered at private hospitals. ANMs were eager to operationalise GDM screening beyond the pilot study.

"Previously we used to do conduct diabetes test, RBS [random blood sugar] test and we used to send it to PHC. OGTT test was done in private hospitals…not all private hospitals had that too, madam. They used to conduct in only in few, selective, big corporate hospitals used to do it. It was not available in small private hospitals too. It was not available in GGH [Government General Hospital] as well."

- ANM, Andhra Pradesh

Integration of intervention practices into daily work of ASHAs

ASHAs were able to integrate the new intervention practices into their routine visits without any perceived increase to their workload.

"It is a part of the work, but we get to know more information because of this."

- ASHA, Andhra Pradesh.

"No, it doesn't really increase the work, it's just that we were already going on the visits, but now we are also more confident we are doing this…"

- ASHA, Haryana

The feeling that the intervention had not increased their workload was, in part, explained by the ASHAs experiencing an improved sense of self-efficacy and social recognition, and the collective value of the intervention to their communities. ASHAs also reported the benefits and convenience of the intervention to local women and their families.

"They say that we are doing this at the comfort of their homes and they don't feel the need to go to the hospital...because we conduct these tests, they will be able to tell us about the delivery...Since we keep in touch with the daughters-in-law, they respect us, as they already know us. Daughters come only during the delivery time and we would not know them very much. But because of this [SMARThealth Pregnancy], we are able to get in touch with them and know them well. It becomes easy."

- ASHA, Andhra Pradesh

The impact of task-sharing on professional hierarchies

ASHAs and ANMs recognised that the intervention had implications for the skills shared between their two cadres and might have the potential to affect professional hierarchies. However, as a result of task-sharing with ASHAs, the nature of the relationships between ASHAs and other healthcare professionals (including ANMs and doctors) improved, with a flattening of the professional hierarchies previously seen in the rural health system.

"*We are happy, as the ANM is happy, because we have got the instruments and everything. She says now we have become our equal and you can do these things also. So, they are happy also…the PHC doctors and everybody, they sometimes tell the mothers that you can get your BP- these things checked from your area ASHA workers."*

- ASHA, Haryana.

Acceptance of new intervention practices into the health system by more senior cadres of healthcare worker was explained, in part, by the new division of labour improving current practice.

"Let it be tab or Hb or BP....Previously ANM's used to do Hb or BP tests. Now, since we are doing it, our knowledge improved. We did not know about this in-depth…we are very happy."

- ASHA, Andhra Pradesh

By sharing tasks including data collection, and Hb and BP measurement with ASHAs, ANMs were able to use these data to populate the Government ANMOL database. Doctors were also able to refer women to the ASHA to have their BP and Hb measured, which not only freed their time for patient-facing duties but was also perceived to improve resource allocation within PHCs. As doctors saw ASHA's working with the intervention and the quality of their skills, they trusted them to conduct Hb and BP measurements and interpret findings using the clinical decision support provided.

Respondent 1: "Doctors have increased respect for ASHAs…Yes, it's really improved.."
Respondent 2 : "They all praise about us…Madam, the most important thing is, now the doctors say that now you have become a doctor too…. ha..ha..ha.."

- ASHAs, Haryana

ANMs were supportive of ASHAs gaining new skills and this, in turn, impacted ASHAs' sense of value and created a sense of accountability for their healthcare colleagues.

"They [ANMs] are supportive and they said that it is also useful so all sorts of work in the future can be performed by ASHA workers."…"They [ANMs] are encouraging us to learn. They tell us that it is good to learn."

- ASHAs, Andhra Pradesh

6.84 Reflexive monitoring: appraisal of impact of intervention practices on quality of care

ASHAs were able to reflect on their experiences of implementing SMARThealth Pregnancy and understand the value of the intervention practices. One ASHA described her experience of measuring postpartum BP and the impact on the clinical outcome on a woman with HDP.

"*One lady had BP before, then it was ignored, she delivered and got discharged. We told her [her BP was still high], then she visited hospital, then we told her several times, we told her BP has increased. She was very happy, she took medicine and now BP is normal"*

- ASHA, Haryana

Respect for the value of the SMARThealth Pregnancy intervention was collectively shared by women, ASHAs and ANMs. Women who had considered Government health services to be less efficient and low quality in comparison to private healthcare, expressed an improvement in their perceived quality of care of government services and expressed gratitude and trust in the ASHAs conducting tests at home.

"*I am also satisfied for the ASHA worker because it's a very nice thing. Our government is giving good facility for me…and it's a very good thing for me and it's on time. I am happy for these things that the government is providing these facilities like done through ASHA workers, it is very nice for me*."

- Postpartum woman, Haryana

The technology and Hb/BP devices used by ASHAs were perceived by women and ASHAs alike to add value to home visits. Furthermore, providing ASHAs with devices translated into improved respect and status of ASHAs within their communities and the health system.

"*They [relatives of pregnant woman] just ask if the test can be done on them as well. Why don't you check others too? Why just the pregnant women? You can check for others too...Now lot of people are suffering from diabetes and high BP…everyone wants to get themselves checked*."

- ASHA, Andhra Pradesh

As the study progressed, ASHAs developed increased self-awareness when delivering intervention practices. This was translated practically into a heightened sense of personal responsibility when conducting their daily work, with improved timeliness of home visits and improved intrinsic motivation to do their work.

"*They [ASHAs] are telling that they are happy. She was telling that their confidence has increased while doing the visits now and she is telling that now we will become more conscious about the timings of all visits…that it is 42 days, we have to go. Earlier it could be like any day, they might skip the date but now they are more conscious, and they are doing it on time like it is in first week, it is in 42 days, so they have become more conscious about the timing of their visits now"*

- ANM group, Haryana

Previously, ASHAs were used to working in isolation when conducting home visits to pregnant/postpartum women. However, as they came to implement SMARThealth Pregnancy intervention practices, ASHAs at both study sites created their own peer support groups. These groups were instrumental in improving ASHAs' abilities, clinical skills, confidence and problem-solving around using the tablet **(communal appraisal)** and delivering intervention practices [283].

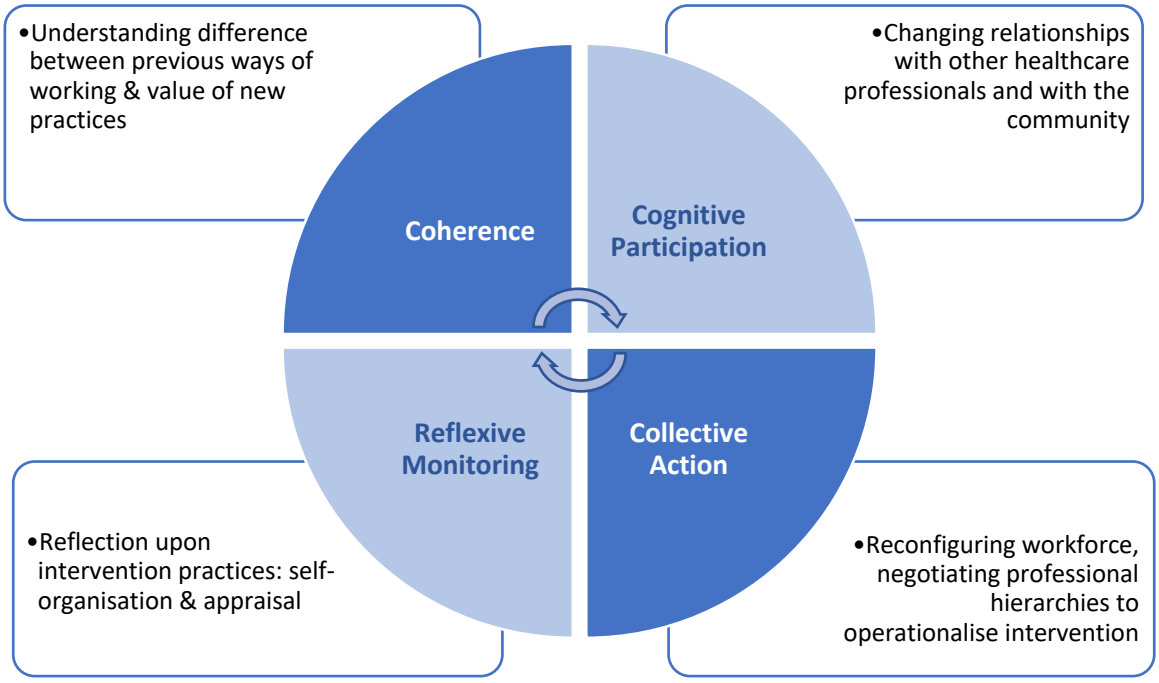
ANM 1: "If they don't know they discuss it among themselves in a group and get to know about it." ANM 2: "They don't ask us."
ANM 1: "But they don't ask us. So far, they have not asked for any help on this…They have good understanding. They discuss among 4-5 ASHA workers as a group, if there is any issue related to Tab or instrument. They are solving the problem by themselves."

- ANM group, Andhra Pradesh

Self-organisation of ASHAs around implementation of the intervention, including the formation of peer groups, illustrated a transition in the pilot study from ASHAs seeing

SMARThealth Pregnancy as a novel intervention implemented outside their daily work, to part of their routine practice, now embedded, accepted and integrated into their daily work.

Figure 6.3: Summary of key factors contributing to successful implementation of SMARThealth Pregnancy



6.9 Discussion

The results of the pilot study highlight that recruitment of PHCs and participants is both feasible and timely, being completed in under 5 months. High levels of engagement were maintained until the end of study, with minimal loss to follow-up (2%). High fidelity to intervention practices by ASHAs pre-pandemic were reflected in both the descriptive statistics and the rich explanation of acceptability of the intervention provided by the qualitative process evaluation. Reasons contributing to these findings are multifactorial. Firstly, sustained engagement with the community, CHWs, and PHCs in the study districts

during the contextual work and intervention development phases, is likely to have facilitated trust-building and faith in the study team. The personal relationships formed with key stakeholders during the early phase of my research aided future interactions with government officials, PHC staff, and community members, during pilot study recruitment. Furthermore, all eligible pregnant women approached consented to being involved in the study. Although, this finding may be associated with the perception of receiving additional or improved ANC and PNC by women in rural areas, it may also be the product of community engagement and trust in the study team. This finding is in keeping with the literature on Community Engagement & Involvement, which advocates for early and continued stakeholder engagement to improve recruitment and acceptability of intervention practices [414–418]. Secondly, retention of women in the study with minimal loss to follow-up, reflects the human-centred approach taken in intervention design and development. Keeping the needs of the key stakeholders within the communities at the heart of intervention development through in-depth and iterative qualitative work (as was conducted during the early chapters of this thesis, and concluding with the qualitative process evaluation outlined in this chapter), has been proposed to improve acceptability and feasibility of interventions [419]. The aim of such person-centred approaches is to "*ground the development of behaviour change interventions in a sensitive awareness of the perspective and lives of the people*" [419]. Use of qualitative methods provided insight into the complex social and cultural context in which the intervention was implemented, and highlighted the experiences of women and healthcare workers. This resulted in an intervention which centred on the needs of rural women, integrating these needs with those of other healthcare workers and health system resources. In rural areas, women often do not have their own means of income or mobility and are reliant on their husband or another family member accompanying them to hospital. Women appreciated the convenience of

having the Hb and BP measurements conducted at home, which acknowledged and respected their postpartum social and cultural practices. Provision of home-based care was further perceived by women to be of high quality and changed their attitude towards government services, as evidenced in the qualitative process evaluation.

High levels of fidelity by ASHAs to intervention delivery practices (pre-pandemic) was reflected in the descriptive statistics, which showed intervention visits and tasks were accomplished on time, with 100% complete entries on the mHealth platform. These findings demonstrated the ASHAs' commitment and interest in delivering SMARThealth Pregnancy. One reason for this was the use of human-centred design and iterative usability testing with end-users during intervention development. Involving ASHAs in the co-design of the mHealth platform and considering their educational background (secondary school education), ensured that their requirements were embedded into the App design, facilitating understanding and navigation of each screen. The simplicity of the design was appreciated by ASHAs and resulted in high fidelity to intervention practices.

The study revealed anaemia in pregnancy affected over half of study participants at baseline, in agreement with studies in India [355,420,421] and Government of India data [317]. The high prevalence of anaemia amongst pregnant women in this study supports the findings of the early contextual work (Chapter 4). The qualitative process evaluation highlighted that SMARThealth Pregnancy home visits have the potential to educate and empower women and their families at the household-level, and improve diets and adherence to iron folate tablets amongst pregnant/postpartum women, although clinical effectiveness relating to the intervention is beyond the scope of this pilot study. The prevalence of HDP in the pilot study (2.5%) was lower than that outlined in other studies

in similar contexts [320–322,422], and may relate to age distribution, socioeconomic status and seasonal variation in BP [423–425]. Similarly, the prevalence of GDM (2%) was low in comparison with other studies in rural India [426–428]. Although, this may be due, in part, to different screening criteria and tests used in other studies, it is unlikely to account for the whole story. A recent cross-sectional study using a nationally representative sample of pregnant women, found the age-adjusted prevalence of GDM in India to be 1.3%, with increased prevalence amongst women with high BMI and those from wealthy backgrounds [334]. The low prevalence of GDM in the pilot study may reflect the level of poverty seen in rural India, and reinforces the finding that undernutrition leading to anaemia, rather than overnutrition associated with GDM, is the main issue faced by women in the areas studied.

