Exploring the role of a semi-automated ultrasound technology in rural Indian antenatal care

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Abstract

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Background: Although obstetric ultrasound is an integral, well-established component of antenatal care (ANC) in high income countries (HICs), women in low-and-middle income countries (LMICs) still face barriers to accessing the technology, e.g. cost and the lack of trained personnel. Most of the evidence for routine obstetric ultrasound has been gathered in HICs and does not necessarily reflect LMIC settings, such as India. The aim of this thesis, therefore, was to take a user-centred approach to understanding: (1) the use and utility of obstetric ultrasound in the primary health care pathway in rural India and (2) the value of semi-automated ultrasound technology in addressing gaps in access to early, high-quality examinations for pregnant women. **Methods:** A scoping pilot phase was first undertaken with stakeholders across the public health system in rural India and consisted of informal interviews that helped to inform study design. Following the pilot phase, qualitative in-depth interviews were conducted with 25 Primary Health Centre (PHC) doctors, Auxiliary Nurse Midwives (ANMs) and government officials in two rural districts in Andhra Pradesh and Haryana. Interviews were analysed using framework analysis, a type of thematic analysis approach. **Results:** Primary level care providers and government officials in both districts perceived ultrasound to be highly beneficial in the clinical management of obstetric problems. Specifically, ultrasound was seen as a necessary tool for decision-making regarding referral practices for high-risk deliveries, given the limited resources available at the primary health level, though was not emphasised for accurate gestational age determination. Participants believed that many women face numerous barriers in accessing ultrasound scanning centres (such as cost, high patient loads, distance to travel and awareness) as machines and personnel are not available at the primary level. Although participants claimed that pregnant women had at least one ultrasound scan, there was little standardisation regarding the number or timing of scans. Most participants strongly preferred the idea of easy-to-use, basic screening through a semi-automated ultrasound machine at the PHC level to improve patient and care provider convenience and decrease the burden on higher-level centres. However, many also expressed concerns about additional workload, the potential of misuse for sex determination and the maintenance of high-quality diagnoses. **Conclusions and implications**: Care providers and government officials perceived ultrasound diagnoses as critical to deciding whether to refer women who might need high-risk support to higher-level centres that are often geographically removed. A low-cost, portable, semi-automated ultrasound machine operated by a PHC doctor would likely improve access to standardised, high-quality antenatal care for women in rural settings, provided it includes effective safety and security mechanisms, limits overburdening PHC doctors and ANMs, and is coupled with systems-level structures (e.g. referral pathways). Findings also suggest a strong need to re-evaluate the evidence base for routine obstetric ultrasound in rural LMIC settings and include more stakeholders in participatory, co-design approaches to innovation.

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I can only imagine how long this list would have been if I had done a DPhil.

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List of Abbreviations

ANC	Antenatal Care
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CHC	Community Health Centre
DLHS	District Level Household Survey
EDD	Estimated Date of Delivery
FOGSI	Federation of Obstetric & Gynaecological Societies of India
HIC	High-Income Country
IMR	Infant Mortality Ratio
JSY	Janani Suraksha Yojana
JSSK	Janani Shishu Suraksha Karyakaram
IRIA	Indian Radiological and Imaging Association
LMIC	Low-and-Middle Income Country
LMP	Last Menstrual Period
MBBS	Bachelor of Medicine, Bachelor of Surgery
MMR	Maternal Mortality Ratio
NFHS	National Family Health Survey
NRHM	National Rural Health Mission
PCPNDT	Pre-Conception and Pre-Natal Diagnostic Techniques Act
PGIMS	Post Graduate Institute of Medical Sciences (Rohtak)
PHC	Primary Health Centre
POCUS	Point-of-care Ultrasound
TIFFA	Targeted Imaging for Fetal Anomalies

Chapter 1: Introduction

1.1 THESIS BACKGROUND

Ultrasound technology, adapted for obstetric applications in the late 1950s, is a diagnostic imaging tool that has become a universal part of obstetric care, particularly in high-income countries (HICs), due to its ability to safely image the fetus throughout pregnancy (1). Routine antenatal ultrasound screenings for a range of clinical applications have been promoted since at least 1978 (2). However, as will be discussed in Chapter 2, the evidence base for routine obstetric ultrasound for specific clinical indications is not strong and lacks standardisation of practice (3, 4). In its 2016 guidelines for a "positive pregnancy experience," WHO cites the most recent systematic reviews of evidence recommending one early ultrasound examination (before 24 weeks' gestation) for every pregnant woman (5).

In addition to conflicting evidence for routine ultrasound examination, there is a lack of robust exploration or evidence in low-and-middle-income countries (LMICs) regarding the effect of ultrasound on the clinical management of pregnancy and maternal and child health (MCH) outcomes. Given low resource levels in health systems overall, there has also been debate about whether any potential benefit from ultrasound is worth the cost to LMIC systems (6). Additionally in South and East Asia, concerns about the misuse of ultrasound for sex determination and female feticide, resulting in millions of "missing women," have led to policies in India with strict regulations on ultrasound (7-9). Particularly in rural areas, there are well-documented barriers within health systems that limit usage of, and access to, ultrasound examinations, including cost, availability of trained personnel and equipment and awareness of the benefits of ultrasound (10-12).

The last few decades have seen a growing body of research on interventions that aim to increase access to obstetric ultrasound in LMICs, alongside technological advances that have made ultrasound machines smaller, cheaper and easier to use (13-21). While these studies demonstrate the feasibility of training local health workers to perform ultrasound examinations reliably, there are still significant questions about scalability and sustainability of these interventions.

Recent advances in the automation of ultrasound image analysis may present opportunities to address this gap (22). Such low-cost systems have the potential to enable health workers to train easily to perform basic ultrasound with standardised accuracy. This study explores the application of such technology to the Indian public health sector, with a specific focus on two rural districts, West Godavari district in Andhra Pradesh and Rohtak district in Haryana.

1.1.1 A human-centred design approach

The design, development and implementation of any new technology into a complex system such as the rural Indian public health sector, requires a user-centred or human-centred design approach. Such approaches have become well-known in part due to their democratisation by organisations like IDEO (23). Human-centred design is not a method itself, but rather a collection of both qualitative and quantitative methods that aim to keep the emotions and behaviours of the human users and beneficiaries of innovation at the centre of design objectives (24, 25). The first step of a human-centred design approach involves listening, observing, and understanding to engage the user and system (23, 26).

As such, a significant part of this study is devoted to understanding the current system with respect to the role ultrasound plays in antenatal care (ANC) at the primary health level. To the best of my knowledge, this is the first study to present a detailed landscape of the clinical use and utility of obstetric ultrasound in India.

1.2 THESIS OBJECTIVES

This study aims to understand how an automated system could address the gap in access to high-quality, early ultrasound for pregnant women in rural India. Specifically, the following three questions are asked:

i) How do primary care providers/health workers and government decision-makers in rural Indian antenatal healthcare systems view the clinical utility of specific diagnostic criteria from ultrasound?

ii) How would the availability of such ultrasound diagnoses in primary care affect the clinical management of pregnancies in these areas?

iii) What are the implications of this context for the design, development and implementation of an appropriate and effective semi-automated ultrasound technology in the Indian context?

In addressing these questions, this thesis aims to do the following:

- To explain why qualitative methodology is a useful and appropriate tool in technological design research for complex interventions in global health
- To explore the literature and evidence base for routine obstetric ultrasound in both HICs and LMICs, with a particular focus on the effectiveness of task-shifting interventions in LMICs
- To explore the literature for ANC and obstetric ultrasound usage in the Indian context, including legal restrictions on its misuse for sex-selective abortions.
- To understand the ultrasound-enabled care pathway at the primary level in rural India and integrate potential users' and decision-makers' perspectives to identify key design and implementation criteria for introducing semi-automated ultrasound at the primary level

1.3 METHODOLOGY

1.2.1 A qualitative approach

This study employs a qualitative methodology using in-depth interviews. Qualitative research involves "nonnumerical information and their phenomenological interpretation" to recognise and understand patterns of human behavior (27). In contrast to quantitative approaches, qualitative ones

enable the researcher to embrace the complex, underlying forces that affect a phenomenon, adding richness and dimensionality to one's understanding (27, 28). Such approaches, which arose from critiques of positivist methodologies as being inadequate for researching human behaviour address humans' interpretations of reality rather than an independent "objective" reality (29).

Such an approach can help reveal the underlying motivations behind behaviours of stakeholders in healthcare, especially with regard to technology usage (27). Since what humans say they do is not always what they actually do, qualitative methods, as compared with surveys or other quantitative tools, can help untangle these underlying forces (30).

There are two aspects of this study for which qualitative methods are particularly useful:

1) *Exploring the integration of technologies in healthcare.* Qualitative research does not assume that technologies naturally diffuse into healthcare systems, but rather that technologies acquire social meaning through their interactions with human actors in a system (31). Thus, this study conducts technological design research that starts from a systems-based, contextual understanding of such interactions.

2) *Understanding a low-resource healthcare context.* This study examines the access to ultrasound diagnostic technology, an international standard in obstetric care, in rural, low-resource regions of India. Historically, studies of health inequalities have centred around statistical, epidemiological evidence, but researchers have since recognised how the behaviours of those in poverty are affected by broader social structures and their perceptions of such structures (32). Exploring these perceptions can provide an understanding of enablers or barriers to the integration of tools and resources that seek to improve health equity.

Thus qualitative research is well-poised to address the social dynamics of a healthcare system, its participants and technologies, because it views social context as an integral influence on the beliefs and behaviors of participants and investigators (33).

1.2.2 Sampling in study design

Sampling for in-depth interviews in qualitative research is a multidimensional concept, and includes not only the number of people involved in the study, but also aspects like interview length and the number of analytical groups of people interviewed (34). Established approaches to determining sample size involve attaining saturation, including theoretical saturation or informational redundancy (35). Theoretical saturation, as discussed by Strauss and Corbin (1990), involves taking initial decisions about sites and subjects, but determines further sampling based on the need to test emerging concepts and theories (36). Informational redundancy, discussed by Lincoln and Guba (1985), aims to maximise information, thus measuring saturation not through theory development but by the emergence of information (29, 37). This study uses a theoretical saturation approach (discussed in Chapter 4).

There are not many specific guidelines for determining the necessary sample size to reach saturation (35). In Mason's (2010) study of achieving saturation in PhD theses, the number of participants/interviews used ranged from 2 to 70 (38). Green & Thorogood (2013) suggest that little new information is acquired from more than 15 participants in a homogeneous group (29). However, all of these numbers depend on factors such as the scope of the study, heterogeneity of the sample, or the skill of the researcher (38).

1.2.3 Trustworthiness

Conceptual frameworks for establishing trustworthiness are critical to ensuring validity in qualitative research (37). Lincoln and Guba's (1985) well-accepted framework is used in this study and includes four key criteria: credibility, transferability, dependability, confirmability.

The *credibility* of qualitative research, often termed "internal validity" in quantitative research, refers to whether the study actually measures the "reality" it is intended to (for instance, by evaluating how the research question has been defined and whether it is addressed with appropriate methods). The *transferability* of results refers to their generalisability beyond the specific participants

studied, which is particularly difficult in context-dependent social science research. Sufficient background information must be provided to enable inferences about transferability to be made. The *dependability*, or reliability of results, refers to the ability to repeat the exact same study with identical methods and acquire the same results. Finally, the *confirmability* or objectivity refers to the biases of the researcher, the data collected and the interpretations of these data (28). Specific strategies employed to achieve these criteria are discussed in Chapters 4 and 7.

1.2.4 Reflexivity

Acknowledging the effect of my role as the primary researcher on the design and analysis of this qualitative study is another important element of trustworthiness. My background as an Indian-American woman enables rapid trust-building through the similarity of external characteristics (i.e. skin colour, gender, language/accent, or type of clothing). However, my Western upbringing and educational background also make me an outsider and can affect perceptions of superiority. My familiarity with the Indian context enhances the credibility of these findings, but may also affect common assumptions that others may interrogate more in an interview (39). Language limitations also affect data collection and analysis—I am semi-fluent in Hindi but not in Telegu, the languages used in the districts studied here.

A unique aspect of this thesis is the input received from a variety of research disciplines. My combined backgrounds in engineering and the social sciences have informed my approach to understanding the utility of ultrasound by focusing on implications for all health system stakeholders and the design and usability criteria for a device to achieve that utility. The thesis has also received supervision and input from experts in obstetrics, fetal medicine, biomedical engineering, qualitative methodology in primary health, as well as global health systems, delivery and user-centred design and innovation.

1.4 THESIS STRUCTURE

Chapter Two (Literature Analysis) explores the literature across several relevant areas, including evidence supporting the use of obstetric ultrasound in HICs and LMICs, task-shifting in LMICs to integrate ultrasound into ANC, and gaps in the technological landscape of obstetric ultrasound.

Chapter Three (Indian Context & Pilot) describes the context of ANC and ultrasound in India, and specifically in the West Godavari and Rohtak districts where the study was conducted, including background on the context of sex determination and female feticide in India. An overview of key findings from the pilot phase scoping exercise that informed study design is also presented.

Chapter Four (Methods) details the qualitative methods of data collection, analysis and achieving trustworthiness used in this study.

Chapter Five (Results I) presents the first section of results from a design-based drawing exercise used in the interviews along with findings pertaining to the health system and social context in the districts studied here.

Chapter Six (Results II) presents the second section of results focused on participants' understanding of the usage and utility of ultrasound diagnoses for the clinical management of pregnancy in primary care and the implications for designing and implementing an appropriate, cost-effective and sustainable technology.

Chapter Seven (Discussion) presents the analysis of findings from Chapters Five and Six and a summary of strengths and limitations of the study.

Chapter Eight (Conclusion & Recommendations) summarises key points of the thesis and presents a set of recommendations for the design and implementation of a technological intervention. Future directions for research in this space are also discussed.

Chapter 2: Literature Analysis

This chapter explores relevant literature across several disciplines. The first section details the development of obstetric ultrasound and the evidence garnered in HICs to support its routine use. The second section explores the relevant evidence in LMICs, particularly rural or low-resource settings. Next, the clinical effectiveness of interventions (such as task-shifting or educational programmes) to expand ultrasound usage in LMICs is discussed. Finally, the product landscape of point-of-care ultrasound technology is examined.

2.1 OBSTETRIC ULTRASOUND: DEVELOPMENT IN HICs

2.1.1 Early ultrasound

The application of ultrasound to obstetric medicine was first reported in 1958, with the publication of a seminal Lancet paper, and became prominent as a lower-cost, real-time imager that avoided harmful ionising radiation (1). In 1978, the first study was published demonstrating the diagnostic value of routine obstetric screening for accurate dating, early detection of twins, and placental location (a high contributor to mortality at the time) in Sweden (1, 2, 40). Also around this time, the development of cheaper, real-time scanning decentralised ultrasound scanning beyond a few experts in well-established clinical centres (1). By the end of the 1970s, ultrasound had become a routine part of ANC in the U.S. and Europe.

2.1.2 Evidence for routine obstetric ultrasound (HICs)

Despite the extensive usage of routine obstetric ultrasound in ANC, the evidence base supporting the impact of such practices on perinatal health is heavily debated. Several large randomised controlled trials in the early 1990s exemplified this debate. In the 1990 Helsinki Ultrasound trial (n=9310), researchers observed a significantly lower perinatal mortality rate for the routinely screened group (vs. selectively screened) because of the early detection of fetal anomalies which enabled the termination of affected pregnancies (41). Meanwhile, results from the larger Routine Antenatal Diagnostic Imaging with Ultrasound (RADIUS) trial in the U.S., a multicentre

study of low-risk pregnant women in 1993 (n=15,151), suggested that two ultrasound scans did not significantly reduce perinatal morbidity or mortality (42). However, findings from the RADIUS trial have been met with significant criticism (43). High-risk pregnancies were excluded from the study, thus representing only 39% of the actual antenatal population (44). Additionally, over half of the anomalies were detected at or after 24 weeks' gestation when legal abortion was not available in most states, and others mostly chose to continue the pregnancy, reducing potential perinatal benefits (42).

Current debate suggests that obtaining perinatal benefits from ultrasound hinges on specific protocol. Whitworth et. al's (2015) Cochrane systematic review that includes 11 randomised controlled trials (including both the RADIUS and Helsinki trials), of which 9 are from HICs, provides the most recent review of evidence (3). The authors conclude that the evidence supports routine ultrasound prior to 24 weeks' gestation for accurate gestational age determination to reduce post-term induction and early detection of multiple pregnancies, but does not support any significant impact on perinatal death. Improved fetal anomaly detection if termination is possible was also found to be justified.

However, the authors point out that the lack of blinding, wide variability in timing and number of scans, quality control and operator skill makes true comparison difficult (3). Additionally, determining whether diagnostic potential translates into improved perinatal outcomes requires much larger studies to account for statistically rarer outcomes.

There is a stronger evidence-base suggesting that routine *late* ultrasound in HICs does not significantly improve antenatal, obstetric and perinatal outcomes (45, 46). In the 2015 Cochrane review (13 randomised controlled trials) authors suggest that the main exception was reduced frequency of post-term delivery, but non-screening groups did not receive early, accurate gestational age measurement. Since clinical practice is to induce labour before 42 weeks' gestation, this association cannot be firmly determined (4). The authors also acknowledge that isolating late ultrasound from the effects of early ultrasound is almost impossible, given that many outcomes are contingent on gestational age.

The most recent WHO recommendations on ANC draw from both of these reviews and recommend one "early" ultrasound scan before 24 weeks' gestation to "estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience" (5). A late ultrasound is only recommended in the absence of an early scan. The International Society of Ultrasound in Obstetrics & Gynaecology (ISUOG) has similar guidelines (47). However, it also recommends ultrasound between 18 and 22 weeks' gestation as a compromise between accurate dating and the detection of congenital anomalies and multiple scans in complicated twin pregnancies (48, 49).

2.1.2 Negative impacts of obstetric ultrasound (HICs)

Although some studies have suggested that high numbers of ultrasound scans and continuous wave Doppler can increase the likelihood of intrauterine growth restriction (IUGR) in fetuses, they do not necessarily reflect typical scan frequencies for routine ultrasounds, and other studies showed conflicting results (43, 50). Today, ultrasound is accepted to be physically safe for both the mother and child (51).

Some have suggested a significant potential for harm from misdiagnoses and subsequent unnecessary obstetric interventions (43). Additionally, psychological impacts, such as symptoms of depression or anxiety, resulting from adverse diagnoses during pregnancy are well cited in the literature (52-55). In HICs, this mostly stems from the anxiety around the decision to terminate after a diagnosis of fetal anomalies (56).

2.1.3 Perceptions of obstetric ultrasound (HICs)

Garcia et al.'s (2002) systematic review is the most recent review of studies examining women's perceptions of ultrasound, with all-but-one of the studies from HICs (52). The review concludes that women and their families have very positive views about obstetric ultrasound because it provides visual reassurance about the fetus, though this benefit is contingent on subsequent

interactions with the operator or clinician. Although earlier studies reported women's fears of harm from ultrasound, this seems to have disappeared from more recent literature.

In two qualitative studies with Australian midwives' (n=37) and obstetricians' (n=37), care providers perceived ultrasound as an invaluable tool to see the most important information about the pregnancy (57, 58). However, they also expressed concerns, such as the challenges with resolving uncertain diagnoses, high expectations from patients regarding the capacity of ultrasound, an increased societal intolerance toward disability, and the normalization of ultrasound exams affecting the ability to really enable informed consent. The former study also references broader feminist and sociological critiques that ultrasound enhances the perceived personification of the fetus and has transformed the fetus into a patient, a concern for pro-choice advocates (40, 52, 57, 59).

2.1.4 Cost and cost-effectiveness (HICs)

The ultrasound literature lacks rigourous cost studies, particularly for routine scanning. A 2002 systematic review of 24 cost and cost-effectiveness studies examining routine ultrasound scanning for fetal anomaly detection found most cost studies were from the U.S. and do not accurately reflect costs to healthcare facilities or to women themselves (60). The only economic evaluation based on a randomised controlled trial is the Helsinki Ultrasound Trial (described in 2.1.1), and suggests that their unit cost of screening, $102 USD, is cost-effective but contingent on the quality of training and the detection rate of fetal abnormalities (61). However, a comprehensive cost study at the Liverpool Women's Hospital in the late 1990s suggested much lower costs of £14-16 per scan to the National Health Service and £9-15 per scan for women, family and employers (62).

In the RADIUS trial (described in Section 2.1.1), which found no association between routine screening and perinatal mortality, authors estimated a yearly increase in costs in the U.S. by more than $1 billion (42). A later, more comprehensive cost-benefit study of the RADIUS trial conducted from a societal perspective suggested that the costs do outweigh the benefits, but with two caveats—if the

sensitivity in measurement is that of tertiary centres and if pregnancies with severe fetal anomalies are terminated (63).

As far as I am aware, no large randomised controlled trials, systematic reviews or meta-analyses have been conducted to re-evaluate the economics of routine obstetric ultrasound in the last 15 years to take into account recent advances in ultrasound technology or other changes in healthcare delivery.

2.2 OBSTETRIC ULTRASOUND IN LMICs

While obstetric ultrasound has been incorporated into routine ANC in HICs since the 1970s, the expansion of ultrasound into LMICs has taken more time, despite recognition that these facilities were lacking as early as the late 1980s (64). Two separate 2011 reviews of ultrasonography usage and indications in LMICs highlight significant usage of ultrasound in LMICs for obstetric applications. Groen et al. (2011) cited 58 studies, many of which found anywhere from 30-86% change in clinical management from ultrasound, though many of these studies are primarily expert-conducted ultrasound examinations, which is not representative of human resources available in such environments (65). Sippel et al. (2011) suggest that the increased portability and durability of ultrasound machines have expanded their use in more remote, rural areas of LMICs, but point out the lack of large, comprehensive long-term studies to evaluate the impact of increased use (10). (See Section 2.4 for the relevant product landscape.)

Within LMICs, rural areas face particular challenges in implementing ultrasound or other imaging diagnostics. Kawooya (2012) identifies low levels of human resources, socioeconomic disparities, limited transport options and distances from academic centres as barriers to training personnel in rural, sub-Saharan Africa (17). The large cost required to run traditional ultrasound services limits the potential to meet the full need in LMICs (6, 65).

The question of whether ultrasound is a “worthwhile” investment for LMICs remains open for debate. It is difficult to answer, given that the majority of evidence regarding routine practice has been

generated in higher-income settings. Some suggest that diagnostic ultrasound could have higher value in LMICs due to the higher frequency of complications and settings in which the majority of antenatal and intrapartum care happens in peripheral, primary centres while care for high-risk pregnancies requires transportation and planning (6). Geerts et al. (2004) also found other benefits from a community ultrasound prospective trial (n=3009), namely the reduced need to refer women to regional centre for fetal surveillance or delivery due to improved dating (66). There is a significant need to further explore the utility of ultrasound in environments with geographically-distributed health facilities.

Hofmeyr (2009), for example, promotes "basic," early level 1 ultrasound to detect viability, number of fetuses and gestational age determination (6). Kiserud (2012) points out the promise of studies like Sayesneh (2012), an observational cohort study (n=204) which showed that compact ultrasound could be used to do emergency obstetric triaging, and Rijken (2012), a prospective observational study (n=1090) which suggests that health workers with low educational levels can still conduct basic ultrasound scans with high levels of accuracy (18, 67, 68). (See 2.3.2 for basic ultrasound and task-shifting). Others have sought to simplify methods of conducting ultrasound examinations (69).

2.2.1 Perceptions of obstetric ultrasound (LMICs)

Studies examining women's perceptions of ultrasound in LMICs and the effect of ultrasound on women's psychological wellbeing tend to be smaller, qualitative studies (with sample sizes ranging from 16 to 60) in specific settings. The most common perception among pregnant women in LMICs is that getting an ultrasound scan provides reassurance, mitigates uncertainty, is enjoyable, and prepares a woman for delivery, due to accurate gestational age determination (56, 70, 71). In a study at the Thai-Burmese border, women believed that ultrasound helped detect fetal malposition, preventing a dangerous childbirth (72). Generally studies show little distrust of the technology or lack of cultural acceptance (5, 73).

Groen et al. (2011) cite studies which found that women often overestimate the diagnostic potential of ultrasound or uncritically accepted diagnoses (65). A study in Tanzania found that some

women thought that ultrasound could even detect infectious disease (56). A Syrian study suggested that women felt shock or betrayal when diagnoses were found to be incorrect (71). Women in a study in Botswana expressed disappointment and fear when a scan did not reflect problems they felt physically (59).

Several patient perception studies in LMICs also document fears that the ultrasound would be painful or invasive (56). This was attributed to a lack of sufficient communication from operators and care providers, a common finding in other similar studies (70, 72). Interestingly, Garcia et al.'s (2002) systematic review found that women's fears of ultrasound in HICs disappeared in the literature over time (52). This is likely because of the increasing ubiquity of ultrasound but the relatively recent introduction in LMICs suggests this can still be an issue.

Few studies have addressed care providers' perceptions. In a Botswana study, doctors and the staff also felt tempted to de-emphasise clinical history-taking and physical exams after the ultrasound was introduced (59). Most studies express positive perceptions of the improved accuracy, reliability and speed of ultrasound diagnosis for a wide variety of obstetric information, including gestational age, fetal health, amniotic fluid volume, placental localization, and fetal presentation, though some about the utility of routine ultrasound. (12, 59, 70). Limited availability of resources, such as trained staff and machines may contribute to such perceptions (11).

2.2.2 Cost and Cost-effectiveness (LMICs)

The only LMIC cost study found here was Geerts et al.'s (1996) study (n=1000) in South Africa which found that routine ultrasonography did not lead to a reduction in number of antenatal visits, admissions or Doppler investigations, so the cost of ANC to the Health Service was lower in the selective ultrasound group compared to the routine ultrasound group (74). The authors suggests that settings where congenital anomalies are not a major contributor to perinatal mortality may not see economic benefits found in other studies (See Section 2.1.4).

2.3 INTERVENTIONS: TRAINING AND CAPACITY-BUILDING IN LMICs

This section details the findings of interventions that seek to expand ultrasound service capacity in LMICs, especially by task-shifting ultrasound. Studies exploring the clinical impact of building such capacity have increased dramatically in the past decade, evaluating innovations in both technology and health delivery.

2.3.1 Education and training

LaGrone et al.'s (2012) review of training opportunities for ultrasonography in LMICs suggests that while such training programmes have increased, the vast majority of people administering ultrasound scans in LMICs do not meet the criteria set by the WHO Ultrasound Manual (75). No standardised approaches have been adopted in the literature, and courses for non-specialists range from 4 days to several months, eliciting concerns regarding the quality of mostly independent rural clinics in LMICs (10). An online learning platform has been created by the World Federation for Ultrasound in Medicine and Biology to complement a wider platform that includes in-person teaching (76). There are unanswered questions about the most effective training models and whether or not they translate into sustainable capacity (75).

2.3.2 Task shifting and "basic" ultrasound

Some studies have tested intervention packages that task-shift ultrasound to non-specialist health workers in rural LMIC primary care settings, due to low numbers of trained experts for the population size (77). Given that midwives, community health workers and other players in primary health systems tend to oversee most ANC provisions, building their technical capacity to acquire diagnostic information from ultrasound scans could be a key strategy in improving access to antenatal care (78). For example, Greenwold et al. (2014) (n=1744) evaluated an 8-week training course for non-specialist health workers supported by videos and 10 months of remote support in Mozambique (79). A study examining point-of-care ultrasound in Liberia delivered a 1-week curriculum for

midwives, and found that scores on examinations were maintained even a year after the initial training (14).

To adapt ultrasound technology to LMICs and other resource-constrained environments, manufacturers have created point-of-care ultrasound (POCUS) machines, which are easy-to-use, compact, and portable, and many studies have reported positively on usability and utility (see Section 2.4 for technological landscape) (13, 21, 67, 80). In obstetrics, many have promoted limited functionality, or "basic ultrasound," which detects certain conditions or clinical information (6, 80). Although there is variation as to what constitutes "basic ultrasound," gestational age is always included because it determines other obstetric management decisions and outcomes, such as the timing of treatment in malaria endemic populations or the classification of birth outcomes, respectively (19, 66). Hofmeyr (2009) suggests that congenital anomalies should not be included because of the general low specificity of detection (6).

Beyond the technology, Stanton and Mwanri (2013) identify six components of health systems that affect the impact of an ultrasound system: referral pathways/clinical guidelines, image reporting infrastructure, record keeping, quality assurance, availability of patient counselling and support, and means to improve management based on results (such as access to a safe abortion or feasible transport to secondary/tertiary health centres) (81). For example, in Kenya, Oluoch et al. (2015) found that women's perceptions of clinical guidelines (i.e. when they should have their first ANC appointment), affected their likelihood of getting an early ultrasound, and thus affected the accuracy of gestational age determination (70).

