Complex reality, implementation and measurement: Evaluation of an electronic decision support system to improve antenatal care quality in South Asia

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Declaration

I, Emma Radovich, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Abstract

High-quality antenatal care (ANC) helps reduce the global burden of maternal and perinatal mortality and morbidity. In Nepal and India, despite progress in ANC coverage, substantial gaps in quality of care remain. Electronic decision support systems (EDSS) have been implemented in many settings with the aim of improving adherence to clinical guidelines, but evidence of their effectiveness remains mixed, and implementation is often challenging.

This mixed-method PhD examined the implementation and consequences of an EDSS that aimed to improve ANC quality in Nepal and India. Data were drawn from the mIRA project and the development and evaluation of a complex EDSS intervention in rural primary care facilities in Bagmati Province, Nepal and Telangana, India. Multiple quantitative data sources were used to describe ANC coverage and quality in India as part of the project's formative phase. Using mixed-method, realist-informed approaches, I examined how EDSS implementation unfolded in Nepal and the effects on healthcare providers' workload in ANC.

ANC quality in the study setting in India identified gaps in some risk screening processes that the mIRA project sought to address, as wells as gaps in counselling and responsive, person-centred care. The EDSS intervention was conceptualised as operating largely through reminders, and the process evaluation focused on documentation and understanding the process of implementation. Fidelity to point-of-care use, which was critical for the reminder function, declined over time as healthcare providers overwhelmingly viewed the intervention as for record keeping rather than decision support. The intervention did not substantially change workload, or healthcare provider performance, in ANC.

The thesis highlights the complexity of improving ANC quality and the mismatch between the potential of an EDSS intervention and how it was used (or not used) in practice, offering an approach for how an EDSS intervention for ANC can be evaluated and its results understood.

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I have studied and worked at LSHTM for as long as I have made the UK my home. Over nearly 10 years I've been fortunate to have so many wonderful colleagues and friends share encouragement, wise advice and laughter. This PhD journey would not have started, nor finished, without such friendship. I particularly want to recognise Lenka Beňová, who gave me the first opportunity, and ongoing mentorship, to imagine a career in research.

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And to Thea, who made my work on antenatal care a lived experience and gave my research and life added meaning. You certainly made this PhD journey more complicated, and yes, I've finished work and will come play with you now.

Table of Contents

List of Tables

List of Figures

Abbreviations

ANC	antenatal care
ANM	auxiliary nurse midwife
BP	blood pressure
CHFW	Commissionerate of Health and Family Welfare (Telangana State, India)
cRCT	cluster randomised control trial
DBT	Department of Biotechnology (India)
DHORC	Dhulikhel Hospital Outreach Center (Nepal)
DHS	Demographic and Health Survey
EDSS	electronic decision support system
GDM	gestational diabetes mellitus
Hb	haemoglobin
HMIS	health management information system
LMICs	low- and middle-income countries
LSHTM	London School of Hygiene & Tropical Medicine
mHealth	mobile health
MoHFW	Ministry of Health and Family Welfare (India)
MRC	Medical Research Council (United Kingdom)
NFHS-5	National Family Health Survey, 2019–21 (India)
OGTT	oral glucose tolerance test
PHC	Primary Health Centre (India)
PHCC	Primary Health Care Center (Nepal)
PHFI	Public Health Foundation of India
PIH	pregnancy induced hypertension
SD	standard deviation
USG	ultrasound scan
WHO	World Health Organization

Abbreviations are defined at first use in the thesis and repeated in research papers, as these are intended to be freestanding.

COVID-19 impact statement

The COVID-19 pandemic impacted this PhD directly through delays to the overall mIRA project of which this PhD is part. Formative phase data collection was completed in 2019 in Nepal and 2020 in India. Data collection in Telangana, India began in February 2020 but was suspended soon after due to the March 2020 national lockdown, and final data collection was not completed until July 2020. The direct delay to formative data collection, as well as interruptions to intervention software development and the limited bandwidth of health officials to engage in (and give approval for) the research during the pandemic, delayed the mIRA project by more than a year.

The delay resulted in some indirect effects on the PhD. While I visited Nepal and India during the formative phase, prior to pandemic lockdowns, I was unable to travel to the study sites or meet in-person with collaborators during the evaluation phase. The delays to the mIRA project also prompted changes to the evaluation design and the decision to implement an additional decision support software, which were undertaken while I was on maternity leave. When I returned from maternity leave in 2022, the evaluation phase data collection was already underway, leaving little time to fully consider the implications of the two decision support systems in the theorising and planning of data collection for the process evaluation and the PhD. I reflect on these issues in the thesis. My substantial work contract on the mIRA project finished before the end of the project's final data collection activities, so I was less able to contribute to some iterative and final analyses for the process evaluation. Analyses for the PhD were completed while I was working on other, unrelated research projects.

Chapter 1: Introduction

This PhD examines the implementation and consequences of an electronic decision support system intervention that aimed to improve the quality of antenatal care provision in Nepal and India. Chapter 1 introduces the PhD work, describing the role of antenatal care, the challenges of providing and assessing good quality care during pregnancy, and the potential role of electronic decision support systems. The chapter presents the larger research project of which this PhD is a part. The chapter concludes with outlining the rationale for the PhD, its aim and objectives, and the structure of the thesis.

1.1 Purpose and importance of antenatal care

Global maternal and perinatal mortality and morbidity remain unacceptably high. Approximately 287,000 women in 2020 died due to complications of pregnancy and childbirth[1], and the burden of morbidity during and after pregnancy is thought to be even higher[2,3]. In 2020, 1.9 million babies were stillborn and 2.4 million babies died within the first 28 days of life, with approximately 75% of newborn deaths occurring in the first week[4–6]. The vast majority of maternal and perinatal deaths were in low- and middle-income countries (LMICs); approximately 16% of maternal deaths and a third of stillbirths and neonatal deaths were in Southern Asia[1,4,6].