Findings in relation to proposed logic model of SMARThealth Pregnancy

Acceptability of the intervention was high amongst women and CHWs alike. For ASHAs the equipment provided to enact the SMARThealth Pregnancy held symbolic value, providing them with legitimacy to perform Hb and BP measurements for women at home [429]. Although the intervention involved performing additional tasks for the ASHA, they did not perceive a resulting increase in their workload. This finding was due to integrating the intervention into routine ASHA visits, and the added value received by ASHAs when implementing the intervention. A combination of improved self-efficacy, social and professional recognition were at the heart of the intervention's acceptability to ASHAs. These factors are known to influence the motivation of ASHAs [430–433], with studies highlighting the important role of recognition for CHW motivation [431], the positive impact of self-efficacy on CHW performance [433], and the need to provide the technical and contextual resources for CHWs to undertake high-quality work [430]. In combination

with financial incentives and remuneration of ASHAs, these factors were likely to have contributed to the successful implementation and acceptability of the intervention.

The findings of the qualitative process evaluation are in keeping with the logic model and the proposed **mechanisms of impact** (Chapter 5). Heightened self-efficacy experienced by ASHAs in the process evaluation was the result of improving the psychological and physical capabilities of ASHAs (knowledge, skills, beliefs about capabilities). Providing ASHAs with the physical and social opportunities to deliver the intervention (including mobile clinical decision support and Hb/BP devices) gave ASHAs legitimacy and status, thus enhancing social and professional recognition within their communities and the health system (improved reflexive and automatic motivation). Collectively, these factors contributed to high levels of intervention fidelity and acceptability (**outcomes**).

Embedding of the intervention into the daily work of ASHAs

Complex interventions become routinised as the result of people working both individually and collectively to implement and integrate a new set of practices into their organisational and professional contexts [69]. NPT explained many factors contributing to the normalisation of SMARThealth Pregnancy into the daily work of ASHAs. Study participants developed an individual and shared understanding of the value of SMARThealth Pregnancy (coherence), negotiated the nature of their relationships with other members of the healthcare system (cognitive participation), reorganised themselves to operationalise the intervention (collective action), and reflected upon their work to optimise intervention delivery (reflexive monitoring). Intervention practices thus came to be integrated into the existing health system through a process of self-organisation [434–436]. Complex adaptive systems, such as the health system in rural India, involve dynamic

interactions between the socio-political context of care and the workforce and resources of the health system. Introduction of a new intervention into this dynamic system has potential to cause disruption. However, evidence from the qualitative process evaluation, highlighted those aspects of the system which started to self-organise [434]. For example, ASHAs and ANMs negotiated their roles in a coordinated effort with pregnant women to deliver GDM screening in the community. This changed the organisational culture between ANMs and ASHAs - shifting from a hierarchy to a team. Newly established ways of working between ASHAs, ANMs and doctors (collective action) resulted in flattening of professional hierarchies and a move towards a team-based approach to healthcare delivery. Such approaches to ASHA programmes have been shown to improve motivation, empowerment and self-efficacy [437] and have the potential to improve the quality of healthcare services [438], impacting intervention acceptability. Additionally, ASHAs formed self-organised peer groups [439] to problem-solve issues around intervention delivery (reflexive monitoring) and supported each other in conducting home visits. Self-organisation within the complex, dynamic rural health system is indicative of the level of acceptability, integration and embedding of SMARThealth Pregnancy into the daily work of ASHAs [434,435,439,440].

Limitations of the study

The intervention did not work as intended in relation to PCP follow-up at the PHC. It was hoped that women would visit the PHC following their ASHA home-visit and the intervention would contribute to strengthening the links between the community and primary care. However, most postpartum women did not visit the PHC, and many women bypassed primary care altogether, seeking private and/or government secondary care services directly. This was the case for most high-risk pregnant women and led to a lack

of consistency in health counselling across different levels of the health system. For example, guideline-based advice given by ASHAs to women with GDM (regarding the need for ongoing screening for T2DM), was not reinforced by local obstetricians, potentially undermining the work done by ASHAs to empower women about their future health. This highlights the importance of engaging and integrating obstetricians as well as PCPs in education and counselling for high-risk pregnant women in the future.

End line Hb and BP measurements were not taken in Haryana for a proportion of women in both the control and intervention groups during the global pandemic. This did not, however, affect the findings of this study relating to feasibility and acceptability, as these data were collected primarily to inform the confidence intervals around a future ICC calculation [409] and assess their suitability as clinical endpoints in a future trial. Both Hb and BP measures were feasible to collect as potential clinical end points, however it is unclear if they adequately reflect the mechanisms of impact outlined in the SMARThealth Pregnancy logic model.

Optimisation of intervention, recommendations for future study and policy implications

The pilot study revealed the need for further integration and consistency in guideline-based care and counselling between the community-level and secondary care (vertical integration), and between healthcare professionals (horizontal integration) [441]. Primary care is often considered the "gatekeeper" to secondary care [442]; however, as evidenced in this study, this is not always the case in rural India. Future refinement of SMARThealth Pregnancy and its associated intervention practices needs to include educating both government and private obstetricians on the importance of postpartum screening for high-

risk women, and linking high-risk women to the NCD programme. Further work would also need to focus beyond the immediate postpartum period into the years following a high-risk pregnancy, and consider clinical endpoints reflective of the level of cardiometabolic risk in the years after pregnancy. Tailoring GDM screening to population-level prevalence has potential to maximise cost-effectiveness and improve clinical outcomes [334]. Cost-effectiveness studies would, therefore, be needed to justify universal GDM screening in rural areas with a low prevalence of GDM, as was seen in this study.

6.10 Conclusion

This chapter has addressed the primary and secondary research questions of my thesis, demonstrating the feasibility and acceptability of SMARThealth Pregnancy and outlining factors contributing to its successful design, delivery and future sustainability, and those areas requiring further optimisation. The SMARThealth Pregnancy model of task-sharing for integrated antenatal, postnatal and ongoing care for high-risk pregnant women is feasible and acceptable to women and CHWs, and may be used as part of a wider strategy for health systems strengthening in similar contexts.

7

Final reflections, policy recommendations, & future directions

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This thesis has outlined my journey from the early exploratory work informing the design of a complex intervention, to building, and subsequently evaluating an intervention for high-risk pregnant women in rural India, using the guidance of the MRC Framework for complex interventions.

7.1 Contributions to the field

Several contributions have been made to existing knowledge during the course of this thesis. Firstly, I have emphasised the centrality of context when designing and implementing complex interventions. The findings of the qualitative study in Chapter 4, gave rise to a conceptual model of the health system priorities for high-risk pregnant women in rural India, which formed the basis of the SMARThealth Pregnancy intervention. Through understanding the context of care and the priorities of local communities, the key strategies required of a complex intervention and barriers to implementation were identified early in the design process. These factors could, therefore, be adequately addressed during intervention design and subsequent implementation. My research thus expands upon the evidence discussed in Chapter 2, and emphasises the need for in-depth contextual work in the development stage of the MRC Framework for complex interventions.

Secondly, continued engagement with communities, through repeated and sustained contact throughout my DPhil, helped develop trust between myself, the study team and the communities we served. In my experience, the development of trust with local communities and healthcare workers was integral to the feasibility of delivering the intervention, and contributed to successful recruitment, retention and the high levels of fidelity to intervention practices seen in the SMARThealth Pregnancy cRCT before the pandemic. Early contextual work and sustained community engagement influenced what is at the heart of this intervention, which is empathy - Empathy for the work of ASHAs, the needs of women and their families, and for the wider health system and government healthcare administrators. Empathy is recognised in human-centred design as integral to the successful design of an intervention. Person-centred approaches to intervention design

meet the needs of those involved and are, therefore, more likely to be accepted and sustained. Involving CHWs in the design of SMARThealth Pregnancy was integral to its subsequent acceptability. Having contributed to its development, ASHAs felt SMARThealth Pregnancy was 'theirs'. This aspect of intervention design has often been overlooked in previous interventions for maternal health in LMIC settings (outlined in Chapter 2), which focus ownership of the intervention with the research team, rather than the communities it serves. Use of human-centred approaches, with iterative usability testing and ownership of the intervention by the communities involved, further helped to 'embed' the intervention into the daily lives of those who used SMARThealth Pregnancy, as demonstrated by the qualitative process evaluation.

Thirdly, the voices of key stakeholders captured during the contextual study were synthesised using behaviour change theory into behavioural constructs. These, in turn, informed the choice of BCTs – the 'active ingredients' of the intervention. This approach to intervention design is unique in the context of rural women's healthcare in India, and adds empirical evidence for the use of specified BCTs and implementation strategies to guide future women's health interventions in similar contexts. Use of theory to inform the design of SMARThealth Pregnancy further enabled clear articulation of the proposed mechanisms of impact in a logic model (Chapter 5), identifying those aspects of the intervention influencing outcomes in the qualitative process evaluation. My research highlights the importance of standardised reporting of behaviour change interventions, which has, to date, been missing from the literature on mHealth interventions for maternal health (discussed in Chapter 2). Transparency and clarity regarding the behavioural elements of this complex intervention promotes further understanding of what 'works' in a given context, and will enable comparability across similar studies in the future.

My experience of using the COM-B/BCW framework and NPT during this study, has demonstrated how these two theories may be used to complement each other. While NPT explained the main factors influencing implementation and embedding of SMARThealth Pregnancy into the routine work of ASHAs, it did not capture the subtlety of individual factors impacting behaviours related to implementation, such as improved self-efficacy and social recognition amongst ASHAs. Used in combination with the COM-B/BCW model, however, the two theories worked synergistically to explain the individual aspects of behaviour change in relation to the wider social influences which impacted acceptability and integration of SMARThealth Pregnancy into the health system. During my DPhil, I have found that, when using theory to design an intervention and explore its implementation, it is important to consider *how* theory is being used to explain or guide the research process, rather than fitting the research to one specific theory. Conducting this work has shown me how different theories can be used to explain various aspects of a study, and used to complement each other.

Finally, the pilot cRCT demonstrated that SMARThealth Pregnancy is a feasible and acceptable model of integrated ANC and PNC in the context of rural India. ANC (specifically in the third trimester of pregnancy) can be used as a window to engage women in the health system, and provide continuity of care during the transition between ANC, delivery, and PNC. The SMARThealth Pregnancy intervention was a vehicle to improve confidence, accountability and trust expressed by women and members of their community towards ASHAs, and enabled home-based care during a time when women were unable to leave their homes.

7.2 Policy recommendations

The pilot cRCT findings suggest that Government investment in the training, mentorship and provision of resources to ASHAs to conduct home-based care for high-risk pregnant women can impact the internal and external motivation of the workforce. Empowering ASHAs through development of their physical and psychological capabilities, providing the physical and social opportunities to conduct home-based care, and facilitating sustained engagement with a complex intervention through provision of both intrinsic and extrinsic motivational factors has shown potential to improve perceived quality of care of government services, whilst addressing the important postpartum needs of rural women and their households in a culturally-sensitive way. This model of task-sharing may be transferable to similar settings. Whether these benefits translate into a cost-effective solution to workforce shortages in rural areas will need further investigation. However, based on the pilot cRCT findings, it is likely that the costs involved in providing ASHAs with inexpensive mobile devices and Hb/BP devices, have the potential to reduce overall health system costs and out-of-pocket expenditure of households, through a model of home-based care and task-sharing of screening for anaemia, HDP and GDM in the community. Furthermore, as ASHAs hold significant social capital and trust within their communities, they are ideally placed to influence the health behaviours of women in rural villages, and increase engagement with health services in the years following a high-risk pregnancy to ensure ongoing follow-up of high-risk women.

The second policy recommendation relates to community-based GDM screening in rural India. Pragmatic guidelines for community-based GDM screening were released by the Government of India in 2018; however, operationalisation of these guidelines has not yet been tested on a large scale for clinical effectiveness. The pilot cRCT revealed that these

guidelines are feasible to implement in rural India, if work between ASHAs and ANMs is reconfigured, in liaison with pregnant women. Although CHWs welcomed the introduction of standardised GDM screening, the overall prevalence of GDM in the areas studied was low. This suggests that further cost-effectiveness studies are needed to justify universal GDM screening in areas of the country with low GDM prevalence. In contrast to the published literature, which presents a narrative of a rapid epidemiological transition to CMDs in India, the low prevalence of GDM, and the high prevalence of anaemia seen in the pilot study, (supported by the descriptive statistics outlining a mean BMI of 22 in the study population), would point to the conclusion that inadequate nutrition and poverty are still key concerns in rural areas.

7.3 Limitations of this thesis study

Awareness of the 'personal influences' on the study, was part of the process of reflexivity and being transparent about my positionality in the research process. These elements of the intervention, though intangible, may have influenced the design, delivery and implementation of SMARThealth Pregnancy, and the subsequent acceptability of the intervention to study participants. This thesis study and the SMARThealth Pregnancy intervention contain a lot of 'me' in them - my values, background and experiences. I have realised during the process of completing my DPhil, that the people involved in the design and delivery of an intervention are also part of the intervention itself. Sustained engagement with the communities, PHC staff and CHWs, made myself and the study team also a part of the intervention and its subsequent acceptability. We (the study team, the CHWs and doctors) provided each other with support and encouragement to implement the intervention during what was a challenging time for all during a global pandemic.

These aspects of intervention evaluation are rarely captured in the reporting of cRCTs, yet it is these hidden elements of intervention design that are integral to successful implementation. These elements do however, become a limitation, when interventions are scaled beyond initial pilot studies as the team cannot be spread across many locations. In this regard, it is hoped that the intervention carries, in part, the consistent, standardised elements of theory (including the BCTs), and embeds the voices of those involved in its design, which, in turn, diffuse into the intervention practices, and will contribute to future scalability.

While Covid-19 did present challenges for implementation of face-to-face, contact-dependent study practices, and limited end line Hb and BP readings for some women, the pandemic also highlighted the value of the SMARThealth Pregnancy model of home-based care. During the pandemic, SMARThealth Pregnancy visits continued as the intervention was judged to provide essential health services to pregnant women. For me, this reinforced the importance of providing patient-centred, home-based care for high-risk women that meets their needs, and integrating these needs with those of the Government health authorities. I feel that the SMARThealth Pregnancy model of care, by providing mobile clinical decision support to ASHAs to conduct home-based visits, will be of great future relevance as we move through the pandemic.