Studies evaluating task-shifting typically address any of three components crucial to evaluating the utility of ultrasound: quality control (the accuracy and precision of scans and their interpretations), the diagnostic impact (whether an ultrasound scan alters the clinical diagnosis that would have been made otherwise), and the effect on clinical management outcomes (whether the resulting actions necessitated by clinical diagnoses can be followed through in the health system). As LaGrone et al. (2013) suggest, many studies show effective assimilation of technology, but fail to evaluate follow-up of skill retention and technology use (75).

2.3.3 Quality control

Operator training and experience is the most important factor affecting the quality and accuracy of ultrasound diagnoses (1). For instance, an ultrasound-based screening programme (n=287) for fetal anomalies in an urban district hospital in Nigeria found that high sensitivity of detection compared to other studies in the literature, but attributed this to the consultant radiologist who had achieved extensive training in a renowned UK centre (82).

In LMIC ultrasound intervention studies, quality is typically evaluated by comparing images and interpretations between the trainee and an expert. For example, Boamah et al.'s (2014) study in Ghana evaluated the training of midwives to conduct fetal biometry scans (83). A senior obstetrician conducted informal reviews of image quality and provided technical feedback to the midwives, and formal quality reviews were conducted for a randomly selected 5% of images. However, the study also shows indicates the extensive resources required to maintain quality control and supervision in such ultrasound interventions.

Other studies have used such methods to show that equipping low-skilled health workers with limited obstetric ultrasound can create high quality ultrasound diagnoses. For example, a study (n=804) in rural Nepal equipped three midwives to conduct 3rd trimester ultrasound in home visits to detect noncephalic presentation, multiple gestation and placenta praevia; comparing midwives' diagnoses with two radiologists' interpretation showed high sensitivity and specificity in detecting presentation and multiple gestations (84). In a Ugandan study (n=939), midwives were trained in a six-week training course for limited obstetric ultrasound (cardiac activity, fetal presentation, fetal number and placental position), and a quality assurance review by two of the investigators (who are radiologists) found specificity and sensitivity for various diagnostic criteria ranging between 90-100% (85).

Stein et al. (2008) in Tanzania found that training midwives in a 2 month course to scan 542 patients with suspected complications enabled the identification of twins, fetal heartbeat and fetal

position with 100% agreement with expert analysis (10, 86). Kimberly et al. (2010) trained Zambian midwives with a six-month, basic obstetric ultrasound curriculum and found detection of fetal heart rate and placental location with 96% and 91% agreement, respectively (73).

Many of these studies include tele-medical oversight to provide feedback, which can present challenges in some rural LMIC settings without internet or electricity access. The FirstLook cluster-randomised control trial, which is the largest trial of routine obstetric ultrasound screening in LMICs to date, was implemented across five different sites in the DRC, Guatemala, Kenya, Pakistan, and Zambia to provide a 2-week basic obstetric ultrasound course to health care workers (87, 88). Findings related to health outcomes of the actual trial are still awaited, but during the training period, quality control was maintained through on-site sonographic supervisors and off-site expert supervisors who checked diagnoses. The team created a web-based quality control system to address connectivity and bandwidth challenges in these areas, and enabled experts to review and comment on images collected by field sonographers. For 3801 examinations conducted, authors found a 94.8% image approval rate by the reviewers and a 99.4% concordance between trainees and reviewers. However, maintaining such a quality review process is quite resource-intensive and required significant feedback during the pilot (87).

There is little agreement regarding which diagnostic components better lend themselves toward higher accuracy with limited training. For example, Rijken et al. (2012) found reasonable accuracy in fetal biometry measurements for gestational age measurements but Kimberly et al. (2010) found that acquiring the right plane for fetal biparietal diameter measurements was the most common mistake (18, 73). Kozuki (2016) found that the midwives in Nepal had the most difficulty acquiring appropriate images to detect placental lie (84). In the FirstLook pretrial, diagnosing placental praevia (low placental lie) and oligohydramnios (excess amniotic fluid) resulted in the most number of errors (88).

2.3.4 Diagnostic impact of basic ultrasound

Diagnostic impact refers to a measure of how clinical diagnoses change before and after an ultrasound diagnosis. This is contingent on the risk factors being screened for, when in the pregnancy they are being screened and the quality of the diagnosis. Boamah et al. (2014) noted qualitatively the diagnostic impact of detecting breech pregnancies and one ectopic pregnancy, which requires a skilled midwife's examination otherwise (83). In rural Nicaragua, a study (n=132) found that after implementing POCUS, 52% of prenatal scans resulted in a new diagnosis (21). Studies in Zambia and Uganda found alteration in diagnoses in 17% and 12% of the clinical encounters respectively when midwives were trained in obstetric ultrasound (73, 85). Swanson et al. (2014) also show that almost half of the diagnostic impact in the Uganda study came from early third trimester diagnosis of malpresentation (85). As Kimberly et al. (2010) point out in their Zambian study, this impact varies depending on how ultrasound application and "clinical change in management" is defined (73).

The authors of both the Zambia and Uganda studies specifically limit their findings to diagnostic impact, pointing out that the study was not powered to measure impact on care-seeking behavior or overall health outcomes. The Zambia study, for instance, did see a large increase in births in one of the rural clinics with ultrasound, but both studies lack control groups and are subject to confounding variables. For example, in the Uganda study, the authors point out that the site being a Millennium Village Project research site would have confounded any analysis of changes in care-seeking behavior.

2.3.5 Clinical management outcomes

Finally, ultrasound task-shifting studies often find relatively high effects of diagnoses on clinical decision-making and management. For example, Stein et al. (2008) found that ultrasound in a district hospital in Tanzania conducted by nurse midwives aided in the diagnosis of 39% of patients and changed clinical management plans in 22% of them (86). In the Nicaragua rural POCUS study, 61% of patients underwent a change in management (21). Shah et al. (2009) found a change in

management in 43% of 345 scans conducted by local physicians in rural Rwanda (13). The latter two studies, however, covered a variety of applications beyond obstetric care.

Enabling change in clinical management is important because diagnosing women without a viable follow-up option is at best unhelpful and at worst ethically harmful. There are supply and demand components that determine whether an altered diagnosis translates into altered clinical management: the care-seeking behaviour of pregnant women and the health system capacity to carry out clinical follow-up.

Some studies have specifically sought to quantify impacts of obstetric ultrasound with regards to care-seeking behaviour. This is similar to the hypothesised "magnet effect" of ultrasound, which suggests that the presence of ultrasound technology draws women and their families toward following necessary ANC procedures, to seek confirmation from ultrasound diagnoses (17, 89). In Uganda, Kawooya et al. (2015) found that introducing obstetric ultrasound resulted in a 32% increase in first ANC attendance and a 40% increase in referrals (90). Another 2013 study in Uganda examined the effects of POCUS provided by the NGO Imaging the World in a community level III health care centre and, using historical controls, found statistically significant increases in the number of deliveries, ANC appointments, and other ANC interventions such as iron tablets and deworming treatment (91, 92).

A similar before-and-after study design was used in a 2015 Tanzania cohort study (n=257), which found that the introduction of routine ultrasound significantly increased the number of women who came to four or more appointments and the number of referrals made (89). Approximately 78% of the study cohort followed through with referrals, although there was no baseline information for comparison. A 2016 pilot in Ghana surveyed 100 women in communities where POCUS services, mobile technologies and community health workers who carry out ANC had been implemented and found statistically significant increases in ANC attendance and hospital deliveries (16).

There are significant concerns about the validity and generalisability of these studies' conclusions. One cannot disregard the foreign influence of ultrasound in LMICs, which could affect

uptake of the technology and its follow-ups. Most importantly, however, none of the studies used external control sites and could have confounding factors, even when controlling for workflow.

Evaluations of health systems components of clinical management change with ultrasound interventions are virtually absent from the literature. Based on challenges found in the DRC site of the FirstLook trial, authors suggest the need for certain health system requirements in order to successfully introduce an ultrasound intervention, such as a functioning antenatal and delivery health system, a referral hospital with comprehensive emergency obstetric and neonatal services, and reasonable cost and distance for travel and hospital care (93).

2.3.6 Challenges with analysing the obstetric ultrasound literature

Synthesising the literature for obstetric ultrasound utility, application and implementation in both HICs and LMICs presents challenges due to the lack of standardisation of variables. Each study uses different ultrasound devices, protocols, diagnostic criteria, and tests for different outcomes; as such an attempt has been made throughout Chapter 2 to provide context about study design and sample size. In LaGrone et al.'s (2013) review on training mentioned above, studies did not necessarily include all aspects important for comparison, such as recruitment methods, location and duration, and methods and outcomes of both education and assessment (75). Understanding the limitations of what studies can reasonably conclude is complicated but critical.

Secondly, most of these trials do not explore the long-term sustainability of delivery mechanisms. In some studies, like Boamah et al.'s (2014) study in Ghana, operators were hired explicitly for scanning during the study (83). For most studies, operators have time-intensive relationships with research staff. The applicability of such models to the daily operations of public health systems in LMICs is highly questionable. In reality, midwives or community health workers, especially in India (the country of interest in this study) are responsible for much of the grassroots healthcare delivery system. Understanding how the introduction of ultrasound draws resources from and interacts with the people within a complex system will be an important part of validating any such

technology in a resource-constrained setting and is a major gap in the literature that this study aims to address.

2.4 PRODUCT LANDSCAPE

An ultrasound device consists of a transducer, a computer processing system which records and outputs an image, and a screen which displays the image to the operator. There are several different modes of ultrasound. The most common form is B-mode ultrasound, a two-dimensional (2D) ultrasound mode in which the back-scattered echo signal is displayed in the processed brightness of a dot (94).

Three-dimensional (3D) ultrasound, typically uses the mechanical motion of a 2D transducer to add the volumetric dimension, and has been found to enhance the detection of a wide variety of congenital anomalies, improve the measurement accuracy, and also enable post-scan analysis and manipulation of the volumetric data (95). Finally Doppler ultrasonography uses the Doppler shift effect to estimate movement, which in obstetrics can detect blood flow in the fetal heart, umbilical cord and placenta and has two variants, colour Doppler and pulsed Doppler (40). The value of Doppler ultrasonography in routine obstetric practice is still a question of considerable debate, and is not recommended in WHO guidelines (5, 40).

The last decade has seen significant growth in the market of point-of-care ultrasound (POCUS), a term referring to machines which are highly portable, easy-to-use and require little infrastructure during use. **Figure 1** displays a variety of products on the market across two main criteria: cost and portability. For comparison, the GE Voluson P8 is an example of a more traditional ultrasound machines, though the price range of such machines can be more than double. POCUS product lines are usually either hand-held devices which include a screen or app-based devices which use the screens and processors of a standard tablet or smartphone. GE, for instance, offers both the GE Voluson P8 and the hand-held GE VScan in Figure 2.

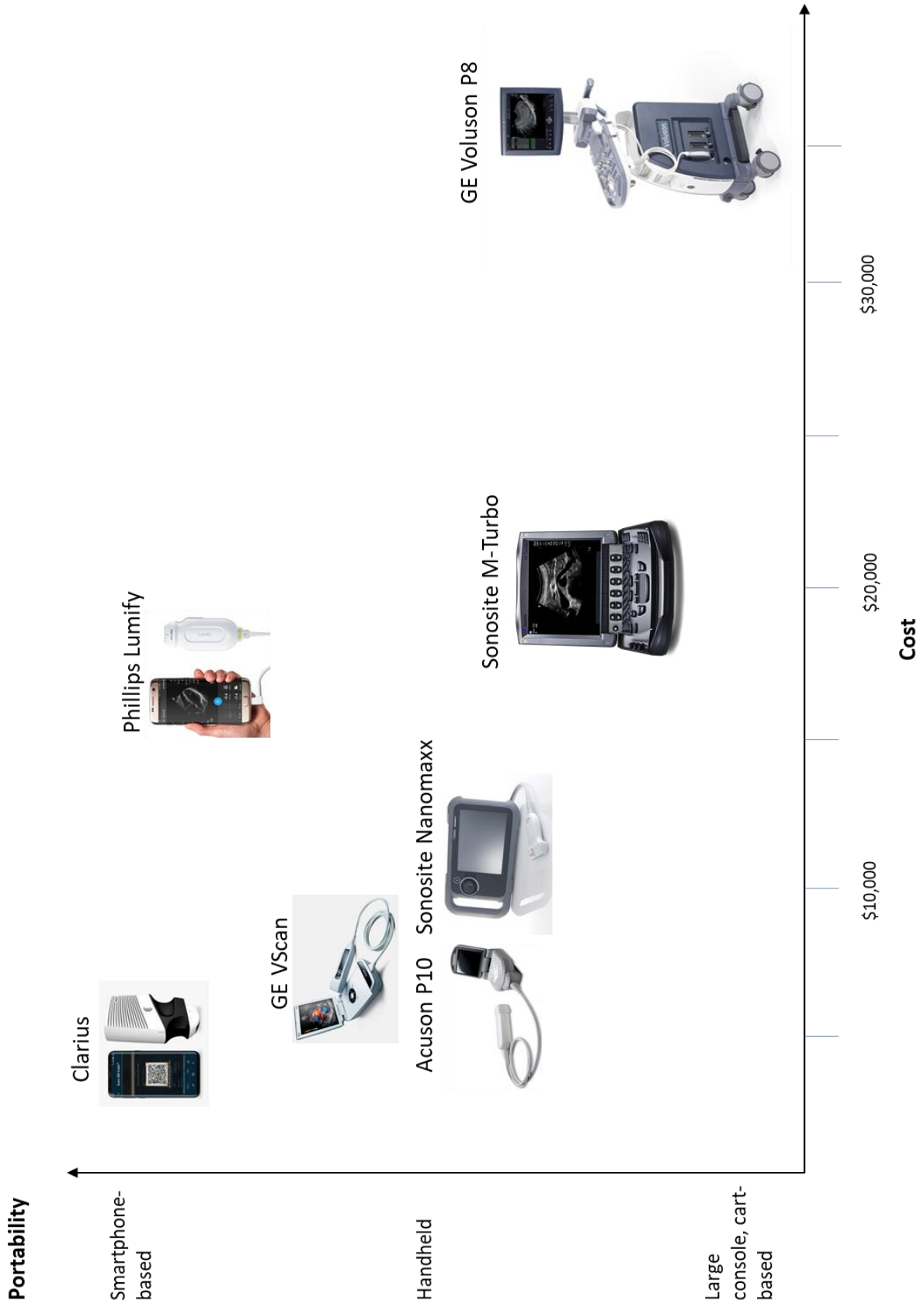

Figure 1. Point-of-care ultrasound product landscape according to cost and portability

POCUS was a reaction to the high cost and low usability of standard ultrasound machines for low-resource settings. Whether hand-held or app-based devices can deliver the necessary image quality for accurate interpretations and clinical diagnoses remains somewhat unanswered. The accuracy of image interpretation is affected by image quality issues, such as speckle and shadow, and other characteristics, including available imaging modes, the spatial and temporal resolution, signal-to-noise ratio, ability to discern fine detail, screen size and battery power (96).

Although there have been several studies directly comparing image quality and usability of portable, POCUS machines with traditional, cart-based machines in cardiology, there are fewer studies in obstetrics (97-101). Sayasneh et al. (2012) and Galjaard et al. (2014) are two of the few and both suggest strong correlation between obstetric diagnoses provided by the high-specification ultrasound machines and the pocket-sized machines (67, 102). A study comparing a large mobile emergency department ultrasound machine with an inexpensive handheld device for typical abdominal and vascular emergencies found that there were differences in resolution and total image quality (99). Still these are small studies with limited metrics (e.g. Galjaard et al. are looking specifically at routine third trimester ultrasound). Without comprehensive, consistent information about image quality and the effect this has in obstetrics, comparing the usability of these machines in clinical decision-making of these machines will remain challenging.

In lieu of the growing market for POCUS particularly for community health settings, PATH, an international global health innovation non-profit, published a guide to selection for portable ultrasound, as part of their Survive and Thrive technology guides (103). They define eight relevant criteria for low-resource settings and compare eight portable ultrasounds across these criteria:

- Lightweight (<10 lbs)
- Durable
- Handheld transducer (2-5MHz) and ultrasound
- Accurate measuring calipers on screen

- Rechargeable batteries
- Password protection on device (to protect patient data)
- Locking mechanism on device (to prevent unauthorised use)
- Service or maintenance available.

While many of the design specifications are for portability and ease of use, others, like password protection locking mechanisms recognise the concern for misuse of ultrasound for fetal sex selection.

2.4.1 Automated ultrasound interpretation

Automation has become increasingly popular in ultrasound imaging, due to its potential to reduce variability, thereby ensuring both consistency and accuracy. The concept of semi-automated ultrasound, which requires an operator to acquire the image but automates image interpretation, could address concerns about differential skill levels and subjective image interpretation (96). There is only a small literature of automated image analysis in ultrasound, a detailed review of which is beyond the scope of this thesis. For a review of state-of-the-art, the reader is referred to Maraci et al. (2017), which shows the automatic detection of various fetal components from low-cost portable ultrasound (22). Future generations of ultrasound devices for LMICs are likely to rely on automated image analysis for measurement to guide non-expert users.

Chapter 3: Indian Context and Pilot Phase

This chapter provides contextual background on ANC and ultrasound at both a national and district level. It also presents an overview of pertinent findings from the pilot phase, a scoping exercise that informed the methods described in Chapter 4.

3.1 THE INDIAN CONTEXT

India has the highest number of neonatal deaths in the world and an estimated 20% of the world's maternal deaths, the highest burden of maternal mortality for any single country (104-106). The reported disparity between states is astonishing, with maternal mortality ratios (MMR) ranging from 60 to 300 deaths per 100,000 live births (107). These numbers are also based on vital registration system data which are often underestimates (108). With less than seven physicians per 10,000 inhabitants, the health system's capacity for quality care and diagnosis is severely limited (109).

3.1.1 Antenatal care (ANC) in India

The public health system in rural areas is organised in a tiered structure. Typically, primary health centres (PHCs) have a non-specialist doctor covering 20,000-30,000 people and serve as hubs for five to six subcentres operated by auxiliary nurse midwives (ANMs) that cover three to four villages (110). ANMs register and manage pregnancies with the assistance of community health workers known as Accredited Social Health Activists (ASHAs). Women can be referred to community health centres (CHCs) or tertiary district-level hospitals which have specialists, and ultrasound machines are only available at such higher centres (110-112). In 2006, the national government, in collaboration with the Federation of Obstetric & Gynaecological Societies of India (FOGSI) began training PHC doctors around the country in comprehensive emergency obstetric care to equip them with the ability to do Caesarean sections and other operations (113).

Launched in 2005, the National Rural Health Mission (NRHM) aims to reduce maternal and neonatal mortality through the scheme Janani Suraksha Yojana (JSY), which uses cash assistance, institutional deliveries and co-ordinated care with field workers throughout the antenatal, intrapartum and postnatal periods—though whether significant gains in safe motherhood have been achieved is questionable (114). The Indian government health ministry recommends at least three ANC visits (one in the first trimester), 90 or more iron-folic acid tablets and at least two tetanus toxoid injections (115, 116). However few of the states reach these standards (see **Table 1**). Radwan (2005) references a range of factors creating poor public sector performance, particularly at the PHC level, including vacancies and poor infrastructure (110). Mavalankar et al. (2009) cite several studies arguing that changes in ANMs' roles over the past few decades from skilled midwives to multi-purpose family planning workers have harmed MCH services in rural areas (117).

There is also significant geographical variation—for example in a study of southern states there were no significant gaps in maternal health outcomes between urban and rural areas, suggesting the high effectiveness of ANMs there (118). Caste and socioeconomic status and educational levels of women and their families is also associated with the likelihood of accessing sufficient ANC (119, 120). In rural areas, the informal practitioner sector (and to a certain extent, accredited private practitioners) also covers a significant percentage of basic healthcare needs, despite a lack of accreditation (121).

3.1.2 Ultrasound in India

The literature on ultrasound usage, practices, and perception in India is quite sparse. A survey conducted with 1801 women across 60 colonies in Delhi found that ultrasound scans were conducted more frequently for women who received ANC in a government (95.5%) or private hospital (99.6%) compared to a women who received ANC at home (68.4%) (122). Delhi, however, is one of the most populated urban centres in the country and, therefore, not representative of rural settings which make in which the vast majority of India's population lives (123).

Table 1*. *State-level data for ANC provisions, demographics and mortality. Sources: District Level Household Survey-IV (DLHS-IV), 2012-2013, Sample Registration System (SRS) Bulletin 2015, and SRS Maternal Mortality Bulletin 2011-2013 (124-126)

State[1]	At least 1 ultrasound examination	Full ANC[2]	Percentage urban	Sex ratio[3]	Institutional delivery	MMR[4]	IMR[5]
Andhra Pradesh	80.4%	42.5%	33.5%	992	88.5%	92	37
Arunachal Pradesh	35.6%	13.5%	22.7%	920	49.5%	--	30
Goa	92.8%	71%	62.2%	973	97.1%	--	9
Haryana	56.5%	14.9%	34.8%	879	77%	127	36
Himachal Pradesh	72.2%	41.1%	10%	972	28.2%	--	28
Karnataka	81.1%	46%	36.6%	973	89.1%	133	28
Kerala	85.3%	70.3%	47.7%	1084	99.6%	61	12
Maharashtra	56.4%	37.3%	45.2%	929	92%	68	21
Manipur	59.6%	28.3%	30.2%	987	61.2%	--	9
Meghalaya	15.7%	21.4%	20.1%	970	47.3%	--	42
Mizoram	22.0%	36.7%	51.5%	975	72.4%	--	32
Nagaland	14.1%	9.8%	29%	931	30.1%	--	12
Punjab	65.2%	20.6%	37.5%	893	82.7%	141	23
Sikkim	79.9%	70.3 %	25%	889	82.7%	--	18
Tamil Nadu	65.6%	36.8%	51.6%	987	99%	79	19
Telangana	74.2%	40.3%	--	--	94.1%	--	34
Tripura	38.6%	27.3%	26.2%	961	72.7%	--	20
West Bengal	42.9%	36.8%	31.9%	950	74.6%	113	26

It is believed that women face structural barriers to ultrasound and ANC due to long queues in secondary and tertiary hospitals (126). Additionally, there is a significant burden of congenital

[1] DLHS-IV data is not yet available for Assam, Bihar, Chattisgarh, Delhi, Jammu & Kashmir, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh, and Uttharkhand.

[2] Full ANC is defined as at least three ANC visits, at least one tetanus toxoid injection, and 100+ iron folic acid tablets/syrup consumed

[3] Sex Ratio is defined as the number of females per 1000 males.

[4] Maternal Mortality Ratio (MMR) is defined as the number of maternal deaths per 100,000 live births. The recent MMR Bulletin (2011-2013) is not publicly available for Smaller States.

[5] Infant Mortality Ratio (IMR) is defined as the number of infant deaths per 1000 live births.

anomalies, which account for 8-15% of perinatal deaths and 13-16% of neonatal deaths in India; these are likely to be underestimates (127-129). The MMR and IMR in both Andhra Pradesh and Haryana are both quite high (see **Table 1**) but the lack of high-quality, granular data pertaining to the causes of maternal and infant mortality in these states makes it difficult to unequivocally conclude whether lacking access to ultrasound diagnoses contributes to mortality. A few studies analysing national surveys and data from a tertiary private hospital in Andhra Pradesh suggest that pre-eclampsia and eclampsia, obstetric haemorrhage, puerperal sepsis, post-abortion complications and obstructed labour are the most common direct causes of maternal deaths, while anaemia is the most common indirect cause (130-132). Verbal and social autopsy studies in Ballabgarh, Haryana and rural Uttar Pradesh found that the main causes of neonatal deaths were birth asphyxia and low birth weight/prematurity, and the primary cause of post-neonatal death was infection, typically pneumonia and sepsis (133, 134). Based on this information, it is plausible that improved access to early ultrasound diagnosis could reduce mortality.

DLHS-IV data (provided in **Table 1** and **Table 2**) from 2012-2013 provides the most recent public ultrasound and ANC usage data, but it only reports on whether a woman received at least one ultrasound scan at some point during pregnancy from any centre (124). Additionally, few ultrasound task-shifting interventions have been tested in the Indian context. The NRHM has provided basic obstetric ultrasound training to generalist physicians in PHCs in Tamil Nadu for pregnancy dating, twin diagnosis, ectopic pregnancy, missed abortions and placenta praevia (20). A case study of a workshop in a Rapid Ultrasound for Shock and Hypotension protocol showed that nursing staff in a 40-bed hospital in Tamil Nadu could be trained on the protocol in a 3-day workshop with portable ultrasound units; however, the average post-test score was still only 69% emphasising the need for long-term supervision even after training (135).

3.1.3 Sex Selection

Understanding the practices of sex determination, sex selection and female feticide are crucial to any study of ultrasound in India. Jha et al. (2006) estimated that such practices have resulted in about 10 million “missing” women in India since 1985 (7).

Sex determination practices became feasible in India in the 1970s through amniocentesis, which provides karyotyping, shortly after the legalization of abortion in 1971 (136, 137). In 1994, following the lead of five states that had passed laws banning sex selection, the central government passed legislation that would eventually become the Pre-Conception and Pre-Natal Diagnostic Techniques Act (PCPNDT) (136, 138, 139). However, only government facilities were originally subject to the ban, and for over 20 years the private sector continued these practices unregulated (136). The current version of the law requires that any clinic with an ultrasound machine must register it, obtain written consent from pregnant women establishing their knowledge of the prohibition on communication of fetal sex, and maintain and submit records, while local governments expand awareness (139).

Some studies argue that the policy has been ineffective due to the reliance on enforcement by medical practitioners, many of whom are still supportive of sex-selective abortion (138, 140). The 2011 Census data showed the ratio of girls to boys below the age of 6 continuing to decline rapidly, likely a result of multiple factors, including prenatal sex selection and excess infant mortality among girls (140). According to National Family Health Survey (NFHS)-III data from 2005-2006, at each parity, the lower the number of living sons a women had, the higher the likelihood that she had gotten ultrasound tests and the lower the adjusted sex ratio of the next child. (7). These findings hold across geographies and religious sects. Additionally, populations in many areas are still unaware of PCPNDT regulations (141, 142).

3.1.4 West Godavari District, Andhra Pradesh &. Rohtak District, Haryana

The two rural areas in India that were explored in this thesis are the West Godavari District in Andhra Pradesh and the Rohtak District in Haryana. These sites were selected for two main reasons. First, both are research sites for several George Institute SMARTHealth studies, which evaluate mobile technologies at the primary health level. This enabled easier access to a wider variety of participants in the health system as well as a long-term engagement with the local context that is useful for ensuring the validity of qualitative studies (See Section 1.3).

Table 2. Health system and ANC data at the state and district-level. Source: District Level Household Survey-IV, 2012-2013 (124). See **Table 1** for additional state-level data.

	State-level	**Andhra Pradesh**	**Haryana**
ANC and delivery	At least 1 US	80.4%	56.5%
	Any delivery complication	19.9%	42.9%
	Premature labour (of those who have a complication)	73.1%	61%
	Obstructed labour (of those who have a complication)	11.6%	43.7%
Facility access	Percentage of villages sampled that live more than 10km from tertiary government hospital	92.4%	64.8%
	Percentage of villages sampled that live within 10km of a PHC	74.4%	87.3%
	District-level	**West Godavari**	**Rohtak**
ANC and delivery	Any ANC Check-up	98.6%	76.4%
	First ANC in the first trimester	82.3%	41.9%
	Full ANC	41.9%	6.1%
	Institutional delivery	81.5%	84.6%
Demographics	Population of district	3,937,000	1,061,200
	Percentage urban	20.5 %	42%
	Sex ratio	1004	867
	Percentage of females who are literate	71.4%	71.7%
Facility access	# centres with an ultrasound facility	4	1
	Percentage of villages with a subcentre/PHC	73.1%/23.9%	73.5%/26.5%
	Average population covered by a PHC	43,228	29,320
	Average population covered by a CHC	146,239	138,500
	Total number of subcentres	25	33
	Total number of PHCs	20	14
	Total number of CHCs	13	5
	Total number of sub-divisional hospitals	4	0
	Total number of CHCs with an obstetric gynecologist	8	1

Secondly, given the extraordinary diversity of India's cultures, geographies, social structures, studying two different rural locations, one in the south (West Godavari) and one in the north (Rohtak) that will enable further generalisability of the study's findings. **Table 2** compares health system data at both the state and district level. Both districts are predominantly rural, with fairly high levels of institutional delivery and female literacy. Higher percentages of women access antenatal care in West Godavari, but both districts are far from 100% access. West Godavari also has more than three times the population as Rohtak and significantly more PHCs and CHCs, but each have to cover slightly larger populations. Given that almost half of Rohtak's population lives *within* 10 kilometers of a tertiary institution and has few specialist care options at the CHC, with only one obstetric gynecologist, it suggests that the population likely relies much more on its limited tertiary institutions. It also suggests that primary and secondary care are more robust in West Godavari. Finally, West Godavari has a normal sex ratio while Rohtak's is significantly lower, consistent with sex ratio data across the north/south divide (137).