Antenatal care (ANC) plays a role in preventing maternal and perinatal mortality and morbidity.[1] Some complications can develop during pregnancy, and most are preventable or treatable; other conditions may pre-date the pregnancy but are worsened by pregnancy if they are not managed[16–18]. ANC offers a critical platform for interventions to improve pregnancy outcomes and is often integrated with other public health programmes, for example malaria prevention via chemoprophylaxis and bed net distribution[19]. ANC is preventive care, with mechanisms in place to identify and treat the minority of pregnant women who develop more serious complications[20]. The aim of ANC is that women and babies remain healthy during the pregnancy and that any complications are diagnosed early and treated appropriately. For most women, ANC is primarily imparting health information, providing some preventive measures (routine mineral/vitamin

[1] The role of ANC, as a programme, in preventing maternal and perinatal mortality rests largely on educated assumptions, rather than scientific evidence[7–9]. This partly reflects historical differences in the content of ANC programmes and high coverage of ANC. Most evidence comes from evaluations of different models of delivering ANC, including trials in the 1990s of the 4+ focused ANC model for low-risk women, on maternal and perinatal mortality and other adverse pregnancy outcomes[8,10–12]. However, strong evidence exists for specific interventions during pregnancy, particularly for preventing or managing the complications of anaemia, hypertensive disorders and infections[7,13,14]. The 2016 WHO guidelines recommending 8+ ANC contacts to reduce perinatal mortality was based on secondary re-analysis of the WHO 4+ focused ANC model trial and further evidence supporting improved safety from increasing the frequency of maternal and feotal assessment in late pregnancy, as well as greater maternal satisfaction with more ANC visits[13,15].

supplementation and vaccinations) and monitoring to make sure the pregnancy is progressing well[21,22]. Monitoring the wellbeing of pregnant women and foetal growth and development is crucial to detecting potential or emerging complications that require more frequent monitoring or intervention, including identification of women and pregnancies that require referral to specialist care. For many women, care during pregnancy initiates a pathway of health system interactions that can shape long-term care-seeking behaviour and offer opportunities to interrupt the chain of events that can lead to adverse pregnancy outcomes[23].

ANC interventions cannot be provided in a single visit but require multiple components of care given at different time points during the pregnancy[13]. In 2016, the World Health Organization (WHO) released updated guidelines for the provision of high-quality care in pregnancy, recommending that women receive a minimum of eight antenatal contacts throughout the pregnancy and receive a range of care components during those ANC visits[13]. The WHO guidelines, in reviewing available evidence, outlined specific recommendations for five types of intervention: nutrition, maternal and foetal assessment, preventive measures, interventions for common physiological symptoms, and health system interventions to improve ANC utilisation and quality[13]. Some essential ANC components—measuring maternal blood pressure, proteinuria and weight, and checking for foetal heart sounds—were considered standard practice and not included in the 2016 guideline update. These components (with the exception of maternal weight measurement, which is usually assessed at the first visit and repeated only as needed) are recommended for every ANC visit[24]. The first ANC visit, recommended by 12 weeks' gestation[13], typically includes taking a detailed medical and obstetric history and physical examination to assess the need for closer monitoring in future visits or more specialised care, such as pre-existing conditions or previous poor pregnancy outcomes. Many of the WHO-recommended care components are woman- and context-specific. The frequency of some monitoring (such as haemoglobin tests for anaemia), and the inclusion of additional investigations and interventions, adapts based on the needs of the pregnancy[13,25].

ANC guidelines have historically emphasised assessment of risk and response to ill health, but there has been increasing attention paid to the experience of care and the maintaining and promoting of positive health and wellbeing during pregnancy and beyond[13,26]. While psychosocial support and provision of health information have long been a part of ANC guidelines, there have been calls to give these components equal emphasis to the recommended clinical investigations and interventions[22,27]. Health education and counselling encompass important provision of information about the pregnancy, including signs of potential complications, preparation for childbirth, newborn care practices, and postpartum family planning[13,25]. A provider's

interpersonal skills and effective communication is essential to provision of health information yet is frequently found lacking[28]. Counselling on danger signs of pregnancy, a critical component of ANC health education, is often the least reported component of care in quality assessments, and even when the counselling does occur, pregnant women report low knowledge of danger signs, suggesting poor communication of this essential information[29,30]. Positive relationships with providers, where providers have the time and capacity to provide personalised information and high-quality, supportive care, enhance ongoing ANC attendance and contribute to more positive pregnancy experiences[20].

However, there is little consensus on measurement of essential components of ANC and how best to monitor the quality of care provided during pregnancy[25,27,31]. A wide variety of process indicators have been used inconsistently across studies evaluating the content and quality of ANC, potentially reflecting differences in country care processes and priorities[27]. A review of health facility assessment tools examined how well the tools captured measures of inputs and processes to provide high-quality maternal and newborn services according to WHO standards[32], finding that a quarter of the quality standards in the review were poorly captured by the tools, particularly standards related to health information systems and the experience of care, including effective communication and emotion support[33]. Many recommended ANC components lack indicators and some components have multiple unique indicators, often driven by what can be reasonably measured in the data source[34]. For example, despite the recommendation for blood pressure measurement at every ANC visit, indicators for this care component have varyingly defined measurement as blood pressure measured at least once during the pregnancy; at least once during the third trimester; or at least five times during the pregnancy[31,34]. Numerous studies point to high coverage but poor quality of ANC in LMICs, usually based on women's self-report of components received at least once[29,31,35]. Household surveys (e.g., Demographic and Health Surveys [DHS]) vary in the ANC components asked, though three indicators have been captured consistently: blood pressure measured, and urine and blood tested[36]. The DHS asks women whether they gave a blood sample for testing at any point during their previous pregnancy. Yet this indicator cannot tell us which blood tests were administered on the sample, the results, or whether appropriate action was taken in response[29,34]. This information is likely better captured via health information systems[34], but this assumes accurate and complete record keeping.

Role of record keeping

Among the challenges for high-quality ANC provision and monitoring is that some care components should be performed at every visit, yet other components might be needed only once or have been

received prior to the current pregnancy (such as tetanus toxoid vaccination)[29]. Further, components may be delivered by multiple providers, in different sectors and facility levels, as women seek care throughout the pregnancy[29,37]. Monitoring pregnancy progress and the delivery of specific investigations and interventions at different gestational weeks is one reason record keeping is of particular importance in ANC. Accurate and complete ANC records document risk factors identified, interventions provided, screening tests administered and their outcomes, and routine maternal and foetal assessments over the duration of the pregnancy. In many LMICs this information is documented in paper records that women carry throughout the pregnancy and bring to health visits, with evidence that these handheld records can improve information availability and continuity[38].

Poor recording of information impedes quality of care and timely intervention. Insufficient or missing information on women's handheld antenatal records can make it difficult for providers to effectively triage and assess risk factors when patients present for delivery care[39]. Incomplete patient records and poor communication between providers of care can also impede the diagnosis of potential or early-stage complications and their effective management. For example, poor documentation of gestational age and foetal growth monitoring can delay identification and management of intrauterine growth restriction. Strengthening patient information systems offers an opportunity to improve the quality of ANC, ensuring that components received in multiple visits, and from multiple providers, are captured and contribute to coordinated care strategies and improved pregnancy outcomes[40].