7.4 Future directions

Future optimisation and refinement of SMARThealth Pregnancy would need to concentrate on addressing the system-level interactions between the community, and both primary and secondary care (to involve obstetricians). Additionally, it would be important

to extend intervention visits beyond the immediate postpartum period to include the years following pregnancy, and identify suitable clinical endpoints which reflect cardiovascular risk in high-risk pregnant women. My research is foundational for these future possibilities. Future evaluations of SMARThealth Pregnancy might focus further upon the impacts of complex interventions beyond their intended effects (Chapter 2), and as highlighted in the qualitative process evaluation (Chapter 6). These include the effects of technology upon the social and professional status of ASHAs, their perceived workload, and the impact of newly formed peer-groups on intervention delivery. Additionally, it would be important to study the value of empathy, trust, and community engagement as integral components of a complex intervention, rather than as elements distinct to intervention delivery.

For women in rural India, both maternal mortality and the rising prevalence of CMDs remain important issues. Strategies and models of care are needed to address the transitions between antenatal, postnatal, and ongoing care for women at high-risk of future CMDs. However, in parallel with these strategies, it is important to recognise the present day needs of rural women and their communities, relating to anaemia and undernutrition, and explore the most cost-effective ways of providing holistic care for rural women. SMARThealth Pregnancy presents one model of care, which is feasible and acceptable to end-users and beneficiaries.

This thesis has outlined the development and evaluation of a complex intervention and highlighted the importance and contribution of early contextual work and stakeholder engagement towards the success and sustainability of interventions within complex, dynamic environments.

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Appendix A: Literature Review methods (Chapter 2)

A1.1: Literature review – methods and searches

The literature review involved synthesis of evidence from several different topic areas (Table A.1). I followed the methods for narrative literature review outlined by Gregory *et al*, 2018 [5]; starting with defining the topic area, then searching the literature, critically appraising the relevant literature, making notes, finding a logical structure within the literature, and finally writing the review (Chapter 2).

Literature searches were conducted using PubMed, MEDLINE, and supplemented by searches of the grey literature and Google Scholar, to identify both systematic reviews and metanalyses in the broad topic areas listed in Table A.1, as well as more targeted search strategies addressing the risks of cardiometabolic disorders following a pregnancy complicated by HDP or GDM in LMIC settings (example given in Figure A.1). In addition, I set up auto-alerts for the search strategies on OVID-MEDLINE (database), to receive monthly updates on new research papers in the topics of interest and iteratively updated the literature review until February 2021. Evidence was critically synthesised into thematic areas, as presented in Chapter 2 of the thesis.

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Table A.1: Topics for literature review

Overview of literature search topic areas and review questions
1. Hypertensive Disorders of Pregnancy & Cardiovascular risk: *What are the risks of developing chronic hypertension and cardiovascular disease following a pregnancy complicated by HDP? [in LMICs?]*
2. Gestational Diabetes & risk of Type 2 Diabetes Mellitus and Cardiovascular disease: *What are the risks of developing T2DM following a pregnancy complicated by GDM? [in LMICs?]*
3. Gestational diabetes and screening in LMICs: *What are the methods for screening for GDM in LMIC settings?*
4. Gestational diabetes and postpartum screening: *What are the postpartum screening practices for women with GDM? [in LMICs?]*
5. Community Health Workers (CHWs) and High-Risk Pregnancy: *How are CHWs involved in the care of women with high-risk pregnancies in LMIC settings?*
6. Community Health Workers and mHealth technology: *For what conditions, and in what contexts do CHWs use mHealth, and is there evidence of clinical effecetiveness?*
7. Community Health Workers and NCD prevention: *What evidence is there for task-sharing with CHWs in NCD prevention?*

Figure A.1: Example of search strategy for investigating risk of T2DM in women with a history of GDM

Ovid MEDLINE(R) <1946 to April Week 3 2021>
Ovid MEDLINE(R) <December Week 3 2020 to April Week 3 2021>
(updates since 2021-04-14)

#	Search History	Results
1	Diabetes, Gestational/	448
2	Gestational diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	549
3	Type 2 diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	3575
4	Diabetes Mellitus, Type 2/	3582
5	1 and 2	406
6	1 or 2	591
7	3 or 4	4410
8	6 and 7	76
9	Niddm.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	4
10	Non insulin dependent diabetes.mp. [mp=title, abstract, original title, name of ! substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	12
11	3 or 4 or 9 or 10	4415
12	6 and 11	76
13	India/	2196
14	India*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	3520
15	Developing Countries/	838
16	(Low and middle income).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	1268
17	LMIC.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	179
18	13 or 14	3520
19	12 and 18	0
20	15 or 16 or 17	1711
21	1! 2 and 20	0
22	limit 21 to updaterange="medl(20210414194236-20210421225132]"	0

A1.2: Systematic review of integration of non-communicable disease (NCD) healthcare programmes into antenatal care platforms in low and middle-income countries (LMICs)

In addition to the literature searches described above, for the chapter 2 section: **2.5 Health systems strengthening for women's life-long health'**, I conducted a systematic review of the literature entitled: *A systematic review of integration of non-communicable disease (NCD) healthcare programmes into antenatal care platforms in low and middle-income countries (LMICs).* The review was registered on the systematic review registration database – PROSPERO [6] . With the guidance of the University librarian (Mrs Liz Callow), I searched the following databases: MEDLINE, EMBASE, CAB abstracts & Global Health, supplemented by grey literature searches. The search strategy was adapted from 'de Jongh et al [7] (Figure A.2).

[6] PROSPERO registration: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42018090215

[7] de Jongh TE, Gurol–Urganci I, Allen E, Zhu NJ, Atun R. Integration of antenatal care services with health programmes in low–and middle–income countries: systematic review. *Journal of global health*. 2016 Jun;6(1)

Figure A.2: Search strategy for systematic review on the integration of non-communicable disease (NCD) healthcare programmes into antenatal care platforms in low and middle-income countries (LMICs)

Search Strategy: A systematic review of integration of non-communicable disease (NCD) healthcare programmes into antenatal care platforms in low and middle-income countries (LMICs).

---

1 (antenatal or ante-natal or (ANC and pregnan*) or prenatal or pre-natal or perinatal or peri-natal).ti,ab,hw.
2 exp Perinatal Care/ or exp Prenatal Care/
3 1 or 2
4 exp "Delivery of Health Care, Integrated"/
5 (integrat* adj3 (care or service* or delivery or strateg* or program* or management or healthcare)).ti,ab,hw.
6 ((deliver* or bring) adj3 (with or within or together)).ti,ab,hw.
7 (integrat* or horizontal or vertical or coordinat* or co-ordinat* or link*).ti,ab,hw.
8 (multi* adj2 (team? or care or service? or clinic?)).ti,ab,hw.
9 (multicare or multiservice? or multiclinic?).ti,ab,hw.
10 (multiskill* or multi skill* or multitask* or multi task*).ti,ab,hw.
11 (continuum or continuity).ti,ab,hw.
12 (intersectoral or inter-sectoral).ti,ab,hw.
13 collab*.ti,ab,hw.
14 (interagenc* or inter-agenc*).ti,ab,hw.
15 (interdisciplinary or inter-disciplinary).ti,ab,hw.
16 joint working.ti,ab,hw.
17 (partner* or partnership).ti,ab,hw.
18 or/4-17
19 exp cardiovascular disease/ or exp non communicable disease/
20 cardiovascular disease*.ti,ab,hw.
21 (non-communicable disease* or noncommunicable disease* or non communicable disease* or NCD* or stroke* or cerebrovascular accident* or heart attack* or myocardial infarction* or diabetes or hypertension).ti,ab,hw.
22 19 or 20 or 21
23 exp neoplasm/
24 (neoplasm* or carcinoma* or tumor* or tumour* or cancer* or malignan*).ti,ab.
25 ((lesion* adj3 cancer*) or (lesion* adj3 malignan*)).ti,ab.
26 or/23-25
27 exp respiratory tract disease/
28 (lung* or pulmonary or pneumo* or respiratory or bronchopulmonary or asthma* or pleurisy or COPD or chronic obstructive pulmonary disease).ti,ab.

Search strategy continued:

29 27 or 28

30 exp mental disease/ or exp mental health/

31 ((perinatal or peri-natal or postnatal or post-natal or postpartum or post-partum) adj3 (depression or mental health or psychosis)).ti,ab.

32 30 or 31

33 exp developing countries/

34 exp medically underserved area/

35 (LIC or LICs or MIC or MICs or LMIC or LMICs or LAMIC or LAMICs or LAMI countr* or third world).ti,ab,hw.

36 (low adj3 middle adj3 countr*).ti,ab,hw.

37 ((developing or (less* adj developed) or under developed or underdeveloped or (middle adj income) or (low* adj income) or underserved or under served or deprived or poor* or shortage or rural or remote or nonmetropolitan or transition*) adj (communit* or countr* or nation* or population* or district* or state* or province* or jurisdiction* or region* or area* or territor* or world or economy or economies)).ti,ab,hw.

38 (Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or "Atlantic Islands" or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Dahomey or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Bechuanaland or Kalahari or Brazil or Bulgaria or "Burkina Faso" or "Burkina Fasso" or "Upper Volta" or Burundi or Urundi or Cambodia or "Khmer Republic" or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or "Cape Verde" or "Central African Republic" or Ubangi-Shari or Chad or Chile or China or Colombia or Comoros or "Comoro Islands" or Comores or Mayotte or (Congo not (congo red or crimean-congo)) or Zaire or "Costa Rica" or "Cote d'Ivoire" or "Ivory Coast" or Croatia or Cuba or Cyprus or Czechoslovakia or "Czech Republic" or Slovakia or "Slovak Republic" or "Democratic People's Republic of Korea" or "north korea" or (democratic people* republic adj2 korea) or Djibouti or "French Somaliland" or Dominica or "Dominican Republic" or "East Timor" or "East Timur" or "Timor Leste" or Ecuador or Egypt or "United Arab Republic" or "El Salvador" or Eritrea or Estonia or Ethiopia or Fiji or Gabon or "Gabonese Republic" or Gambia or Gaza or Georgia or Georgian or Ghana or "Gold Coast" or Greece or Grenada or Guatemala or (Guinea not (New Guinea or Guinea Pig* or Guinea Fowl)) or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or "Indian Ocean Islands" or Maldives or Indonesia or Iran or Iraq or "Isle of Man" or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or "Kyrgyz Republic" or Kirghiz or Kirgizstan or "Lao PDR" or Laos or (lao adj1 democratic republic) or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Melanesia or "Malagasy Republic" or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Island* or Mauritania or Mauritius or "Agalega Islands" or Mexico or Micronesia or "Middle East" or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or "Portuguese East Africa" or Myanmar or Myanma or Burma or Namibia or Nepal or "Netherlands Antilles" or "New Caledonia" or Nicaragua or (Niger not (Aspergillus or Peptococcus or Schizothorax or Cruciferae or Gobius or Lasius or Agelastes or Melanosuchus or radish or Parastromateus or Orius or Apergillus or Parastromateus or Stomoxys)) or Nigeria or "Northern Mariana Islands" or Oman or Muscat or Pakistan or Palau or Palestine or Panama or "Papua New Guinea" or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or "Puerto Rico" or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or "Saint Kitts" or "St Kitts" or Nevis or "Saint Lucia" or "St Lucia" or "Saint Vincent" or "St Vincent" or Grenadines or Samoa or "American Samoa" or "independent state of samoa" or "Samoan Islands" or "Navigator Island" or "Navigator Islands" or "Sao Tome" or "Saudi Arabia" or Senegal or Serbia or Montenegro or Seychelles or "Sierra Leone" or Slovenia or "Sri Lanka" or Ceylon or "Solomon Islands" or "South Africa" or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria* or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Zanzibar or Thailand or Togo or "Togolese Republic" or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Tuvalu or Uganda or Ukraine or Uruguay or USSR or "Soviet Union" or "Union of Soviet Socialist Republics" or Uzbekistan or Uzbek or Vanuatu or "New Hebrides" or Venezuela or Vietnam or "Viet Nam" or "West Bank" or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).ti,ab,hw.

39 exp China/ or exp Russia/ or exp India/

Figure A.3 outlines the screening process in a PRISMA flowchart, and the results of the relevant studies (n=8) are synthesised in Table A.2. The findings of the systematic review contributed to Chapter 2, and to the discussion of Chapter 6 of my thesis.