3.2 PILOT PHASE

Given the lack of literature pertaining to obstetric ultrasound use in rural India, a pilot, scoping exercise was conducted in December 2016 with three objectives:

- To understand antenatal health care delivery and public health structure for ANC in rural Indian settings
- To understand the existing usage of ultrasound during pregnancy (i.e. who is using it, where and when)
- To acquire opinions from stakeholders regarding the value and feasibility of a low-cost, semi-automated ultrasound device for gestational age determination.

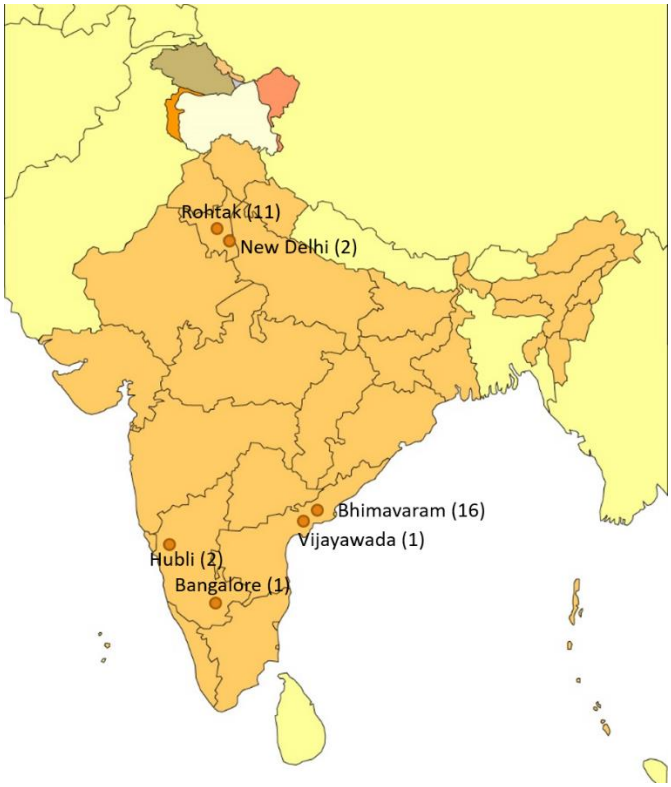

Figure 2. Sites for pilot phase (informal scoping interviews)

The pilot scoping exercise consisted of informal interviews with 33 health system stakeholders including radiologists, public health professionals, PHC doctors, CHC obstetrician and gynecologists, pregnant women and frontline health workers (ASHAs and ANMs). The majority of the interviews took place in the West Godavari District and the Rohtak District (see **Figure 2**), in collaboration with the George Institute of Global Health which has research sites in both of these districts. Their presence and connections with various physicians, health workers and government officials enabled rapid access to a wide variety of stakeholders. A few other interviews were conducted in New Delhi, Bangalore and Hubli. This work was not filed for ethical review, and as such, only an overview of pertinent insights that informed study design is presented here (see A1 for interview guide).

The interviews confirmed the descriptions found in the literature about the structure of ANC in the rural public sector. Ultrasound was never found in subcentres and PHCs, which were usually the first stop and major ANC-provider for pregnant woman. Ultrasounds were often found in CHCs,

though this was subject to the availability of a radiologist or gynaecologist with a licence to use an ultrasound machine. In the sites that were examined here, an ultrasound machine was present at all tertiary care centres.

Guidelines defining routine ultrasound protocol, such as how many times a scan should be conducted in pregnancy, seemed vague and inconsistent across all participants, with answers ranging from one to nine. However, a vast majority of participants felt that all of their patients get at least one ultrasound scan done, though few thought that this scan was done in the first trimester. Participants believed that ultrasound provided vital information for the wellbeing of the mother and fetus, and many care providers were concerned about the subjectivity and inaccuracy of ultrasound interpretation.

Participants also pointed to sociocultural factors that affect ultrasound and ANC, such as the Southern customs of married women going back to their mother's house in the last three months of pregnancy and the beginning of the delivery, which complicates transferring records and ensuring adherence. Other geographical differences were revealed, such as Rohtak's history of rampant sex determination and female feticide and the government's decision to revoke the licences of many local practitioners, which may have decreased access to ultrasound.

The pilot phase provided some key insights for further study design. First, it helped to identify key stakeholders who would be most relevant to exploring the potential utility of semi-automated ultrasound in the health system. This was determined to be potential users of the technology in settings without ultrasound (i.e. PHC doctors and ANMs) and decision-makers (i.e. government officials), who could address the legal context and provide a systems-level perspective. Findings suggest that at this stage, insight about utility in clinical management and implications on early phase design and development would be better addressed by these stakeholders, rather than pregnant women.

Second, the pilot phase helped refine the interview guide. For example, it revealed that asking people to estimate proportions of people that engaged in a specific behaviour, was not useful for

acquiring accurate answers, but did enable a rich conversation about participants' perceptions of barriers. It also revealed the need to refine wording to limit biasing participants' responses, especially around sensitive topics like sex determination.

Finally, the pilot helped validate that these research sites would be appropriate to conduct in-depth interviews, in terms of available resources (e.g. translation, transportation, contacts, etc.) and richness of data.

Chapter 4: Methods

Qualitative methods were utilised to better understand current ultrasound usage and how a semi-automated system of ultrasound can address any gaps in access and provide better diagnostic methods for pregnant women in rural India. (See Section 1.2-1.3 for research aims and research methodology.) The following sections detail the research methods, including conducting in-depth interviews in two rural districts in India and the analysis of the interview data using a framework analysis approach.

4.1 IN-DEPTH INTERVIEWS

4.1.1 Data Collection

Two semi-structured interview guides were developed for data collection. The first interview guide was for care providers, i.e. ANMs and general physicians in PHCs (see A4). The second interview guide was for public health and/or government administrative officials (see A5). Interview guides drew from a variety of sources, including pilot phase findings and previous qualitative studies focused on systems-level factors in ultrasound usage (93). Additionally, a senior program officer at the Bill & Melinda Gates Foundation—an anthropologist with experience in user-centred design—advised about refining interview prompts to ground conversation in participants' actual experiences rather than their perceptions of "clinically correct" answers. A drawing exercise at the beginning of each interview was also proposed and included, in which participants were given a drawing of a circular island with a river flowing through it, trees in the north and mountains in the south, with a boat tied up at one end of the river (see **Figure 3** in Chapter 5). They were then asked to draw themselves, other stakeholders, and various tools on the island and to explain these placements. This exercise helped break the ice, establish rapport and provided a context in which to situate responses by understanding how the participant sees themselves and their role in the system.

As the primary researcher, I conducted interviews in English with PHC doctors and government officials while accompanied by George Institute research staff. All interviews with ANMs were conducted in local languages (Telegu in West Godavari District and Hindi in Rohtak District), for which research staff assisted in translation. Interviews were audio recorded. Most interviews were conducted in separate rooms, though some had to be conducted in available office spaces.

4.1.2 Sampling and recruitment

Three professional categories of participants were selected: ANMs, PHC doctors (both to represent potential users of a semi-automated ultrasound) and government officials associated with MCH (health system decision-makers).

Participants were recruited in several stages. Initially, participants were recruited through convenience sampling, by drawing from participants whom George Institute staff had contacted or involved in previous studies. Later participants were recruited based on a "theoretical sampling" approach to represent variation along criteria that were identified hypothesised to be important, specifically, gender, years of experience, and experience in the private sector (See Section 1.2.2). Originally, the criterion of whether the individual was attached to a primary or secondary centre of care was also included, but this was discarded as no ANMs are affiliated with secondary health centres in West Godavari district. The distance between a participants' workplace from the main urban hub of the district was later added as a variation sampling characteristic to test the hypothesis that distance affected ultrasound access.

There is little agreement or consistency in defining how saturation of sampling is attained, though Green and Thorogood (2013) suggest that most studies find little new information after 15 subjects in a given category (29). Three factors were considered in recruitment sample size. First, the pilot interviews provided some benchmark for the range of diversity of themes that inform hypothesis development. Secondly, after each interview, notes were taken on newly emerged hypotheses. These

were incorporated into future interviews but were also a proxy for whether thematic saturation had been reached. Finally, the limited timeline of the research as a whole provided reasonable constraints on sample size. In two-and-a-half weeks with one to two days of internal travel and an average of two interviews conducted per day, a maximum of 30 interviews could be conducted.

Ultimately, a total of 25 participants were recruited, 18 in the West Godavari district and seven in the Rohtak district based on available access to supporting resources. Three participants were also interviewed in the pilot. One government official, one PHC doctor, and one ANM actually work in Rohtak's neighbouring Jhajjar district, but were close to the border and therefore served both populations. Additionally three of the government officials in the West Godavari district were interviewed together due to limitations on space and time. Their interview was conducted and analysed with the same methods as others. Implications and limitations of these methods are discussed in Section 7.7.

4.1.3 Ethical review

Ethical approval was obtained both from the University of Oxford Tropical Ethics Committee (518-17) and the George Institute of Global Health Independent Ethics Committee in India (003-2017). Participants were provided with a written participant information sheet, which was verbally explained to all participants. Written consent was obtained from all participants (see A2, A3)

4.1.4 Data Analysis

This study uses a framework analysis method, which was developed by the National Centre for Social Research especially for studies focused on generating "policy or practice-oriented findings," making it applicable for such health system and experience and studies (29, 112, 143, 144). The first several steps are similar to most thematic content analysis methods in qualitative research, i.e. familiarisation and thematic coding of data (29, 144). Here, I transcribed English and Hindi interviews verbatim and checked translations/transcriptions of Telegu interviews from a company. A

coding framework was developed based on the interview guide and co-coding two interviews with another qualitative researcher. This coding framework was used to code the remaining interviews in NVivo 11, and a few codes were also added later. This thematic coding approach was also used for responses to several exercises used in the interview, including the island drawing exercise and an exercise to rank the importance of various clinical information obtainable from ultrasound. These exercises were used as tools to generate discussion rather than for their own analysis.

Next, the data were charted, or rearranged by thematic content into seven framework matrices, each representing a macro category of the coding framework: design system exercise, social/health system context, benefits and disadvantages of ultrasound, clinical information, ultrasound practice, clinical management post scan, ultrasound solutions and strategy. Charts were created in NVivo 11, in which rows represent cases and columns represent nodes or themes and each cell contains a summary of the data and the reference back to the source. These charts enabled interpretation of the data through comparative analysis across codes to examine the range of themes potential relationships between codes (29). As is common in framework analysis, interpretation included creating visual representations of patterns to enable further insight (145).

4.2 TRUSTWORTHINESS

Trustworthiness in this study was achieved through the following practices as suggested by Shenton (2004) and Guba (1981) (28, 146):

i) *Using well-established research methods.* As discussed in Section 1.3, a qualitative in-depth interview-based approach to understanding the applications of a technology in a low-resource health care system is well-established and justified.

ii) *Prolonged engagement at the research site.* Formal data collection occurred over the course of two weeks, and was preceded by consistent engagement with the research staff at the site over the previous six months, beginning with a two-week pilot phase to acquire familiarity with the local health system context and inform interview design.

iii) *Peer debriefing.* Various researchers in Oxford with expertise ranging across engineering, obstetrics, and qualitative methodology, were consulted throughout the entire research process. Additionally results from the pilot phase were discussed with experts within the Bill & Melinda Gates Foundation to acquire feedback and inform next stages.

iv) *Triangulation of methods and data sources.* Triangulation of data sources was done through the incorporation of three tiers of the Indian public health care system, including both potential users of the technology and decision-makers in the system. Additionally, available public data was analysed for background and discussion (Chapters 3 and 7).

v) *Collection of materials against which findings and interpretations can also be tested later.* All interviews were audio recorded and manually transcribed. The interview coding and framework matrices were done in NVivo 11, enabling all of the original material to be re-interpreted and tested later.

vi) *Methods that encourage honesty from participants.* Interviews were conducted without participants' superiors (with one exception). At the beginning of the interview, participants were assured that their answers would remain fully confidential, there were no right or wrong answers and they could withdraw from the study at any time.

vii) *Context for generalisability.* Interviews were conducted in two geographically and culturally different rural settings in India to expand generalisability of the results. Additionally, the Chapters 3 and 7 both incorporate socio-cultural, historical and technological context to the analysis to inform the generalisability.

viii) *Replicable study design.* The methods, including the interview guides and coding frameworks have been detailed here to enable replication.

ix) *Discussion of reflexivity.* See Section 1.2.4.

Although designing qualitative studies to adhere to checklists can limit the contextual flexibility that qualitative methodology offers, checklists can serve as a useful additional tool to ensure that a researcher has considered all dimensions of designing a rigourous study. Here the

Critical Appraisal Skills Programme (CASP) checklist was consulted, which details factors to consider regarding the appropriateness of the research design and recruitment strategies, the clarity and transparency of analysis, and the value of the research (147).

Chapter 5: Results I (Social & Health Systems Context)

The findings of this qualitative study are presented in Chapter 5 and 6. Chapter 5 firstly provides an overview of participants included in the study. The second section presents results from the island drawing exercise, which was conducted with each participant at the beginning of the interview. The third section details sociocultural, health system-based findings that are relevant to both existing and future usage of ultrasound technology. Chapter 6 will then present findings regarding current and potential ultrasound usage and utility in rural primary level ANC.

5.1 OVERVIEW OF RESULTS IN CHAPTERS 5 AND 6

In total, 25 participants (18 in West Godavari and seven in Rohtak/Jhajjar) were recruited to participate in this study, and variation across several factors was sought in sampling (see **Table 3**). Male PHC doctors in Rohtak were excluded because they do not conduct much ANC management in the area.

In the results, the word "patient," "woman" and "pregnant woman" are used interchangeably, as are "gynaecologist" and "obstetrician" to reflect the language of participants. The term "care providers" refers to the combination of PHC doctors and ANMs (as opposed to government officials).

5.2 DESIGN DRAWING EXERCISE: EMERGING THEMES

Section 4.1.1 describes the island drawing exercise provided to each participant and **Figure 3** displays two such drawings as an example. In responding to the exercise, some participants, especially government officials, drew an ideal system, while others drew depictions of the current system, and still others combined these approaches.

Table 3. Profile of study participants.

Code	Role[6]	District	Sex	Years of experience in public health sector (years)	Worked in private or NGO sector[7]
P1	PHC Doctor	West Godavari	Male	0-9	No
P2	PHC Doctor	West Godavari	Male	20 or more	Yes
P3	PHC Doctor	West Godavari	Male	10-19	Yes
P4	PHC Doctor	West Godavari	Female	0-9	No
P5	PHC Doctor	West Godavari	Female	0-9	Yes
P6	PHC Doctor	West Godavari	Male	0-9	No
P7	PHC Doctor	West Godavari	Male	20 or more	Yes
A1	ANM	West Godavari	Female	0-9	No
A2	ANM	West Godavari	Female	10-19	Yes
A3	ANM	West Godavari	Female	0-9	Yes
A4	ANM	West Godavari	Female	20 or more	Yes
A5	ANM	West Godavari	Female	10-19	No
A6	ANM	West Godavari	Female	10-19	Yes
A7	ANM	West Godavari	Female	10-19	No
G1	Government official	West Godavari	Male	20 or more	Yes
G2L	Government official	West Godavari	Male	20 or more	No
G2C	Government official	West Godavari	Male	20 or more	No
G2R	Government official	West Godavari	Male	20 or more	No
PB	PHC Doctor	Rohtak	Female	10-19	No
PD	PHC Doctor	Rohtak	Female	0-9	No
PN	PHC Doctor	Jhajjar	Female	10-19	No
AD	ANM	Rohtak	Female	20 or more	No
AN	ANM	Jhajjar	Female	20 or more	No
GJ	Government official	Jhajjar	Male	10-19	Yes
GR	Government official	Rohtak	Male	20 or more	No

The most prevailing insight from the exercise was the depiction of hierarchy in the health and social system. Many participants, typically ANMs and PHC doctors drew government officials at higher topographical locations (e.g. above the trees or in the mountains) to represent this hierarchy:

> *P5: [Government officials would be] near the mountains…They should be in higher position so nothing happens to them…So they have to be first safe to save us…*
>
> *P1: …no government will be actually staying in the trees like we do, because…we get appointed by these people, so… in a way we are inferior to them…they will be visiting us sometimes, but they can't be with us every time.*
>
> *Interviewer: Why did you put the doctor in higher place than you?*

[6] Primary Health Centre (PHC) Doctors are general physicians with an M.B.B.S. degree, while Auxiliary Nurse Midwives (ANMs) are village-level female health workers who work at health Subcentres.

[7] Indicates any prior experience in the private or NGO sector (i.e. whether participants have had experience outside of the government sector). All participants are currently employed in the government sector.

A3: Most of us are common people, the officials are rare, they are superior to us.

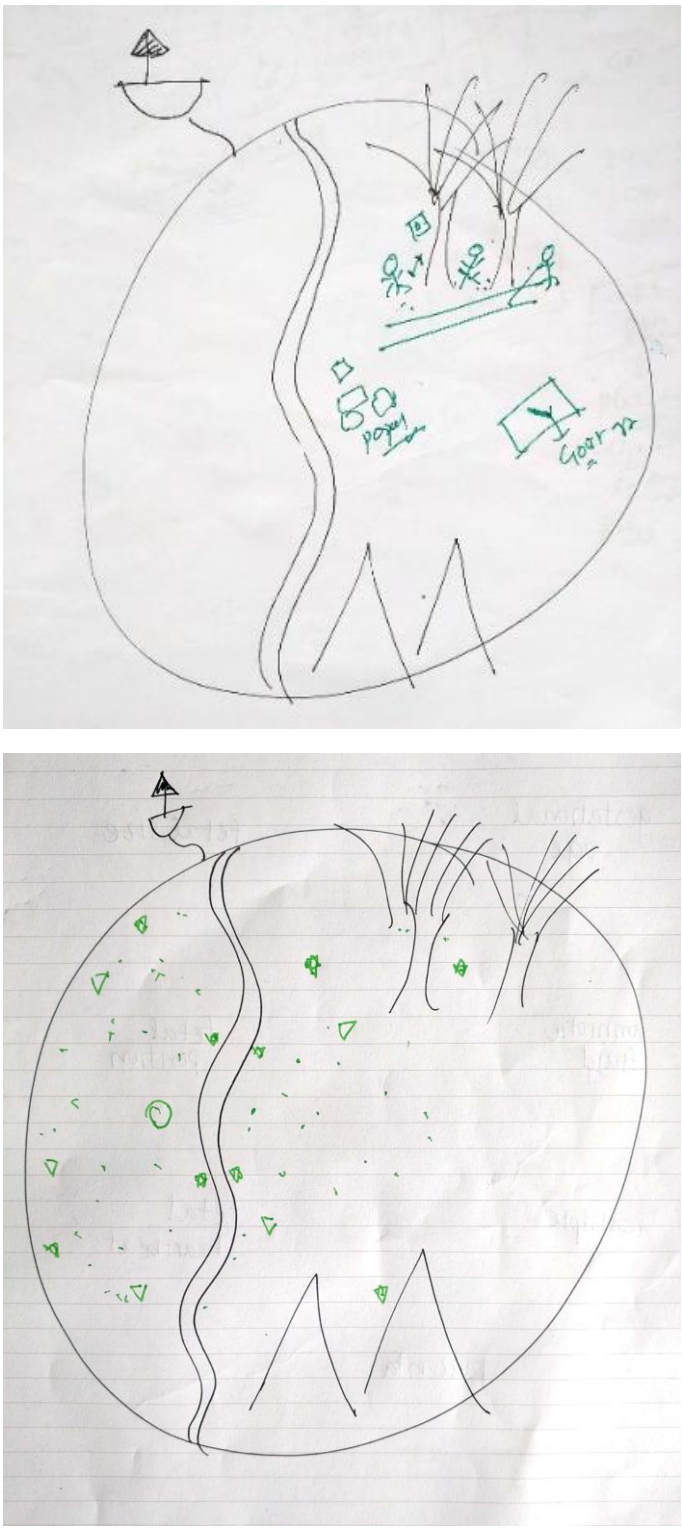

Figure 3. Island drawing exercise results from two participants. (top) From P1, in which PHC doctors, ANMs, ASHAs were drawn in the trees along with various tools (blood pressure monitor, mobile phones and tablets, and an ultrasound machine with the PHC doctor). The population was drawn in open land, and government officials were drawn further from everyone on higher ground.

(bottom) From GJ, in which the circle represents a government district office, triangles represent PHCs distributed throughout the island, stars represent ANMs and ASHAs who are distributed around, and the dots represent the population. Tools were described as being distributed across the region.

Some participants represented clinical hierarchies by placing stakeholders close to each other to enable better supervision and service delivery.

> *GR: And as administrator I have to look after or supervise the work of the doctors, that's why I want to work near the proximity of the district hospital…*
>
> *P5: Yeah. I'll make [ASHAs] do work…they are closer to me because they don't have as much knowledge as the ANM has…ANMs I can like teach them and they will understand. And [ASHAs] don't have basic knowledge right, so I will allow them to be…close.*
>
> *A6, It would be nice if it is closer like this…We can give more services by being nearer and closer to each other sir…Now if the doctor is at Narsapur, it would be 1 hour by the time he reaches here.*

The second main theme from the design exercises revolved around the equitable distribution of both human and technical resources, so that even remote populations could access the healthcare system. Participants spoke about the need to "cover" the whole population, often through enabling communication between health system stakeholders and the population. For instance, PN felt that ANMs should have many ASHAs to increase access:

> *PN: every ANM should have 3-4 ASHAs so that they can be deep inside the population and reach the each and every person and we will be able to communicate with this ANM, and these ANMs can communicate with me.*

While all participants felt that community health workers should be geographically spread throughout the population, specialist services or administration were typically placed in the centre for "equal access." Blood pressure machines and phones were depicted as decentralised and close to the population. However, PHC doctors and government officials often suggested that ultrasound should not be any lower than the PHC based on perceptions of the technical competence of ANMs/ASHAs.

Participants' responses also varied by profession. ANMs typically placed themselves among the population and did not discuss overall health system architecture. Government officials and many PHC doctors, however, often explained their drawings based on system-based organisation that caters to an entire population, particularly with a focus on remote, marginalised groups of people.

Regional differences can also be observed. Most participants in West Godavari, a forested, river-centred area, described the trees and the river as conducive to life, though one ANM explicitly distanced herself from the river because of potential flooding. A PHC doctor placed himself in the trees to avoid Naxalite riots, communist revolutionaries who are present in neighbouring areas of West Godavari. Participants in Rohtak, with mostly flat and open areas, usually placed themselves in the open areas of the diagram.

5.2 HEALTH SYSTEM STRUCTURE

Participants explained several different components of the health system infrastructure that were relevant to ANC during the island drawing exercise and throughout the interview. These findings have been summarised here to provide the health system context with which to understand the results in Chapter 6.

Subcentre. The subcentre, the lowest tier of the rural health structure, was described as the primary seat of the ANM, who supervises 3-5 ASHAs. These health workers register pregnancies, conduct basic first aid and clinical care, and were described as "motivators" and the main connection between the health system and the population. ANMs repeatedly emphasised that most other issues were referred to the PHC doctors' discretion, and that they accompanied women throughout the referral process. One ANM expressed frustration that she had lost the responsibility of conducting deliveries and other significant treatments, so all she could do was refer to the PHC.

PHC. PHCs, which include MBBS-qualified doctors and staff nurses, were described by one government official as "cater[ing] to the masses" because of their rural, geographic distribution. Several participants mentioned recent increases in the number of female PHC doctors, whom pregnant women preferred. The PHC was described as the first point from which referrals to higher level hospitals might occur based on physical examinations or ultrasound results. Participants said that the government scheme JSY provided regular ANC-focused days at the PHC, where ANMs and ASHAs

would bring pregnant women from their area to get checkups and show ultrasound reports. PHCs were also described as a main delivery hub, but only for vaginal, low-risk deliveries.

CHC. PHC doctors described referring patients to CHCs, the first referral unit of the health system with a variety of specialist clinicians, for their ultrasound examinations and high-risk deliveries (e.g. Caesarean sections). However, this varied by region: the Rohtak CHC did not have an ultrasound machine or a gynaecologist. Additionally, not all CHCs were staffed as described on paper: an ANM in West Godavari said their CHC had inexplicably stopped performing ultrasound recently. Some participants also described referring patients to get ultrasound scans at other secondary and tertiary hospitals, because of distance or staff availability.

District Hospital. Participants described district hospitals as the highest level of institutional health care in the district with the highest patient loads. In Rohtak, according to a government official, the district hospital sees over 300 deliveries per month, conducted by three doctors. At PGIMS, a local government medical college and tertiary care hospital, they conduct about 900 deliveries per month, or more than one delivery per hour. In West Godavari, the district's only radiologist was based in the district hospital.

Private healthcare. Participants said that patients often access both private and public healthcare centres and perceive the private sector as expensive but high-quality. In West Godavari, some patients apparently even self-referred to private hospitals rather than navigating government referral systems. One ANM said that women in her area would go to a private charity hospital until their 7^{th} or 8^{th} month and then arrive at the PHC for the last trimester and delivery. Several participants said that the government sector needed to provide more reliable, high-quality services to earn patients' trust.

Physical infrastructure. Participants described deficiencies in physical infrastructure that limited healthcare provision. ANMs said that subcentres were often temporary, rented private buildings because the government did not provide its own building. Additionally, while West Godavari PHC doctors said that internet and electricity access at the PHC was sufficient, ANMs said that they experienced occasional power cuts and had to travel to PHCs for internet access to upload their

antenatal registration data. In Rohtak, all PHC doctors and ANMs expressed frustrations with electricity cuts through most of the day, requiring invertors to maintain the PHC. Government officials, however, typically did not recognise these challenges in either location.

Technology infrastructure. None of the PHC doctors in West Godavari reported receiving any new medical technologies in the PHC or training for tablets or laptops they received. A few mentioned receiving fetal Dopplers and data-based clinical management training. All of the care providers had government phones and some had smartphones. Though the ANMs in West Godavari had received tablets and a 1-day training, tablets had only recently begun to be distributed among ANMs and ASHAs in Rohtak through independent research projects like those of the George Institute. ANMs frequently said that the training alone was not enough, and required trial-and-error or support from IT staff in PHCs.

Participants' evaluations of government maintenance systems for technology varied widely. Most participants said that devices broke frequently, especially blood pressure monitors. But while some were satisfied with government maintenance services, others described frustration from months of waiting, resorting to borrowing from other hospitals and finding alternatives. One PHC doctor said that devices donated privately were often not eligible for government maintenance services.

In general, most participants had very positive perceptions of the role of technology in their work. PHC doctors described an enhanced ability to generate reports that summarised the state of their population's health. While a few ANMs felt that technology had simplified some tasks, they also acknowledged the additional workload burden. One PHC doctor said that when a new "fetoscope" was given to ANMs, she had to carefully explain that the simple device would help them better engage with pregnant women, so that they did not feel burdened with more work that a doctor should be doing.

5.3 SOCIOCULTURAL CONTEXT

Throughout the interview, participants referenced various region-specific sociocultural customs that affected ANC and ultrasound usage. For example, West Godavari participants described the common practice of consanguineous marriages between first cousins, to explain the utility of ultrasound in detecting congenital anomalies. Additionally, they referenced the custom of a woman, who would join her husband's household after marriage, returning to her mother's village during the late antenatal and early postnatal periods. This affected continuity of care, with doctors lacking adequate obstetric history information. The role of patriarchal traditions and gender discrimination is discussed in Section 6.3.

Finally, participants frequently referenced associations between healthcare access and social determinants or socioeconomic factors. Poverty and lower levels of education were associated with lower castes, nomadic and tribal groups and with lower levels of healthcare access.

5.4 SUMMARY OF CHAPTER 5

The findings presented in this chapter pertain to the social and health systems context of these two rural Indian districts. The island drawing exercise (Section 5.1), which was conducted with every participant at the beginning of the interviews, helped build rapport with the participants but also provided an understanding of a participant's perception of health system stakeholders and their role in this system. These exercises a tension between the desire to distribute healthcare access geographically to the whole population but also a deeply hierarchical health system structure, detailed in Section 5.2. Finally various sociocultural customs and socioeconomic factors were mentioned throughout the interviews that have implications on antenatal care access.