1.2 Making good quality care happen

The effectiveness of ANC in preventing adverse pregnancy outcomes, depends on the quality of care provided. One study estimated that improving the quality of maternal and newborn health services would reduce maternal and perinatal deaths by a quarter[41]. Despite relatively high coverage of ANC in LMICs, the content of care has often been found lacking[29,35]. Much has been written about the problem of poor quality care in maternal and newborn health services, and the immense challenges in changing practices and getting 'what works' to happen[42–44]. Many strategies have been used to try to improve healthcare provider performance in LMICs. However, developing effective interventions to improve adherence to evidence-based guidelines and ensure pregnant women receive high quality care remains challenging, in part, because interventions found to work in some settings then fail in others.

Understanding the processes of implementation can help to explain why similar interventions may have different results in different settings, providing valuable insights into how and under what circumstances interventions create change[45]. Interventions to improve quality interact with their specific contexts, including organisational factors, healthcare settings, and the individuals involved, and explaining this process requires drawing on theories of implementation[46,47]. Insufficient theorising – about how an intervention works or the strategies to put evidence-based practices in place – can limit opportunities to identify the contextual factors and mechanisms leading to implementation (and intervention) success[47,48]. There are calls for closer study of the processes of implementation in quality improvement efforts in LMICs, where addressing gaps in evidence-based practices could result in large improvements to pregnancy and other health outcomes[44,46].

Studying implementation in evaluations of interventions to improve quality of care is crucial for understanding the factors that influence the success or failure of these initiatives. Guidance on the evaluation of complex interventions has emphasised that the evidence base requires not just answering whether interventions work, but how interventions were implemented, their causal mechanisms, and how effects changed from one context to another[45,49,50]. Often process evaluations of complex interventions have focussed on distinguishing between intervention failure and implementation failure[45]. Fidelity, or the consistency with which the intervention was implemented as intended, is frequently cited in explanations of intervention effects, particularly when a lack of fidelity can be blamed for a null result[51–53]. However, there is increasing recognition of the dynamic interplay between interventions and their environments and how fidelity is moderated by contextual factors[50,54–56]. Seeing intervention effects and implementation processes as contextually contingent requires attention to both intervention design and also the conditions needed to realise an intervention's mechanisms of change in real-world settings[50,57].

Greater understanding of how context influences strategies to improve provider performance is needed[58]. A 2018 review by Rowe and colleagues examined intervention approaches to improve healthcare provider performance in LMICs and found large variability in the effects of nearly all interventions which were evaluated in multiple settings[58]. The authors noted that even among more successful approaches, like group problem solving and training, important performance gaps often remained in the proportion of patients receiving recommended care. Among interventions to improve provider performance and quality of care, digital health interventions have been widely used in high-income settings and are increasingly implemented in LMICs, where they are often delivered via mobile devices[58–61]. Digital health interventions for healthcare providers

demonstrate modest effects on provider performance, though effects vary, as do the settings and specific practices targeted by the tools[58,60,61].

Potential role of electronic decision support systems

Efforts to improve ANC quality have increasingly looked to apply digital health technologies to improve services and strengthen health systems in LMICs[62–67]. Pregnant women frequently have compound needs—co-morbidities, evolving care and complex social support needs—that require healthcare providers to adapt practices in response, while ensuring women receive essential components of ANC throughout the pregnancy. Decision support tools can help providers to meet these needs. Electronic decision support systems (EDSS) are designed to aid clinical decision making, integrating demographic and clinical characteristics of individual patients to generate tailored assessments or recommendations for the provider to consider[68]. EDSS interventions aim to help healthcare providers apply current evidence and guidelines consistently and integrate reminders and advice on diagnosis and management, providing information at the point-of-care[61]. However, few studies of digital decision support interventions for healthcare providers in LMICs have examined outcomes around quality of ANC and provider performance[63,64,66,69]; EDSS interventions have shown modest, though inconsistent, improvements in the quality of ANC[70–72].

There is considerable interest in the potential for digital decision support tools to improve care processes and health outcomes, but the literature on effectiveness remains mixed and offers little understanding about how and in what circumstances EDSS interventions work to improve quality of care[58,73–76]. Factors related to the process of EDSS implementation, including the organisational context, are often poorly investigated, despite being important to implementation and intervention success[77,78]. Contributing to this evidence gap has the potential to advance the design and implementation of EDSS interventions to improve quality of ANC in LMICs.

1.3 mIRA project

This staff PhD was conducted as part of my work on the mIRA project in India and Nepal. The mIRA project ("mHealth integrated model of hypertension, diabetes and antenatal care in primary care settings in India and Nepal") was co-led by the London School of Hygiene & Tropical Medicine (LSHTM) and Public Health Foundation of India (PHFI). LSHTM's involvement lasted from 2018-2023. The project received joint funding from the Medical Research Council (MRC) UK and the Department of Biotechnology (DBT) India; LSHTM and the collaborating partner of Dhulikhel Hospital, Kathmandu University in Nepal were funded by MRC, whereas PHFI was funded by DBT in independent

agreements. The unique funding structure would have important implications for the project's timeline, discussed in more detail in Chapter 2.

The mIRA project aimed to conduct a cluster randomised control trial (cRCT) to evaluate whether a tablet-based EDSS, provided to frontline health workers, would enhance ANC by improving adherence to national ANC guidelines, and improve the screening, detection, referral and management of gestational diabetes and hypertension in pregnancy, compared with usual care, in primary healthcare settings in India and Nepal. In the original research plans, India was to provide 80% of the clusters and trial participants and was statistically powered to be analysed independently, while Nepal would provide additional information from a different context. The originally planned three-year project included a formative phase to develop the EDSS intervention and parallel process and cost-effectiveness evaluations running alongside the cRCT. However, the mIRA project encountered substantial delays, including from impacts of the COVID-19 pandemic. As a result, in 2021, the mIRA project changed course from a multi-country cRCT and split into separate research studies in India and Nepal. The research in India, led by PHFI and funded by DBT, planned to continue with a cRCT[79]. The research in Nepal, led by LSHTM and Dhulikhel Hospital and funded by MRC, shifted to a before-and-after evaluation without a control group[80]. The Nepal study implemented and evaluated two similar EDSS: the custom mIRA EDSS (developed as a result of the mIRA project) and the WHO digital ANC reference module[81], which was added to the study based on formative engagement with Nepali policymakers who were interested in the potential of the WHO EDSS for scale-up. My PhD plans and analyses responded to the changes in the overall research project's design. The mIRA project's evaluation in Nepal found the intervention had no impact on the selected quality of care outcomes and faced numerous challenges in implementation, which are discussed throughout the thesis.