Figure A.3: PRISMA flowchart for systematic review of integrated care healthcare programmes into antenatal care platforms in low and middle-income countries (LMICs)

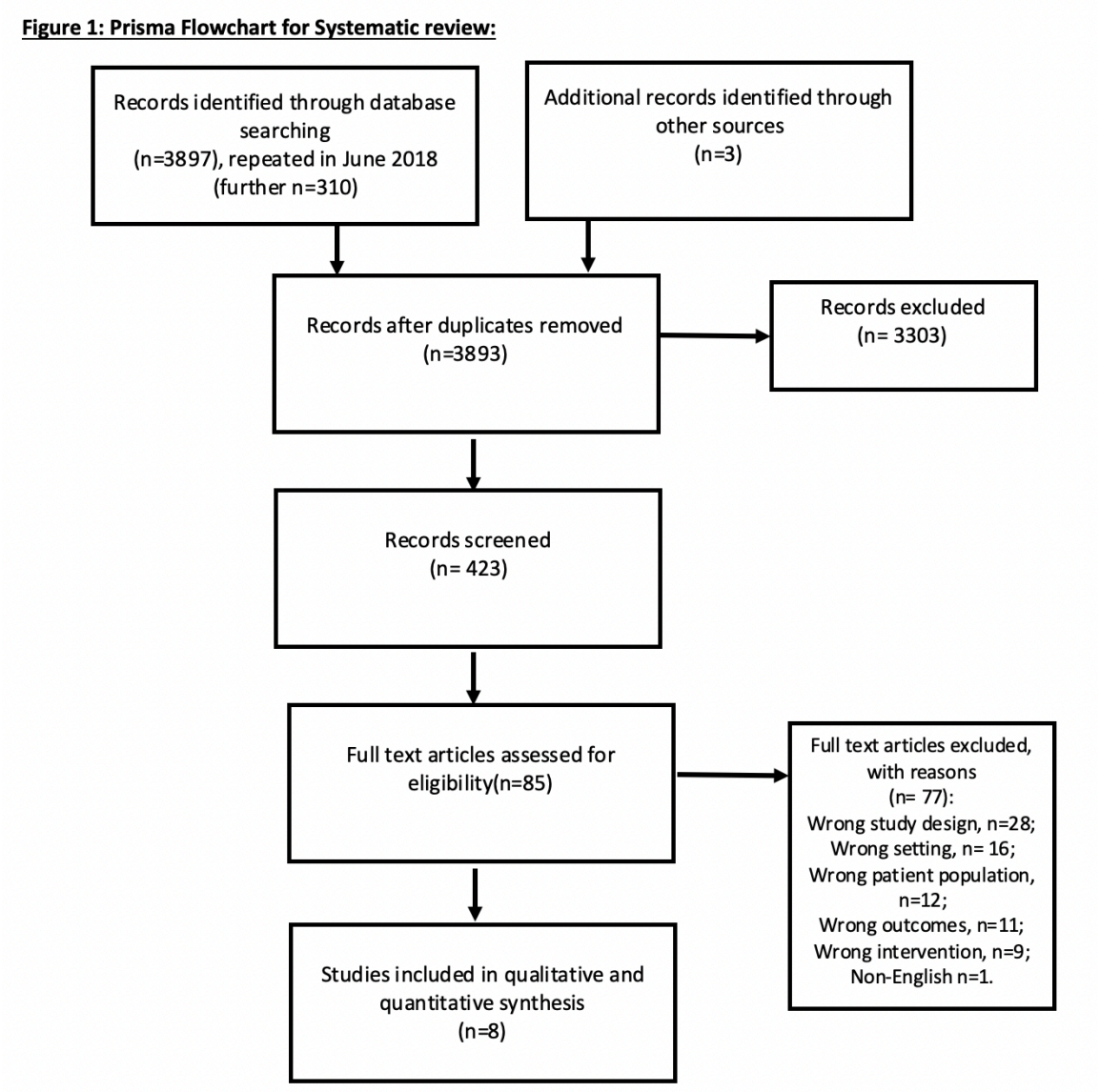

Table A.2: Table of results for systematic review

Table 3: Summary of results

STUDY	DESIGN & SETTING	PARTICIPANTS	INTERVENTION	ANALYSIS	KEY FINDINGS	RISK OF BIAS
ANYANWU ET AL, 2016.	Cross-sectional survey. Urban teaching hospital, Nigeria.	492 women aged 15-49 years attending postnatal and infant immunization clinics of the hospital.	Breast awareness information during ANC & PNC.	Quantitative	Half of the 492 women received breast awareness information during the previous two years. The majority (81.7%) received this information during ANC, in the form of a group discussion (96.1%), delivered by nurses and midwives (93.4%). Women who had received only primary school education or less, were more likely to report a missed opportunity for breast awareness information (0.007), as were women with lower family income (less than $122.70 per month) p= 0.019.	High
ATIF ET AL, 2017.	Feasibility study. Community-based in rural Pakistan and urban India.	44 women aged 18 years or older in their second or third trimester of pregnancy or had infants up to four months of age.	THP adapted for delivery by peer volunteers during routine ANC & PNC.	Qualitative	All 44 mothers found the intervention acceptable and relevant to their needs, with the majority reporting improvement in their mental health. Motivations for peer volunteers included altruism, improving skills and employability, and appreciation from the community. In Pakistan, peers were happy to work on a voluntary basis. In Goa, India, the peers expressed the need for financial incentives.	Unclear
FISHER ET AL, 2014	Feasibility study (field trial). Community-based, rural Vietnam.	6 pregnant women, aged 18 years or above, and at least 28 weeks pregnant.	THP (first four sessions) during last trimester of pregnancy.	Descriptive results of quantitative data.	All participants (6/6) found the sessions understandable and most (5/6) found these sessions interesting. All women reported that the skills developed through the THP were useful. The mean of the 21-item Depression & Anxiety Stress Scales (DASS-21-V) scores did not change significantly between baseline and end line assessments.	High
HONKIMAN ET AL, 2012.	Impact evaluation. Urban Midwife Obstetric Unit, South Africa.	1079 women in the last trimester of pregnancy with depression (EPDS).	Perinatal Mental Health Programme (PMHP).	Quantitative	Of 1079 women who accepted referral, 77% (832) attended their appointments and received an average of 2.7 face-to-face sessions. Two percent (n =20) of women were referred and seen by a psychiatrist. Of these women, 75% reported inadequate partner or family support, 45% reported past psychiatric problems, 40% reported past or present abuse (any form), and 5% had problems with substance abuse. At 6–10 weeks post-partum, 87.8% of women reported an improvement in their presenting problem, 91.7% of these women rated the sessions as a positive experience.	Low
RAHMAN ET AL, 2008.	Cluster randomised controlled trial.	903 women aged 16–45 years, married, and in	THP	Quantitative	Integration of a cognitive behavioural therapy-based intervention into the routine work of CHWs more than halved the rate of depression in prenatally depressed women	Low

	Community-based, rural Pakistan.	their third trimester of pregnancy, diagnosed with major depressive disorder (DSM-IV criteria).			compared with those receiving enhanced routine care. The intervention did not have a statistically significant effect on infant growth indices, however infants in the intervention group were less likely to have had a diarrhoeal episode in the 2 weeks preceding the 12-month assessment (OR 0.6 (0.39-0.98), p= 0.04) and were more likely to have completed their scheduled immunisation (OR 2.5 (1.47-4.72), p=0.001).	
ROTHERAM-BORUS ET AL, 2015.	Cluster randomised controlled trial. Community-based, urban South Africa.	Pregnant women aged 18 or over.	Mentor Mother scheme: Home visiting during ANC and PNC by CHWs.	Quantitative	Depression, emotional health, alcohol use and intimate partner violence were assessed at 18 and 36 months postpartum. The intervention reduced depression even though initially the mothers in this group were more depressed than those in the control group. Relative to standard care, mothers were significantly less likely to report symptoms and more positive quality of life at 36 months.	
SORSDAHL ET AL, 2014.	Feasibility study. Midwife-led Obstetric Unit (MOU) for a disadvantaged community in urban South Africa.	302 pregnant women attending MOU, scoring 15 or higher on EPDS. 5 staff members of Midwife Led Obstetric Unit.	Screening, Brief Intervention & Referral to treatment (SBIRT) using 5A's model for motivational interviewing.	Quantitative and Qualitative	Of the 302 women who underwent SBIRT and met criteria for depression, 70 completed the 3-month follow up interview. In these women, the EPDS scores decreased significantly following the SBIRT intervention. 15 (5 %) of the 302 women were referred specialist treatment, with the majority of these women at risk of suicide. None of the women screening positive for drug and alcohol use were referred for specialised substance use treatment. All 5 MOU staff felt SBIRT was useful for increasing the quality of mental health services, however they reported an increase in their workload, and felt inadequately prepared and informed about the proposed SBIRT programme.	High
SPYRIDOU ET AL, 2016	Feasibility study. Hospital in urban Lima, Peru.	95 Pregnant women who had completed the 16th week of gestation and could understand Spanish.	The KINDEX questionnaire to assesses risk factors for psychosocial stress.	Quantitative	There were high rates of psychosocial risk factors identified in pregnant women in Lima. Significant correlations were found between the KINDEX sum score and the three risk areas; stress, psychopathology and trauma load. Participants reported they felt more cared for by the medical staff after participating in the KINDEX interview and stated that these kinds of enquiries made the medical treatment more humanized and patient-centred.	Unclear

* ANC = Antenatal care; PNC = Postnatal care; THP = Thinking Healthy Programme; EPDS = Edinburgh Postnatal Depression Score; DSM-IV = Diagnostic & Statistical Manual IV; CHW = Community Health Workers.

Table 3: Summary of results

STUDY	DESIGN & SETTING	PARTICIPANTS	INTERVENTION	ANALYSIS	KEY FINDINGS	RISK OF BIAS
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ATIF ET AL, 2017.	Feasibility study. Community-based in rural Pakistan and urban India.	44 women aged 18 years or older in their second or third trimester of pregnancy or had infants up to four months of age.	THP adapted for delivery by peer volunteers during routine ANC & PNC.	Qualitative	All 44 mothers found the intervention acceptable and relevant to their needs, with the majority reporting improvement in their mental health. Motivations for peer volunteers included altruism, improving skills and employability, and appreciation from the community. In Pakistan, peers were happy to work on a voluntary basis. In Goa, India, the peers expressed the need for financial incentives.	Unclear
FISHER ET AL, 2014	Feasibility study (field trial). Community-based, rural Vietnam.	6 pregnant women, aged 18 years or above, and at least 28 weeks pregnant.	THP (first four sessions) during last trimester of pregnancy.	Descriptive results of quantitative data.	All participants (6/6) found the sessions understandable and most (5/6) found these sessions interesting. All women reported that the skills developed through the THP were useful. The mean of the 21-item Depression & Anxiety Stress Scales (DASS-21-V) scores did not change significantly between baseline and end line assessments.	High
HONKIMAN ET AL, 2012.	Impact evaluation. Urban Midwife Obstetric Unit, South Africa.	1079 women in the last trimester of pregnancy with depression (EPDS).	Perinatal Mental Health Programme (PMHP).	Quantitative	Of 1079 women who accepted referral, 77% (832) attended their appointments and received an average of 2.7 face-to-face sessions. Two percent (n =20) of women were referred and seen by a psychiatrist. Of these women, 75% reported inadequate partner or family support, 45% reported past psychiatric problems, 40% reported past or present abuse (any form), and 5% had problems with substance abuse. At 6–10 weeks post-partum, 87.8% of women reported an improvement in their presenting problem, 91.7% of these women rated the sessions as a positive experience.	Low
RAHMAN ET AL, 2008.	Cluster randomised controlled trial.	903 women aged 16–45 years, married, and in	THP	Quantitative	Integration of a cognitive behavioural therapy-based intervention into the routine work of CHWs more than halved the rate of depression in prenatally depressed women	Low

Appendix B: Qualitative Study documents (Chapter 4)

B1.1 Phase 1: Topic Guides

The George Institute for Global Health
Nuffield Department of Women's and Reproductive Health
University of Oxford

Interview guide for Government officials

1) Participant information sheet read out and questions (5 mins)
2) Consent forms signed and permission to start audio recording taken (2 mins)
3) Introductions (2 mins)

Broad topic area	Areas for discussion
The context of healthcare for women in the region **(40 minutes)**	1) What do you feel are the main medical challenges facing women in your communities? 2) What steps might be taken to improve these challenges? 3) What is the role of technology in healthcare delivery – do you see it as a help or a hindrance? Are there any examples you can give..? 4) Are you aware of any links between women with high blood pressure and high blood sugar in pregnancy and their long-term health? 5) *How* do you feel women with complicated pregnancies are best managed and by *whom*? 6) Are there any cultural practices in your region around pregnancy/child-birth/postpartum that are widely practiced? 7) How might regional and state government help in improving women's health outcomes in this region? 8) What do you see as the major challenges to providing best care to these women at high-risk of future heart disease, stroke and diabetes? 9) What in your opinion would ensure better continuity of care and integration of care within the health system? 10) How are health conditions prioritised in terms of funding? 11) How are health technologies prioritised in terms of funding?
Closure **(1 min)**	Thank you for participating in the discussion.
Total time approx.: 55 mins	

The George Institute for Global Health
Nuffield Department of Women's and Reproductive Health
University of Oxford

Focus Group Guide Pregnant and Post-pregnant women:

1) Participant information sheet read out and questions (5 mins)
2) Consent forms signed and permission to start audio recording taken (10 mins)
3) Introductions around the group and setting ground rules (5 mins)
4) Warm-up opening question (2 mins)

Broad topic area	Areas to cover and to stimulate discussion
The context of antenatal and postnatal care: How pregnant women access and use the health service in their region. **(15 mins)**	1) When you found out you were pregnant, whom did you contact in the health system? 2) There are some free schemes for antenatal and postnatal care – have you heard of these? 3) How often during your pregnancy have you seen/do you intend to see a healthcare professional? 4) Where are you planning to have your delivery? Will you pay for this? 5) Have you had your blood pressure measured/blood tests done/urine test? Where did you get this done? Who performed these tests? 6) What are the main problems you face accessing healthcare during your pregnancy/after your pregnancy? 7) Are there any cultural practices around the birth/postpartum period that you plan to observe? 8) Where would you prefer to be seen following birth of your baby eg: in your home/at the hospital? 9) Which health professional would you prefer to see?
Understanding of High blood pressure and high blood glucose and long-term consequences **(15 mins)**	1) Are you aware of any conditions during pregnancy that may re-occur in future pregnancies or affect a woman in the future? Tell me more… 2) What do you understand by the term "high blood pressure" in pregnancy? 3) What do you understand by the term "high blood sugar" in pregnancy? 4) Do you know if these issues affect women in the future both during and after their pregnancy? 5) What actions might be taken to reduce high blood pressure/ high blood sugar and long-term health problems that you know of? Can you tell me more..?
Practices around antenatal and postnatal care in women with pregnancies	1) In your opinion, *where* should women with complicated pregnancies be managed during and after their pregnancy and by *whom*?