Chapter 6: Results II (Ultrasound Care Pathway & Solutions)

While Chapter 5 presented findings regarding participants' social/health system context, this chapter presents findings on current and potential ultrasound usage in rural Indian antenatal healthcare. The first section presents findings on participants' perceptions of ultrasound usage and utility in the clinical management of pregnancy. The second section reports on participants' evaluation of potential design and implementation strategies for a technological obstetric ultrasound intervention, namely semi-automated ultrasound. Finally the last section details participants' experiences and perceptions of sex determination activities in light of the PCPNDT Act, and its effects on obstetric ultrasound in rural India.

6.1 ULTRASOUND USAGE AND UTILITY IN CLINICAL MANAGEMENT OF PREGNANCY

A substantial focus of the in-depth interviews was to understand participants' perspectives on the use of obstetric ultrasound in clinical management. The findings in Section 6.1 are presented in five subsections: (1) the perceived benefits and disadvantages of ultrasound, (2) ultrasound protocol and practice, including enablers and barriers to accessing ultrasound, (3) clinical information provided by ultrasound, (4) the impact of ultrasound on clinical management, and (5) the importance of patient communication.

6.1.1 Benefits/disadvantages of ultrasound

Participants consistently mentioned two primary benefits of ultrasound in ANC: (1) the ability to accurately see or determine otherwise unobtainable information about the pregnancy, and (2) to serve as an effective preventive health measure ensuring the safety of both mother and child.

All participants explained that ultrasound revealed the wellbeing of the mother and the baby. For instance, an ANM said that ultrasound could identify high-risk conditions that "checking normally," or physical examinations, could not:

> *A5: There is a chance to us to identify "high-risk" through that…we can identify the decrease in MMR, IMR. If there is no scanning…[we] can't expect the exact situation of the baby. Checking normally is entirely different from doing scanning…*

Such clinical information, like fetal growth or amniotic fluid levels, was described as being uniquely or more accurately determined:

> *P3: The growth of the fetus only we will find with ultrasound only*
>
> *P5: …we can predict that she might be having oligohydromnios, we can't say 100% confirmation…through scanning only we can do 100%. But prediction will be 50-50, might be having, might not be having.*
>
> *PB: Ultrasound is like proof.*

Another ANM suggested that ultrasound gave definitive answers, and remembered repeatedly providing urine pregnancy tests for a women she thought to be pregnant and finally sending her for an ultrasound that confirmed her suspicions.

> *AN: [The woman's] date didn't come, and her stomach was feeling heavy. Test didn't show anything…But she feels that she still has. Then we sent for ultrasound and the report came…In that it said she was 16 weeks.*

Participants claimed that ultrasound was perceived similarly by patients and that it provided them reassurance, particularly through the process of discussing ultrasound results with the care providers (also see Section 6.1.6):

> *A7: Now there will be anxiety for the pregnant women to know how is the baby inside, how is its growth. If we do the scanning and tell about these things there is a chance that she can tell required care.*
>
> *PN: It is a kind of jaadoo ke pudiya [magic powder] type, "everything will be okay if we get the ultrasound done"… [So] they are like more satisfied if ultrasound has been done and other things have been cleared, [that] everything is okay.*

Secondly, ultrasound examinations were seen as crucial for effective, preventive obstetric care, because care providers could use the information to, for instance, encourage the mother to eat well to prevent low birthweights or advise medical termination for congenital malformations. A PHC

doctor said ultrasound helped determine whether to refer a high-risk pregnancy to a higher centre, thereby preventing deaths:

> *P2: In the previous 20 years back, we are not having any ultrasound machines…mothers are dying, children are dying during delivery. That complications are now prevented because we are having ultrasound machines now…I can refer the case.*

Many suggested that ultrasound examinations reduced maternal and infant mortality rates and kept mothers "safe." One government official in Haryana speculated that most maternal mortalities in his district likely resulted from the lack of early detection of complications by ultrasound.

Perceptions of disadvantages of ultrasound were limited. One concern was the fear of harm from ultrasound radiation, leading a few participants to avoid very early or frequent scans:

> *P6: …It is better to avoid before 3 months…Due to radiation, baby have some growth problems…Some developmental problems I think…*
> *P4: I think the regularly doing the ultrasound is not necessary, why to have a pressure on the uterus?.. Necessary things are for every three months…not every month…*

Another disadvantage mentioned was the concern of harm caused by missed diagnoses. An ANM recounted the story of an infant who died of an undiagnosed congenital heart anomaly due to a poor quality radiologist. She expressed confusion regarding the blame she received from the woman and her family:

> *A6: Are we responsible for this, sir? Even after four scans, [the radiologist] need[s] to tell the [condition] of the baby, sir.*

The other primary disadvantage that was explored with participants was the usage of ultrasound for sex determination (discussed in Section 6.3).

6.1.2 Ultrasound practice

The main reason participants cited for sending a woman to get an ultrasound scan was for routine screening to detect certain information (see **Figure 4**), but protocols varied drastically across participants. The number of recommended scans ranged from two to four or more. Some only

emphasised the second and third trimester. The most consistently mentioned examination was a second trimester scan (typically fifth month), the Targeted Imaging For Fetal Anomalies (TIFFA) scan. Government officials confirmed that there were no official guidelines on ultrasound protocol beyond sex determination regulations and suggested that organisations like FOGSI provided recommendations.

Participants also described recommending scans to women based on physical symptoms (e.g. bleeding, abdominal pain, an inability to feel fetal movements, or an abnormally-sized abdomen) or poor obstetric history to manage a potential complication. Most felt first trimester ultrasounds were not routinely necessary unless either issue was present:

> *PN: [I]n the early pregnancies… just if there's a bleeding to rule out the missed or threatened abortions…because if it's a missed the line of treatment is different and if it's a threatened, the line of treatment is totally different.*
>
> *A1: That particular woman did not get pregnancy since many years, two times pregnancy aborted also, and so this time after conceiving madam suggested scanning for seeing the [condition]…*

A normal obstetric history, however, could also discourage women from getting early scans in their later pregnancies:

> *A3: If anybody got normal delivery in first pregnancy, then in their second pregnancy they will go for 7th month scanning…First time pregnant ladies will follow doctor's advice strictly and go for all three scans...*

Several participants also advised more scans "as needed," such as rescanning after providing some sort of clinical intervention for a complication (see Section 6.1.5).

Participants did not agree on whether everyone followed these practices. Some believed that a majority of patients got all of their scans, while others, like A3 above and this PHC doctor, felt that a majority did get at least one examination, though not usually early in pregnancy:

> *PB: In rural setup…60-70% [get all scans]…actually this might also be a bit high…The old conception, [you have to do in the 4th or 5th month] is common…70% they do get those 2 ultrasounds if everything is going well.*

Government v. Private sector scan centres. Participants felt that those who access care in the private sector would likely have more scans than those in the government sector because of their ability to pay:

> *P5: Before delivery also…some doctors will order…In private hospitals mostly…But in government they can't afford that much scanning that's why it will do 3.*
>
> *P4: …generally the private sector people do every, every month… as they get money and all.*

Patients were often described as accessing scanning services from both the government and private sector based on which ones were freely provided, whether they had married into the village or were simply visiting (see Section 5.4), and their socioeconomic status. The TIFFA scan had to be done privately, so some suggested prioritising it over other scans if patients were poor:

> *P4: If the patient is very poor then we'll directly go for either TIFFA scan and then directly to the 9th month. So now government have given us one free scan for every antenatal…so that is so advantageous that we are doing only two scans privately, and then one free scan. If the people cannot afford those two scans also, one we will compulsory compel them and motivate them and counsel them to do at least one scan*

There was a perception of higher quality in the private sector. One PHC doctor mentioned that government ultrasound examinations did not accurately show cord around the neck, so she would recommend private scans patients. Several West Godavari ANMs mentioned that the women would often go on their own to private facilities because they felt they could better address potential complications:

> *A4: If they faced two, three abortions, they felt anxious, and [go] to the private doctors, and [ask] for scanning and [show] interest to take the costly injection like Rs.250 or Rs.500… They are doing scanning even for once or twice in a month…*

Participants suggested that patients' perceptions of lack of quality in the government sector were exacerbated by the lack of trained ultrasound operators in these facilities (see Section 6.1.3)

> *GJ: In government setup…we have 16,000 antenatal mothers every year. So we have a limited capacity of say 4 or 5000 ultrasounds per year…Simple reason is the facility…is not readily available…arranging ultrasound machine is not difficult for the government, but arranging a trained operator, that is challenging.*

To address this issue, participants said that the government provided at least one free scan per

woman through a government scheme called Janani Shishu Suraksha Karyakaram (JSSK), in which the government contracts a lower rate for their patients' ultrasound scans to be done in private scan centres (see Section 3.1.2). This was mentioned by very few people in the pilot interviews, perhaps because of recent expansion of the programme.

6.1.3 Enablers/Barriers.

Cost. Some participants felt that the cost of ultrasound services was a barrier for patients, but most felt that cost was no longer a factor for the vast majority of the population (with the exception of the TIFFA scan).

> *A2: …people used to neglect [ultrasound] because it used to cost from 350 to 1000rs basing on the centre but now after government introduced the free scan everyone is getting it done at early stage itself.*

However, some participants said that wages lost in the time it took to access ultrasound centres still affected those in poverty, especially labouring populations.

Distance to travel. The distance to ultrasound centres and inconsistent transportation options were mentioned frequently as barriers for government ultrasound centres, particularly for those in remote areas. Getting an ultrasound scan could often require a full day of travel, which could discourage patients:

> *PB: … by the time they come here, it's already 11 or 12:00 from the periphery. And then…you have to go to the doctor…[after that] you stand in the [outpatient] queue, [after that] you get [the scan], [so]that day is gone…So generally people tend to get in private.*

> *P7: …the transport is very very bad…they will come twenty, thirty kilometers…to the PHC…they will stay for 1 hour, 2 hours, after that…they will advise go for another 50 kilometers go for ultrasound scanning. How is it possible? So in interior areas, and hill areas and [tribal] areas, people will suffer a lot madam. They wouldn't follow all our rules.*

Some PHC doctors acknowledged the distances, but said that other barriers were more significant like patient awareness or long queues at higher level scanning centres.

High patient loads (high patient-to-provider ratio). The most frequently mentioned barrier in rural settings was long queues in higher centres, resulting in women waiting for a whole day but still not getting an ultrasound scan. In Rohtak, this was attributed to a severe lack of trained healthcare professionals in the government sector who could perform ultrasound:

> *GJ: …there are women who come to [get] ultrasound and they wait for hours together in the queue, only to listen finally that "come tomorrow"…we have only two trained doctors for ultrasound in our district. And naturally there is no reliever for them.*

While high patient caseloads and lack of human resources were mentioned everywhere, the Haryana participants seemed particularly concerned about this issue, often attributing it to the closing of many centres due to sex determination practices.

Patient educational awareness. Participants had different views on whether women's lack of awareness of the importance of ultrasound was a barrier. Many claimed that women understood the importance, and a few even described women going of their own accord, because families were having fewer children and recognised the need to take care of their health:

> *AN: Sometimes…before even coming to me they will get their ultrasound done, and say look, I have a baby. We'll say, why did you do it before. We say, go when the doctor writes for the ultrasound, but they say we already got it done to find out how the baby is.*
>
> *A6: No sir, we do not say, they go to the private hospital, they get it done on their own.*
>
> *P3: nowadays, these couples they want [1 or 2 children]. So they are more concerned about the health systems…If I prescribe, do it ultrasound, they are immediately getting done.*

Others felt the need to motivate and convince their patients to make these decisions (further discussed in Section 6.1.6).

6.1.4 Clinical information from ultrasound

Participants frequently explained the utility and practice of ultrasound by pointing to the clinical information it provided. All care providers[8] were asked about seven pieces of information provided by ultrasound: gestational age, fetal size or weight (or "growth"), fetal heartbeat, amniotic fluid, fetal position, multiple pregnancies, and placental position. Participants were asked to rank these components by importance in early and late pregnancy as a way to initiate discussion about how they used such information (See **Figure 4**).

Although no two participants' set of rankings were exactly the same, there were some overarching trends in their explanations. Fetal heartbeat was typically considered one of the most important indications throughout the entire pregnancy, because it was described as the most basic measure of viability and could lead to potentially fatal complications requiring termination or a Caesarean section:

> *P3: whether the fetus is dead or living, first we should know heart. If it is heartbeat no, then you go for MTP.*[9]
>
> *P5: If the fetal heart is decreasing or increasing anything, I need to go for caesarean.*
>
> *A5: [The third one is] heartbeat. Through that we can know the complications which are related to that just like, the delivery of dead baby or after delivery, the baby dies… like that so I felt that is important.*

The gestational age, or "date," of the pregnancy was considered important for most PHC doctors as a reference for progress in the pregnancy. ANMs described using gestational age as a guide for following up with their patients. Although all care providers said they calculated the expected date of delivery (EDD) from the last menstrual period (LMP), they also acknowledged a 2 day to 3 week difference between the EDD calculated from the LMP and from ultrasound. Most of the West Godavari care providers said they would use the ultrasound date, as women did not know their exact

[8] This question was originally included in the interview guide for government officials, however following the first two interviews, this question was deemed inapplicable for their roles because of their lack of involvement with clinical management.

[9] Medical Termination of Pregnancy

dates or often had amenorrhea. A few West Godavari ANMs said they might tell women to be prepared for either date:

> *A7: We will be available with both the dates sir, we will see till these dates sir, then also if pains not start, then we will wait up to scanning date sir do*

The Rohtak PHC doctors (as well as two of the West Godavari participants), said that they would follow the LMP over the ultrasound for calculating the EDD, unless the woman was not certain about her LMP:

> *PN: If she's saying my LMP is this and it's been confirmed you just write that and we'll go by that only.*

There was a concern among a few of the participants that the LMP was more accurate because ultrasound was not done until later in pregnancy:

> *A7: Scanning is taken in fourth month or fifth month, but we follow her immediately from the date when she misses the periods.*

Other explanations for the ranking of clinical information referred to the frequency of complications or the severity of potential impacts, such as fetal or maternal death. A few participants changed their rankings when they discussed conditions like multiple pregnancies or placenta praevia, which have high impacts but are rarer.

> *PB: multiple also actually quite important…But the incidence is quite low… the family has to know it, mentally get prepared, such a big thing I mean delivering twins…body demands, nutritional demands, the ultimate need to go to a facility…*

> *A4: In the scan report if placenta praevia is there, we must be very careful from starting onwards. We suggest them to take bed rest; don't do heavy works…we must go for C-section…Frankly speaking, [pause] placenta must be given the first rank…*

As suggested by both participants, another criterion that was discussed was clinical management options—one participant ranked fetal size at the bottom for late pregnancy because she felt her options for intervention were quite limited compared to earlier in pregnancy.

Participants also mentioned three other important diagnoses from ultrasound: a confirmation of pregnancy, cord around the neck and congenital anomalies. Due to low-quality urine pregnancy tests and the high prevalence of consanguineous marriages, patients might experience early physical symptoms of a pregnancy without an actual fetus.

P4: Someone who has first pregnancy and she didn't have her period. And she might be feeling that she might have conceived…[we need to know] whether it is a pregnancy, or ectopic, blighted ovum anything.

A6: There will not be baby in the womb sir, but still that woman will have vomiting, and all the rest symptoms of the pregnancy will be there. Then scanning will be useful…

The importance of detecting "cord around the neck" was mentioned by a few participants, though there was disagreement regarding whether such a pregnancy could be delivered in the PHC.

Congenital anomalies were the most consistently discussed diagnosis from ultrasound. In West Godavari in particular, this was attributed to the prevalence of consanguineous marriages (see Section 5.4):

P4: …for the past so many years and decades onwards, we do have so many chromosomal…syndromes, so genetic problems. We cannot examine and we cannot tell it clearly…

Many participants explained that detecting and terminating such pregnancies was important for the mother's safety and to prevent the clinical and social "burden" of having a congenitally malformed child.

G2L: We cannot welcome the malformation baby into the society…That's why first of all we do a TIFFA scan…if there is any congenital problem, we may wish to discard… the parents will face many problems, and society also will not welcome…

PB: I mean why should the lady suffer for so long…Why she should go through the agony of giving birth getting those pains and then maybe the child may be retarded…

6.1.5 Clinical management of pregnancy

The most important theme in discussions about the utility of ultrasound diagnoses at the primary level was the assistance they provided for three types of clinical management decisions:

- to prescribe simple interventions at the PHC and monitor with follow-up scans
- to refer patients to secondary/tertiary centres early for a specialist to monitor or advise for termination
- to refer patients to secondary/tertiary centres for delivery because of a high-risk complication

(often necessitating a Caesarean section).

Interventions at the PHC and early referrals. As depicted in **Figure 4**, if complications were detected earlier in the pregnancy (e.g. first or second trimester), participants spoke primarily about interventions at the PHC or early referrals, depending on the complication. Typically complications with fetal size and amniotic fluid volume levels were described as initially manageable at the PHC by recommending more fluids, rest from strenuous work, or increased nutrition intake. Several participants also recommended scanning again, for example,

> *P7: [If] amniotic fluid is low, we will ask them to improve the oral fluids…We'll wait and then immediately we'll do another ultrasound…*

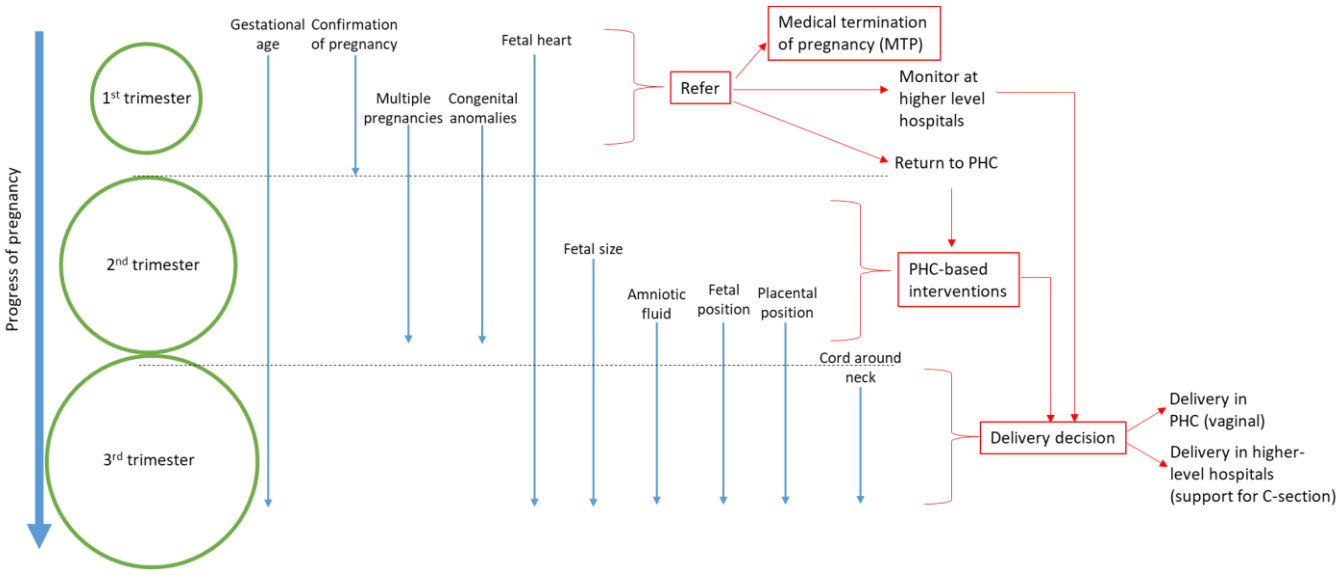

Figure 4. Participants' descriptions of ultrasound practice and the clinical management of pregnancy. The figure depicts a summary of the ultrasound-enabled care pathway according to participants. The green circles represent the relative emphasis placed on ultrasound scans in each trimester. The blue arrows indicate the relevance of various clinical criteria during different parts of pregnancy. The red represents clinical management decisions based on this clinical information.

For managing all other complications or advising a medical termination of pregnancy (MTP), care providers described referring patients to secondary or tertiary centres. GR in Rohtak estimated that 15% of the deliveries in his district involved legal abortion, due to congenital malformations. This

was portrayed as an important and timely decision because of the social and personal impact of disability (see Section 6.1.4), the safety of the mother, as well as restrictions on the timing of legal abortion:

> *A5: …they can abort that in [the fifth] month only, because after six months, there no chances to do abortion. After that the operation can be done to deliver the baby and the baby must be kept in incubation…*

Participants described a variety of limitations with these two options (i.e. managing at the PHC or referring early). For example, women often presented late in the pregnancy or even during delivery, often without ultrasound reports, forcing care providers to resort to clinical experience and physical exams, which was more challenging for junior doctors.

> *P4: But if all of a sudden a patient from the other area came…and she do have labour pain, she doesn't have any reports or anything, then we'll face whether to refer her or not. We'll just checkup all her fetal heart and whether the position is [cephalic] or not, and if we think it will be okay then we'll keep her in our PHC. If not, then we'll refer her.*
>
> *P2: It may be difficult to the junior doctors. He may not know which one is cephalic and which one is breech…but it is very easy for the senior doctors…*

When women presented late, issues like low levels of amniotic fluid, which would have been managed in the PHC, would be referred because it was too late to do anything:

> *P5: Actually in uh, if she comes in 6th month and she's having oligohydromnios I can give her like uh sachets…which she needs to mix it in water and she need to drink. At the end of the 9th month… the same thing if it comes…we will refer her to higher centre…*

Additionally, some doctors claimed that the referral process, which involved the doctor providing a referral slip and sending ANMs and ASHAs to accompany women, worked smoothly. Others felt that the distance, queues, hot weather, and numerous re-referrals were stressful for patients, particularly if ASHAs or ANMs did not accompany them:

> *P4: If it is the [summer]time, the temperature also [has] to cooperate …They will go to ANM visit first, then to anganwadi, then to PHC, then we'll tell them to go to CHC…if there is some complication they will ask them to go for the higher centre like district hospitals…The patient here is taking the more stress.*
>
> *G1: …whenever the people are being referred from this peripheral setup, they should be followed with the ANMs. ASHAs. That is mandatory…Sometimes these ANMs they*

couldn't find the time…[patients] are coming on their own without the referral slip…[In] such a circumstance…we don't have proper information…

Several participants like this PHC doctor felt that this often led to patients turning toward the private sector if they could afford it because of the perceived inferior resources (See Section 6.1.2):

P1: …Some patients…feel some services here are not that adequate… patients [believe] even if [the private sector] charge[s] they do it good…when they go to government hospital they tend to refer from this setup to another setup, saying we don't have a doctor in the hospital…or we are not having blood bank here…they feel they are not being adequately treated…

One ANM described challenges with a gynecologist at the CHC who would force patients to pay for ultrasound scans at a local private scanning centre before treating them. The ANM speculated that it was because the gynaecologist was taking a cut from the private scanning centre:

A6: Whatever the scanning reports we take with us, she will not touch them also…She throw them aside…She writes for private scanning sir…She does not like [other scanning reports] sir. We don't know why, maybe because of the percentage…

Finally, there was an acknowledgment that generally, there were few options at the PHC level, and that they had to determine whether or not to refer a patient for delivery.

P1: ....factors which can be modified are only few. If it is placenta position, I can't change it…and ah fetal position…by 9 months the patient may be converted to cephalic…If not…we have to go for a higher centre where the doctor can do uh Caesarean section…

<u>*Delivery Decision*</u>. Due to such limitations, the most prevalent conversation in clinical management was the utility of ultrasound to decide whether a delivery would occur "normally," i.e. vaginally, or by Caesarean section, as P1 described above (see **Figure 4**). Since Caesarean deliveries cannot be done in the PHC, most participants felt referrals were crucial to save the lives of both mother and baby during delivery, when deaths were most likely.

Interviewer: ...why these four (heart, placenta, position, dating) are most important in early [pregnancy]?
P7:…because we have to uh conclude for one whether we will do a normal delivery or whether you'll go for a surgery. To assess that one these four are very very important.

GJ: So naturally most important part of the ultrasonographic examination is the one which can save more number of lives…detecting a cephalo pelvic obstruction, so C-section can be planned in advance…detection of twins…detection of placental lie…these things are most important.

P2: …[Most] problems are occurring during delivery. Antenatal [period,] they may not be having any problems. During delivery there are deaths occurring…

PHC doctors, like PN, suggested that their resources to manage delivery were quite limited, requiring them to refer early and frequently:

PN: We have to refer the patient… Because we are not equipped uh for that Caesarean, or for that NICU, or for that any complication, because no anesthetist, no gynecologist, even the light is not there, it's like 2 hours, 3 hours and we are here on inverter. That's it.

Some doctors specifically described this decision as a way to avoid risk, but also to avoid blame in potentially negative outcomes.

P4: according to the scan if [the fetal weight] is less than two kgs,…[If] the position is face above, breach, buttocks anything, then we won't take the risk…If it is already at the station…We'll try to do [delivery]…if we do have some time…we'll refer…with an ANM or staff nurse.

A4: Three months back I found a case related to "umma neeru" [tr. amniotic fluid], in that [amniotic fluid index] is 4 only, so we take her to PHC… I asked doctor, "can I do this," but doctor stopped me, as there is "less amount of umma neeru we can't handle these type of cases, if something happens they would blame us so let them go"…

PB: … by this 14-15 years of job, you know like your limitations, so it's easy…why to take risk or chances, it's not good for your job, for you and for the patient.

6.1.6 Importance of patient communication

Care providers often referred to the crucial role of communication that accompanies ultrasound-enabled clinical management as patients frequently returned to them with ultrasound reports for their opinions. For example, they described using an ultrasound report to reassure women when the pregnancy was normal or mentally prepare and console women when a complication was found. P1 explained how he would reassure a woman after her seventh month ultrasound:

P1: When it comes to 7th month what we say is…"baby is good, there is nothing to worry about. The baby weight is being good…the liquor is good, everything is fine. You just need to focus on your diet and have some small exercise." That's all we say.

On the other hand, A5 described how she helped prepare a patient after discovering breech presentation in the ultrasound:

A4: …I told her "you have the baby in breech presentation, but there are chances to change the position of the baby in 8th and 9th months, before delivery also, if it doesn't happens, then there is a chance for C- section (operation) so be prepared for that also"…

Although some care providers felt that patients were aware of utility of ultrasound, others felt that communication was necessary to convince, motivate and educate women, who were unlikely to follow advice otherwise. For example, PN described trying to convince a patient with placenta praevia who would have tried to deliver at home or the PHC to avoid a Caesarean section:

PN: …everybody thinks [that] that delivery should be normal and Caesarean section should not happen, but I have to convince her and the family the mother-in-law especially [that] she can't be delivered normally…if you feel the pains you just go to your gynecologist…and get your Caesarean done timely. Don't wait...and [let] yourself bleed to death.

Some care providers similarly tried to convince women, who might feel that ANC provisions were not that important, to get their scans, often by describing the cost of inaction.

P4: …"everything is okay so why do we always need to take a scan?" They will always say that…we'll explain everything from the starting of the pregnancy to the end. So then, one or the other time they will definitely get convinced.

A3:, we will give advice…to take more sufficient and nutritious food…otherwise, if the weight of the baby is less, then you have to face so many risks...So by that they will follow our advices…

Many participants felt that ASHAs and ANMs were critical in communicating with patients and encouraging follow-up based on ultrasound diagnoses. One doctor said that she made sure every patient had written the ASHA's number on their calendar for quick communication. Their effectiveness was often attributed to patients trusting ASHAs and ANMs.

A2: the same thing doctor also will tell them…but they may not understand that, but when we tell the same thing they listen as they have belief in our words…

P5: …I might be having a connection of each, in every month once…the ANMs might be having regular connection. ASHAs very frequently. So I'll explain [to ANMs and ASHAs] like you need to ask her to do these things…

Participants also believed that the patients valued this communication, which explained why they preferred local subcentres and PHCs rather than secondary or tertiary centres where clinicians would not spend as much time with them.

PN: Um basically here, they communicate better with us because…they say, if we go to a new place we are slightly hesitant in talking…they come here for my assurance. [Because] I know her and…I can give them more time…they'll ask me, ["Is everything okay, what is it, what is written here"]…they can connect with me better.