1.4 Rationale of the PhD, aim and objectives

The previous sections described the importance of ANC and challenges in the provision and monitoring of quality in ANC, and introduced the potential role that an EDSS intervention might play in its improvement. The mIRA project sought to improve the quality of ANC in India and Nepal and considered how an EDSS intervention should be evaluated and how its results should be understood. Complex interventions, like an EDSS, work through intersecting causal pathways that are shaped by their context[82]. Process evaluations seek to understand how an intervention works, why and for whom, uncovering the pathways linking an intervention to the outcomes produced[45,49]. The focus and structure of the thesis evolved during my PhD, responding to changes in the overall mIRA

project. However, the knowledge gaps around understanding the implementation of EDSS interventions for ANC shaped the final PhD.

This PhD aimed to examine the implementation and consequences of an EDSS intervention to improve ANC quality. The overall aim is achieved through four objectives:

1. to describe the state of ANC quality in the study setting.
2. to conceptualise EDSS intervention functions and the pathways leading to improved quality of ANC.
3. to evaluate implementation and understand the contextual factors and mechanisms shaping fidelity to the EDSS intervention.
4. to investigate the consequences of the EDSS intervention on changes in workload in ANC.

1.5 Structure of the thesis

This thesis follows a 'research paper' style, with additional linking material. Three papers, which I led as first author, are included. One has been published in a peer-reviewed journal, and the others are presented as manuscripts, prepared for publication. An additional first author paper is included as an appendix, providing the methods for the mIRA project's evaluation in Nepal. Three additional papers I contributed to as part of the mIRA project team have been adapted into a summary of findings from the overall evaluation and are included in appendices.

The thesis is organised into three sections, described here, and summarised in Table 1.1.

Section 1 consists of four chapters outlining the literature, context, and methods of the PhD. The present *Chapter 1* introduces the PhD and outlines the aims and objectives of the thesis. Chapter 2 examines the evidence base for EDSS impacts on clinical care performance in maternal health and provides background on the study contexts in India and Nepal and how the intervention, including the EDSS software, was developed. *Chapter 3* (research paper 1) describes findings from the formative phase study in India on the quality of ANC as captured through multiple data sources, addressing **objective 1** (to describe the state of ANC quality). *Chapter 4* addresses **objective 2** (to conceptualise the EDSS intervention functions), describing the pathways through which the EDSS intervention was hypothesised to lead to improved quality of ANC and the rationale for the design of the process evaluation. It provides methods and context for the selection of study sites and intervention implementation in the evaluation in Nepal, including my role in the mIRA project evaluation team.

Section 2 comprises two chapters addressing findings from this PhD work. *Chapter 5* (research paper 2) addresses **objective 3** (to evaluate implementation): it proposes a realist approach to conceptualising implementation fidelity and provides a worked example of how this was operationalised in a mixed-method assessment of implementation fidelity in Nepal. *Chapter 6* (research paper 3) addresses **objective 4** (to investigate the consequences of the intervention): it presents findings from a time-motion study in Nepal describing change in how healthcare providers spent time during the workday before and after introduction of the EDSS intervention.

Section 3 includes two chapters discussing findings and conclusions of the thesis. *Chapter 7* presents key findings from the mIRA project in Nepal and critical reflections on the results of the overall evaluation. This chapter is based on three papers currently under review or in preparation, which I contributed to as a co-author. *Chapter 8* synthesises findings around the four objectives of the thesis and discusses the contributions and limitations of the PhD. I reflect on the implications of the thesis for the implementation and evaluation of EDSS interventions for improving ANC quality. I conclude with recommendations for researchers and practitioners looking to understand and leverage the potential of digital decision support interventions to change and improve ANC practices.

Table 1.1 Overview of the thesis structure, PhD objectives and related authored papers

Section and chapter	PhD Objective	Authored papers contributing to the chapter
Section 1 – Chapter 1	Introduction and thesis objectives	
Section 1 – Chapter 2	Background	
Section 1 – Chapter 3	Objective 1: to describe the state of ANC quality in the study setting	Research paper 1: Radovich E, Chaudhry M, Penn-Kekana L, et al. (2022) Measuring the quality of antenatal care in a context of high utilisation: evidence from Telangana, India. *BMC Pregnancy and Childbirth* 22, 876.
Section 1 – Chapter 4	Objective 2: to conceptualise EDSS intervention functions and the pathways leading to improved quality of ANC	Radovich E, Penn-Kekana L, Karki S, et al. (2023) Assessing the potential of two electronic decision support systems to improve the quality of antenatal care in primary care facilities in Nepal: study protocol. [Manuscript, published as a preprint]
Section 2 – Chapter 5	Objective 3: to evaluate implementation and understand the contextual factors and mechanisms shaping fidelity to the EDSS intervention	Research paper 2: Radovich E, Karki S, Das S, et al. (2024) A realist approach to implementation fidelity in a mixed-method evaluation of electronic decision support systems to improve the quality of antenatal care in Nepal. [Manuscript, published as a preprint]
Section 2 – Chapter 6	Objective 4: to investigate the consequences of the EDSS intervention on changes in workload in ANC	Research paper 3: Radovich E, Das S, Karki S, et al. (2024) Workload in antenatal care before and after implementation of an electronic decision support system: an observed time-motion study of healthcare providers in Nepal. [Manuscript, unpublished]
Section 3 – Chapter 7	Reflections on evaluation findings	Karmacharya BM, Das S, Shrestha A, Shrestha A, Karki S, Shakya R, Radovich E, et al. (2023) A novel approach to assessing the potential of electronic decision support systems to improve the quality of antenatal care in Nepal [under review] Das S, Radovich E, Karki S, et al. (2024) The impact of digital antenatal care intervention on paper-based recordkeeping: results from an audit of antenatal records in primary health care facilities in Nepal [under review] Karki S, Das S, Radovich E, et al. (2024) The implementation realities of a digital antenatal care improvement intervention in Nepal: insights from ethnographic work in primary health facilities [in preparation]
Section 3 – Chapter 8	Discussion	

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Chapter 2: Background to the mIRA project and intervention

This chapter offers background to the mIRA project and the thesis, beginning with a summary of the evidence base for mobile decision support systems for improving quality of ANC. The chapter describes the role of the project's formative research phase and the process of developing the mIRA project's EDSS intervention, with descriptions of the study contexts in India and Nepal. It provides background on the debates about how the intervention would work (considered in more detail in Chapter 4) and how it would be evaluated, offering context for changes in the mIRA project's evaluation phase and the separation of the India and Nepal studies. This background is important for understanding how challenges faced by the mIRA project shaped the PhD.