Version 1.0 19.01.2018

The George Institute for Global Health
Nuffield Department of Women's and Reproductive Health
University of Oxford

complicated by hypertension and gestational diabetes **(10 mins)**	2) Do you know anything about how women with high blood pressure and/or high blood sugar are managed and followed up after their pregnancy in your area? 3) How often would you prefer your blood pressure/blood sugar to be tested during/after pregnancy? What would be acceptable for you? Tell me more about why….?
Closure **(3 mins)**	Thank you for participating in the discussion. Is there anything you would like to comment on before we finish?
Total time approx.: 65 mins	

The George Institute for Global Health
Nuffield Department of Women's and Reproductive Health
University of Oxford

Focus Group Guide for Community Health Workers:

1) Participant information sheet read out and questions (5 mins)
2) Consent forms signed and permission to start audio recording taken (10 mins)
3) Introductions around the group and setting ground rules (5 mins)
1) Warm-up question (2 mins) eg: When I say the term "high-risk pregnancy" can you give me one sentence that reflects your understanding of this term?

Broad topic area	Questions
Practices around antenatal and postnatal care in women with pregnancies complicated by hypertension and gestational diabetes **(30 minutes)**	2) What do you understand by the term "high blood pressure" in pregnancy? 3) What do you understand by the term "high blood sugar" in pregnancy? 4) Do you see these conditions regularly in the context of your work? 5) How are women with these conditions detected and managed in the community? 6) Who takes their blood pressure? Who performs their blood tests and monitoring? 7) What are the referral pathways and follow-up mechanisms in place for women with high-risk pregnancies? 8) Are you aware of any links between women with high-risk pregnancies and their long-term health? 9) How about links to problems during current and future pregnancies? 10) In your opinion, *where* should high-risk women be managed? 11) *How* should they be manged and by *whom?* 12) What happens to women with these problems after pregnancy/in current and future pregnancies?
Participatory rural appraisal exercise: Timeline and Diagramming. **Participants given sheet of paper and pens** **(25 mins)**	• Can you draw a timeline of your typical day as a Community Health Worker from when you wake up in the morning to when you go to sleep? • Can you indicate where and when you use technology during your day and for what purpose e.g: I use mobile phone to call my family. • Where do you see mobile technology helping you in your day/within your work if you had access to technology? Can you draw this on your timeline?

Version 1.0 19.01.2018

The George Institute for Global Health
Nuffield Department of Women's and Reproductive Health
University of Oxford

Interview guide for Primary and Secondary Care Physicians

1) Participant information sheet read out and questions (5 mins)
2) Consent forms signed and permission to start audio recording taken (10 mins)
3) Introductions around the group and setting ground rules (5 mins)
4) Warm-up question: When I say the term "*high-risk pregnancy*" can you give me one sentence that reflects your understanding of this term? (2 mins)

Broad topic area	Areas to cover and to stimulate discussion
Practices around antenatal and postnatal care in women with pregnancies complicated by hypertension and gestational diabetes **(30 minutes)**	1) How are women with hypertension and gestational diabetes in the villages in your region detected and managed in the community? 2) Who takes their blood pressure? Who performs their blood tests and monitoring? 3) What are the referral pathways and follow-up mechanisms in place for women with high-risk pregnancies? 4) Are you aware of any links between women with high-risk pregnancies and their long-term health? 5) How about links to problems during current and future pregnancies? 6) In your opinion, *where* should high-risk women be managed? 7) *How* should they be manged and by *whom?* 8) What happens to women with these problems after pregnancy/in future pregnancies? 9) What problems or barriers have you faced in your work that prevent effective management of high-risk women? 10) Do you know of any ways or have any ideas about preventing future complications in these women? 11) How might you engage women with high-risk pregnancies following delivery?
Workload and technology use. (10 mins)	1) How do you feel about your current workload? 2) What would make your role relating to antenatal and postnatal care easier/more interesting? 3) Have you any experience of using a mobile tablet at work or at home? 4) Would you feel comfortable using a mobile tablet-based system in your daily work? 5) The World Health Organisation has recently introduced guidelines that women should be contacted by health professionals at 8 time points during their pregnancy. Do you feel this is achievable in your role as a….?

Version 1.0 19.01.2018

B1.2 Chapter 4: Interview codes for Qualitative Study Participants

Code	Role	District
HGOV01	National Health Mission lead	Jhajjar
HGOV02	National Health Mission lead	Jhajjar
APGOV01	National Health Mission lead	Guntur
HOBGY01	Government Obstetrician	Jhajjar
HOBGY02	Government Obstetrician	Jhajjar
APOBGY01	Government Obstetrician	Guntur
APOBGY02	Government Obstetrician	Guntur
HPCP01	Government Primary Care Physician	Jhajjar
HPCP02	Government Primary Care Physician	Jhajjar
APPCP01	Government Primary Care Physician	Guntur
APPCP02	Government Primary Care Physician	Guntur
HANM01 to ANM04	Auxiliary Nurse Midwife	Jhajjar
APANM 01 to 11	Auxiliary Nurse Midwife	Guntur
HASHA 01 to 06	Accredited Social Health Activist	Jhajjar
HANGA 01 to 02	Anganwadi	Jhajjar
APASHA 01 to 05	Accredited Social Health Activist	Guntur
APANG 01 to 04	Anganwadi	Guntur
HLAB 01 to 02	Government Laboratory Technician	Jhajjar
APLAB01	Government Laboratory Technician	Guntur
HPREG 01 to 04	Pregnant/Postpartum woman	Jhajjar
APPREG 01 to 10	Pregnant/Postpartum woman	Guntur
APPREG 11 to 20	Pregnant/Postpartum woman	Guntur

Appendix C: Ethical Approval letters (UK and India)

C1.1 Phase 1: Qualitative Study (Chapter 4)

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, University Offices
Wellington Square, Oxford OX1 2JD
Tel. +44 (0)1865 (2)82106
E-mail: oxtrec@admin.ox.ac.uk

Dr. Shobhana Nagraj
Green Templeton College
43 Woodstock Road
Oxford OX2 6HG

1 February 2018

Dear Dr Nagraj

Full Title of Study: SMARThealth Pregnancy Phase 1: A qualitative study to explore and describe factors influencing the detection, referral and management of pregnant women at high-risk of future cardiometabolic disorders in rural India

OxTREC Reference: 506-18

Thank you for your email of the 29 January 2018, and for your minimal risk application form.

I am pleased to confirm that approval has now been granted for this study. This is valid for the first five years and is subject to receiving the local ethical approval (if this approval has not yet been received).

The documents approved for this study are as follows:

Documents:	Version:	Date:
Protocol	V2.0	29/01/18
PIS – Pregnant Women	V2.0	29/01/18
PIS – Government Representatives	V2.0	29/01/18
PIS – HCPs	V2.0	29/01/18
Consent Form	V1.0	19/01/18
Consent Form for those unable to sign	V1.0	19/01/18
Interview Guide – Primary and Secondary Care Physicians	V1.0	19/01/18
Interview Guide – Government Officials	V1.0	19/01/18
Focus Group Guide – Pregnant Women	V1.0	19/01/18
Focus Group Guide – Community Health Workers	V1.0	19/01/18
Appendix A – Phases 1-4		

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website: https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec.

Tel: +44 (0)1865 (2)82106
Email: oxtrec@admin.ox.ac.uk
Web: https://researchsupport.admin.ox.ac.uk/governance/ethics

Finally, for any study that will involve storing human tissue samples in Oxford, please note the following important information:

As you are planning to import the samples into England, you will need to make arrangements before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages: https://researchsupport.admin.ox.ac.uk/governance/human-tissue.

Yours sincerely

Dr Rebecca Bryant
Research Ethics Manager, OxTREC

The George Institute for Global Health India

George Institute for Global Health

311 – 312, Elegance Tower,
Plot No. 8,
Jasola District Centre
New Delhi– 110025
INDIA

T +91 11 4158 8091-93
F +91 11 4158 8090

info@georgeinstitute.org.in
www.georgeinstitute.org.in

CIN – U74900TG2007NPL055085

Date: 07 March, 2018

Dr.D Praveen
George Institute for Global Health,
Unit No. 301, Second Floor,
ANR Center, Road No.1,
Banjara Hills
Hyderabad - 500 034
Telangana

Sub: Ethics Approval (subject to recommended amendment) for Project Number 004/2018, Titled: SMARThealth Pregnancy Phase 1: A qualitative study to explore and describe factors influencing the detection, referral and management of pregnant women at high-risk of future cardiometabolic disorders in rural India.

Dear Dr Praveen,

Thank you for the application sent to us on 27 January, 2018. The following documents were submitted for review:

- Ethics application form_ V 1.0_25Jan2018
- Protocol V 1.0_25Jan2018
- Protocol abstract_ V 1.0_25Jan2018
- PIS_Pregnant women (English version)_ V 1.0_25Jan2018
- PIS_HCP (English version)_ V 1.0_25Jan2018
- PIS_Govt representative (English version)_ V 1.0_25Jan2018
- Consent form_signature (English version)_ V 1.0_25Jan2018
- Consent form_unable to sign (English version)_ V 1.0_25Jan2018
- Interview guide_Physicians_ V 1.0_25Jan2018
- Interview guide_Govt officials_ V 1.0_25Jan2018
- FGD guide_CHWs_ V 1.0_25Jan2018
- FGE guide_Pregnant women_ V 1.0_25Jan2018
- List of CVs of investigators

The Executive Body of The George Institute Ethics Committee (TGIEC) considered the above protocol for review, and had given the following recommendation:

- It was recommended to change "Phase 1" from the title and replace it with "Pilot study".

The Executive Body approved the project to proceed. Would you please note -:

- Approval is valid for the project duration (maximum of 8 months)
- Approval is subject to ratification by the next meeting of the full Institutional Ethics Committee.
- You will be required to provide annual reports to the study's progress to the TGIEC.

- You are required to immediately report to TGIEC anything which might warrant review of ethical approval of the protocol including:
    a) Serious or unexpected outcomes experienced by research participants (using the Serious Adverse Event proforma available from TGIEC;
    b) Proposed changes in the protocol; and
    c) Unforeseen events or new information(eg.from other studies) that might affect continued ethical acceptability of the project or may indicate the need for amendments to the protocol;
- Any modifications to the project must have prior written approval and be ratified by any other relevant Institutional Ethics Committee, as appropriate;
- If there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the appropriate monitoring organization;
- If the research project is discontinued before the expected date of completion, the researcher is required to inform TGIEC and other relevant institutions (and where possible, research participants), giving reasons. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins;
- Consent forms are to be retained within the archives of the Department /School /Unit/ Centre /Institute and made available to the Committee upon request.

Yours sincerely

Pallab K Maulik
Member Secretary
The George Institute Ethics Committee
The George Institute for Global Health

C1.2 Ethical Approvals Phase 2: Usability testing of SMARThealth Pregnancy (Chapter 5)

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, University Offices
Wellington Square, Oxford OX1 2JD
Tel. +44 (0)1865 (2)82106
E-mail: oxtrec@admin.ox.ac.uk

Dr. Shobhana Nagraj
Green Templeton College
43 Woodstock Road
Oxford
OX2 6HG

31 January 2019

Dear Dr. Nagraj

Full Title of Study: SMARThealth Pregnancy Phase 2: Usability testing of a mobile clinical decision support system for the detection, referral and management of pregnant women at high risk of future cardiometabolic disorders in rural India

OxTREC Reference: 501-19

Thank you for your email of the 27 January 2019, and for your minimal risk application form.

I am pleased to confirm that approval has now been granted for this study. This is valid for the first five years and is subject to receiving the local ethical approval (if this approval has not yet been received).

The documents approved for this study are as follows:

Documents:	Version:	Date:
Minimal Risk Application Form		
Protocol	V2.0	26/01/19
PIS – healthcare professionals	V3.0	16/01/19
ICF	V1.0	14/01/19
Focus Group & Interview Guide – round 1	V1.0	14/01/19
Interview Guide – round 2	V1.0	14/01/19

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website: https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec.

Finally, please note the following **important information**:

Data safety—all studies
It is the responsibility of the PI to ensure that all data collected during the course of the study is

stored and transferred safely and securely. Further guidance and advice is available from the Research Data Team.

Studies that will involve storing human tissue samples in Oxford
As you are planning to import the samples into England, you will need to make arrangements before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages: https://researchsupport.admin.ox.ac.uk/governance/human-tissue.

Yours sincerely

Dr Rebecca Bryant
Research Ethics Manager, OxTREC

The George Institute for Global Health India

George Institute for Global Health

311 – 312, Elegance Tower,
Plot No. 8,
Jasola District Centre
New Delhi– 110025
INDIA

T +91 11 4158 8091-93
F +91 11 4158 8090

info@georgeinstitute.org.in
www.georgeinstitute.org.in

CIN – U74900TG2007NPL055085

20 February 2019

Dr.D Praveen
George Institute for Global Health,
Unit No. 301, Second Floor,
ANR Center, Road No.1,
Banjara Hills
Hyderabad - 500 034
Telangana

Sub: Ethics Approval for Project Number 03/2019, Titled: SMARThealth Pregnancy Phase 2: Usability testing of a mobile clinical decision support system for the detection, referral and management of pregnant women at high risk of future cardiometabolic disorders in rural India.

Dear Dr D Praveen,

Thank you for the clarifications submitted by you for your project, through your letter dated 07 February 2019.

The following documents were submitted for review:

- Support letter from Civil Surgeon Jhajjar, Haryana
- Support letters from PHC's in Nudurupadu and Sangam Jagaralamudi
- Information regarding compensation of ASHA

The Executive Body of The George Institute Ethics Committee (TGIEC) considered the additional documents and has approved the project to proceed.