Finally, there was a pervasive belief that clear communication around pregnancy and ultrasound findings contributed to a more positive pregnancy experience for women both physically and psychologically because patients valued this communication in navigating various complex options:

A5: By hearing the suggestion from me and from the doctor, and by knowing the condition of the baby which we told to her by watching scanning reports, she felt very happy. And they told to us "We know all these things through you, the other doctor where we went for check-up earlier doesn't say anything".

P1: [in the] private sector the doctor may say…you have to go for operation. And some people may say no no it's not required… The patient will be confused…if I can explain to her, in a manner that is quite simply understandable… they can count on us. They will know, oh if we go to this person, he will speak genuinely, not about some commercial aspects…

6.2 SOLUTIONS AND STRATEGIES FOR IMPROVING ACCESS TO ULTRASOUND AT THE PRIMARY CARE LEVEL

To explore perceptions of strategies to improve access to obstetric ultrasound at primary health levels, several hypothetical scenarios were discussed with participants: (1) an easy-to-use, semi-automated, limited-functionality ultrasound device available at the PHC, (2) the same at a subcentre, (3) a certified mobile radiologist who will perform ultrasound at PHCs or subcentres once a month, or (4) free transportation and a guaranteed appointment provided at an existing ultrasound centre. Most participants strongly preferred having an easy-to-use technology at the PHC, though

several preferred a mobile radiologist. The explanations participants gave for their choices revealed factors that were important to participants' perceptions of any effective strategy for expanding ultrasound access. These factors primarily focus on the comfort and convenience of the patient and the care provider and the impact on the system as a whole (see **Figure 5**).

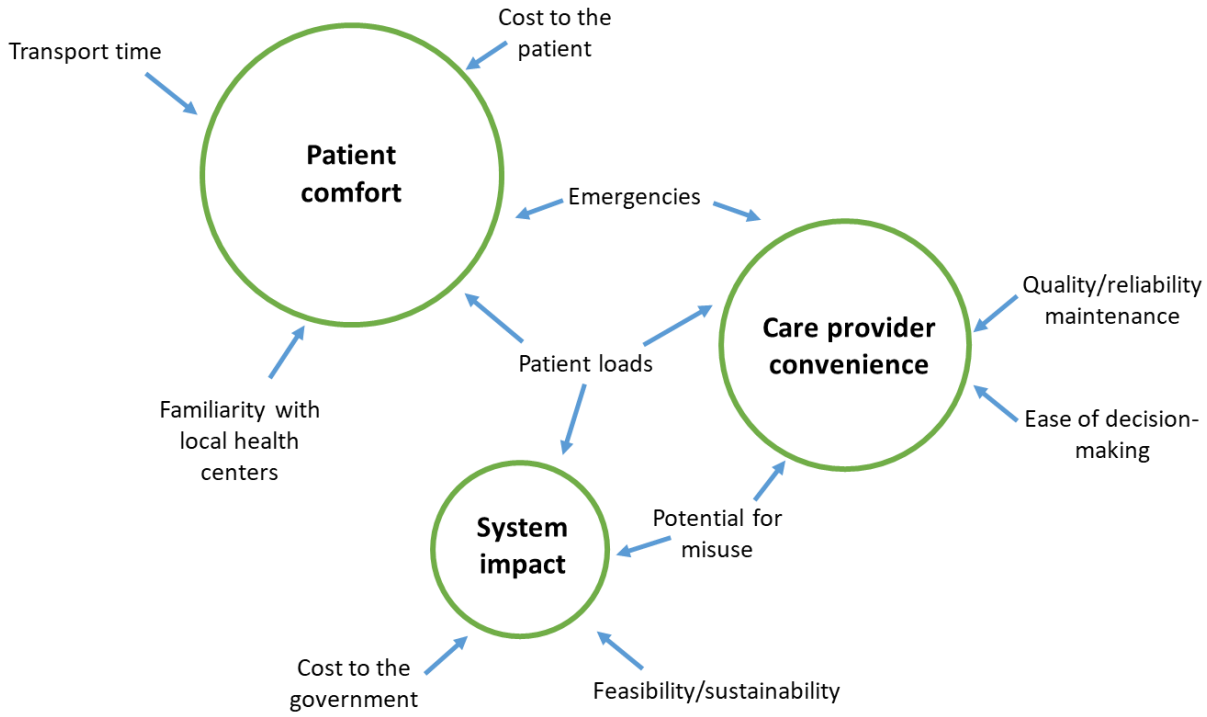

Figure 5. Factors contributing to participants' preferences for ultrasound interventions

6.2.1 Ultrasound in the PHC

The option of ultrasound in the PHC where either the doctor or a staff nurse were trained to perform a basic ultrasound that could detect six to seven key clinical criteria was most appealing to participants. Participants pointed to the significantly increased comfort and convenience for the patient if ultrasound was at the PHC because of reduced travel costs, time and transport in the heat, and the number of unnecessary or repeated referrals to centres with unreliable services. Care providers

felt that the ability to immediately conduct a scan whenever they had a concern also improved their own convenience given their strong connections with patients:

> *P4: So we want to make [it] more easy [for them]. Whenever I want to see her fetus whether it is okay or not according to my knowledge and her history…Then all of a sudden I can do it.*
>
> *P1: [Patients] come every month randomly…If I have at my disposal I can just perform a scan, see how the baby is…that would be very helpful.*
>
> *A5: …everybody will come and use [the ultrasound here], if it comes nearer to them ...they may feel happy because there is no need for distant journey, so they can decrease strain, stress…*

Participants also pointed to the increased comfort for patients when antenatal and intrapartum care was available at local PHCs due to familiarity and accessibility, especially with female care providers. Some also felt this would improve the patient's trust in the government health system as a whole:

> *P7: … they are uneducated. They are tigers in their own native place no doubt. But [if] they go for outside…They will [be] shy for everything, they won't get anything…*
>
> *PB: [The patients] know me…ASHAs are mobilising them to me, under my name to this PHC…In my…surrounding areas…[they know] a lady doctor is sitting there…So, the patients always feel like in their periphery, some doctor listens to them in their own language, with their own mobilizers, they feel acquainted.*

Another frequently discussed potential use-case was emergencies in the PHC, typically labour cases, which care providers described as high-pressure, time-critical situations that immediate access to ultrasound could ameliorate:

> *P1: …For example, at night a patient comes to us, and presents saying I'm having pain in my abdomen, at that time if there is a machine possible where I can perform ultrasound and see the wellbeing… I can assure the patient. If not I have to send that patient somewhere else, where she gets a scan and then come back to me so that I can see the report…*

P3 and PB described sudden labour and delivery emergencies as stressful for care providers as well. P3 also pointed out that despite improved access to ultrasound, he still experienced some emergencies with women who had no ultrasound scans.

> *P3: [Back then we did] only the clinical examination…keeping the ambulance ready, and trial labour and if you get any problem, shifting immediately to community health*

centre. Very painstaking, very stressful for doctors and these patients also. Nowadays, that entire pain has come down by 90%, we are very safe by ultrasound…[But still] [s]uddenly some 1-5% of pregnant ladies, they are living in remote areas, and…they land in the PHC. They don't have…any ultrasound scans.

PB: [The other day] there was a delivery, she was having good pains, fully dilated, then suddenly she relaxed, no pains…We don't know what to do, [even to refer] it will take maybe half an hour. So like if I have a [ultrasonography] machine I can detect whether there is no cord around the neck or why is there a delay…

A few participants thought that the intervention could increase the detection of previously missed high-risk women. Alternatively, many felt that providing ultrasound at the PHC would reduce heavy patient loads at secondary and tertiary hospitals by providing a more accurate filter for high-risk referrals.

GR: Now every patient whether it is high risk or it is a normal ANC patient all go to the tertiary…by [this] modality, only genuine referral will be there.

However, participants also expressed concerns about the increased workload and responsibility to maintain a machine, attend trainings, and conduct consistently high-quality examinations, given the perceived impact of missed diagnoses (see Section 6.2.6). Some PHC staff already felt overburdened and believed another staff member would be required to conduct ultrasound at the PHC:

PB: Yeah actually we are understaffed… If I designate one staff nurse for this…then that nurse will be exempted from all other duties… So I think if such a thing is to be brought then one person to be designated…manpower should be there.

PD: …you can't do everything at the PHC level… I need [another] doctor [or] staff nurse who will check the ultrasounds or the reports, and I can [focus on] the complications.

PHC doctors, like P1, also believed that ultrasound at the PHC would attract many more patients, exacerbating the workload issue:

P1: Every person with a bit of jolt [will come] to me, "I'm feeling, please do [the ultrasound]." I can't just deny, because being a government thing…we are doing it free of charge…

While these concerns were expressed by participants across various professions and regions, the West Godavari participants were more positive about the idea overall. Rohtak participants spoke extensively about the additional hassle from PCPNDT regulations on providing an ultrasound service

that required additional maintenance of the machine and its records. PB, for example, expressed the tension between recognising the limitations of her resources and the desire to provide ultrasound to improve both health outcomes and relationships with her patients:

> *PB: I don't have any room right now in my PHC… record maintenance will increase. Already…[we are] overburdened because of so many other things...it's not easy like in those days, [anyone used to do ultrasound]…[So definitely if there is ultrasound in my PHC, the patients will increase, their trust will increase, there will be more institutional deliveries], but [there are lots of legal issues].*
>
> *PN: PCPNDT, everyone is scared of that. And anybody can come and question your integrity…So I just say [that] there's no fuss taking on these responsibilities in the present scenario…*

6.2.2 Radiologist to PHC/subcentre

Proposing the idea of a certified mobile radiologist regularly visiting the PHC or subcentre enabled a discussion about whether task-shifting with new technologies was truly necessary. Some care providers believed it would provide the same benefits to the patient as having an ultrasound at the PHC without burdening care providers' workloads. Additionally radiologists were seen as having higher expertise and conducting higher quality examinations, especially for congenital anomaly detection.

> *P5: …over here, first degree marriages are very common here… the baby might be having like a eye disturbances like squint, [hole in the heart], undeveloped legs…So if the radiologist is confirming that case, then it's very good. If I'm having machine if I can do normal things like checking placenta…*
>
> *A3: if somebody came here and doing scanning rather than us, they believe, experts and doctors are doing that…*

One PHC doctor in West Godavari also felt that limiting ultrasound access to certain regular days would make women value the technology more and plan around it, instead of taking it for granted in the PHC.

However, the discussion also revealed some important situations for which having a tool readily available at the primary level was still preferable, such as emergencies:

P2: Radiologist may not be available [during a labour case]. I want to see the diagnosis within minutes or within seconds…When the doctor ask the radiologist in the night time, that man may not come…If the machine is in the PHC and the doctor is trained or staff nurse is trained…or the ANM is trained, they will get the picture…we will send the patient to the higher centre as early as possible. That is the advantage.

P7: …what happens if the lady come with the bleeding, if the antepartum haemorrhage? And also the baby is live or not she has to know. So the [radiologist] once in a month coming, what is that useful?.. In some aspects in gynecology, in obstetrics I think especially, it is very very very emergency.

A7: Antenatal is [a] continuous process…So we feel if it is available in the PHC continuously it would be better.

Others were skeptical of this strategy's effectiveness. Care providers predicted that the high number of patients a radiologist would see on just one day of the month would affect the quality of examinations. They also doubted the reliability of someone regularly serving rural areas.

P1: [I get around] 70 to 80 antenatals if I'm asking them to come on a single day, and this load is quite high…He can't perform 70-80 scans on a same day and give reports. Rather than that, if he comes weekly, they will be distributed…

P3:. If he [doesn't] come, [the patients] will wait in the room, and that too these are pregnant women. Unnecessarily, we will suffer them. If they come also…he will be in a hurry.

A6: That will be good but it would be only one day in the month…Patient and the radiologist both will be face inconvenience…[They] feel irritated also and [the radiologist] also get irritated to stay for more time…

Government officials echoed concerns about reliability, feasibility and sustainability of a mobile radiologist, given that they could not staff current radiology posts in the government system. The Rohtak government officials also said that a similar plan had previously failed due to many disincentives to work in government systems.

GJ. …such kind of models have already been tried … And they have not succeeded… because they won't last long… [the radiologist] would not like to go to remote area…Secondly the remuneration … is not going to be very much given the government funds… they may not even find good electricity there…they know there are certain gaps in government systems. Hiring private practitioners…and sending them to remote areas… that is definitely not sustainable.

GR This kind of modality we have tried in the past…With the portable ultrasound machines. But that hardly worked…Because we can't get uh radiologist frequently because of the…scarcity of the radiologists.

6.2.3 Ultrasound in the subcentre

Most participants did not believe that ultrasound should be implemented at a Subcentre under the ANM's responsibility, despite the desire of many ANMs to use ultrasound and make the process more convenient for patients. One ANM felt that conducting ultrasound would make her more important as a health worker, especially in relation to a doctor.

> *AN: I will also have value, doctor will come here to see what's going on.*

Every PHC doctor and several other ANMs and government officials, however, felt that ultrasound should be at the PHC rather than the Subcentre. Some ANMs explained that they were required to defer to doctors' suggestions regardless and that the PHC would cover more people. ANMs also raised other practical issues such as the lack of physical space to maintain and secure ultrasounds in subcentres, many of which are private buildings rented by the government. However, PHC doctors typically disapproved because they perceived ANMs to be incapable of handling an ultrasound at their education level:

> *P3: [If] you keep in a technical instrument there, it needs knowledge. So [PHC doctor]? Yes. He can scope up the knowledge. And these ANMs also just they are messengers.*
>
> *PN: If [the ANM] is saying [that] placenta praevia is not there…And [believing that], [the woman] will just sit at home and feel comfortable [because] my ANM is saying…I have to go for my normal delivery in my last month. That can even do much harm than good… expertise must be there.*

A few ANMs similarly worried that others would doubt their ability to conduct ultrasound.

> *AN: Without training, such a big job, how will we do? Then we'll have to get MBBS training. (laughs)*
>
> *A4: [The patients] prefer radiologist only…they think ANM means, the person who is doing registration of pregnant ladies, giving TT injections, doing immunization…If we say we are doing scanning, they may think "Doctors may do scans how an ANM may do that?"*

The Rohtak/Jhajjar government officials felt that ANMs could do ultrasound, but also raised concerns about the clinical expertise, training, and cost of providing so many machines. GJ summarised the tradeoff between decentralising ultrasound and maintaining high quality care:

> *GJ: …definitely staff nurse is more trained and IQ-wise is better than ANM and that way doctor performs better than staff nurse. So definitely same hierarchy comes into play. But ultimately our aim is to decentralise things and to make the things happen by ANM so that it reaches the masses.*

6.2.4 Free transportation and appointment

Participants were least interested in free transportation and appointments at higher level centres. Many participants, especially government officials, said that this option involved too many moving parts, human resources and infrastructure to carry out andwas too similar to the status quo. They also believed it would not address barriers of distance, time, or patient awareness.

6.2.5 Necessity of a solution

Although many participants said their patients accessed ultrasound regularly, they also suggested that such solutions discussed in Section 6.2.1-6.2.4 were necessary. In later interviews, I began explicitly asking participants to point out what about the status quo truly necessitated such an intervention. Often, participants would cite emergencies or emphasise certain barriers patients faced.

6.2.6 Design questions

Although most interview findings revealed design-related insights, participants were also asked specifically about three design features: limited functionality, portability, and the need for an image. (See Section 6.3.3 or the implications of sex determination practices on design.)

Limited functionality. Participants were asked whether a device with limited functionality (e.g. with seven detectable criteria) would add sufficient clinical value at the primary level. Most felt that the vast majority of their work would be covered, but some participants viewed the ability to detect congenital anomalies as a requirement in even the most basic ultrasound service. Even government officials, who preferred a limited ultrasound because it restricted the potential for misuse, felt this was

important. PN, after realising that such a basic screening device might not include the ability to diagnose congenital anomalies felt that the burden of maintaining and conducting ultrasound in the PHC was not worth it:

> *PN: …for 20th week we have to refer the mother [anyway]… 90% of people are going and getting it done, and [the third trimester anyway] hardly anyone is going and getting it done…*
>
> *Interviewer: So in your mind, this is only really useful if it can do the anomalies.*
>
> *PN: Yeah yeah at least then we can lessen the load of the district hospital and the higher centres…it's a basic thing…Otherwise of no use…then why are we taking that [responsibility, no]? Because it's a very cumbersome job here for doing scanning and all.*

A few participants also thought limited functionality could cause physical or ethical harm because missed conditions could give women false reassurance about their health and limit further health-seeking behaviour:

> *GJ: If nothing comes out in those 7 points then woman is bound to feel that she is okay. But there may be certain points like congenital anomalies to the baby…And the woman remains in false belief…[because] [w]e are giving her a stamp of OK…Secondly the women may not go to the higher centres in a belief that… [the] ANM…had already screened for ultrasound [so] why should she go to higher up centres...*

<u>*Portability*</u>. Most participants felt that a portable machine would be ideal in the PHC so that it did not have as many maintenance requirements, like electricity, air conditioning or a large room. A few ANMs said that portability would allow them to carry the machine to villages or transport between subcentres.

<u>*Need for an image*</u>. A semi-automated, basic ultrasound could be designed to provide an automated report, without the need for a screen with images. Participants were asked for their opinions on this design choice to understand the role of the screen and image in their conception of ultrasound. Government officials and PHC doctors in particular expressed discomfort at the idea of relying solely on the machine's analysis, which was not foolproof.

> *PN: …we are dependent on the machine basically, if there's any default or something…machine can [at] anytime can put you in the dark…Then your personal skills are nowhere. It's the skills of the machine basically who's telling.*

> *G2L: …if we once depend on computer systems, it can it may generate false [information]… we are dealing with lives, how can you assess without image?*

Another PHC doctor felt that the screen and image was necessary to match the patient's expectation of ultrasound:

> *PB: No I think I need to have a screen, [the patient also has a mindset about ultrasound, like] we see in the movies [that] the baby is moving and the full baby is seen. [Because the patient's connectivity lies in that]… [see your own baby on the screen] and all, that feeling of bonding.*

However, a Rohtak government official felt that the automation and objectivity obtained from a semi-automated device outweighed the lack of a screen. Additionally, many participants said they did not use images in reports even now as only private sector reports came with pictures, and they typically did not know how to interpret ultrasound images.

6.3 SEX DETERMINATION, FEMALE FETICIDE AND THE EFFECT OF PCPNDT ON OBSTETRIC ULTRASOUND

6.3.1 PCPNDT and perceptions on the current prevalence of sex determination

Perceptions of the risk of misuse of ultrasound for sex determination varied significantly by location and profession. Government officials in both districts described the enforcement of the PCPNDT Act, which makes sex determination and sex-selective abortion illegal. This included conducting quarterly inspections of all scan centres, reviewing records for every scan done, conducting decoy operations in suspected scan centres, and revoking their licences temporarily if a centre was caught conducting these activities. They also described public awareness campaigns conducted by mobilising staff across the health system, including the publicising of a large cash reward in Rohtak for providing accurate tips about centres engaging in illegal activity.

In the West Godavari district, the vast majority of participants said that women still ask about the sex of the fetus, especially if they already had one female child, though a few PHC doctors were

adamant that no one asked anymore. One ANM said that a woman had asked to be taken to someone who could determine the sex of her baby. West Godavari participants described explaining to patients the illegality of sex determination, changing gender norms and increased opportunities for women.

In Rohtak, however, all participants said that no one asked about the sex of the baby anymore because its criminality was deeply ingrained in the population from government enforcement. However, PHC doctors still recounted examples which raised their suspicions because they claimed the activity has been pushed to secret routes.

> *PD: They don't ask me about sex of the baby, but they go to the private facilities and they check the patient and they …will come to me and say [that] they don't want this child. Then I'll ask why… they said our family members doesn't want, my husband doesn't want, there's no big issue…*
>
> *PN: Because it's been very deep rooted in the population and even we have conveyed that message that it's illegal…if the person really wants to get it done…she will not get herself registered even for the first trimester, she will hide the pregnancy, and she will go [through] the secret routes…and get it done. If it is okay she will come for the registration in second trimester, otherwise we will never come to know if she was pregnant also. But at times my ANMs are able to get to know… but if she goes and asks they will say no…we will not come for the registration…*

West Godavari care providers often said they had never heard of sex determination and female feticide happening in the area. One PHC doctor said that he was suspicious when a woman would suddenly come to him with bleeding when she was previously fine:

> *P1: A patient who is good around 7 months, suddenly she starts saying I'm bleeding, she comes to PHC, and we ask, [she'll say,] "I don't know, suddenly I am bleeding, I am having some pains." So the fact is, they may have gotten some induction…they want to get abortion.*

Government officials in West Godavari also felt that sex determination and female feticide did not seem to be happening in the district, from the regular inspections and decoy operations they had conducted. However they acknowledged that the lack of evidence was not complete proof that the practice was not occurring.

In Rohtak, while there were still stories of raids that had revealed and shut down centres conducting illegal sex determination, the participants felt that the strict government enforcement of

PCPNDT in recent years alongside public awareness campaigns had been critical in reversing the problem

> *PN: But it's changing…last year's sex ratio, it's 992. Earlier it was 600, 700, even at times some villages were around 500… And people are getting aware also…they are thinking [that]…child should be of any sex…But it's very deep-rooted. It's because…very strict actions have been taken in the last year or the last two years that have been improved.*

Participants in both districts point to patriarchal traditions, such as strict gender roles, as being the root of sex determination practices. P1 in West Godavari, for example, found patients who would try for three or four children in order to get a boy:

> *P1: ,,,after two babies, they are supposed to get tubectomy done. But the people you know, they come around third pregnancy, some around fourth. Because they're trying to have a male baby. Because they can go for labour and earn something, whereas a female they have to give money to get her married or something.*

Others in Rohtak echoed these observations of root causes, such as the custom of a woman leaving her family and joining her husband's family, and believed that any progress would be slow.

> *PN: people are changing, but still it's a male dominating society. Every mother wants a male child. It's not that they're not loving their girls…But it's a deep rooted system…they want who can look after their property and take care of them in their old age…*
>
> *GR: [The behavioral change doesn't happen quickly] And this is uh thousand year mentality of having son preference in India…It takes a very long time, only 15% population are accepting the female baby very well [if] both the child[ren]…are female…*

6.3.2 Effect on ultrasound

The West Godavari participants, particularly PHC doctors and ANMs did not typically discuss PCPNDT or sex determination while explaining current ultrasound practice. For Rohtak participants, however, the Act's impacts were mentioned immediately; they described its implementation as having added more barriers for women to get ultrasound because of the increased administrative tasks, such as filling out forms or carrying photo ID, which some women did not have.

However, there was also a sentiment that this was an unfortunate side effect of necessary, strict enforcement to curb sex determination:

> *GJ: Now private partners are afraid…because…if they are going to do ultrasound they have to do it accountably and otherwise they have to shut their practice down…but given the magnitude of the problem and feticide going on…the teeth that were given to this act, they were really mandatory… although it is true that…the access to the ultrasound of certain people has decreased a bit…*

6.3.3 Effect on design and implementation of semi-automated ultrasound at the primary level

West Godavari participants, were typically not concerned about the potential for misuse of ultrasound at the PHC for sex determination as long as ANMs and staff nurses could not use it. Many participants, especially Rohtak/Jhajjar government officials, raised concerns about misuse and the need for rigorous maintenance and security measures built into device design, to ensure it did not get into the wrong hands.

Limited functionality and the need for an image. Both limited functionality and the absence of a screen were considered to be advantageous for preventing sex determination activities. Nonetheless, government officials recognised the tradeoff between the clinical utility of a full ultrasound image and the risk of misuse. In West Godavari, they felt that sexual organs were the only acceptable part of the image to block to balance this tradeoff. One of the officials also suggested having a camera built into the device that could be monitored by the PCPNDT committees to provide evidence that a doctor may be practicing sex determination.

Rohtak/Jhajjar government officials, however, feared that people could still alter the machine in some way by adding a screen or determine a way to extract the images. They emphasised that this was a primary concern that had to be addressed technologically in order to persuade governments to invest in semi-automated ultrasound at PHCs.

Portability. Although one government official said that the PCPNDT Act did not allow for portable ultrasound to be used at all, another government official said that it only stipulated that portable

ultrasound must be used alongside other Reproductive and Child Health (RCH) equipment and activities.

6.3.4 SUMMARY

The results in Chapters 5 and 6 suggest that primary level healthcare providers and government officials in both the West Godavari and Rohtak districts in India perceive ultrasound to be highly beneficial to obstetric clinical management. The utility of ultrasound diagnoses at the primary level, where pregnant women have the most contact with the health system, lies specifically in its use as a decision-making tool to determine when and where to refer women for delivery. The exact extent to which pregnant women experience the barriers discussed by participants in accessing ultrasound in these areas is not entirely clear from the results. However, integrating an easy-to-use, semi-automated, basic obstetric ultrasound at the PHC level might address many of the current challenges faced by women, PHC doctors, ANMs, and higher level hospitals. There are significant implementation and design challenges to ensure that such a technology would have the necessary support for broader systems integration and would not lend itself to illegal usage for sex determination and female feticide.

Chapter 7: Discussion

7.1 ON THE UTILITY/USAGE OF ULTRASOUND

The first goal of this study was to explore the current landscape of ultrasound usage and utility at the primary health level in two rural Indian districts. This is the first study to my knowledge that details the ultrasound-enabled care pathway in the Indian healthcare system.

The results (Section 6.1) suggest that PHC doctors, ANMs, and government officials in both the West Godavari and Rohtak rural districts in India repeatedly portrayed ultrasound diagnoses as a necessary, beneficial and accurate tool for both routine and emergency usage in the clinical management of pregnancy. Diagnoses provided confidence in making decisions when a patient presented late in pregnancy or without clear obstetric history, which happened frequently. Participants also raised benefits to pregnant women, such as the reassurance of knowing the wellbeing of both the mother and baby. This is consistent with the perceived benefits for both providers and patients in LMICs and HICs (6, 12, 56, 58, 59, 70, 72). Unlike many of these studies, the benefits described here were obtained solely from information in reports, not the image of the baby; there are no machines or personnel trained to interpret images at the primary level, and government scanning reports lack images. As in other studies, sociocultural resistance or distrust of the technology did not seem to be an issue here (73).

A common argument in the literature is that ultrasound provides collateral health benefits by motivating women and their families to attend more ANC visits or follow through on clinical advice (16, 89-92). Although these arguments lack rigourous evidence (see Section 2.3.4), similar explanations were provided by participants here. For example, doctors and ANMs said their suggestions had more weight when they were based on an ultrasound report. They also believed that having ultrasound at the primary health level would increase the number of ANC visits, pointing to similar effects seen when ANMs began to use fetal Dopplers.

Very few disadvantages of ultrasound in its current context were discussed, other than sex determination and the impact of missed diagnoses. The primary fear expressed was harm from radiation, which has been found in other LMIC ultrasound studies and in older studies from HICs (52, 56).

The results also suggest that the main utility of ultrasound diagnoses at the primary level is their impact on managing the pregnancy clinically and logistically, specifically by assisting in the decision to refer women to a secondary or tertiary centre for a potentially high-risk delivery. It is difficult to overstate the emphasis participants placed on framing ultrasound in this way; every participant consistently linked discussions of clinical criteria, ultrasound practices, or their communications with patients to the ultimate decision of whether to refer someone to CHCs or district hospitals (with neonatal specialists and Caesarean section capacity) or whether they could manage with a vaginal delivery at the PHC. Doctors appeared to perceive a limit to their capacity to intervene at the PHC level. This suggests that primary level care provisions are not well-equipped in terms of the staff, tools, or training to handle many complicated pregnancies, which has been found in other studies as well (113, 148, 149). Ultrasound was therefore seen as a way to avoid potentially stressful and dangerous deliveries in the PHC.

The perception of ultrasound primarily as a delivery decision-making tool to ensure patient safety in low-income countries has not been directly concluded before, though a few previous observations have been found to be consistent with this outcome. Hofmeyr (2009) in his discussion of whether ultrasound is worthwhile in LMICs made a similar conceptual argument because LMICs often have geographically distributed health institutions in which births tend to take place in rural and remote areas, and Caesarean sections and neonatal care are only available in referral centres (6). In such situations early ultrasound diagnoses would enable a timely referral. This was also alluded to in Shah (2008)'s study introducing general compact ultrasound into rural Rwanda, where they found that the most common change in patient management plans was a new surgical procedure, such as a Caesarean section (13)

Framing the utility of ultrasound primarily around planning for the delivery also helps explain why participants valued certain types of clinical information at various points in the pregnancy. For example, detecting amniotic fluid volumes, placental lie, fetal size, and fetal presentation in the third trimester was described as particularly important because it affected risks in delivery that a PHC could no longer handle. Swanson et al. (2014) show a similar result in their Uganda study in which a significant part of change in diagnosis from midwife-conducted ultrasound came from third trimester ultrasounds that showed fetal malpresentation (85).Thus, although the current evidence base, which draws primarily on studies in HICs, states that there is no observable effect of routine ultrasound in late pregnancy on perinatal outcome, these findings suggest the need to re-evaluate this link in rural, LMIC settings with geographically distributed health institutions.