2.1 Evidence base for the effect of EDSS on quality of maternal health care

mHealth for maternal and newborn health

Information and communication technologies are increasingly important for health services delivery. Mobile health (mHealth), which WHO defines as "the use of mobile wireless technologies for health"[1], has been enthusiastically embraced by funders, governments and programme implementors, particularly in LMICs. The now near ubiquity of mobile devices and potential of advancing technology to be applied to a range of health issues and behaviours has translated into an enormous diversity of digital tools and rapid proliferation of pilot mHealth initiatives. Less attention has been paid to sustainable, large-scale implementation, and health system effects, including integration with other systems[1,2].

Many mHealth initiatives have important synergies with larger strategies to improve maternal and newborn health access and quality via care in communities, often by strengthening the role of rural healthcare workers. Broadly, mHealth interventions have been used to target communication between health services and patients (such as appointment reminders, test result notifications and health information) or to offer support and services to healthcare providers (such as training, diagnostic or patient management support, and provider-to-provider communication). Although global use of mHealth interventions is increasing, until recently, most evidence on effectiveness was limited to high-income contexts[3]. This is changing. Several recent systematic reviews and reports have examined the feasibility and effectiveness of mHealth interventions for frontline health workers in LMICs[4–10]. Additional systematic reviews have examined the role of mHealth interventions specifically in improving maternal and newborn health services, combining studies of

interventions for pregnant women, families, community health workers and healthcare providers[11–14]. Still other mHealth reviews have focused on interventions specifically targeting pregnant women[15] and those targeting maternal and newborn healthcare providers[8,16,17].

As part of the mIRA project's formative phase (Section 2.3), I collaborated with Dr Monica Chaudhry, PHFI to undertake a rapid systematic review of reviews on mHealth interventions for ANC in LMICs, including interventions targeting healthcare providers to improve quality of care. A review of reviews, variously known as an umbrella review, meta-review or overview, gathers evidence from multiple literature reviews, where the search strategy leads to the identification of review papers rather than primary studies[18–20]. The purpose of the mIRA project's modified review of reviews was not to synthesise evidence of effectiveness but to identify reviews that had included relevant primary studies that could inform the design and implementation of the mIRA project's EDSS intervention and the outcomes to assess in the cRCT. Appendix A details the methods of the systematic review of reviews. Searches were conducted in two databases specialising in systematic reviews, Cochrane Library and 3ie Systematic Review Repository, using key words and indexing terms around two domains: mHealth and literature reviews. Searches were conducted in June 2019; 405 deduplicated records were title and abstract screened, yielding 19 full-text review articles to assess for eligibility. This resulted in 12 reviews included for extraction of primary studies (Appendix A, Table A-4). The primary studies included in the 12 reviews were screened to find those most similar to plans or offering potentially useful ideas for the mIRA project. These primary studies were summarised and referenced in debates about how to implement and evaluate the planned EDSS intervention in India and Nepal.

I returned to the formative phase systematic review of reviews to describe the state of evidence around mHealth interventions to improve quality of care in maternal and newborn health services for the PhD. The publications identified in the review of reviews covered a search timeframe from 1999 to 2018 (Appendix A, Table A-4). Five of the included reviews examined interventions specifically targeting healthcare providers[5,6,16,17,21]; the other reviews examined primary studies of interventions for pregnant women and for providers[11,12,14,22–24].

The reviews identified in the systematic review of reviews, as well as additional and more recent reviews identified via snowball searches, build a mixed picture for the role of mHealth interventions to improve maternal and newborn health services, including ANC. Many of the mHealth interventions included in the reviews were primarily for client education and behaviour change, rather than for providers or improving quality of care. Most of the client-targeted interventions

comprised text message reminders to improve health-seeking behaviour (such as reminders for ANC appointments) – a relatively well-studied intervention with good evidence of success[12,13,22,24]. However, fewer studies in the reviews targeted healthcare providers and their performance, and the evidence base for effectiveness of different mHealth approaches for improving quality of care and maternal health outcomes was mixed or missing[5,6,16,24–26].

The body of mHealth literature often highlighted the potential for impact on care outcomes, but evidence for effectiveness and scalability was scant[25,26]. Several reviews noted that the mHealth evidence base largely consisted of pilot studies[14,24,25,27]. Reviews stated that many studies presented process measures, including the adoption or acceptability of interventions, and fewer studies examined change in healthcare provider performance or the impact on patient outcomes[16,17,24,25,28]. A 2014 review by Aranda-Jan and colleagues called for caution in interpretation of the benefits of mHealth interventions in healthcare provider performance as the design and functions of different interventions varied widely, and few projects were implemented at scale[25]. While the reliance on process measures was frequently critiqued, there has been a slow, emerging shift in the evidence base to using clinical outcomes in studies of mHealth interventions attempting to improve maternal health, though the findings remain uncertain[24,28].

Reviews observed that many mHealth studies inadequately described their intervention and did not explain or critique their intervention's explanatory linkages or underlying assumptions in the theory of change[12,17]. How mHealth interventions lead to improvements in care provision remains underexplored empirically, and there has been a relative lack of theoretically-informed frameworks or models underpinning many mHealth interventions[24,29]. Two recent realist reviews (by Abejirinde and colleagues and Kabongo and colleagues) investigated the mechanisms by which mHealth interventions might improve the quality of maternal health care delivered by healthcare providers and lead to better health outcomes[17,30]. Both reviews emphasised the important role of enabling environments and technology usability in facilitating adoption and utilisation of the mHealth intervention. Abejirinde and colleagues concluded that mHealth interventions were only as effective as the health systems they were embedded within[17]. Kabongo and colleagues posited that the mechanisms of motivation and perceived support, within enabling contexts, improved provider performance[30]. However, as most primary studies included in the reviews focused on process measures, rather than outcomes of healthcare provider competence or performance, evidence has been limited on how or under what circumstances utilisation of mHealth leads to improved quality of care in maternal health.

EDSS interventions and quality of care

The expansion of mobile technology in LMICs creates scope for use of mHealth applications by frontline healthcare providers at the point of care. Mobile devices, including tablets, have increased opportunities to employ electronic health records outside of hospital settings, where healthcare providers can access and input to longitudinal clinical records, contributing to continuity of care[31]. Electronic records often integrate point-of-care decision support tools such as checklists or automated algorithm-based instructions to prompt healthcare providers to follow guidelines[1,31]. Clinical decision support systems can support diagnosis and treatment by presenting healthcare providers with patient-specific recommendations based on information inputted about an individual and can be designed to facilitate thorough, evidence-based care[1]. For example, an EDSS can prompt a provider to screen a pregnant woman for anaemia via a checklist of recommended first ANC visit tests, offer a recommended treatment if found positive, and by integrating information from the electronic health record, can issue a reminder for a follow-up haemoglobin test at a subsequent ANC visit. EDSS are thought to aid providers in applying current recommended practice consistently when interacting with patients and to improve efficiencies by reducing the amount of time healthcare providers need to consider different diagnoses and treatment options[32,33].