Would you please note -:

- Approval is valid for the project duration (maximum of 12 weeks from the start of project)
- Approval is subject to ratification by the next meeting of the full Institutional Ethics Committee.
- You will be required to provide annual reports to the study's progress to the TGIEC.
- You are required to immediately report to TGIEC anything which might warrant review of ethical approval of the protocol including:
    a) Serious or unexpected outcomes experienced by research participants (using the Serious Adverse Event proforma available from TGIEC;
    b) Proposed changes in the protocol; and
    c) Unforeseen events or new information(eg.from other studies) that might affect continued ethical acceptability of the project or may indicate the need for amendments to the protocol;
- Any modifications to the project must have prior written approval and be ratified by any other relevant Institutional Ethics Committee, as appropriate;

- If there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the appropriate monitoring organization;
- If the research project is discontinued before the expected date of completion, the researcher is required to inform TGIEC and other relevant institutions (and where possible, research participants), giving reasons. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins;
- Consent forms are to be retained within the archives of the Department /School /Unit/ Centre /Institute and made available to the Committee upon request.

Yours sincerely

Pallab K Maulik
Member Secretary
The George Institute Ethics Committee
The George Institute for Global Health

C1.3 Ethical Approvals Phase 3: Pilot study of SMARThealth Pregnancy (Chapter 6)

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, University Offices
Wellington Square, Oxford OX1 2JD
Tel. +44 (0) 1865 (2)82106
E-mail: oxtrec@admin.ox.ac.uk

Dr Shobhana Nagraj
The George Institute for Global Health
1st Floor,Hayes House
75 George Street
Oxford
OX1 3QY

2 May 2019

Dear Dr Nagraj

Full Title of Study: SMARThealth Pregnancy Phase 3: A pilot cluster randomised controlled study to assess the feasibility and acceptability of SMARThealth Pregnancy: a complex intervention using mobile clinical decision support system for the detection, referral and management of pregnant women at high risk of future cardiometabolic disorders in rural India

OxTREC Reference: 22-19

Thank you for your letter of 18 April 2019 in which you have responded to the Committee's request for further clarification.

I am pleased to confirm that approval has now been granted for this study. This is valid for the first five years and is subject to receiving the local ethical approval (if this approval has not yet been received).

Please also note that this approval is subject to clinical trial registration. Please forward the trial registration number to OxTREC as soon as it is available.

The documents approved for this study are as follows:

Documents:	Version:	Date:
OxTREC application form		
Protocol	V1.0	06/02/19
PIS – pregnant women (qualitative interview)	V1.0	07/02/19
PIS – healthcare workers (qualitative interview)	V1.0	07/02/19
PIS – pregnant women (control group)	V2.0	17/04/19
PIS – pregnant women (intervention group)	V2.0	17/04/19
PIS – primary health centre cluster	V1.0	07/02/19
ICF	V1.0	07/02/19
ICF – unable to sign	V2.0	17/04/19
ICF – primary health centre cluster	V2.0	17/04/19
Focus Group Guide – community health workers	V1.0	07/02/19
Focus Group Guide – postpartum women	V1.0	07/02/19
Interview Guide – primary care physicians	V1.0	07/02/19
General Self-Efficacy Scale		
Study Timeline		
PI signature form		

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website: https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec.

Finally, please note the following **important information**:

Data safety—all studies
It is the responsibility of the PI to ensure that all data collected during the course of the study is stored and transferred safely and securely. Further guidance and advice is available from the Research Data Team.

Studies that will involve storing human tissue samples in Oxford
As you are planning to import the samples into England, you will need to make arrangements before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages: https://researchsupport.admin.ox.ac.uk/governance/human-tissue.

Yours sincerely

Dr Rebecca Bryant
Research Ethics Manager, OxTREC

The George Institute
for Global Health India

George Institute for Global Health
311 – 312, Elegance Tower,
Plot No. 8, Jasola District Centre,
New Delhi – 110 025
India
Telephone +91 11 4158 8091 - 93
Facsimile +91 11 4158 8090
info@georgeinstitute.org.in
www.georgeinstitute.org.in
CIN : U74900TG2007NPL055085

Date: 24/06/2019

Dr D Praveen
George Institute for Global Health,
Unit 301, Second Floor,
ANR Centre, Road # 1,
Banjara Hills,
Hyderabad – 500034
India

Sub: Ratification letter for Project Number: 010/2019, Titled: SMARThealth Pregnancy Phase 3: A pilot cluster randomised controlled study to assess the feasibility and acceptability of SMARThealth Pregnancy: a complex intervention using mobile clinical decision support system for the detection, referral and management of pregnant women at high risk of future cardiometabolic disorders in rural India.

Dear Dr D Praveen,

This is in reference to the Ethics approval of your above mentioned project vide letter dated 15 April, 2019.

We are happy to inform you that the application for your project titled: *SMARThealth Pregnancy Phase 3: A pilot cluster randomised controlled study to assess the feasibility and acceptability of SMARThealth Pregnancy: a complex intervention using mobile clinical decision support system for the detection, referral and management of pregnant women at high risk of future cardiometabolic disorders in rural India.,* has been ratified by the IEC of The George Institute for Global Health, in their meeting held on 08 June 2019.

Yours sincerely,

GEORGE INSTITUTE FOR GLOBAL HEALTH NEW DELHI

Pallab Maulik
Member Secretary
The George Institute Ethics Committee
The George Institute for Global Health, India

C1.4 Certificate of Transcription services in India

Feenix Language Solution
Multi-channel communication service

Translation Certificate

Source Files name:	1) Final TGIEC - pis pregnant women control group v2.0 2) Final TGIEC pis for pregnant women intervention group v2.0 3) TGIEC participant consent form v1.0 4) TGIEC Phase 3 -consent form for primary health centre cluster v10 5) TGIEC-consent form for those un able to sign v1.0	
Date of Translation	**Source Language**	**Target Languages**
27 Aug 2019	English	Hindi & Telugu
Comments	"We, Feenix language Solution, certify that the above mentioned translations are certified of the translated language pair and we are authenticating its true to the best of our knowledge."	
Translation Agency	Feenix Language Solution, Bangalore-560032, India	

Date: 09 Oct 2019

Authorized Signatory

Feenix Language Solution
Bangalore-560032, India

Feenix Language Solution
No.5, 2nd Floor, 5th Main, KHM Block, R.T. Nagar Bangalore 560 032.
Phone: +91 080 41244092 /23332762
www.feenixlanguage.com - Email info@feenixlanguage.com

Appendix D: Usability testing & Intervention (Chapter 5)

D1.1 Usability testing scenarios and procedures

Usability testing research question: *What are the task performance outcomes, error rates, and satisfaction of CHWs and PCPs in completing two clinical scenarios relating to the screening, referral and management of high-risk pregnant women, using the SMARThealth Pregnancy mobile clinical decision support system?*

The aims of the usability testing were to determine:

a) **Time on Task**: Measured by "clicks" to completion, and time taken to successfully complete each task.
b) **Task Completion:** Whether CHWs and PCPs can complete the task without making errors to ensure correct outcomes and safety.
c) **Satisfaction** of the end-users (CHWs and PCPs) in using the SMARThealth Pregnancy platform.

Objectives:

1. To assess the ***time to completion*** of each mock clinical scenario using the SMARThealth Pregnancy platform by CHWs and PCPs.

2. To assess the ***correct completion*** of each clinical scenario by CHWs and PCPs, and if there are any errors made (human error rate).

3. To ***obtain feedback*** from CHWs and PCPs on the ease of using the SMARThealth Pregnancy platform, their satisfaction with the design.

Structure of Usability testing sessions

Timing	Task
0 – 15 mins	Introduction to SMARThealth Pregnancy and the digital platform.
15 – 25 mins	Introduction to the tasks and questions relating to this.
25 – 40 mins	Completion of task 1: Each CHW/PCP will complete the task independently
40 – 50 mins	Feedback from task 1: Satisfaction, concerns or errors?
50 – 65 mins	Completion of task 2.
65 – 75 mins	Feedback from task 2 (as above).
75 – 90 mins	Discussion and closure of session.

Measures of Task Completion (adapted from ISO usability testing manual):

1) Fails to complete the task correctly, gives up, or succeeds only with an assist from moderator.

2) Succeeds, but in a roundabout way, making errors, needing to back track or using on-line help.
3) Succeeds quickly, following the route the designers intended.

Observational code:

Observers (myself and research assistant) will use observational code (see below) to describe any issues faced by the participant during the tasks, and their associated verbal comments.

S	Start task
E	End task
G	General comment
P	Positive opinion
N	Negative opinion
X	Usability problem
*	Video highlight — an "Ah-ha!" moment
B	Bug
F	Facial reaction (e.g. surprise)
A	Assist from moderator
Q	Gives up or wrongly thinks finished
H	Help or documentation accessed
M	Miscellaneous (general observation by logger)

Discussion points during user-feedback (adapted from the System Usability Scale – a validated tool for usability testing (Brooke J, 1996):

1. Was the platform easy to use? What makes you feel this way?

2. Was any part unnecessarily complex? How so?

3. Did you feel confident using the platform and completing the tasks?

4. Would you have liked more training?

5. What would make this easier to use?

D1.2: Example of usability testing feedback and iterative refinement of SMARThealth Pregnancy App

APK = Android Package (App)

Feature on Tablet	Changes needed	Reason for changes	Clinical Importance/Safety	Completed? Yes/No & detail/version APK
ANC Treatment recommendations given to ASHA after first visit are not appearing for Doctor tab Visit 1 (third trimester antenatal care visit).	Treatment recommendations from Visit 1 need to synch to Doctor tab and be visible on ASHA recommendations screen for Doctor visit 1.	Doctor needs to know whether pregnant woman requires Tetanus dose or Albendazole during antenatal visit 1.	Clinically important safety issue. High priority	Yes APK v2.4 18/3/19
ASHAs suggest changing Mother's name in demographic data entry to: ANC case name; and ANC case mother's name.	Change "Mother's name" to "ANC woman name", and change "Mother's mother name/ mobile" to ANC case mother's name/mobile. and to add "ANC woman village/address".	The ASHAs got confused with Mother's name and if this referred to pregnant woman or the pregnant woman's mother. They suggested changing to ANC case name.	Moderate	
Anaemia treatment recommendations (yellow outcome).	Change wording: Currently reads: "***Is*** iv iron sucrose given?" should read ***"Has*** iv iron sucrose been given?"	The sentence doesn't make sense currently and confused the doctors.	No clinical safety implications	Yes APK v 2.4 18/3/19

Spelling of DOSE incorrect for Tetanus toxoid and for iv iron sucrose doses.	Change spelling and the numerical sequence of doses: change to: Dose 1, Dose 2… for Iv iron sucrose in treatment recommendations and also for tetanus toxoid.	Currently reads: "Does 1 and Does 1" twice under iv iron sucrose doses. This doesn't make sense.	Moderate clinical safety issues.	Yes APK v 2.4 18/3/19
Decimal point on calculator very small and unable to see.	Make decimal point bigger.	ASHAs and Doctors unable to see decimal point easily.	Clinical implications are there if unable to see this.	This is a Tablet issue, not due to APK software.
Hb value entry	To put **units (g/dL)** of entry next to entry text box ie: "_____**g/dL**" So it will appear once text entered as: 6.2 g/dL. Currently just says: 6.2 Make the decimal point to one decimal place compulsory ie: they must enter: 10.0 or 10.1 or 7.5 or 3.2. to move forward. This will prevent	For entering the Hb reading, some ASHAs are not putting the decimal place (see above). Eg: they enter 75 rather than 7.5 g/dL. This leads to potentially serious consequences: 75 – would give Green Hb recommendation, when reality is 7.5 g/dL would be RED Hb recommendation.	Clinical Safety issue. High Priority.	

D1.3 Example of training manual contents and learning outcomes

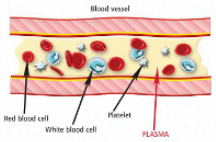
Anaemia in Pregnancy

By the end of this chapter you will be able to:

1) Understand the components of Blood.
2) Define the term anaemia.
3) List the common causes of anaemia including: Nutritional deficiencies, Infections & Red Blood Cell (inherited) disorders.
4) Understand importance of inherited blood disorders and how to suspect and detect these.
5) List the complications of anaemia in pregnancy affecting a) the mother and b) the baby.
6) Explain how anaemia is diagnosed using ASK, EXAMINE, INVESTIGATE approach.
7) Recognise the features of severe anaemia.
8) Interpret the results of the blood test for anaemia as mild, moderate or severe anaemia.
9) Explain how anaemia is managed in a step-wise way.
10) Understand the importance of postnatal follow-up testing of women with anaemia.

What is anaemia?

Anaemia is a condition affecting the blood. Blood is made up of cells (red and white blood cells) and liquid surrounding the cells (called plasma).



- Red blood cells, contain a molecule called haemoglobin.
- Haemoglobin is what gives blood its red colour and it helps carry oxygen through the blood to the organs and tissues of the body, making the body's organs work properly.
- White blood cells help us fight infections.

When there is a reduction in the number of red blood cells or when the red blood cells aren't able to carry as much oxygen as usual, then there may be anaemia.

What are the causes of anaemia?

Anaemia can be broadly caused by nutritional deficiencies, infections and inherited blood disorders. The major causes of anaemia in pregnancy are outlined in the diagram on the next page.

The most common cause of anaemia is Iron deficiency. This affects almost 50% of pregnant women in some areas.

Blood Pressure in Pregnancy

By the end of this chapter you will be able to:

1) Understand the components of Blood Pressure including Systolic and Diastolic blood pressure.
2) Define the term preeclampsia.
3) List the complications of preeclampsia affecting a) the mother and b) the baby.
4) Explain how preeclampsia is diagnosed using ASK, EXAMINE, INVESTIGATE approach.
5) Recognise the features of severe preeclampsia.
6) Interpret the results of the blood pressure readings in the diagnosis of both high blood pressure and low blood pressure.
7) Explain how preeclampsia is managed in a step-wise way.
8) Understand the importance of postnatal follow-up testing of women with high blood pressure.
9) Understand the implications of raised blood pressure on the long-term health of

What is Blood Pressure?