Although the limited causal data available for maternal morbidity and mortality in India makes it difficult to determine whether ultrasound access plays a crucial role in such cases, most participants, regardless of their professional identity, believed that ultrasound improved maternal and infant mortality by enabling the determination of whether a pregnant woman might have a complicated delivery and need additional support from a secondary or tertiary centre. Although their perceptions do not imply statistical evidence, the results do suggest that environments with limited primary and preventive care and geographically dispersed support for high-risk obstetric care, are fundamentally different than the HICs in the Cochrane reviews that form the basis of WHO guidelines (3-5). When used as a delivery decision-making tool in LMICs, access to high-quality, timely ultrasound examinations could help reduce maternal morbidity and mortality by ensuring that women are receiving appropriate care at appropriately equipped institutions. The FirstLook trial, the large randomised-controlled trial conducted across five LMICs, might provide further answers to this question (150)

It is also important to note the lack of emphasis or discussion with many participants about the importance of ultrasound in gestational age determination. While a large number of participants did rank gestational age as important in the ranking exercise, it was not extensively discussed as beneficial usage of ultrasound. Moreover many said they might use the LMP date over the ultrasound-

determined date, or that they might use both, and did not perceive the level of error with LMP to be an issue. This is not consistent with the evidence, as accurate gestational age determination is known to be best achieved with ultrasound, and is necessary to determine the timing of administering drugs for infections during pregnancy, interpreting the growth patterns of the fetus, planning for delivery and determining whether pregnancies are pre- or post-term (152-157). On a population health level, it enables the accurate acquisition of data regarding the frequency of growth-restricted and pre-term births (158). Another important finding from this study included identifying barriers faced by patients in accessing routine, timely ultrasound examinations. Participants mentioned monetary cost, time (and lost wages), travel distances, awareness in the patient population and low levels of trained human resource to support ultrasound usage as some of these barriers, which are consistent with other LMIC studies (11, 12). The qualitative approach used in this study does not enable quantification of the effects of such barriers—some participants changed their opinions on the magnitude of barriers over the course of conversation, and participants could be biased. However, understanding whether care providers and government officials perceive barriers in the system is still important in understanding the desirability of a potential solution.

The closest set of data with which to triangulate these findings is the District Level Household Survey-IV from 2012-2013 (124) . As presented in Table 2, in the state of Andhra Pradesh, about 80% of women in rural areas get one ultrasound scan sometime during pregnancy; the figure is about 53% in Haryana. However there is no available data for district-level access or details about the ultrasound examination (e.g. when or where it was conducted). From a facility perspective, DLHS-IV reports that three of the four sub-divisional hospitals and the district hospital in West Godavari have an ultrasound service. Rohtak does not have any sub-divisional hospitals and has only one district hospital with ultrasound. As mentioned in Chapter 3, Rohtak has significantly fewer CHCs, and only one with an obstetric gynecologist, which supports the findings in Rohtak suggesting high loads at the fewer number of tertiary centres. However, DLHS and other national health management data collection processes are often incomplete and of varying quality, limiting their usability for guiding policy decisions (151, 152).

Another key finding from the exploration of the current ultrasound-enabled care pathway was the lack of standardisation and evidence-based practice. Factors such as the timing of the recommended scans, the particular clinical indications during different parts of pregnancy, and perceptions of how many scans were offered for free from the government varied widely within and across the two districts. Many suggested that first trimester ultrasounds were not routinely needed except for women with complicated obstetric history or certain physical symptoms, despite the literature clearly showing that early ultrasounds are crucial for accurate gestational age measurements. The only truly consistent practice was a routine second trimester TIFFA scan, which the literature suggests should be done between 18-22 weeks to detect congenital anomalies in time to terminate the pregnancy if necessary (assuming patients could afford it in the private sector) (153). The emphasis placed on this scan might reflect a lower societal tolerance for disability, as many participants commented on the burden that children with major mental and physical malformations were on the family and on society and Edvardsson et al.'s (2015) interviews with Australian midwives suggested that ultrasound's availability might contribute to this attitude (57).

The lack of comprehensive electronic records seemed to exacerbate the lack of standardisation, particularly given practices in the South, such as moving between a woman's in-laws' and parents' houses during the antenatal and delivery periods. The increased distribution of tablets to ANMs to record activities such as immunisations and tetanus injections suggests that this platform could be utilised to enhance accurate recordkeeping and standardisation of ultrasound practice.

The LMIC ultrasound literature does not include much on existing ultrasound usage and care pathways as compared to clinical effectiveness or perceptions and attitudes. Whitworth et al. (2015) point out in their Cochrane review that ultrasound studies across many different countries use very different protocols, which makes outcomes difficult to compare (3). Studies of obstetricians' perspectives on ultrasound in Vietnam and Syria do suggest that its availability, especially in the private sector, encourages unnecessary overuse, which reflects care providers' perceptions in this study as well (71, 154).

Miller et al. (2016) discuss the phenomenon of simultaneously "too little too late" and "too much too soon" maternity care around the world, referring to the push for care in facilities with inadequate staff, training and infrastructure alongside an increasing over-medicalisation of maternal and perinatal care, often in the same countries or even the same districts (155). They cite unnecessary ultrasound examinations and Caesarean sections as two of the many examples and present a package for evidence-based, respectful maternity care. This reflects findings in this study that show simultaneous concerns about missed and unnecessary referrals in the health system. It is worth considering how interventions, particularly technological ones, can enable standardised, evidence-based care. Participants here suggested that government schemes, like JSSK, the program that contracts reduced rates for government patients in private ultrasound centres, played a large role in ensuring that women were getting at least one ultrasound during pregnancy helped them overcome some barriers like cost and time. Free, basic standardised screening at PHCs could help such systems better align with evidence-based guidelines. Section 7.2 further elaborates on the significance of these findings for the design of appropriate solutions.

7.2 PERCEPTIONS OF ULTRASOUND SOLUTION IMPLEMENTATION

The second objective of this study was to use the findings from exploring the current landscape of ultrasound usage to understand whether a solution is needed, whether semi-automated ultrasound technology would provide an appropriate solution, and if so, what it should look like. The results suggest that there is significant support from care providers and decision-makers for an easy-to-use, semi-automated, basic ultrasound machine at the PHC because it is the locus through which women have the most contact with the health system during and after pregnancy and the main delivery hub for women in rural areas.

Given recent explosive levels of interest in technology in global health, especially mHealth and eHealth-enabled solutions, which do not always reflect the evidence for their efficacy, there are reasons to be skeptical about overly positive attitudes toward new technology (156, 157). To address

these biases (an important part of human-centred design principles, see Section 7.6), two additional strategies were discussed with participants: a mobile radiologist and free transportation with guaranteed appointments at existing ultrasound centres. Introducing three very different types of options enabled a rich discussion that helped explore factors that are important to participants and patients (**Figure 5** in Sec 6.2).

Arguments for having an ultrasound in the PHC most often centred around the comfort of pregnant women by decreasing the stress and time associated with ultrasound examinations at crowded, higher level centres, where patients were described as feeling less comfortable than in local PHCs and Subcentres. A quick, decisive, accurate tool in the PHC was also seen as significantly easing care providers' jobs when faced with emergency labour cases or antepartum haemorrhage.

Understanding whether having an ultrasound at the PHC would improve the current gap in usage seen in the DLHS-IV data, as many participants suggested, would require a different kind of study to quantify the prevalence of suggested barriers. However, even under the assumption that usage statistics would not change, which is unlikely given the precedent for women accessing free antenatal services provided at the PHC under JSY, as discussed in Chapter 3 and by participants here, a semi-automated device could enable better standardisation of protocols, training, and diagnoses. Participants felt that such a device would also increasing patient trust in the system, and improve follow-up rates, so much so that PHC doctors were worried about being able to handle the potential increased patient loads if a device were implemented. Many felt that introducing an ultrasound at the PHCs would decrease referrals by providing a more accurate filter, which has also been documented in Greenwold et al. (2014)'s evaluation of an ultrasound training program for nurses and clinical officers in Mozambique (79).

There was also a recognition among many participants that decentralising higher-quality, comprehensive healthcare to primary level centres was a worthy goal in and of itself because it improved health equity and patient empowerment to access care at local levels. This was also reflected in the design exercise in which most participants preferred to distribute people and resources, including tools like ultrasound to maximise access even to remote populations.

Interestingly, participants, especially government officials who have a systems' perspective, felt that strategies with mobile radiologists or transportation services had higher costs and were less feasible than implementing an entirely new technology in the PHC. These responses, alongside concerns about relying on someone from the city to travel to rural areas, display a deep skepticism of the government's existing capacity to address any gaps in access.

Discussing options like a mobile radiologist, which solves some problems from the perspective of the care provider, however also revealed disadvantages or concerns in implementing semi-automated ultrasound at the PHC level. Participants cited already overburdened and underequipped primary care centres, including limitations in physical infrastructure and systems support for maintenance. To some extent, some issues can be taken into consideration in design (e.g. by using parts that can be locally sourced or focusing on improved battery life for areas without consistent electricity availability).

Engaging participants' in discussions about technology use also revealed on-the-ground realities of its implementation in rural public health. They described mostly positive experiences with past technology, which is consistent with other studies that report health care professionals and midwives or community health workers feeling empowered through technology use (158). However, they also acknowledged the time and difficulty involved with learning the technology and seeking out support at the PHCs due to unreliable internet access. They worried about introducing yet another medical technology like ultrasound, which also requires supervision, to their existing workload. This resonates with Kimberly et al.'s (2010) descriptions of training midwives in Zambia to use ultrasound, which suggested that there was a range of technological aptitude amongst midwives affecting how quickly they adopted the technology and that their workloads became unmanageable with the addition of ultrasound (73). The fact that a few participants actually preferred the mobile radiologist strategy, especially Rohtak participants given the additional administrative requirements under PCPNDT (see Section 3.1.3), suggests that many PHC doctors feel uncomfortable taking on the responsibility for ultrasound, which they perceived as high-impact, complex technology.

Additionally, despite the benefit of task-shifting and decentralisation expressed across almost all participants, deference to education and social hierarchies repeatedly arose in many parts of the interview from the drawing exercise to discussions of clinical workflows. PHC doctors felt that a radiologist would always be more accurate and did not believe that ANMs could be trusted with an ultrasound. It is important to note the evidence does not support a lack of tertiary education as preventing effective provision of ultrasound (159). These sentiments were similar to how obstetricians in the pilot did not trust PHC doctors to conduct ultrasound examinations.[10] And most ANMs said that they had little independent authority and had to defer most decisions to the PHCs, rendering an ultrasound machine in the subcentre useless. India's social, caste-based hierarchies have been well-documented, but there have been only a few other studies in India that examine how clinical and social hierarchy within the government health system affects care pathways. Kok (2015) cites two studies in India and Uganda where the social status of the community health workers affected their acceptability (160). In Scott (2010)'s and Mishra (2013)'s qualitative interviews with ASHAs and ANMs in North India, they suggest that the rigid, hierarchical public system limits communication across status levels and creates top-down information channels that devalue and disempower ASHAs' and ANMs' experiential knowledge (161, 162).

Further exploring the effects of these hierarchies is critical to informing the design and implementation of an increasingly popular set of interventions that involve task shifting. The results here suggest that, at this point, key stakeholders would perceive PHC doctors trained on semi-automated ultrasound as acceptable.

7.3 SYSTEMS SUPPORT FOR NEW TECHNOLOGY

In addition to human resources, the results focused on health systems infrastructure, such as robust referral mechanisms, electricity and internet access, technological training and equipment

[10] By law, PHC doctors (who have an MBBS qualification) cannot conduct ultrasound without further specialisation or certification.

maintenance, because the literature has suggested that these are important factors for the success of implementation (81, 93). While both districts reported having free transport to referral centres with specialist services during both antenatal and delivery periods, participants detailed problems with the timeliness of these services, particularly in emergencies, the long distances and wait times at higher centres, and often unexpected re-referrals. Although the difference in sample sizes makes a robust comparison difficult, participants in West Godavari seemed to describe a greater number of options for referral than Rohtak, both to access ultrasound services but also to follow through on high-risk diagnoses. This is supported in the data on facility availability form DLHS-IV (**Table 2**).

This raises the question of whether districts that have the systems to support ultrasound technology might also have less need for it, because in theory, these stronger support systems should also improve maternal and neonatal outcomes overall. The need for additional resources or system infrastructure to support individual interventions such as ultrasound in addressing health outcomes has been observed elsewhere in the literature as well (68, 73, 81, 93, 107). Goldie et al. (2010)'s model, for example, suggests that benefits to maternal mortality and other health outcomes are minimal unless ANC is linked with improved frequencies of institutional delivery through accurate referral and transport (107). Stanton & Mwanri (2013) point out that the provision of the ultrasound service must be coupled with courses of action, like referral pathways, access to safe abortions, and the availability of patient counseling and support, the latter of which is probably most challenging in environments with such high patient-to-provider ratios (81).

7.4 DESIGN STRATEGY

Findings suggest that a device introduced at the PHC level must be easy-to-use, fairly portable, and not require 24/7 electricity and internet access (see Section 7.5 for restrictions on portability). More broadly, the results identify the need for an accurate, quick and easy way to stratify high-risk pregnancies and deliveries. Such a tool will likely include semi-automated ultrasound, but

given the increasing use of tablets at the primary level, it could also draw from other data and integrate into a mobile platform.

Some design characteristics, such as limited functionality or the absence of a screen or image, while being conducive to protecting against illegal sex determination activities, were not universally popular. Some questioned whether a limited device would provide a sufficient replacement to address existing gaps and make the increased "burden" involved with maintaining an ultrasound at the PHC worthwhile. Many emphasised the importance of detecting congenital anomalies as part of a "basic" ultrasound, while others also believed that the seven components discussed would cover the vast majority of issues they might see at the PHC. Presently, congenital anomaly detection is not even available at government centres and the uncertainty involved in this kind of screening suggests that automating it is not feasible in the current situation (6).

Another concern about these design characteristics was the potential to lead to missed or incorrect diagnoses that could cause significant harm. The psychological impacts of negative ultrasound findings, for example, have been well documented in both HICs and LMICs , and psychological stress during pregnancy has been linked to adverse perinatal outcome (6, 52, 59, 163). Participants perceived the gravity of these diagnoses and worried about relying wholly on a machine. This observation is interesting, however, given the level of trust that these same individuals place in the accuracy of ultrasound currently, suggesting that much of this trust stems from the perceived expertise of the operator.

Concerns about the automation of technology more broadly were also found. One participant felt that relying on an automated device would strip users (i.e. doctors) of the development and usage of skills. There were also questions of responsibility for the quality of the examination if the diagnosis is made by a machine. Even in the story that one ANM told about a poor quality ultrasound centre that missed serious fetal heart complications, she expressed confusion for why she became the object of the parents' blame. With a semi-automated ultrasound machine, the responsibility for diagnostic quality is even more unclear and suggests the need for a robust quality control and supervision mechanism, such as a remote image review by experts. Training in patient communication to ensure

that both care providers and patients fully understand what such a device can and cannot do would be an important part of any semi-automated ultrasound intervention.

Concerns about theft and maintenance, particularly given the context of illegal sex determination, suggest that security mechanisms would be an important design component of such a device.

7.5 THE POTENTIAL FOR MISUSE (SEX DETERMINATION)

Concern regarding current levels of ultrasound misuse for sex determination varied greatly across regions and professional groups in the participant population. The government officials in both districts, a few of whom were in charge of enforcing the PCPNDT act in the district, unsurprisingly, showed the most concern, and felt that even precautions such as blocking any images and limited functionality might not prevent machines from being hacked into. Broadly, participants in Rohtak showed much more awareness of sex determination practices and of the effects of the PCPNDT act on the health system, as the government has investigated and closed many centres found to be conducting sex determination. While they claimed they were not asked by patients to divulge the sex of the fetus, some were aware of suspicious cases in the community. Meanwhile West Godavari participants said they were always asked to reveal the sex of the fetus, particularly if there were already one or two daughters in the family, which is consistent with data on missing females at the third birth order (8). All participants believed that sex selection practices had significantly decreased over time, due to government action and changing attitudes, although many acknowledged that such deeply ingrained behavioral change was difficult. One PHC doctor in Haryana showed charts with the most recent sex ratios at birth and pointed out that they had increased significantly over her time there.

However, given the sensitivity of the topic of sex determination and sex-selective abortion, there is not much incentive for participants to answer completely truthfully. These questions were asked at the very end of the interview to limit biasing other responses, but there were still participants who appeared uncomfortable discussing the issue. Additionally, data suggests that the national

population has become more male-biased in recent decades, especially in high-income households (8, 140). Although sweeping generalizations are difficult to make, the findings in this study reflect the general north/south divide, with the north and west being described as more patriarchal, though from 2001-2011 some of these states, including Haryana, have actually slightly improved their sex ratios (137, 140). This could be due to the increased crackdown on sex determination from the PCPNDT Act that was described in the interviews in Haryana. However, at a national level, it has been suggested that the PCPNDT Act has failed to stem the increase in the practice of prenatal sex selection and is making it more difficult for women to get safe abortions (138, 164). Moreover, sex ratio data are tenuous due to multiple types of survey sampling some of which depends on birth registration data (138). As one of the PHC doctors in Rohtak said, if a family wants to determine the sex of the child, they will not even get it registered.

Despite the lack of literature to support this claim, participants believed that the crackdown on illegal sex determination activities had limited access to ultrasound. The Indian Radiological and Imaging Association (IRIA) has gone on strike several times in recent years due to complaints of harassment by enforcers of the PCPNDT Act and the implementation of harsh punishments for even minor administrative errors (165). Thus, a semi-automated, limited functionality ultrasound in the PHC which is officially deemed safe from misuse could be desirable for many stakeholders.

Additionally, the acceptability of portable ultrasounds will likely be different across states. Although the Maharashtra High Court dismissed a petition filed by the state branch of the IRIA to allow for portable ultrasound, Rule 3 of the PCPNDT Act allows for portable ultrasounds as long as they are used alongside other Reproductive and Child Health services which was confirmed by a Rohtak government official (166, 167). The findings in this study suggest that advanced security mechanisms in these machines which do not undermine the clinical efficacy of diagnosis will be an important design feature to appeal to local governments.

7.6 REFLECTION ON CO-INNOVATION & HUMAN-CENTRED DESIGN APPROACHES

This study drew upon human-centred design techniques to gain deeper insight into the relevant system context of the beneficiaries of innovation and to ensure that any solution is appropriate and effective, especially in areas that are affected by the biases of clinicians and patients (23, 168). People's systematic cognitive biases affect their perceptions of their needs, strengths, and the frequency of certain challenges (168). By drawing on interdisciplinary insights while delving into existing behaviour and decision-making and including prompts in the interview guide to question technocratic assumptions, the impacts of such biases can be recognised and understood in the context of designing an innovative solution. The island drawing exercise was one such example—it provided context for how individuals perceived themselves and their role in the health system, which helped legitimate other observations from participants throughout the interviews.

There have also been calls to move from user-centred design to co-design, in which the user is considered a full partner in the process (169). As this project moves into its design stages, it is worth thinking critically about how such participatory methods can be employed to improve the efficacy, ownership and sustainability of such public health innovations.

7.7 LIMITATIONS AND STRENGTHS OF THE STUDY

Using existing George Institute research sites was both a strength and limitation of the study. It provided easier access to a greater number and variety of participants than may have otherwise been available due to the familiarity of research staff with local PHCs and subcentres. Additionally, this familiarity provided important contextual sensitivity and likely made participants feel more comfortable in the interviews. However, it also could have biased the participant pool to include those with a personal interest in such research and with awareness of typical questions in such studies.

Another limitation was the large difference in sample sizes between the two locations. There were 16 participants from West Godavari district compared to only seven from Rohtak district. A few

of the participants in Rohtak district were in fact from the neighbouring Jhajjar district, but were deemed appropriate to include given their proximity. Thus the potential for a comparative analysis between the two districts is limited and must incorporate other available data.

Third, the participant pool did not include patients or current ultrasound providers. Although this was an intentional decision based on the research questions being addressed, patients are important stakeholders in the health system, and the lack of their inclusion in the study limits generalisability of the results. Future studies should seek to capture the views of women and their families. Including ultrasound providers could further elucidate how semi-automated ultrasound technology could address their challenges as well.

The need to conduct some interviews in local languages with a translator was another limitation, as a great deal hinges on the choices made by the translator. Having real-time translations, even short ones, enabled better follow-up questioning but also broke up interview flow and could have occasionally resulted in missed opportunities for further such questioning.

Three West Godavari officials were interviewed together due to limitations on space and time. While the social dynamics of such an interview can affect the expression of participants' opinions, these participants were very comfortable with one another and I attempted to use my role as the interviewer to ensure that participants all contributed equally and genuinely to the interview. One ANM was also interviewed in front of the PHC doctor, due to the need for a translator, which could have limited some of her insights.

The assumption of competence in English was sometimes made incorrectly with certain participants. A few could speak English sufficiently to answer initial questions, but as the discussion became more complicated and nuanced, they felt more comfortable switching into the local language (either Telegu or Hindi). This may have limited richness of these interviews or created misunderstandings.

The length of the interviews was an important ethical consideration. After the first few interviews extended to 1 hour and 15 minutes, the interview guide was shortened, and most remaining

interviews were approximately an hour long. However, in very few cases participants felt uncomfortable providing a full hour of their time, due to other responsibilities or their level of focus in the conversation.

Employing a qualitative methodology to address the research questions enabled a rapport to be built with participants and brought out more detailed nuance, which is important in evaluating the implementation of complex technology into already complex systems. However, it also limits certain types of questions—for example, a relevant question that kept emerging from the interviews and analysis was how many people the barriers to ultrasound actually affect.

One of the main strengths of this study was that it received input and supervision from a wide range of disciplines. While the primary supervisors of this thesis came from the fields of obstetrics, fetal medicine and engineering, the thesis also received significant supervision from a qualitative methodologist with extensive experience in primary care. During fieldwork, a user-centred design expert and anthropologist (Bill & Melinda Gates Foundation) contributed to the development of interview guides to ensure that participants would respond based on actual lived experiences rather than solely clinical knowledge or answers they thought they "should" give. The pilot phase results received input from global maternal health experts at the Bill & Melinda Gates Foundation, which were also used to iterate the interview guides. Moreover, research staff from the George Institute provided integral support in collecting the data. Such an interdisciplinary set of influences helped shape a comprehensive, detailed and nuanced approach to understanding not only the potential applications of new ultrasound technology but also how surrounding sociocultural and health systems contexts should be incorporated into a more informed understanding, which is often missing in global public health technology studies. (See Section 1.2.4 for a discussion of reflexivity.)

Lastly, as discussed in Section 4.1.3, methods to increase the trustworthiness of the study were employed, such as prolonged engagement with the research sites through a pilot phase. Interviews were manually transcribed by the primary researcher (with the exception of those that were translated from Telegu), enabling deeper understanding and familiarity with the data. The first few interviews were co-coded with another qualitative researcher who assisted in developing the coding

framework which was applied to the other interviews. The data were situated within geographical and sociocultural information in the Background and Literature to provide a context within which the results could be generalised.

Chapter 8: Conclusion & Recommendations

8.1 SUMMARY OF KEY POINTS

The following list contains the ten key points presented in this thesis:

- Recent WHO guidelines recommend one ultrasound scan prior to 24 weeks' gestation, despite conflicting evidence (mostly obtained in HICs) regarding the impact of routine screening on perinatal outcomes. For women in LMICs, cost and a lack of personnel remain well-documented barriers to accessing high-quality ultrasound, especially early in pregnancy.
- Task-shifting studies in LMICs report high accuracy, diagnostic impact (and to a lesser extent) change in clinical management when point-of-care (POCUS) ultrasound is conducted by non-specialists; the scalability and sustainability of such interventions, which often rely heavily on human resources, remains unclear.
- The POCUS technological landscape has significantly expanded and lowered cost in the last decade (**Figure 1**), although improving image quality and ease-of-use continues to be a technological objective. Recent developments in automated image interpretation could help overcome cost, quality and personnel barriers in LMICs.
- In India, which has the highest number of stillbirths and neonatal deaths in the world, ultrasound technology is only available at distant secondary and tertiary levels of the tiered rural public health system and is subject to regulation due to rampant use for sex determination.
- Interviews with 25 Primary Health Centre (PHC) doctors, auxiliary nurse midwives (ANMs) and government officials across two rural districts in India were conducted to explore the existing use and utility of antenatal ultrasound diagnoses in primary care and the potential for semi-automated ultrasound to address gaps.
- The findings suggest that ultrasound is perceived as a necessary tool to obtain clinical information, provide reassurance and encourage antenatal follow-up. Travel times and

distances, as well as low levels of human resources at higher-level centres resulting in long patient queues, were cited as barriers faced by women, despite government partnerships with private scan centres to provide at least one free ultrasound.

- Despite the lack of standardised, evidence-based practice in obstetric ultrasound, the findings suggest that the primary utility of ultrasound reports are their use as a delivery decision-making tool (i.e. to determine whether women have to be referred for high-risk deliveries) (**Figure 4**). Perceived gaps in access were believed to be causing both missed and unnecessary referrals.
- Participants cited the potential for semi-automated ultrasound in PHCs to improve access to early, high-quality ultrasound diagnoses, clinical management decisions and follow-up, patient trust, and access to antenatal care more broadly. However, significant concerns remained, including overburdened PHCs and subcentres, gaps in electricity, internet access and maintenance systems, clinical/social hierarchies, the bureaucratic requirements of complying with anti-sex determination regulation and the potential for misuse.
- The findings indicate the need for a tool to enable primary care providers to accurately and easily stratify high-risk pregnancies. An easy-to-use, low-cost, semi-automated POCUS that detects six to seven key clinical findings and integrates with other sources of data and existing mobile platforms, coupled with strong safety and security mechanisms and systems-level support, could address such needs.
- Further areas of research include quantifying the barriers faced by women and collecting more robust data on ultrasound use and the association with adverse outcomes. There is also a need for larger, ultrasound task-shifting studies in LMICs and the inclusion of other stakeholders, especially women, in exploring the role of semi-automated ultrasound.

8.2 CONCLUSION

Despite the lack of ultrasound machines and trained personnel at the primary health level in rural India, the findings in the West Godavari and Rohtak districts suggest that many women do get at

least one ultrasound examination at some point during their pregnancy. The primary level care providers (PHC doctors and ANMs) and district-level government officials in this study all considered ultrasound to be a necessary and highly beneficial tool in the clinical management of pregnancies. As discussed in previous chapters, study participants perceived ultrasound's primary benefit in its use as a delivery logistics decision-making tool. In rural environments where local PHCscannot effectively manage high-risk conditions during pregnancy or delivery, the early and accurate determination of whether a woman should be referred to distant higher-level centres is essential.

The qualitative, user-centred approach adopted in this study was particularly valuable in gaining a nuanced understanding of how ultrasound adds value to care providers and those responsible for health system outcomes. Equipping primary centres to support high-risk pregnancies and deliveries will certainly be an important part of tackling gaps in maternal and perinatal health and has already begun (113). However, the relative lack of human resources in the health system and the need for improved standardisation of protocols suggests that an accurate, easy-to-use tool that enables quick stratification of "high-risk" conditions could both empower primary level care providers and improve health outcomes.

The concept of task-shifting healthcare to the primary level has been promoted and practised for decades now, and the increasing number of technologies that have been designed for community health workers' use is testament to the demand for better equipping "last mile healthcare." However, the findings in this study suggest that the lowest tiers of the public health system are already, or at high risk of, being overburdened as more initiatives get task-shifted. Understanding how social hierarchies impact the effectiveness of task-shifting will be important not only in the Indian context, but worldwide.

Alongside the advantages that low-cost, semi-automated ultrasound could provide, the study revealed that participants were concerned about the risk of overuse, missed diagnoses, and incorrect diagnoses. These concerns should be taken into consideration in both the design and implementation of semi-automated ultrasound technology. Additionally, from a social perspective, patriarchal structures in many parts of India have enabled rampant sex determination and sex selection practices

that are still a significant problem, despite the noncommittal responses from many of the participants. The sensitivity surrounding ultrasound technology is understandable given the legal context and the integral role that ultrasound plays in these practices. However, at best, ultrasound can be designed prevent its use for sex determination; the root causes lie in sociocultural practices and the empowerment of women in society.