Several systematic reviews have examined the impacts of electronic health records[34] and of EDSS on quality of care and health outcomes across a variety of settings[33,35–41], including decision support delivered specifically on mobile devices[6,28,32,42]. Other reviews have examined "e-health",[2] a broad category of interventions that includes electronic health records and computerised decision support systems (on stationary or mobile devices) as well as communication systems and the internet as an information resource[43,44]. While few reviews have specifically focused on EDSS for care during pregnancy[28], several reviews examining EDSS more broadly found substantial numbers of interventions focused on maternal health[6,32].

The literature suggests EDSS interventions can make modest improvements to care provision, though there is considerable heterogeneity—in some studies, the impacts of EDSS on quality of care measures have been substantial[33,36]. A 2011 systematic review of reviews noted strong evidence for the positive effects of EDSS on healthcare providers' performance with drug prescription or preventive care reminder systems but that diagnostic aids have had less positive results[33]. Several reviews concluded that there is insufficient evidence for the effect of EDSS on health outcomes and

[2] WHO considers "digital health" to be an umbrella term encompassing the use of information and communications technology for health, known as eHealth, of which mHealth is a subset[1].

inconsistent findings on quality of care[6,32,36]. Despite the purpose of decision support tools to aid provider performance, not all primary studies reported on quality of care indicators[6]. In a 2021 review of mobile-based EDSS in primary care settings, there was low certainty of evidence for improvements in provider adherence to recommended practices because only two studies reported on this, both of which had few participants[32]. A meta-analysis of trials found EDSS improved the percentage of patients receiving the desired care component by a modest 5.8%, though some studies reported much stronger effects, with improvements ranging from 10% to 62%[36]. The review noted that for some care components, such as vaccination, even a small increase can result in population-level benefits, but for services less strongly linked to health outcomes, modest improvements must be balanced against the challenges and costs of implementing EDSS[36]. The substantial variation in EDSS evaluation results have been attributed to challenges in both the design of decision support software and to the implementation of EDSS in complex systems and settings where multiple barriers exist to providing guideline-recommended care[39].

Despite limited evidence of effectiveness of EDSS, WHO guidance recommends deploying these tools for "tasks that are already defined as within the scope of practice for these health workers"[1]. In part this recommendation reflects positive findings in the literature on providers' views about the acceptability and usefulness of decision support provided via mobile devices[16,28]. A scoping review by Carter and colleagues of mobile apps for decision support in pregnancy found a limited number of rigorous evaluations but noted that ease of use made the apps practical and acceptable tools for healthcare providers[28].

Wide variation in the effects of EDSS have prompted reviews aimed at identifying intervention features associated with successful outcomes[35,40] and systematic reviews of reviews that sought to explain the factors underlying implementation[43,44]. In a 2005 review, Kawamoto and colleagues found more successful trials of EDSS interventions delivered decision support automatically (as opposed to needing to request that the system offer a recommendation) at the time and location of decision making and provided actionable recommendations for healthcare providers[35]. A 2018 review found similar positive findings for EDSS offering automatic decision support but no evidence that offering an actionable recommendation, rather than only an assessment, improved provider adherence to guidelines[40]. Both reviews drew from studies almost exclusively in high-income country contexts, where electronic health records are more common, and neither review considered implementation factors that may be relevant to different types of EDSS[35,40]. EDSS for diagnostic support can be more difficult to implement, compared to other decision support tools, due to the large amount of patient data needed. Where these data are not

already in electronic formats (such as electronic health records) and require manual entry, evidence suggests providers' willingness to use the EDSS declines[33]. A systematic review of reviews from 2012, updated and re-analysed in 2016, examined factors influencing implementation of eHealth interventions, including EDSS[43,44]. Organisational issues, including inadequate resources, were noted as persistent and significant implementation challenges[43,44]. Characteristics of the intervention, such as lack of interoperability with existing systems and complexity in the user interface or in the software leading to slow speeds, adversely impacted implementation. The fit between intervention and organisational workflow was particularly important, as healthcare providers viewing tools as disrupting workflow became a substantial barrier to uptake. Studying the effects on workflow, offering dedicated technical support staff, and providing a transitional period to learn how to use new systems were suggested as strategies to address workflow disruptions[44].

Challenges in summarising the literature

The ever-growing body of literature examining mHealth interventions is becoming unwieldy[28]. This summary of the literature was shaped by the inclusion and exclusion criteria imposed by the included reviews, likely applied, in part, to make the reviews more manageable. Some reviews focused on particular geographic contexts, such as sub-Saharan Africa[6,25] or LMICs more generally[13,15–17,26,30], and others on hospital[33] or primary care settings[32]. These restrictions in setting may help in making comparisons. Other reviews imposed restrictions on intervention characteristics. Notably, Agarwal and colleagues' systematic review of mobile decision-support tools excluded studies of EDSS that integrated electronic health records or longitudinal tracking of patients[32], which likely omitted many interventions, particularly from LMICs, where electronic health records often incorporate EDSS functions[31].

mHealth interventions comprise a range of functions, and several reviews summarised evidence around the technology rather than its purpose, putting the emphasis on the physical object – the tablet or mobile phone – rather than the specific processes and behaviours the intervention sought to change. Many reviews of EDSS defined inclusion based on the mode of delivery, on either mobile devices or stationary computers, combining decision support tools with somewhat different functionality across a wide range of health conditions[32,40]. The resulting reviews encompass heterogeneity in interventions and outcomes, with often ambiguous conclusions. Even reviews examining a particular mHealth purpose, such as EDSS to improve healthcare provider performance, drew evidence from interventions targeting a range of behaviours and health service areas that varied in complexity and clinical skill[31]. This raises the question of whether these mHealth and

EDSS interventions should be reviewed together. Alternate evidence synthesis approaches might include focusing on intervention function(s) to foster better understanding of how the intervention changes a behaviour system[45], though this requires improved reporting of mHealth interventions, including their core functions, technical specifications, and maturity (from prototyping, piloting to scaled deployment)[46].

In summary, the literature is fragmented, with little consensus on the functions, services and settings in which EDSS are likely to succeed or fail. This makes it challenging to understand the potential transferability of success stories to new contexts. Systematic reviews of reviews on implementation factors[43,44] and recent realist syntheses[17,30] offer useful insights in unpacking how and in what circumstances mHealth and EDSS interventions work, but these reviews are only as good as the primary studies that form the evidence base. Despite the mixed picture for improvements in care provision, mobile-based EDSS continue to be implemented across a range of services and settings, raising questions about how and in what contexts EDSS studies might be best able to achieve positive effects on quality of care for maternal health. However, the current body of evidence offers limited guidance for how, when and under what circumstances an EDSS intervention can lead to improvements in care[47].