Blood pressure is a measure of the force in which blood is pumped out of the heart.

Blood pressure (BP) is measured in millimetres of mercury (mmHg).

There are two components of the blood pressure:

The **Systolic Blood Pressure** (SBP) refers to the pressure when the heart pushes out blood.

The **Diastolic Blood Pressure** (DBP refers to the pressure of blood when the heart is resting in between heart beats.

- Preeclampsia is the second leading cause of maternal deaths worldwide, after postpartum haemorrhage.
- We can prevent a lot of maternal deaths due to high blood pressure in pregnancy through standardised measurement of blood pressure, and timely referral to a specialist for treatment.
- By measuring the blood pressure in the weeks following pregnancy, we can also help identify women who might be at risk of these on-going problems and refer them to the Government's Non-Communicable Disease (NCD) programme to have their blood pressure checked regularly.

High Blood Pressure in Pregnancy

Some women can develop high blood pressure (hypertension) in pregnancy or Hypertensive Disorders of Pregnancy (HDPs).

About 10% of women will have HDPs in their pregnancy. The hypertensive disorders of pregnancy can occur due to pre-existing hypertension (elevation of the BP before 20 weeks of gestation) or can be related to the pregnancy (Pregnancy Induced Hypertension).

One very serious type of pregnancy-induced hypertension is a disorder called Preeclampsia, which affects 3-5% of pregnancies.

Gestational Diabetes Mellitus

Learning outcomes

By the end of this chapter you will be able to:

1) Define the term Gestational Diabetes Mellitus (GDM).
2) List the complications of GDM affecting a) the mother and b) the baby.
3) Understand the importance of antenatal testing for GDM.
4) Explain the steps of the single-step oral glucose tolerance test (OGTT).
5) Interpret the results of an OGTT in the diagnosis of GDM.
6) Explain how GDM is treated in a step-wise way.
7) Outline the principles of Medical Nutrition Therapy.
8) Understand the importance of postnatal follow-up testing of women with GDM.
9) Interpret the results of a postnatal OGTT of women with GDM.
10) Understand the implications of raised blood sugar on the long-term health of women.

What is Gestational Diabetes Mellitus?

Gestational Diabetes Mellitus (GDM) occurs when a raised blood sugar (impaired glucose tolerance) is detected for the first time or has its onset during pregnancy.

Blood sugar levels are controlled by a hormone called insulin. In pregnancy, women need more insulin than usual. Most women are able to produce more insulin during pregnancy however, some women are not able to produce enough. Women who are overweight, have a family history of diabetes and older women are at increased risk of developing GDM.

In India, the incidence of GDM is between 10 -14.3% and rising.

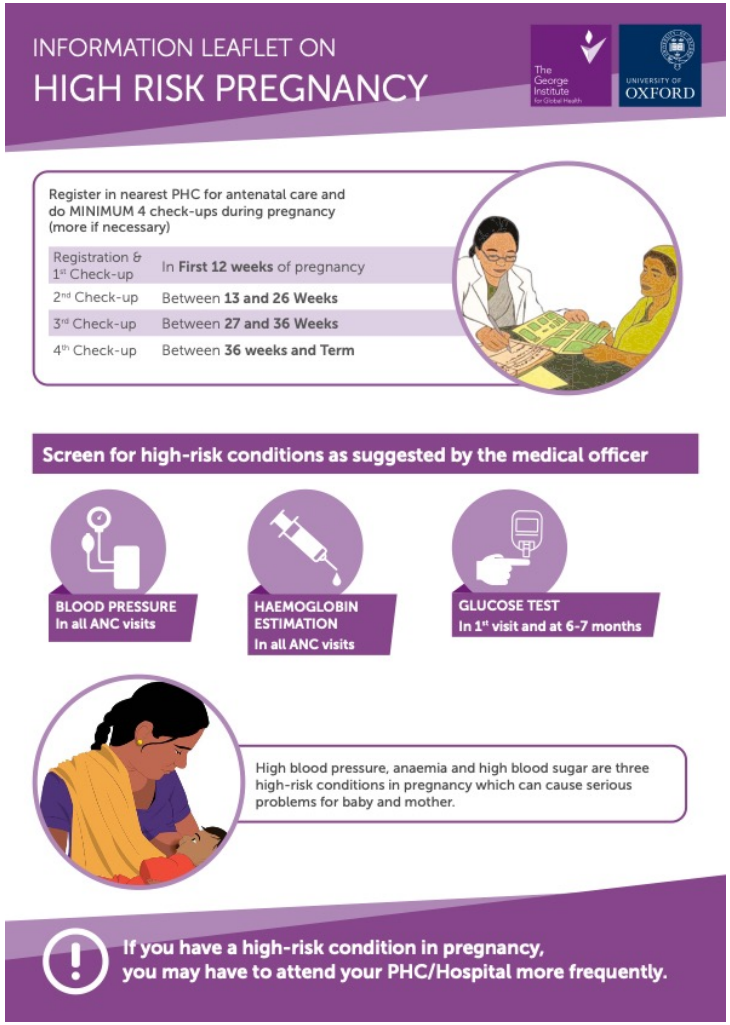
The incidence of GDM is expected to increase to 20% i.e. one in every 5 pregnant women is likely to have GDM.

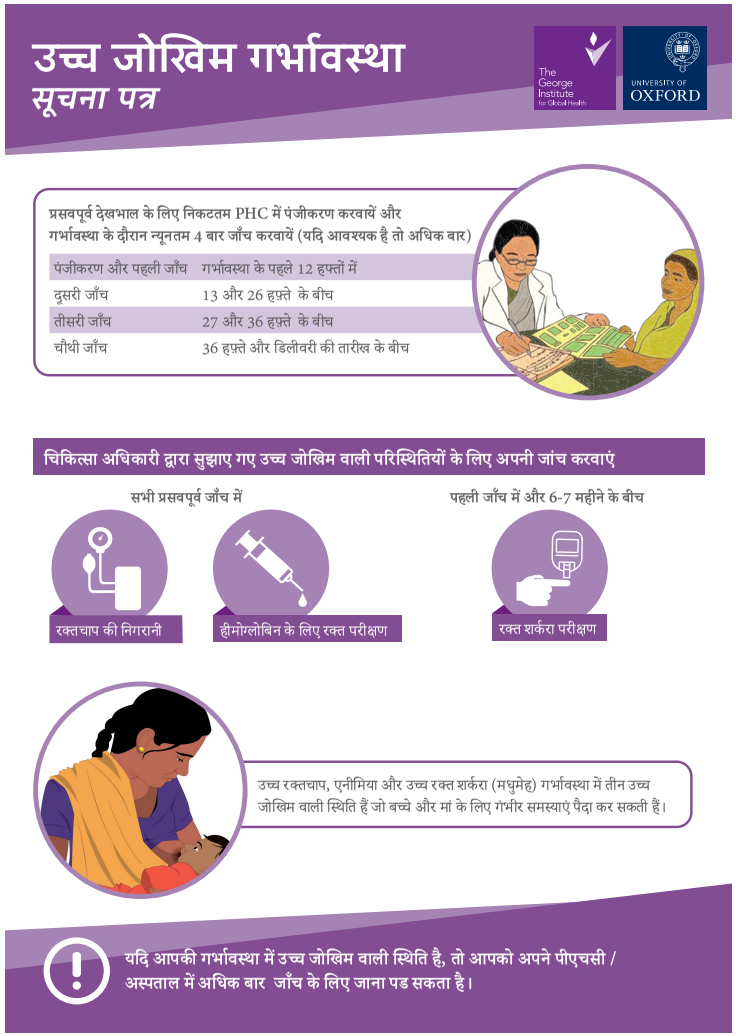
D1.4 Example of education & training session plans

Training plan for Community Health Workers - Auxiliary Nurse Midwives (ANMs) and Accredited Social Health Activists (ASHAs) on antenatal and postnatal care, with focus on anaemia, HDP, and GDM, and the SMARThealth Pregnancy Application

Activity	Duration	Objectives	Methodology	Logistics
• Welcome/Registration • Introduction • Objective setting	20 min	Set the background for training	Participant introductions using ice-breaker exercises	- Registration forms - Participant folders with training manual, notepads and pen - Logistics for icebreakers
Pre-knowledge assessment	30 min	Assess baseline knowledge of CHWs	Multiple choice questions	- Questionnaires - 20
Overview of maternal health scenario in India with focus on AN & PN care and health indicators	20 min	Sensitize participants about importance of quality of antenatal/postnatal care (ANC/PNC) Introduce concept of SMARThealth Pregnancy relating to life-long health of women	Interactive presentation	- Laptop and LCD projector - Flipcharts and markers
Small group discussion: • Group-1: Do's and Don'ts in ANC • Group-2: Do's and Don'ts in PNC • Group-3: Role of CHWs in ANC & ANC	50 min	Create awareness about importance of CHW's role in ANC & PNC	Participants divided into three groups. 20 min for group discussion. Facilitators will guide and oversee the group discussion. Each group will get 5-7 min for presenting their points and facilitator will summarize the discussion.	- Flipcharts and markers

D1.5 Examples of awareness programme leaflets





D1.6 Tidier checklist for the SMARThealth Pregnancy

TiDIER Checklist for the SMARThealth Pregnancy intervention

Brief name	
1	**Provide the name or a phrase that describes the intervention** SMARThealth Pregnancy is a multi-faceted mobile Clinical Decision Support System (CDSS), and a targeted education & training programme for Community Health Workers (CHWs) and Primary Care Physicians (PCPs) to screen, refer and manage pregnant women at high risk of future cardiometabolic disorders in rural India.
Why	
2	**Describe any rationale, theory, or goal of the elements essential to the intervention.** **Rationale:** The intervention was developed following in-depth contextual work in two diverse areas of rural India, to identify local priorities and gaps in care, readiness for technology, and to understand the health system. The contextual work identified that due to well-established cultural practices, women were vulnerable during the transition between antenatal and postnatal care, and that home-based visits would be required in the postpartum period to engage high-risk pregnant women with the health system for ongoing care. These visits could be completed by Community Health Workers (CHWs) known as ASHAs. Three priority conditions were identified by stakeholders: anaemia in pregnancy, hypertensive disorders of pregnancy (HDP) and gestational diabetes (GDM). **Theory:** The intervention development was guided by behaviour change theory (COM-B/BCW and TDF frameworks). Evaluation of the intervention will be guided by Normalisation Process Theory (NPT) to address how agents work collectively within the health system to embed new technologies & practices into their daily work. **Goal of the interventions:** The goals of the intervention are to: a) Improve knowledge and awareness of anaemia, HDP and GDM, and their long-term sequelae in women, emphasising the need for screening, referral and on-going postpartum care. b) Detect, refer, and counsel women with anaemia in pregnancy, HDP and GDM before delivery and continue home-based follow-up in the postpartum period (to reduce maternal mortality & morbidity associated with these conditions) and to; c) Detect, refer and manage women with persistent anaemia, high blood pressure at six weeks postpartum, and arrange postpartum OGTT for women with GDM, who may be at risk of future cardiometabolic disorders (CMDs); to provide

	counselling and refer women at high-risk of future CMDs to the national non-communicable disease (NCD) programme for ongoing follow-up.
What	
3	**Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers.** The SMARThealth Pregnancy platform is a java-based app within a 7-inch screen mobile tablet using the Android 4.1 operating system. It contains an internal messaging system via the portal for messaging between the CHW and PCP, with no data charges. The app has offline functionality, can auto-synchronise with adequate connectivity, and with minimal data usage (KB's). Each CHW has a unique log-in identification. Data are stored locally on the tablet and are securely uploaded to a server hosted at The George Institute for Global Health, Hyderabad, using Open Medical Record System (OpenMRS) version 1.9. There will be future capabilities for integration with hospital electronic health records, (including DHIS-2 systems), ensuring interoperability within the existing health system. Training manuals for ASHAs and PCPs have been developed, together with a face-to-face targeted education & training programme on the three priority high-risk conditions in pregnancy and their long term sequelae.
4	**Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.** The SMARThealth Pregnancy intervention consists of a) a village awareness programme, b) targeted education and training programme; and a c) multi-faceted mobile clinical decision support system, providing CHWs with the support to diagnose, refer and counsel women in their homes. The training programme consists of five sessions delivered over 2.5 days, with a one-day refresher session after one month, and hand-holding in the field in-between these training sessions. The targeted training includes a knowledge component on three (targeted) high-risk pregnancy conditions: anaemia, HDP and GDM, and their impact on the long-term health of women. CHWs will be trained to measure Hb (using the TrueHb haemoglobinometer), BP (using the CRADLE device), and conduct OGTT testing in the community using established clinical guidelines. CHWs will also be taught how to use the SMARThealth Pregnancy mHealth platform.