As an engineer and social scientist by background, I often find myself torn between worlds that exhibit high technological optimism and skepticism. In analysing the findings, I have attempted to walk a middle ground—with a recognition that technology alone likely will not solve deep-rooted system problems, but that incorporating system-based, sociocultural information into the design, development and dissemination of technology can enable behavioural change.

8.3 FURTHER RECOMMENDATIONS

As mentioned in Chapter 7, the next logical research question from this study is understanding the patient perspective. The pilot phase in this study included patients and suggested that perceptions of and barriers to ultrasound often aligned with both care providers' discussions and with the LMIC ultrasound literature. Still, in-depth qualitative studies will help uncover further nuance, particularly through the inclusion of family members, i.e. husbands and in-laws. This will also provide a better understanding for the context of sex determination at the village levels.

Incorporating other key stakeholders from the health system will also be crucial. For example, the private sector, and especially the informal sector, plays a significant role in providing care in rural Indian communities. There is limited literature on the quality, accreditation levels, and practices of the informal sector. As the results of this study suggest, women access services from public, private, and informal sectors simultaneously, adding yet another level of complexity in understanding the kind of care women are actually receiving before and after pregnancy. Additionally, a more detailed exploration of systems-level requirements to support the implementation of ultrasound at primary

health levels, should be conducted as ultrasound and other imaging diagnostics are introduced in non-specialist healthcare centres, both in India and around the world.

Moreover, the absence of detailed data pertaining to ultrasound usage and other diagnostic examinations must be addressed in order to quantify barriers women face in accessing ultrasound and the association of such barriers with health outcomes. A well-designed survey in these districts could provide more accurate usage statistics It is also worth considering how existing mobile platforms, such as tablets, which have been distributed in some districts to record data through government reporting portals, could be leveraged to gather some of these data easily and cost-effectively.

Finally, as discussed in Section 7.6 the subsequent research and design phases of this study should critically consider ways to continue to empower the voices of users, decision-makers and beneficiaries of this innovation process.

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Appendices

A1. PILOT INTERVIEW GUIDE

Informal Scoping Fieldwork in India (Dec 2016)

Itinerary
1-Dec: Hyderabad (George Institute center)
2-Dec: Hyderabad (George Institute center), travel to Bhimavaram in the evening
3-Dec: Bhimavaram (PHC and CHC)
4-Dec: Bhimavaram (ASHA and ANC interviews in villages)
5-Dec: Eluru (District medical and health office for Maternal and Child Health district program)
6-Dec: Vijayawada (public health officials, State MCH Program officer + other government officials (?))
7-Dec: Vijayawada (other government officials), travel to Delhi in the evening
8-Dec: George Institute conference in Delhi, travel to Rohtak in the evening
9-Dec: Rohtak, Haryana
10-Dec: Rohtak, Haryana
11-Dec: Rohtak Haryana
12-Dec: Rohtak Haryana
13-Dec: Delhi- various academics, public health experts (Dr. Sanjay Zodpey from PHFI, Dr. Jyoti Vajpayee from Gates Foundation India) leave from Delhi in the evening

Objectives
- Understand antenatal health care delivery and public health structure for maternal/child health in urban, semi-urban and rural settings in India
- Understand who is performing ultrasound, where and when
- Engage stakeholders in discussions regarding pain points of ultrasound usage and evaluating the clinical need
- Acquire opinions from providers (including healthcare professionals and CHWs) and other decision-makers on the value of a low-cost automated ultrasound device for gestational age

Questions
For health care professionals (OB/GYNs, Neonatologists, community health workers)
- *Understanding healthcare delivery structure*
  - At what points in the pregnancy do women tend to engage with ANC services? (e.g. first trimester, as soon as they think they may be pregnant, etc.)
  - What are typical clinical management decisions you have to make? (e.g. the need to deliver before term? The need to transport a patient to a different clinical site? The need to deliver a specific intervention?)
  - What information do you need to have to make those decisions? Do you have tools to acquire that information? Are there problems with those tools?
  - Is gestational age determination important? How do you estimate gestational age? How do you ensure gestational age determination is accurate and do you have difficulty with doing so? How does that affect delivery of care?
- *Understanding ultrasound usage*
  - Do you use an obstetric ultrasound during pregnancy?
    - When? How frequently? Why/For what information
    - If not, why not?
    - How were you trained on using ultrasound? Did you get a certificate?
    - Do you get any refresher training on ultrasound use?
    - When you find something on an ultrasound scan that you cannot interpret, do you have anyone to ask for help with interpretation and further clinical management?

- On average how many ultrasound examinations will a woman undergo during a normal pregnancy? When and from whom?
- What are difficulties faced with using ultrasound as a clinical tool?
- How do patients react to the ultrasound scan or the information derived from it? (indifferently, appreciatively, fearfully, etc.)

- *Opinions on low-cost ultrasound*
  - If you had a cheap, easy-to-use tool that would accurately calculate gestational age, would you use it?
    - If so, how or why?
    - If not, why not? Are there additional pieces of information you need to get in an automated/easy-to-use fashion?
    - How might your decisions change with this information?
    - Would it be acceptable with an ultrasound machine that could only calculate GA and diagnose twins?

<u>For hospital/clinic decision-makers, public health officials</u>

- *Understanding healthcare delivery structure*
  - What is the distribution among women in these areas who access maternal and child healthcare from public sector services vs. private sector services? Is there an informal sector of care as well? Does this vary depending on the kind of setting (e.g. urban, semi-urban, rural)?
  - What organizations (including non-medical or third sector organizations) are involved in providing women in this area access to maternal and child healthcare? Does this vary depending on the kind of setting (e.g. urban, semi-urban, rural)?
  - What are the kinds of decision-making factors involved in purchasing medical devices in general? Specifically ultrasound? Is there a tradeoff?
  - How many ANC visits do women in this setting typically get?
  - What are the typical decisions in the clinical management of a pregnant woman that lack information?
  - What barriers, if any, do you see in improving maternal, fetal and child health during the antenatal period through the usage of ultrasound?
- *Understanding ultrasound usage*
  - How many obstetric ultrasound machines are in use (in this setting, in the state, in the country)?
  - What kind of ultrasound machines do you use?
  - How many healthcare professionals or workers have access to an obstetric ultrasound machine, and is it used for calculating gestational age?
  - How do the users of ultrasound currently get trained on it?
  - Is there any supervision for providers of ultrasound examinations?
  - What is the proportion of pregnant women who actually get an ultrasound scan?
    - If there is a gap, what are the reasons for this gap?
  - Would obstetric ultrasound (and specifically data that would come from accurate calculations of gestational age) help in acquiring a better picture of perinatal health in India?
  - Does the existing legislative framework around sex selection affect the usage of ultrasound?
    - Providers' perceptions of ultrasound? Patients' perceptions of ultrasound

    - How much do ultrasound machines cost? What are the cost-effectiveness decisions involved with determining how many ultrasound machines to buy?
        - Are there tradeoffs?
        - Is there any cost to the patient to receive ultrasound scans?
- *Opinions on low-cost ultrasound*
    - If you could buy a device that anyone with limited experience could be trained to use and could automatically tell you the gestational age of the baby-- would you buy it? Why or why not?

<u>For pregnant women (off the record)</u>

- What do you hope to get out of an ANC visit? What information do you want to know about your pregnancy?
- Have you ever had an ultrasound scan done? What were the circumstances surrounding that? What did you think about your experience?
- Did you trust the person doing the scan? Who would you prefer to do it? Why?

PHC- ask why not using US, provision,
Go to CHC- talk to gynaecologist, see the US how they're used, are they satisfied; will find a pediatrician here.
Pregnant women- 2nd or 3rd trimester

In Rohtak, can go to tertiary care- neonatologist- can also ask them about general conditions in rural areas.

ASHAs belong to community and are in contact with pregnant ladies so they bring them to hospital.

Add questions about electricity, size of device
Retention of ASHA/ anganwadi

Beti bachao, Beti padao- UP and Bihar

A2. PARTICIPANT INFORMATION SHEET

Evaluation the role of a semi-automated ultrasound in Indian antenatal care

Participant Information Sheet

OxTREC reference number 518-17
Version 3 dated April 17, 2017

Introduction to the study

The goal of this study is to understand how developments in ultrasound technology, specifically the automation of ultrasound, could help address the gap in access to high-quality, early obstetric ultrasound for pregnant women in rural India.

This Participant Information Sheet contains detailed information about the study. Its purpose is to explain to you as clearly as possible all the procedures involved in this study before you decide whether or not to take part in it. Feel free to ask any questions about any information in the document. If you decide to participate in this study, you will need to sign an Informed Consent Form, and by signing the Informed Consent Form you indicate that you understand the information provided in this sheet and you give your voluntary consent to participate in the study.

What is the background and purpose of the study?

The George Institute for Global Health India in collaboration with the University of Oxford is conducting this research study to understand the usage and access to ultrasound in antenatal care in rural India. The information collected from this study will be used to develop strategies for developing better solutions to improve the access to high-quality, early ultrasound to pregnant women in rural India.

What procedures do you have to undergo?

For this study, you will be asked questions about your experiences and opinions about ultrasound as a part of routine antenatal care pregnancy, the potential value of a low-cost, semi-automated ultrasound in your work, and the challenges in implementing such a technology.

Are there any possible benefits to you?

There are no immediate benefits to you in taking part; however, this research is part of a larger study to understand the value of low-cost automated ultrasound, which could potentially enhance the ability of primary care physicians and health workers to diagnose issues in a pregnancy earlier and more easily.

Are there any possible risks to you?

There are no risks of harm in taking part. The questions will revolve around opinions on ultrasound usage based on your experiences in healthcare delivery.

What about privacy, confidentiality and disclosure of information?
The discussion during the interview will be recorded on a voice recorder and then transferred to a secure University of Oxford and server. The data from the interviews will be analysed and potentially included in a publication, but will be presented anonymously without enabling your identification.

THE GEORGE INSTITUTE
for Global Health

INDIA

Evaluation the role of a semi-automated ultrasound in Indian antenatal care

Participant Information Sheet

OxTREC reference number 518-17
Version 3 dated April 17, 2017

Information that identifies you personally (such as your name, address, etc.) will be kept in a separate location from the other content of your interview, and will only be linked back to your results by an unique identification number if we need to contact you personally. The information that identifies you personally (such as your name, address, etc.) will not be available to any of the researchers analysing the results of the study. You will not be identified in any reports or publications of the findings from the study.

Access to the information provided by you will be granted only to the researchers from the University of Oxford and the George Institute for Global Health India, and to other approved collaborators who meet the stringent requirements of the George Institute for Global Health India, Independent Ethics Committee.

The information that you provide is totally confidential and will not be disclosed to anyone else other than the researchers and approved collaborators without your permission, except if required by law.

How do you know the results of the study?

A summary of the overall results of the study will be available after they are published.

Is your participation voluntary?

There is no requirement to take part. You may ask any questions about the study before deciding whether to take part. Moreover, if you agree to take part, you can also withdraw from the study without any penalty at any time. If you do choose to withdraw, any recordings of the interviews and personal data will be deleted permanently from our records.

What if something goes wrong?

As this survey collects only verbal information related to the use of ultrasonography machine during your pregnancy, we do not perceive of any harm or risk to you that is a direct result of your participation in this study.

Do you get any incentives?

You will not be paid any incentives for your participation in this study.

Who is leading this study?

This study in your area is being conducted by researchers from The George Institute for Global Health, India and the University of Oxford, who have a lot of research experience conducting similar research studies and is led by Dr. D Praveen and Ms. Anisha Gururaj.

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INDIA

Evaluation the role of a semi-automated ultrasound in Indian antenatal care

Participant Information Sheet

OxTREC reference number 518-17
Version 3 dated April 17, 2017

The contact details of the principal investigator of the study in your area are:

Dr. D Praveen,
Head, Primary Health Care Research, The George Institute for Global Health, India. Unt 301, Second Floor, ANR Centre, Road Number 1, Banjara Hills, Hyderabad 500034. Email: dpraveen@georgeinstitute.org.in

What if you have any queries or need further information?

You may ask any questions or raise any concerns at any time, including before, during or after the interview takes place. You may reach out to Dr. D Praveen at the contact info ahead.

What if you have any complaints?

This study has received ethical approval from the Independent Ethics Committee at the George Institute for Global health, India. If you have any complaints regarding this study, you may contact the Member Secretary, Independent Ethics Committee, **The George Institute for Global Health | INDIA** 311-312, Third Floor, Elegance Tower, Plot No. 8, Jasola District Centre, New Delhi 110025 | India **T** +91 11 4158 8091-93 | **F** +91 11 4158 8090

A3. INTERVIEW CONSENT FORM

THE GEORGE INSTITUTE
for Global Health

INDIA

Evaluation the role of a semi-automated ultrasound in Indian antenatal care

Informed Consent Sheet

OxTREC reference number 518-17
Version 3 dated April 17, 2017

Date: ___ / ___ /_____ **Participant ID:**

Please read the following before putting your signature or thumb impression on this form:
The procedures that I have to undergo for this study including any risks, side effects, or discomfort and the time involved have been explained to me, and the questions that I have about the study have been answered to my satisfaction.

_____ I have read the Participant Information Sheet and have been given the opportunity to discuss the information and my involvement in this study with the study team.

_____ I understand that my participation in this study is voluntary and I am not under any obligation to participate.

_____ I understand that I can withdraw from this study at any time, without affecting my relationship with the study team now or in the future. I agree to being audio recorded during my interview.

_____ I understand that my information is strictly confidential and no information about me will be used in any way that reveals my identity.

_____ I understand that I can withdraw my participation from this study at any time if I do not wish to continue and any information that I have already shared can be removed if I so desire.

By signing this Informed Consent Form, I give my informed consent to participate in this study as outlined in the Participant Information Sheet. By signing this Informed Consent Form, I have not given up my legal rights. I have been given a copy of this Informed Consent Form.

Full Name and Address of the Participant

_____

_____

_____

Signature / Thumb Impression of the Participant

_____

Name of the Study Staff _____

Signature of the Study Staff _____

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INDIA

Evaluation the role of a semi-automated ultrasound in Indian antenatal care

Informed Consent Sheet

OxTREC reference number 518-17
Version 3 dated April 17, 2017

Name of the Witness _____

Signature / Thumb Impression of the Witness _____

Name of the Principal Investigator: Dr. D Praveen

Signature of the Principal Investigator:

For any further clarification or information, kindly contact:
Dr. D Praveen
Head, Primary Health Care Research, The George Institute for Global Health – India
Unit No. 301, Second Floor, ANR Center
Road No.1, Banjara Hills | Hyderabad - 500 034 | Telangana India
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Email: dpraveen@georgeinstitute.org.in

A4. CARE PROVIDER (PHC DOCTOR AND ANM) INTERVIEW GUIDE

OxTREC ethics application 518-17
Version 3
12-May-2017

Evaluating the role of a semi-automated ultrasound device in Indian antenatal care

Semi-structured interview schedule: clinicians and health workers

Opening

- Introduction to build rapport: Introduce self and involvement with project
- Consent: Verbally discuss consent form with interviewee and obtain written consent
- Purpose and Impact: Explain the role of the interview and why
- Interview structure: Explain length of the interview (~1 hour) and ask if interviewee has any questions before starting

Collect information:

- Sex
- Position (ANM, GP, policymaker)
- Years of experience
- Public sector/Private sector positions
- Attachment to primary center v. secondary center

Interview

1. Exercise

Draw an island. *This is an island. There's a river cutting through a part of the island. There's a group of trees here, a big rock here, a boat is tied up here. Draw where you see yourself. Where do you put the following people: ASHA, pregnant women, mothers, their families, ANMs, PHC doctors, CHC doctors, government officials?*

Draw tools you use like a phone, the tablet, stethoscope, blood pressure cuff. Draw an ultrasound machine (if you aren't sure how to draw a machine, just a box is fine). Explain why you drew those in the location and the way you did.

2. Existing practices and access

Understand how ultrasound is currently used in antenatal care and interviewee's perception of its value. Start with some general questions around the importance of ultrasound. *When was the last time you gave someone their ultrasound results? Can you walk me through that experience? Why is it important to you? How do you explain the value of an ultrasound to a pregnant woman? What about the value of the ultrasound is most important to the woman?*

Ask about what the ideal protocol is for ultrasound during the pregnancy. *How do you decide when to advise a woman to get an ultrasound scan? How many ultrasounds should a woman have during her pregnancy? At what months? What do you look for in those ultrasounds?*

Based on answers above: *Do you think an US is needed early in the pregnancy (e.g. 1st trimester or 2nd trimester)? Have you ever advised a woman to get an ultrasound early? Why?*

Eventually get to the gap in outcomes for ultrasound: *We talked about what is supposed to happen. Does this usually happen? If not, why not and what is more typical? What are some of the things that cause that difference? Are there challenges women face in agreeing to an ultrasound? Are there challenges they face in getting an ultrasound done?* Follow up around the gap specifically for early ultrasound.

3. Value of a semi-automated US and effects on clinical management

The seven things that are currently being focused on for automation include: gestational age, fetal size, amniotic fluid (liquor) volume, fetal position, multiple pregnancies, fetal heartbeat, placenta.

For gestational age: *How do you date the pregnancy? Is the date from the ultrasound helpful? Why/why not*

For the others: *Have you ever had to discuss ultrasound results with a woman where there was an issue with one of these things?* (Pick one) *Can you walk me through that situation? When you got that information from the ultrasound, was that helpful and timely? In your mind, is there something that would have made that information more valuable? Is there something that could have changed about that situation that would have helped with the final clinical outcome?*

Relative importance: *How would you rank these six things in terms of what is important for you to do your job? Can you explain the ranking? How does the ranking differ when you are seeing a woman who is early in her pregnancy vs. late in her pregnancy? Which of the six things are things that women ask about? Why?*

Referrals: *Have you ever referred a woman to another clinic because of something that you saw in an ultrasound? Have you ever referred anyone because of concerns regarding these 6 things? Walk me through those times. Can you tell me about the process itself (in terms of information flow)? Was it difficult to make that decision?*

Ask about the effect of having the ability to obtain this information in their setting on their job: *Has there been a time when having a way to get that information here in this clinic would have made a difference to you or to the patient? What if I gave you the ability to find out any of these 6 pieces of information right here in the clinic—would you want to do that?*

4. Opinions about feasibility and alternatives

Ask the participant to brainstorm barriers: *Can you think of any reasons why bringing the ultrasound here would be difficult? Can you think of reasons why women might not use the ultrasound here?*

Probe about other alternatives: *Would you rather have the device here or would you rather have a radiologist come here once a week? A free transportation service for women to go to a radiologist? A*

guaranteed appointment system for women to go to CHCs? Why/why not? How do these compare to the status quo?

5. Training, supervision, health needs assessment

Ask about processes for implementing new technologies or interventions, for example, *Have you ever had experience implementing a new protocol or using a new device?* If they can't think of one use the tablet as an example. *How were you trained on it? What was it like to start using it? How did it affect your relationships with your staff, with ANMs, with the patients?*

Technological maintenance: *Tell me about the last piece of equipment that broke here. Was it repaired? Why/why not? Is it difficult to get replacement parts/repairs done?*

Do you have consistent internet access here? Do you have consistent access to electricity? How does this affect your work/usage of other technology here? How do you get around any inconsistent access?

6. Concerns about ultrasound misuse

General misuse/overuse: *Do you think ultrasound machines are ever used in ways that are not helpful for a woman's or fetus's health? Can you give me any examples?*

If sex selection does not come up in answer to question above, probe specifically about interviewee's experience dealing with patients' interest in sex determination: *Have women expressed concern about the sex of the baby? How so? Can you tell me about such a time?*

If not addressed in answers above: *Do you think that female feticide happens frequently? Would you be worried about this happening more if all the PHCs and subcenters were given an ultrasound like the one we discussed above?*

Closing

- Thank interviewee for their time
- Ask interviewee if there are any additional questions

A5. GOVERNMENT OFFICIALS INTERVIEW GUIDE

OxTREC ethics application 518-17
Version 3
12-May-2017

Evaluating the role of a semi-automated ultrasound device in Indian antenatal care

Semi-structured interview schedule: policymakers

Opening

- Introduction to build rapport: Introduce self and involvement with project
- Consent: Verbally discuss consent form with interviewee and obtain written consent
- Purpose and Impact: Explain the role of the interview and why
- Interview structure: Explain length of the interview (~1 hour) and ask if interviewee has any questions before starting

Collect information:

- Sex
- Position (ANM, GP, policymaker)
- Years of experience
- Public sector/Private sector positions
- Attachment to primary center v. secondary center

Interview

1. Exercise

Draw an island. *This is an island. There's a river cutting through a part of the island. There's a group of trees here, a big rock here, a boat is tied up here. Draw where you see yourself. Where do you put the following people: ASHA, pregnant women, mothers, their families, ANMs, PHC doctors, CHC doctors, government officials?*

Draw an ultrasound machine (if you aren't sure how to draw a machine, just a box is fine). Explain why you drew it in the location and the way you did.

2. Existing practices and access

Understand how ultrasound is currently used in antenatal care and interviewee's perception of its value. Start with some general questions around the importance of ultrasound. *Have you visited an ultrasound facility in a public hospital? Have you seen one done? What was that like? Can you describe the setting you saw it in? Did you feel that it was an important part of the hospital or of antenatal care—why/why not? What did the ultrasound provide the doctor? What did the ultrasound provide for the woman? How did it really make a difference?*

Ask about what the ideal protocol is for ultrasound during the pregnancy. *Are there policies/recommendations in practice regarding ultrasound? (e.g. How many ultrasounds should a woman have during her pregnancy? At what months? What do you look for in those ultrasounds?) If yes, where do those policies/recommendations come from? If no, why not? Do you think doctors should have guidelines for ultrasound practices?*

Gap in outcomes for ultrasound: *From what you have seen do you think these guidelines are followed? Why/why not? What are the biggest challenges to following these guidelines if they exist?*

Do you think enough people get ultrasound early enough? What is that estimation based on? (e.g. data, talking to doctors/ASHAs, etc.)

3. Value of a semi-automated US and effects on public health management

Understand the components and uses of ultrasound that are most important to them. *Of all the information you can get from an ultrasound, what information do you feel is most important from a public health perspective?*

List the six things that are currently being focused on for automation (gestational age, fetal size/amniotic fluid volume, fetal position, multiple pregnancies, fetal heartbeat, placenta).

Relative importance: *How would you rank these six things in terms of what is most important at the primary care level? Can you explain the ranking? How does the ranking differ for early pregnancy vs. late pregnancy? Which of these things are most important to women/their families?*

Explain the idea and potential for a semi-automated ultrasound: *There are developments in ultrasound technology that allow for the interpretation of this information in ultrasound to be automated. As the operator, you would not need to see the image or know how to interpret it in order to get the information; the device itself would tell you the information you need. Do you believe that such a device would be useful to GPs and/or ANMs in primary health centers and subcenters? How so?*

Understand implication from a systems perspective: *Why isn't there ultrasound in primary health settings now? How does that affect where women get their ultrasound scans (public v. private)? How would adding access to such information in a primary health setting affect the CHC and district hospital settings?*

Referrals: *Do secondary and tertiary settings have the capacity to handle referrals? Can you tell me about the process itself (in terms of information flow)? How effective is the current referral process and what are the challenges to maintaining effectiveness? How would this limit the effectiveness of such a device?*

4. Opinions about feasibility, alternatives

Ask the participant to brainstorm barriers: *Can you think of any reasons why keeping the ultrasound in a primary health setting would be difficult? Can you think of reasons why women might not use the ultrasound here?*

Probe about other alternatives: *How does this compare to other types of programs that could expand access (e.g. where the radiologists are brought to these centers once a week, or where women are provided compensation to get an ultrasound at a nearby authorized private center, or a guaranteed appointment system for women to go to CHCs)?* Explore across dimensions of access, quality of care, cost, etc. Ask if the payment program for getting ultrasound done at private providers is "working?"

5. Training, supervision, health needs assessment

Ask about processes for implementing new technologies or interventions, for example, *Can you give me an example of a recent technology that has been introduced in the health system? What was that process like? Was there any backlash, or unexpected difficulty in doing so?*

More generally on training capacity: *Do you think primary health staff receive sufficient training for their jobs? To maintain new skills? Why/why not?*

Technological maintenance: *What happens if a machine breaks? Is it difficult to get replacement parts/repairs done?*

Resources: *Do PHCs and subcenters have consistent internet and electricity access here? How does this affect their work/usage of other technology? How do they get around any inconsistent access?*

6. Concerns about ultrasound misuse

General misuse/overuse: *Have you ever heard of ultrasounds being used in a way that isn't completely beneficial to the health of the fetus or the woman? What happened? Why does that happen? Do you worry about this happening—why/why not?*

Understand policy stance perspective on sex determination and female feticide: *Do women or their families tend to express concern about the sex of the baby? How so? Do you think that female feticide and sex selection practices in general happen frequently?*

Explore regulations on ultrasound and effectiveness in addressing female feticide: *How do you regulate ultrasound registration and usage? How do these regulations help reduce the prevalence of sex selection practices? Do you believe that this is the best way to do so?*

Concern regarding a wider distribution of a restricted, semi-automated ultrasound: *Would you be worried about PHCs and subcenters being given an ultrasound like the one we discussed above with regards to sex selection practices?*

Closing

- Thank interviewee for their time
- Ask interviewee if there are any additional questions

A6. CODING FRAMEWORK

The coding framework, which was applied to all interviews, was created based on the interview guide and co-coding two interviews with another qualitative researcher in NVivo 11. While creating charts (see A7) some codes were combined into columns.