2.2 Study settings

The mIRA project took place in Telangana, India and Bagmati Province, Nepal. India and Nepal have made significant gains in recent years to improve coverage of essential maternal and newborn health services, yet both contexts face an ongoing burden of pregnancy-related mortality and morbidity.

Telangana, India

Telangana State has high levels of ANC use. India's National Family Health Survey 2019-21 found less than one percent of pregnant women in Telangana did not receive any ANC[48]. In the five years before the survey, 70% of pregnant women received four or more ANC visits. Coverage for delivery care was similarly high with 97% of births taking place in a health facility; the majority of these births were in government facilities[48].

Telangana, like much of India, has a large private healthcare sector, including for maternity services[49,50]. Research by the mIRA project found many women had large numbers of visits to various health facilities throughout their pregnancy, and most made some ANC visits to private sector providers. This was sometimes due to the unavailability of some services in public facilities,

such as lab tests or ultrasound scans, or due to perceptions that the private sector offered better quality of care.

Telangana has an incentive programme known as MCH Kit (formerly KCR Kit) to encourage maternity care use in government health facilities. For care during pregnancy, the MCH Kit programme provides incentive payments and supplies to women for using government services for a minimum of four ANC visits (with additional incentives for childbirth in a government facility and for child immunizations)[51]. For women classified as "low risk" for pregnancy complications, ANC visits take place at government sub-centres, staffed by auxiliary nurse midwives (ANMs), and the supervising Primary Health Centres (PHCs), staffed by ANMs and Medical Officers (MBBS doctors). Under the MCH incentive programme at least one ANC visit should be with an obstetrician at a higher-level facility. For women classified as "high risk" for complications, most of their ANC visits are provided at higher-level facilities, although depending on obstetrician recommendations, women may still receive some ANC components at sub-centre and PHC levels.

Women have handheld paper records to document care received during pregnancy, but some elements of ANC visits are also recorded in the MCH Kit programme's online platform to track incentive eligibility. Only care received at government facilities is captured in the handheld or MCH Kit records. In addition to the MCH platform, Telangana government healthcare providers use a variety of tablet-based software programmes and paper-based registers to track pregnant women, though these are primarily health management information systems (HMIS) or supervision systems rather than point-of-care tools.

Bagmati Province, Nepal

Nepal has made dramatic progress in improving ANC coverage, with more than 90% of pregnant women receiving ANC from a skilled provider, and the provision of quality ANC has become a strategic government priority[52–54]. With its rugged terrain and low population density, Nepal faces an ongoing challenge in creating access and maintaining quality in maternal and newborn health services, though both access and quality of ANC have increased over time[54]. From 2020-2022, in rural Bagmati Province, nearly 80% of women had 4+ ANC visits; 46% of pregnant women reported that their ANC was provided by an ANM as the most skilled provider and 41% by a doctor[52]. Pregnant women in rural areas generally seek care at their nearest Health Post, staffed by ANMs, or Primary Health Care Centers (PHCC), staffed by ANMs and Medical Officers. Dhulikhel Hospital runs 18 outreach centres (DHORC) that are similar in size, staffing and function to PHCCs.

Most women in rural Bagmati Province reported receiving essential ANC services at least once during their most recent pregnancy: more than 80% reported blood pressure measured, urine sample taken, foetal heartbeat checked, weight measured and abdominal examination performed[52]. More than 70% reported a blood sample taken at least once[52]. Counselling on several topics and being asked about potential signs of complications were performed less often, for instance 53% of women reported being asked about vaginal bleeding[52]. However, receipt of services at least once during a pregnancy may overestimate coverage of appropriate frequency of care components throughout the pregnancy, including in Nepal[55]. A 2018 study in southern Nepal found that while blood pressure and weight were measured multiple times, only a third of women were given referrals for blood and urine tests more than once during the pregnancy (ANC guidelines at the time did not require urine or blood tests to be performed at every ANC consultation)[55].

In both government facilities and DHORCs, women are provided with handheld paper records for ANC. Nearly all record keeping is paper based, though some facilities file monthly HMIS reports online to their local municipality or district using laptops or desktop computers.

2.3 Formative research and development of the mIRA project EDSS

Development of the EDSS intervention began during the mIRA project's initial one-year formative phase. The focus of formative research and EDSS intervention development was on the study setting in Telangana, India, where 80% of the facility clusters and participants would be in the planned trial. The formative phase included a review of the literature to identify similar primary studies to inform the selection of outcomes of the evaluation and implementation factors to consider (Appendix A). These studies were referenced particularly in discussions about potential methods to capture the trial's primary and secondary outcomes.

The formative phase also included primary data collection in the study settings. While intended to feed into the intervention development process, formative data collection in India was delayed (see Section 2.4), so planning of the intervention, and creation of the EDSS software, began before the formative research was complete. Analyses of the formative findings from Telangana (including those presented in Chapter 3) were restricted in informing the development of the intervention. Further, formative data collection in Nepal was very limited, with few observations in health facilities or engagement with ANC providers about intervention development. The focus of data collection in Nepal was largely examining the infrastructure requirements—availability of electricity and mobile network connectivity—that would be needed for an EDSS. There were also 10 interviews conducted

with Nepal policymakers and experts in mHealth application development, which identified concerns about how software upgrades and data hosting would be managed with the Indian-developed app.

Software development

PHFI managed development of the mIRA project intervention, including the decision support system software. International and Indian national experts in treating pregnancy complications were convened in four Subject Expert Committees focused on general ANC, pregnancy induced hypertension (PIH), anaemia and gestational diabetes mellitus (GDM) to review existing guidelines and evidence on the management of PIH, anaemia, GDM and other conditions in ANC (Figure 2.1)[56]. The expert committees created a series of decision trees, essentially flowcharts to determine optimal courses of action when faced with a patient presenting with certain clinical symptoms. The decision trees formed the basis of algorithms in the software's decision support system. These algorithms were then modified to reflect differences in ANC guidelines in India and Nepal, such as the cadre of healthcare provider able to perform some care components or whether, for example, iron and folic acid supplements were given as separate or combined tablets. The mIRA EDSS algorithms, partly by virtue of being developed by specialists in treating pregnancy complications, focussed largely on the diagnosis and treatment of complications, rather than other routine ANC practices. This is consistent with the broader literature where many EDSS for care during pregnancy focus on diagnosing and responding to complications. For example, of the 13 studies included in Carter and colleagues' review, six focused on preeclampsia and gestational diabetes, including three papers from the same project, PIER: Pre-eclampsia Integrated Estimate of Risk[28].