	The SMARThealth Pregnancy platform will be used by the ASHA during home-visits to women, to enter data relating to the pregnant woman and her previous pregnancies, to record BP and Hb readings, and clinical decision support will be provided via the SMARThealth Pregnancy App, based on these data. The intervention involves: a finger-prick Hb measurement and BP measurement, at the woman's home by the ASHA, in addition to standard antenatal and postnatal care, at three time points: a. Third trimester of pregnancy (28-36 weeks). b. 1 week postpartum. c. 6 weeks postpartum. The information from the ASHA will be automatically uploaded and synchronised with a similar tablet held by the PCP in the PHC, to identify high-risk women, ensure they have been referred, managed and treated appropriately, and that they receive ongoing follow-up care, and enable two-way communication between the village-level healthcare worker and the PHC.
Who provided	
5	**For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given.** The intervention will be provided by ASHAs, with support from local PCPs in two diverse districts of rural India. ASHAs are local village women aged 25 to 45 years, who have completed schooling up to the age of 16 years. They have a good knowledge of their local cultural practices relating to childbirth in their areas, and most have an experience of child birth themselves (requirement to be an ASHA in some areas of India). The initial training for ASHAs consists of 23 days of training divided into 5 episodes. They subsequently receive ongoing training in their respective Primary Health Centres (PHCs) on at least a yearly basis. PCPs are medical doctors who have completed their MBBS degree. Some of them will have undergone speciality training in community medicine. They are based at a PHC.
How	
6	**Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.** The awareness programme will be delivered by local health professionals during the village health & nutrition days. The education & training component of the SMARThealth Pregnancy intervention will be provided through face-to-face training of CHWs in a group environment. PCP doctors will receive individual training within their respective PHCs. Training will be provided through a combination of oral presentations and hands-on practical training, on how to use the mobile SMARThealth Pregnancy platform, as well as subsequent direct observation of patient encounters in the field by mentor trainers.

Where	
7	**Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.** The SMARThealth Pregnancy platform will be used at the community-level in the villages and their corresponding PHCs, within two districts in rural India: Jhajjar district of Haryana, and the Guntur district of Andhra Pradesh.
When and How Much	
8	**Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose** The intervention will be delivered by the ASHA at 3 time points: At 28-36 weeks of pregnancy; at 1 week postpartum and; at 6 weeks postpartum.
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

Appendix E: Pilot study of SMARThealth Pregnancy (Chapter 6)

E1.1 ASHA demographic data

ASHA demographics	Mean (Range)
Age	39 (28 – 56)
Years in full time education	9.7 (5-15)
Years as an ASHA	10.7 (2-14)
Smartphone use	29/44 (66%) had used Smartphone
Total	**44**

E1.2 Qualitative process evaluation: Focus group and interview descriptive data

	Haryana		Andhra Pradesh	
	FGD	IDI	FGD	IDI
Pregnant/postpartum women (n=5)	-	3 (4)	-	1 (1)
ASHAs (n= 52) and ANMs (n = 4)	3 (26)	2 (2)	2 (26)	1 (2)
Total no: of participants n= 61				

E1.3 Framework analysis matrix using Normalisation Process Theory constructs (excerpt)

Interview code NPT construct & (component)	Coherence = Sense making	Cognitive Participation = Relational work	Collective Action = Operational work	Reflexive Monitoring = Appraisal work
FGDAPAS1	"The work it does is also good. We can see the percentage and who and where did they consult etc. We are already seeing the special [inaudible]. The information we get by ourselves is a different from what we get from elsewhere." (Differentiation) **Workload not increased:** Respondents – It is normal. It did not increase our load, ma'am. But now we too know the importance. We know and it is very easy to use. Translator – It's very useful. Respondents – We can forget about writing it down and can see it in the tab. (individual specification and internalisation)	Relationship with ANMs and community: "[some] ANM's also feel why are Asha workers conducting a BP test, etc. They are like we have this technician who are trained for this. Asha workers are workers." (Legitimation) "Why was it given to you? Are you eligible to this? Why should you perform this? Are you being trained for this?" Some of them say such things, sir." Translator – You mean, they don't think you are qualified to do this? Respondents – "Yes." (Legitimation)	"Why was it given to you? Are you eligible to this? Why should you perform this? Are you being trained for this?" Some of them say such things, sir." Translator – You mean, they don't think you are qualified to do this? Respondents – "Yes." (Relational integration) Relationship with community then improved over time: "Previously we used to do this [home visits and chat]. Now, we too know to measure BP, Hb… Other people ask if the tests can be done to them too. Now they want the tests to be done to them too." (Relational integration) Relationship with ANMs: "They are encouraging us to learn. They tell us that it is good to learn, sir." (Interactional workability) "They [ANMs] are supportive and they said that it is also useful so all sorts of work in the future can be performed by Asha workers." Relationship with community: "They [relatives of pregnant woman] just ask if the test can be done on them as well. Why don't you check others too? Why just the pregnant women? You can check for others too…..Now lot of people	

1

Interview code NPT construct & (component)	Coherence = Sense making	Cognitive Participation = Relational work	Collective Action = Operational work	Reflexive Monitoring = Appraisal work
			are suffering from diabetes and High BP, sir…..Right, everyone wants to get themselves checked." (Relational integration)	
FGDAPAS2	Sense making of using App and data. Reorganizing way in which they do visits and comparing and contrasting with written notes: "If we miss out on writing any anything, since the data is saved on the Tab, if we enter their ID in the next visit, everything will come up." (Differentiation) Translator – So, you say it is very useful? Respondents – "Useful. There are lot of uses with the Tab. It is very good. Even if miss putting down anything in the book, if we take a look at the tab, we will get to see all the information. When we visit the pregnant woman, if you check the info on the Tab, it give's their name…" (Internalization) **Technology as an enabler:** "It is already fed and safe. All information is fed in the tab. It is very useful. If the record or the book gets lost, the entire information is lost. Since the information of pregnant women is fed into the tab, it is available anytime". (Differentiation)	Respondents – "We were not doing much for the women before, sir. Now they ask us not to do the tests on daughters in law, as they will leave but the daughters who come for deliver, we can do these tests. So, it is very useful". (Legitimation) "Let it be tab or HB or BP etc. Previously ANM's used to do HB or BP tests. Now, since we are doing it, our knowledge improved. We did not know about this in-depth. We used to do it, but…Sir, we are very happy, sir. (Enrolment) **Improving skills and work and its nature has changed in comparison to what they did before.:** "We did not know much before, but now, we are doing better work, we did not know what ANM's used to do before. Now since we are doing it and not the ANM's, it is very helpful for us to give information and work on the field. (Enrolment) Translator – Previously ANM used to do all this work. Interviewer – ANM.	TRUST of community and confidence in ASHA. Women also confident of ASHA. Reorganisation of the way ASHAs work and how they are viewed by their community: "We were not doing much for the women before, sir. Now they ask us not to do the tests on daughters in law, as they will leave but the daughters who come for deliver, we can do these tests. So, it is very useful." (Relational integration) Renegotiated work – although it is technically more work, they get more information from the visits so there is a gain, Coherence, (collective action), Reflexive monitoring (reconfiguration): Translator – "So as an Asha worker, do you think because of this your work has increased or do you think this is a part of your work?" Respondents – "It is a part of the work but we get to know more information because of this. " (Contextual integration) Collective action – cognitive participation with ANMs and roles and skills: "Let it be	Useful Nature of Technology: "Useful. There are lot of uses with the Tab. It is very good. Even if miss putting down anything in the book, if we take a look at the tab, we will get to see all the information. When we visit the pregnant woman, if you check the info on the Tab, it give's their name…" (Individual appraisal) Improving the ASHA's visits and quality of care and information gathering and individual knowledge: "We never used to take much information before from them. They used to come down and we used to note after they deliver the baby. Now, because of this tab, we are able to take their information completely. (Individual appraisal) Translator – So as a Asha worker, do you think because of this your work has increased or do you think this is a part of your work? [Unclear]

Presentations, Publications, Public Engagement & Funding

Presentations during DPhil

- **2021:** Finalist presentation: *SMARThealth Pregnancy: The development & evaluation of a complex intervention for pregnant women at high risk of future cardiometabolic disorders in rural India.* Royal College of Obstetrics & Gynaecology, Annual Academic Meeting, London, UK.

- **2019**: Poster Presentation: *Hypertension and diabetes in pregnancy and long-term risk of type 2 diabetes and cardiovascular disease: A qualitative study of the perceptions of women and healthcare workers in rural India,* Royal College of Obstetrics & Gynaecology World Congress, London, UK.

- **2019**: National Policy Meeting - Speaker: *SMARThealth Pregnancy*, and panel member National Workshop on High-risk Pregnancies & NCDs, The India International Centre, New Delhi, March 2019 and Vijayawada, India, April 2019.

- **2019**: Panel expert: *Gender health equity over the life course: Identifying and overcoming the barriers women face in accessing health systems in low-resource settings* for Taskforce on Women and NCDs to the Global Symposium on Health Systems Research, Heath Services Global Conference, Liverpool, UK.

- **2018**: Oral Presentation: *SMARThealth Pregnancy: Strengthening community-level detection, referral and management of pregnant women at high-risk of future cardiometabolic disorders in rural India.* 15th World Organization of Family Doctors (WONCA) World Rural Health conference, New Delhi 26-29th April 2018.

- **2018**: Oral presentation: "*Implementation Science: Theories & Frameworks*", Skills Building session on *Innovative methodologies for global health systems strengthening*, at Health Systems Global Conference, Liverpool, UK.

- **2018**: Presentation and organising committee member Mobile Health in Low and Middle Income Settings conference, Oxford UK. Presented on *"mHealth Evaluation*", and "*Summary of the mHealth conference*", Green Templeton College, Oxford, UK.

- **2018**: Oral presentation: *The development and evaluation of a complex intervention: SMARThealth Pregnancy*, Crossing Boundaries Conference DPhil presentation day, University of Oxford.

- **2017**: Oral presentation: *The development and evaluation of a complex intervention: SMARThealth Pregnancy*, DPhil presentation day, Nuffield Department of Women's & Reproductive Health, Oxford.

Publications during DPhil

Related to Thesis

1. Nagraj S, Kennedy SH, Jha V, Norton R, Hinton L, Rajan E, Arora V, Praveen D, Hirst JE. SMARThealth Pregnancy: The development & evaluation of a complex intervention for pregnant women at high risk of future cardiometabolic disorders in rural India (RCOG conference issue). *BJOG: An International Journal of Obstetrics & Gynaecology*. *In press* 2021.

2. Nagraj S, Kennedy SH, Jha V, Norton R, Hinton L, Rajan E, Arora V, Praveen D, Hirst JE. SMARThealth Pregnancy: Feasibility and acceptability of a complex intervention for high-risk pregnant women in rural India: Protocol for a pilot cluster randomised controlled trial. *Frontiers in Global Women's Health,* 2021:2; 620759.

3. Nagraj S, Kennedy SH, Norton R, Jha V, Praveen D, Hinton L, Hirst JE. Cardiometabolic Risk Factors in Pregnancy and Implications for Long-Term Health: Identifying the Research Priorities for Low-Resource Settings. *Frontiers in Cardiovascular Medicine.* 2020 Mar 20;7:40.

4. Nagraj S, Hinton L, Praveen D, Kennedy S, Norton R, Hirst J. Women's and healthcare providers' perceptions of long-term complications associated with hypertension and diabetes in pregnancy: a qualitative study. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2019 Aug 16.

5. Hirst J, Nagraj S, Norton R, Kennedy S, Mackillop L, Henry A. The obstetrician's role in preventing cardiometabolic disease. *The Obstetrician and Gynaecologist*, 2019.

6. Winters N, Langer L, Nduku P, Robson J, O'Donovan J, Maulik P, Paton C, Geniets A, Peiris D, Nagraj S. Using mobile technologies to support the training of community health workers in low-income and middle-income countries: mapping the evidence. *BMJ Global Health*. 2019 Jul 1;4(4):e001421.

7. O'Donovan J, O'Donovan C, Nagraj S. The role of community health workers in cervical cancer screening in low-income and middle-income countries: a systematic scoping review of the literature. *BMJ Global Health*. 2019 May 1;4(3):e001452.

Book Chapter related to Thesis

8. Nagraj S. Designing pedagogically-driven approaches to technology-enhanced learning for community health workers in *Training for Community Health: bridging the healthcare gap*. Eds: Geniets A, O'Donovan J, Winters N, Hakimi L. Oxford University Press. *In press*.

Other publications during DPhil

9. Sy MP, O'Leary N, Nagraj S, El-Awaisi A, O'Carroll V, Xyrichis A. Doing interprofessional research in the COVID-19 era: A discussion paper. *Journal of Interprofessional Care*. DOI: 10.1080/13561820.2020.1791808. 2020 Jul 27.

10. O'Carroll V, Owens M, Sy M, El-Awaisi A, Xyrichis A, Leigh J, Nagraj S, Huber M, Hutchings M, McFadyen A. Top tips for interprofessional education and collaborative practice research: a guide for students and early career researchers. *Journal of Interprofessional Care*. 2020 Jul 2:1-6.

11. Philipo GS, Nagraj S, Bokhary ZM, Lakhoo K. Lessons from developing, implementing and sustaining a participatory partnership for children's surgical care in Tanzania. *BMJ Global Health*. 2020 Mar 1;5(3):e002118.

12. Nagraj S, Miles S, Bryant P, Holland R. Medical Students' Views About Having Different Types of Problem-Based Learning Tutors. *Medical Science Educator*. 2019 Mar 15;29(1):93-100.

13. Nagraj S, Harrison J, Hill L, Bowker L, Lindqvist S. Promoting collaboration in emergency medicine. *The Clinical Teacher*. 2018 Dec;15(6):500-5.

Engagement Activities

In 2019, I was chosen as an MRC Fellow to feature in *"I'm a scientist, get me out of here!"*, a national competition which involves engaging with secondary school children across the UK to answer questions and stimulate discussions on a broad range of science topics, through live online chats.

Funding obtained during DPhil

- MRC Clinical Research Training Fellowship: SMARThealth Pregnancy: Development of a complex intervention using clinical decision support to detect & refer high-risk pregnant women in rural India; Medical Research Council (London) 2018-05-31 to 2021-05-30|Grant: MR/R017182/1. Total: £320,047.

- Co-Investigator Global Challenges Research Fund Grant, University of Oxford HEFCE-GCRF support fund project number: 0005267: Building an evidence network on technology-enhanced community health worker training in low and middle income countries (LMICS) 01/03/2018 - 30/09/2018. Total: £68,243.

लोकाः समस्ताः सुखिनोभवंतु ॥

lōkāḥ samastāḥ sukhinōbhavantu ॥

May all the beings in all the worlds be happy