Macro Codes	Code	Definition
01 Benefits and disadv of ultrasound	0101 Ability to see clearly from US	Interviewee's belief that ultrasound enables "seeing" or clarifying information
	0102 Accuracy of US (compared to physical methods)	Interviewee's belief that ultrasound diagnoses have higher levels of accuracy
	0103 US as preventive health measure	Interviewee's belief that ultrasound diagnoses can prevent future health problems
	0104 Reassurance	Interviewee's belief that ultrasound helps provide reassurance to the patient
	0105 Harm from US	Interviewee's opinions on whether US can cause harm in general
	0106 Sex determination	Any reference to the practice (or absence of the practice) of sex determination
	0107 Fetal wellbeing	Explicit references to an effect on fetal health
	0107 US useful in public health	Interviewee's discussion of how ultrasound is useful for public health management
02 Clinical management of pregnancy	0201 Ranking of clinical info	How the interviewee ranks the importance of 7 pieces of clinical info from US in early pregnancy
	0202 Referrals	Components of decisionmaking process to refer a patient to a higher level centre
	0203 Interventions following scan	Clinical management decision-making and actions following a diagnosis from a scan (other than referrals)
	0204 Enough time for intervention	References to information arriving in time to make a clinical decision for the patient (including referrals)
	0205 Medical termination of pregnancy	References to decision-making around terminating a pregnancy
	0206 Decisions about delivery	Importance of determining whether delivery is vaginal or Caesarean
	0207 Emergencies	Any reference to responding to emergencies
	0208 Corroboration of US results with other	References to the process of comparing ultrasound scan results to other methods of examination (oral history, physical examination etc.)
	0209 Pre- or post-term delivery	Any reference to preterm or post-term delivery
03 Enablers and barriers of ultrasound scanning	0301 Cost barriers	Ways in which the cost of various health services does/does not act as a barrier to patient access; also used for when referring to patients who are poor
	0302 Distance and travel barriers	Ways in which the distance of a patient from various health centres does/does not act as a barrier to patient access
	0303 High patient load	References to high volumes of patients at various healthcare centres

	0304 Patient education	References to levels of education of patient population affecting understanding of healthcare
04 Ultrasound practice	0401 1st trimester scan	Any reference to importance/utility of conducting a 1st trimester scan
	0402 2nd trimester scan	Any reference to importance/utility of conducting a 2nd trimester scan
	0403 3rd trimester scan (early)	Any reference to importance/utility of conducting a scan early in the 3rd trimester (7th or 8th month)
	0404 3rd trimester scan (late)	Any reference to importance/utility of conducting a scan in late in the 3rd trimester (either 9th month or right before delivery)
	0405 Ideal protocol of scans	Interviewee's opinion on the number and timing of routine ultrasound scans a woman should ideally have during pregnancy
	0406 Actual US practices	How ultrasound tends to actually be used (as opposed to the ideal protocol that interviewees believe should be followed) in terms of timing or number of scans
	0407 Importance of early scan	Interviewee's perception of whether or not an "early" scan is important and why/why not
	0408 Most important scans	Interviewee's opinions on scans that fall under a minimum requirement
	0409 Physical symptoms leading to scan	When referral to a scan is done following a concern arising from a physical examination
	0410 Obstetric history	References to past experiences with pregnancy and effects on current practice
	0411 US in PHC	Interviewee's opinions on how US would be used in a PHC, or references to advantages of implementation of US in PHC
	0412 Disadv of US in PHC	Any disadvantages arising from having an ultrasound machine in a PHC
	0413 Radiologist to PHC	Interviewee's opinions on an intervention in which a radiologist comes to a PHC once a month to conduct routine ultrasound scans for patients in that area
	0414 Transportation provision plan	Interviewee's opinions on an intervention in which free transportation and guaranteed appointments are arranged for patients to get scans done at higher gov centres/private centres
	0415 Necessity of change in status quo	Interviewee's opinions on whether the status quo is sufficient with regards to ultrasound
	0416 US in Subcentre	Interviewee's opinions on how US would be used in a Subcentre, or references to advantages of implementation of US in a Subcentre
05 Structure of ANC and health system	0501 Location of ASHA on island	Information on where ASHAs should be in the design exercise
	0502 Location of ANM on island	Information on where a ANM or subcentre should be in the design exercise
	0503 Location of PHC on island	Information on where a PHC or PHC doctor should be in the design exercise
	0504 Location of CHC on island	Information on where a CHC or higher level hospital/specialist doctors should be in the design exercise

	0505 Location of govt officials on island	Information on where govt officials should be in the design exercise
	0506 Location of tech resources on island	Information on where various technologies should be in the design exercise
	0507 PHC	Any reference to PHCs
	0508 CHC	Any reference to CHCs
	0509 Tertiary hospital	Any reference to tertiary care centres (like district hospitals, sub-district hospitals, or area hospitals)
	0510 Role of ANMs	Responsibilities of Auxiliary Nurse Midwife
	0511 Government sector scans	Any reference to ultrasound scans being done in the government sector
	0512 Private sector scans	Any reference to ultrasound scans being done in the private sector
	0513 Hierarchy	References to a hierarchical structure of organisation in the health system, often manifesting as trust
	0514 Importance of communication	References to the need for communication across different parts of the health system (excluding between doctor and patient)
	0515 Government programs	Government provisions, schemes or funds for health system (not related to basic ANC and scanning)
	0516 Late presentation for ANC	Any reference to pregnant women presenting for their first ANC appointments late in the pregnancy (or the exact opposite)
	0517 Role of ASHAs	Responsibilities of Accredited Social Health Activists
	0518 Location of pregnant women on island	Information on where a ANM or subcentre should be in the design exercise
	0519 Role of radiologist	Responsibilities of radiologists
06 Physical environment	0601 Geographic resource distribution	The importance of distributing resources in the health system across all geographies (to cover locations of the whole population)
	0602 Role of natural environment	References made to nature, climate, terrain, or natural resources and how that affects parameters in the health system
	0603 Importance of population density	The effect that population density has on the distribution of resources across a population and health system
	0604 Physical building space	References made to (typically limitations on) physical spaces or buildings available in a health institution
07 Society and Sociocultural elements	0701 Sociocultural influences	Ways in which cultural practices affect health outcomes
	0702 Nomadic populations	References to nomadic parts of the population
	0703 Tribal areas	References made to tribal populations
08 Patient focus	0801 Patient concerns	What patients ask or express concern about any part of pregnancy
	0802 Patient communication	Any reference to communication (e.g. explanation, convincing) between health care workers or officers and patients
	0803 Patient comfort	Factors that affect convenience and comfort to patients (women) accessing care

	0804 Patient delays	References to patients delaying their access to care
09 Tech	0901 Tech training	Interviewee's experience with getting trained for any technology that has been introduced
	0902 Tech maintenance	Any reference to the process of maintaining tech in the PHC or subcentre
	0903 Essential technology	Interviewee's opinion on the most important technologies
	0904 Portable US	References to the importance of portability of ultrasound
	0905 Limited US	Interviewee's opinions on the utility of a US machine with limited functionality (6-7 clinical info determination)
	0906 Internet and electricity access	Presence of internet and electricity at the location of interviewee (PHC or subcentre)
	0907 Need for US image	Interviewee discusses preference or need to see images from ultrasound or for the machine providing images
Clinical info	Congenital anomalies	Reference to detecting congenital anomalies/chromosomal abnormalities/malformations through ultrasound
	Amniotic fluid	Reference to detecting amniotic fluid levels
	Confirmation of uterine pregnancy	Refererence to confirming pregnancy in the uterus
	Dating-LMP	Reference to using LMP to date the pregnancy
	Dating-US	Reference to using ultrasound to date the pregnancy
	Dating-fundal height	Reference to using the fundal height to date the pregnancy
	Cord around neck	Reference to detecting an umbilical cord around the neck of the fetus
	Fetal heart	Reference to fetal heart health
	Fetal movements	Reference to fetal movements
	Fetal position	Reference to fetal position (e.g. cephalic, breach)
	Fetal size and weight	Reference to fetal size, weight, or growth
	Multiple pregnancies	Reference to multiple gestations (e.g. twins, triplets)
	Placenta	Reference to placenta position and health
Miscellaneous	participant didn't understand question	When participant either misunderstood or asked for re-clarification on a question
	Demographic info, clinical experience	Information about the interviewee's career and professional experiences (including training and education) and any other demographic info
	References to the private sector	Any references made to the private sector or differences between private and government sector that are not specifically about ultrasound
	Notable quotes	Salient or rich quotes
	corruption	References to corruption within the public health system
	General advantage of tech	Discussions of general advantages gained from using technologies (that are not ultrasound)

A7. EXAMPLES OF CHARTING

The following pages contain an example of one of the charts (or framework matrices) created to compile, summarise and analyse interview data. Seven such charts were created based on macro categories of thematic codes: design system exercise, social/health system context, benefits and disadvantages of ultrasound, clinical information, ultrasound practice, clinical management post scan, ultrasound solutions and strategy. In this chart, the columns represent codes within the macro category "clinical management post scan" and the rows represent each interview case. The charts were created in NVivo 11, in which each cell provided a reference back to the relevant coded text for that cell.

	A : 0202 Referrals	205 Medical termination or abortion of pregn	C : 0206 Decisions about delivery	D : 0207 Emergencies	E : 02 Interventions post scan- COMBINED	F : 0802 Patient communication
PB	congenital malformations --> PGIMS, GH bad obstetric history (abortions), eclampsia (needs serial ultrasound) --> gynec (but if things are looking good early on might not immediately refer, just look for precautions) write OPD slips with brief history (GH rohtak or nearby gynec), but new req is made there, knows the radiologist with experience you know limitations and when to refer **	after 12 weeks scan impt to detect anomalies and abort (why go through the agony/suffer with malformations) if woman has completed the family can do an MTP, so she will be in a hurry to confirm pregnancy if UPT unclear civil surgeon been very strict, so not in Rohtak anymore, maybe outside	this PHC being major delivery point, where locals feel comfortable. US would have been helpful in patient ex where labor pains happening and suddenly went away later scan impt: cord around neck deliveries shouldn't be done in PHC - practice of having PHC, ASHA, ANM # on calendar in case of high risk delivery happening to make quick decisions easy to refer now because you know what deliveries you can handle and not, no need to take risks for you or for your patient	patients in labor class or Bahtas and Rikkims come straight fully dilated and need to make decisions immediately in PHC, recent ex where labor pains suddenly stopped shouldn't conduct breach deliveries unless real emergency because very stressful	IUGR: convince family to take care of patient, rest, diet cervical incompetence from multiple abortions: if it comes in time we can stitch the uterus US timeliness very important in high risk pregnancies	** explain to village person (10th-12th) so little bit of education, "doctor has a way of saying" that everything is normal. Everyone feels relaxed because ultrasound is like proof. If advise for followup they'll go. need to convince family to take care of ANC in case of less growth. patient needs to have ASHA's number handy to communicate immediately in any situation/delivery; will tell symptoms to be on the lookout for they don't ask about sex, I ask them if it's 3rd child
P1	7th month IUGR issues from liquor or consanguineous marriages --> higher center opinion if issues come at 9th month no choice but to refer to higher center for C-section some not willing to go to higher level govt hospitals, quality worse than private. worried about re-referrals. FRU's have to be good **	1st tri, TIFFA scan thanks to consanguineous marriages, so some babies have malformations, if not correctable, suggest to abort child patient ex: multiple pregnancy, scan showed 1 twin not responding, but couldn't terminate pregnancy because would affect good twin women ask about sex, feticide could be happening, has seen patients come suddenly at 7 months with bleeding	minor things can have drastic impact (e.g. low weight), but also if going to need a C-section because of breach then need to improve Hb status patient ex: twins scan where one has no heartbeat, continue monitoring "if there's any complication we'll go for Caesarean" when things come in 9th month like placenta, no choice but C-section though main goal of PHC is to deliver normally, but mostly to plan delivery. same with breach ** obstetric history: previous C-section means later C-sections too	many who are located far away don't come reguarly for checkups, just emergencies try to plan though sometimes have to do an emergency delivery if tachycardia (high heartbeat), fetus is in distress and have to go for emergency C-section	low amniotic fluid: L-arginine sachets twice a day low weight: ICDS project to get extra breakfast and lunch, can get a double ration, fortified meals to improve weight and Hb content. but needs to be made aware of this first and of consequences to know to improve their diet or Hb status for potential C-sec. patients ask about growth and how to change it some with hormone defects from consanguinity, doesn't matter what intake you have, will still be IUGR factors that can be changed are few: placenta and position have to change on their own, just have to take precautions	different language to talk to woman, "baby is good nothing to worry, focus on diet/exercise" have to make them aware of issues for them to know to do anything, have to explain why US impt (also b/c so many sources of communication, it's confusing) ** complications that are reversible, try to assure patient, explain referrals. console for not wanting to go to gov hospitals ask about sex, tell them you can't say, no one will tell
P2	patient ex, twin referral for delivery. govt or private referral depending on ability to pay. ** scan impt: can know potential problems and refer (early now because scans happen very frequently 15 days,1 month) refer for position, multiple, heart disease (higher Ekapara hospital), placenta, size transportation provided most referrals for delivery not antenatal part, PV done (easier with more experience) patient ex. Achandavaram, twins, no scan report, suspicious from size of abdomen and sent to area hospital, which saved her life	3rd month scan impt: to detect anomalies and abort early to prevent disorders later hasn't heard of feticde happening b/c not finding sex of the baby anymore	patient ex: twins, high risk so referred to higher level hospital for C-section (govt/private depending on econ level) because PHC doctor might not be able to deliver you if you go there 20 years ago didn't have US and mothers/children dying during delivery, now can prevent complications by referring for surgery 9th month scan impt: placenta, refer for C-sectionto prevent bleeding in delivery, also the same with breach and all the other complications fetal size, will refer early to gynec, esp if PIH, but most deliveries in delivery same multiple pregnancy night emerg case	see design exercise and US in PHC: need phone and US in PHC for emergencies emergency example in Achandavaram where suddenly woman shows up with twins but no scans, so just see bulky abdomen, from PV, knew to send to area hospital for C-section. can't wait for some radiologist to come that night	information comes quite frequently so we get it in time and refer early	have to explain results and any problems - twins referral example for gov/private because PHC won't deliver it) - breach, refer to big hospital - explain congenital heart disease, placenta, low growth don't need to convince them, they go women don't ask because they know about law
P3	if any problem in scan, refer to gynecologist in the antenatal period and don't take to PHC at all, deliver in CHC for the C-section setup. no difficulty in making referral decision	early scan impt: congenital anomalies to do MTP if needed and save life of mother hasn't seen or heard of female feticide (nothing, nothing)	US is a must because if any complications in US report we refer to CHC because they can do C-section "once we have US report can plan for the delivery" look for abnormal presentations before the delivery look at the scan to know if you need to refer delivery. used to be very difficult (see US in PHC)	see US in PHC: in the past, used to do trial labor, keep ambulance ready and then move to CHC if emergency, very stressful/dangerous. also emergency for people who are far and suddenly land up in PHC without scans	if fetal size low in 7th month: ensure nourishment and nutrition and re-scan 1-2 weeks later, enough time to give nourishment, can change in 2 weeks	don't need to convince, they come b/c they have fewer children and care more ASHA and ANM motivate women, husband, family to bring into online system ex. 7th month for growth, enough time to educate patient and intervene, improved women don't ask

P4	refer for fetal size (<2kg, otherwise might deliver and rush to pediatrician) and position, if it's already at the station will need to do it, otherwise try to send off because there they have C-section referrals not difficult decision unless there's no histtory ** patients suffer in traveling (hot temps), re-referrals high levels of referrals/load at higher centers	3rd month scan impt: basic viability, if no heartbeat, will terminate terminate the pregannncy if placenta and liquor don't sustain till the term	might deliver low fetal size but will take to pediatrician, if too low then definitely refer for delivery; refer to CHC b/c they have specialists without history, will check vitals, if we think PHC delivery fine, otherwise refer they ask about things that they know will affect whether normal or C-section (position and size)	might do emergency scan for free in CHC if position is breach, and already there then we can't refer, but will try to refer if there's time for the C-section difficulty to know if to refer when woman suddenly lands in PHC with labor pains without reports or history	7th month- low liquor: use sachets intervention will be changed, if liquor is less	tell them to do at least one scan to see viability (and all other stuff) early on, then go to final free scan, if they miss try to motivate for 2nd tri ex. uneducated woman came with small uterus, advised about nutrition. similar examples with nomadic people, but ANMs motivate them ** challenges to convince no one asks about sex and no one tells
P5	refer for surgery if suspicions of less amniotic fluid, FHS, IUGR to area hospital, palakollu, bhimavaram chc ** during antenatal period if still issues in 9th month have to refer her (no more time for intervention) patient ex of coming only 10 days before delivery (not EC from here) will call senior who she knows and tell them about patient if patient delays the referral, might get delivery on the way never difficult to decide to refer as long as scan is clear; need clearer tools to refer ** congenital anomalies must refer to radiologist if can't detect it	if consanguineous marriages leading to fetal anomalies then will ask to terminate to avoid suffering afterwards People avoid the 3rd month scan, and do the 6th month because she insists and then will find undeveloped fetus feticide stil happens but not in this area. might get conducted by non-doctors like ANMs with a machine if you get caught, you lose license to prescribe/do real medical abortions	if less fluid, refer to higher center and it will be C-section because baby will be scratched in normal delivery; if come in 6th month still time, but at end of 9th month have to refer patient ex. who came 10 days before delivery for the first time breach, 3 loops of cord around neck (9th month scan) --> C-section (scanning helps prevent death from these things) as PHC doctor need to know these things and refer	sometimes person won't come till later in pregnancy, and if referred then delivery might happen on the way because she doesn't go on time. if fetal heart lowered in scan need to go for emergency C-section immediately	if low amniotic fluid in 6th month: take sachets and then re-scan in 9th month if low growth: multivitamin tablets, amino acids, protein powder, more fluids, need to start treatment as soon as you suspect, and can only confirm when she brings the ultrasound (and patients often delay this)	amniotic fluid ex: explain about sachets and potential for referral and surgery will explain reason for scanning (either routine or abnormality) and consequences, along with ANM and staff nurse, ASHA (dr also tells them to help communicate) have to insist for them to go **don't have to explain things if do it here they ask, I say zip it
P6	twins case referred to GH, because high risk case and all departments are in district hospital refer for oligo, not always for poly (amniotic fluid), suspected it through fundal height issues and referred for scan referred for twins and oligo, nothing else, send by 108 vehicle (takes 30-1hr to get vehicle), came in with fluid leaked, so immediately referred	hasn't heard of feticide happening	x	x	in cases of polyhdromnios, take rest, bedrest, medication, regulate diet, frequent visits by ASHAs and ANMs	explain the whole report, patient didn't ask anything also convince them to get the scan
P7	if fetal heart sounds decreasing, or come in with pain (in case of C-section) they take reports, with a cover letter. sometimes quality not great there, they will be rude to patient, but will still do the work too many re-referrals ** in emergency, need quick decisionmaking to refer away *	feticide not in our area, though people feel sad about having a female, but educate them, they might try to go somewhere else like Hyd	prefer ANMs to be with them at delivery, ANM is there to make a good delivery 9th month scan: size, if too large, 7th month scan: placenta, amniotic fluid, twin, previous C-section --> all reasons to plan a C-section	ANM are trained so they need to be around the village, to give first line of aid in emergency (e.g. heart attack), same with antenatal, be there with them during delivery see US in PHC-- in obstetrics, many things are emergencies, so needs to be timely, can't wait for people to come from far away	IUGR: improve nutrition even if you know amniotic fluid in 7th month not too late, will tell them to improve oral fluid intake, and then rescan	explain all the report, US should be explained by lady doctor but we also explain. especially ask about date which we tell repeatedly. give advice for any complications get bad communication when they go for referrals (higher) ** patients get angry when equipment is broken ask about sex, says he doesn't know and explain legal problems and gender discrim
PD	patient ex: report came today, but she still suspected some complication so referred to gynec opinion referred for amniotic fluid, twins, early stage heartbeat issues write down history/complaint and send to GH, OPD number (tracking), refer on ambulance	women come back asking her for abortion, without good reason, probably because they did sex determination feticide doesn't really happen anymore because of govt strictness	9th month scan impt: any complication before the delivery	x	x	communicate with ANC b/c they come to PHC mostly, tell all report, any issues ex. where suspicion of complication even though reports were normal, explain some women come on their own to do US, don't have to explain/convince don't ask about sex, but will have gotten it checked somewhere else and come to ask for abortion **

PN	BP monitors on the island and need for periphery referral tools** go through report, if there's any issue refer them **because we can't do anything here**. main question is to know if it's high risk and referral needed for delivery **,**,** write an OPD slip, but they make a separate one there, signature of gynec needed for US; they are at the mercy there. big queues,	20th week scan impt: rule out anomalies to know if need to terminate the pregnancy (through referral)	scan impt to know if woman shouldd be referred to higher center for delivery or if it can be at PHC level if breach/placenta tell them don't try to deliver it where there's no gynec and emerg C-section available "don't wait for yourself to bleed, plan your C-section" patient ex. had to convince whole family that shouldn't try to deliver normally with placenta previa have to refer, not equipped for anything here, USG should be where deliveries/gynec is there where further action can be taken	if breach position tell them they need to deliver in a place with emergency C-section capabilities, can't do PHC. same with placenta, don't try to deliver with normal otherwise will bleed and end up in emergency. plan C-section	go through the report generally and if everything is okay just tell them to generally take care of themselves, otherwise refer we don't keep things here much we usually refer if fluid and growth are detected early can do timely interventions and lessn the complications	go through the report and discuss wellbeing of the child and any diet/other advice. tell about referring in case of anomaly and listen to gynec there better communication here at PHC, therre they are hesitant to talk. they want assurance ** ANM advise that 20th week scan is mandatory placenta example (convincing family to do C-section) ** they don't ask because illegality is deep rooted ****
A1	refer growth, heartbeat issues to CHC bhimavaram or might go to private themselves. if time before delivery do more interventions, otherwise direct referral recent patient ex: breach, 7th month, 9th moonth showed no change so refer to CHC, C-section, motivated her to go **	scan impt: at early stage can tell if organs have formed otherwise opportunity for abortion early	"if they want normal delivery they do as we say, otherwise may not care" dating-US needed to know what the expected date is for delivery and in case of C-section patient ex: referred, labor pains so went straight to CHC, then found breach and did C-section	x	breach presentation: sleep on her left less fluid: write medicines, packets to improve fluid growth: take more food, if time before delivery, otherwise refer *and rescan twins: take more precautions, eat more than normal, don't lift heavy things, travel much	explain about report (presentation, fluid, weight) what to improve. advice like sleeping on left side and nutrition (which they listen if they care about normal delivery) motivate them to get US and madam does too but anyway everyone is getting it done earlier. also motivate for referral by saying normal delivery pains will be too much twins ex. where patients didn't tell ANM for evil eye for a while, gave advice after that sex determination, they ask if first child is a girl, we say we don't know
A2	x	patient ex: 12th week scan for twins, found out one twin wasn't okay, told to abort both the fetus, but parents didn't want to, then found out it was dead-- went to gynec patient ex: 20 weeks scan, no head, abortion hasn't seen female feticide cases, tell the women about the act, no one gives the sex	3rd tri scan impt: to know if it will be a normal delivery or C-section patient ex: scan before EDD showed less fluid so used medicines and C-section scans with position: before EDD we check scan to see if it will be normal or C-section	x	seen a patient with liquor issues, doctor gave treatment, used medicine and did C-section	give full detail of the report, "educate" mother and tell her to take rest and other advices when doctor tells they may not understand, but they have belief in our words and nurses so they are satisfied (we have been with them the whole time). listen to us about when to get US (except not always 1st tri) ask about sex, but we tell it's a crime and gender tests done nowhere, and boy/girl equal
A3	first to PHC doctor, then he will suggest area hospital for ex. if post-term and still no labor pains **	if any problems in 5th month, might need to terminate pregnancy hasn't seen female feticide, they don't say anything about sex, shouldn't be revealed	breach (telegu name): based onr eports, doctors will decide if normal or not, based on that we follow	x	5th month scan to know condition of the baby (for MTP) low weight in 7th month: advice for more nutritious food, or else incr risk low amniotic fluid in 8th month: take more fluids twins ex: rest, no long journeys, no spicy food, has to take extra precaution, more nutritious food were also low weight: so told egg and milk, gave IFA tablets, daal, leafy vegetables placenta ex: don't take tension, journeys, more water, and 7th month it turned back around scans are timely	assure if normal presentation that baby is moving, will check in next scan, to tell if she gets pain, give "moral support." they feel tense and ask not difficult to convince they ask how scanning is, if everything is normal ask about sex, say we don't know anything and it's illegal and boy/girl are equal
A4	patient ex. referred for low amniotic fluid, got medicines, but then let them go for no liability, went to private and got C-section pre-term ** certain hospitals require referrals early in antenatal to do delivery have to call 108, sometimes it doesn't come, then have to take auto, ANM can't do anything on their own anymore, feel bad that we have to refer always in this heat	heard of abortion cases, never faced one herself, which is why PNDT act was created women will ask but she won't say so they can't do anything	patient ex: baby in breach, might change, but if not then C-section so told her to be prepared before going to her inlaws village scan impt: check safety, to know about normal delivery or not (e.g. amniotic fluid less so c-section) before delivery scan impt: sufficient weight, fluid, to know about C-section (although # is increasing, MMR/IMR decr) all complications are C-sec, patient ex. with amniotic fluid where decided to let them go to another hospital. not allowed to do anything on our own anymore	(see US in PHC)-- even though we have experience, have to call 108 and it won't come al the time and take an auto even	if 6th or 7th month and low weight: tell to take food based on scan complications, doctor will give iron and calcium tablets patient ex with low amniotic fluid, referred to doctor for medicines, but they went to private and got C-section, doctor normally suggests packets to improve placenta: have to be careful from the beginning, bedrest, nothing heavy workwise	if no problem, will assure them, explain about any complications and potential outcomes. ex of patient who always calls for suggestions ** no need to convince, they don't listen and do more than necessary explain discrepancies in date, and give advice for when to go placenta interventions they ask about sex, we say we don't know anything

A5	any issues, first refer to PHC doctor then he refers to others, including date if there's no agreement between LMP and scan	if complications under 5 months, can do abortion, but not after 6 months. esp in situations of consanguineous marriage and organ disability hasn't seen female feticide cases	9th month scan impt: any complications with delivery (just to make sure, unless econ condition doesn't let them) tell them that if they don't increase fluid, chance of C-section increases scanning report tells complications, show to PHC doctor, who decides if it's normal in PHC or C-section **	x	US helps identify high risk cases and then suggest solutions by motivating them e.g. abortion (otherwise if you wait till after 6 months it will be delivery and incubation) low amniotic fluid: liquids, coconut water, barley, fruits, juice, tell them that chance for C-section increases, but never faced this case	ex. Gravida 4, parity 1, hgih risk, ANM and doctor told her everything looks fine based on doctor advice, we will educate and motivate them. advise them of solutions based on complications. (breach, saying it could change) give them mental preparation to handle. ** patient happy about communication, other doctors don't give if we motivate them and family correctly they go for scan they ask about sex, we say we don't know anything
A6	any issues PHC doctor will refer, ANM accompanies if they go to CHC, Eluru, Kakinada, not to private less blood, high BP, amniotic fluid, edema, breach difficult to go so far off and leave work so they'll go to private if they can afford, they fear re-referral	hasn't seen female feticide incidents, no one is telling sex	up to 7th month go to outside sources, and then come here after 7th month to delivery (unless not normal)- because they think more expenditure is better decisions on EDD dependent on what actually happen if post-term, do scanning if 36 weeks over, then lady is fine for C-section patients used to not come when no C-section facilities, way more expensive in private hospital	x	twins: advice that you have to take more food, be more careful, bedrest amniotic fluid: medicine packets, saline bottle (has seen such a case), take them to the doctor, usually should ask if they'd like to be admitted but they don't want to do that (should give IV fluids for 2 days). 7th month was sufficient time for fluids, might not be for growth. generally getting info in enough time	ex. ANM asked them to come to PHC but went to CHC instead don't tell them to get scan they go to private and get done on their own. ask about health of the baby, growth, we tell them to be brave and not worry **scans don't always tell everything in them (organs), patients asked why death happened, scan should have showed ask about sex, say no one will tell, we can't say, it's illegal
A7	go with referrals, along with ASHA worker first to PHC, with him write the referral slip and go to GH so MO is aware	hasn't seen female feticide incidents, believes women ask out of anxiety not because they want to abort, only town area people do that, not village	patient ex: breach, could change to normal, but regardless should do delivery at hospital in case make advance birth plan for multiple pregnancy cases patient ex. less amniotic fluid, went to gov hospital b/c of need for C-section	x	growth ex. told her to go to anganwadi center and take food from there, egg, milk, leafy vegetables, iron tablets breach presentation: tell her that position can change in 9th month, take rest in afternoon and sleep well at night amniotic fluid: injections/meds if we know abnormal conditions from US can follow up, conduct regular checkups. immediately bring to doctor. woman will be anxious about baby, scan helps tell her what to do	ex. told her about breach and that it could change. advised about rest. if we tell they will come and get scanning done in time they ask about sex, say they shouldn't tell and there's no difference. they ask to take to a center where they willt ell
G1	referrals should be followed by ANMs and ASHAs, if they don't then they have to go on their own, lack proper history/records crowding because referrals from all the PHCs	consanguinity in certain areas means more threatened abortionsand early abortions done thanks to consanguineous marriages feticide probably happening secretly, but no record for it	without scans can't plan deliveries, based on size of the baby ro twins, position --> have to plan for C-section including all the tools scans essential to maintain safety of mother and child at delivery	x	small baby: giving extra food (big baby planning C-section) no manipulations for placenta (can't do anything), can manually manipulate some of the positions (depends)	x
G2	early scan: early referral referral for the more sophisticated, complete ultrasound for congenital anomalies is a must (potential referral impacts in solutions)	TIFFA scan impt for malformations to be able to "discard" pregnancy can't say if feticide is still happening, no evidence	x	x	x	x
G3	(see the US in PHC affect on referrals)	middle trimester can tell us major defects to guide for fetal abortions feticide not frequent anymore because of govt action, but still going on; given what was going on needed to give the law some teeth	most impt scan info is one which saves lives like C-section being planned in advance (twins, CPD, placenta)	x	x	x

G4	most load of referrals happen for ultrasound anyway, you can only get a date after a month. now all cases high risk or not get referred up to district hospital (#s given for load of hospital) **	high number of congenital malformations and wastage of delivery, so scan diagnosis needed reverse track the miscarriages that happen, especially if woman has had 2 girls already, likelihood of abortion or not which tells us if there's suspicion at the center	x	x	x	x
AD	bring to PHC first and then refer to GH (position, heartbeat, fluid), based on position we know if we need to refer referrals: call 102, for high risk also call the doctor. there's a referral slip. referral process is fine, no difficulty in referring	in 4th month can do abortion, after that we can't (later said 3rd month) hasn't heard of female feticide happening	if position is normal can be in PHC, otherwise GH, based on position we refer **	x		explain reports to the woman, they say "tell me if everything is okay or not" only advises early if problem. push them for govt not private
AN	referred: call 102 and send to GH who sent to PGI. antenatlaly refers to PHC, but in labor refers direct to higher centers ultrasound helps to know to refer	feticide doesn't happen with anyone who comes to her	baby keeps moving around, if breach can't do normal twins ex. told her she needs to go to GH b/c they have machines	x		patient ex with the woman who got pregnancy confirmed only in 4th month (after 2 UPT false negatives): she said if she goes home they will tell her to have the baby, but it's her 3rd child some women get it done before and come to tell her about the baby, say they wanted to know how it is if she wants them to get early she will tell them