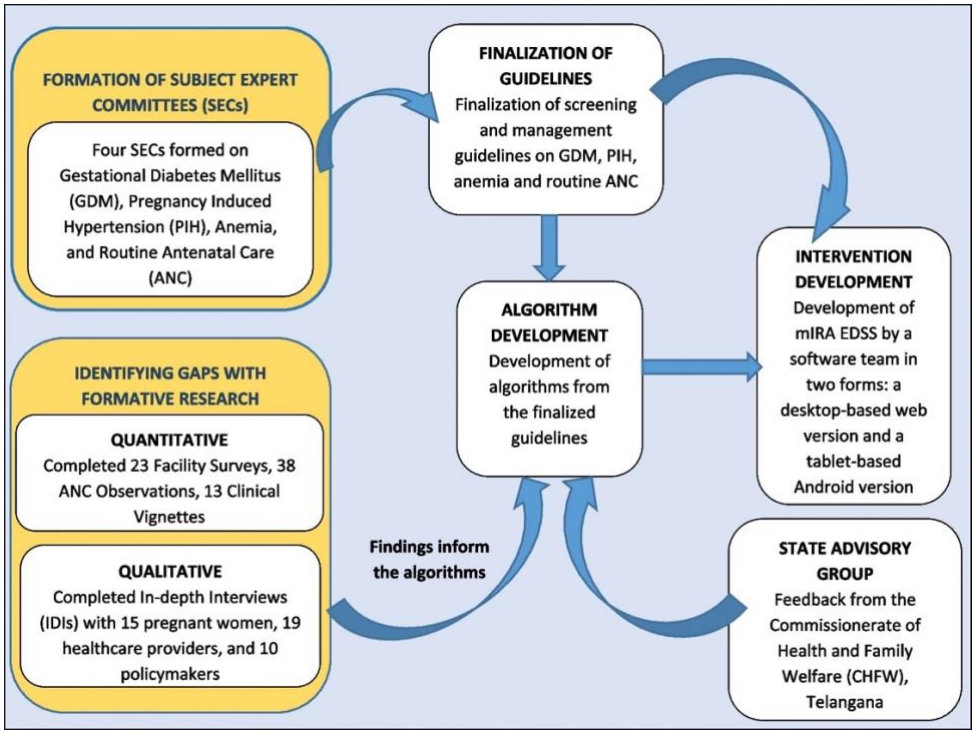

Figure 2.1 mIRA EDSS development process, reproduced from Mohan et al. (2022)

The algorithms developed fed into the EDSS software development (Figure 2.1). PHFI contracted the services of the Telangana-based software development company, Quad One. PHFI investigators had extensive experience working with software developers to create digital health interventions, including EDSS, but this was the first time that PHFI had worked with Quad One. As software development progressed, it became apparent that Quad One, which had previously worked primarily in trial management databases, lacked experience in developing user-friendly health apps. As a result, the software team took far longer to produce a working prototype of the app than had been anticipated, which impacted the project's timeline (Section 2.4).

The MRC-DBT Newton funding call focused on interventions "to prevent, diagnose and manage prevalent chronic and infectious diseases facing women and their unborn children" in LMICs, listing four topics to be the focus of proposals: hypertensive disorders, GDM, anaemia and sexually transmitted diseases[57]. The original mIRA proposal focused on the first two. However, intervention development plans were expanded to include anaemia as it became apparent that the relatively low prevalence of PIH[58,59] and GDM[60] in the study settings would require unfeasibly large numbers of trial participants to have the sample size of cases with complications to detect improvements in their diagnosis and/or treatment. Even with the inclusion of anaemia, the anticipated numbers of pregnant women attending participating facilities during the recruitment period presented issues for the sample size and power of the trial. Other outcomes, including those relevant to all pregnant women, were needed.

As the primary outcomes shifted so did discussion about what should be the focus and function(s) of the EDSS. The debate between focusing on pregnancy complications or routine care also stemmed from investigators' different backgrounds (non-communicable disease vs maternal health) and different research concentrations (clinical response to disease vs quality of ANC more broadly). The PHFI team had worked previously on hypertension and diabetes diagnosis and management using EDSS and other digital tools[61,62], and the focus on non-communicable disease treatment may have informed the emphasis on diagnosis and response in the intervention development process. Other team members, particularly from LSHTM, approached from a perspective informed by the WHO guidelines, which stress the importance of a positive experience of ANC for all women, irrespective of whether they required a response for a pregnancy complication[63]. The mIRA team wrestled with what was the main purpose of the EDSS intervention: was it to improve quality of routine ANC visits? Was it to facilitate identification of pregnancy complications by healthcare providers that might otherwise be missed? Was it to improve lower-level healthcare providers' confidence and/or knowledge in managing pregnancy complications within their scope of practice? And was the primary purpose the same across the two study contexts in India and Nepal?

Questions lingered about the main purpose and what functions should be included in the mIRA app throughout its development. Consideration was given to try to integrate the app with existing HMIS reporting and electronic documentation systems, most notably the MCH Kit system in Telangana[2,31]. However, software interoperability challenges and budget constraints meant it was not possible to integrate these additional functions within the context of the research project.

Ultimately the mIRA EDSS was developed around two functions: 1) guidance through routine activities of ANC by a checklist for medical history taking and physical examinations, and 2) integration of clinical data recorded during examination and history taking to detect potential complications via algorithms[64]. The app software contained multiple components[56]:

i. user interface, also known as the 'front-end' of the app or what the healthcare providers would see on the tablet;
ii. patient database, also known as the 'backend' web-based database hosted on a central server to aggregate data (collating manual inputs and automatic information, such as logins) from the user interface, which could be extracted for reports;

iii. algorithms to screen inputted signs, symptoms and clinical parameters and produce outputs (the decision support component of the software); and
iv. information and clinical guideline documents for the healthcare provider to reference.

Through the user interface, healthcare providers would be prompted by the data entry input forms for provision of care components in the ANC visit and the decision support algorithms would give alerts or recommendations for missing data entry and/or danger signs interpreted from the entered information. Information inputted would include medical history, findings from clinical and physical examinations, and counselling and preventive measures provided. For example, when a healthcare provider recorded a high blood pressure reading (entered values for systolic and diastolic blood pressure equal to or greater than 150mmHg and 100mmHg, respectively), algorithms would prompt the provider to check for oedema of feet, hands, face and ankles and other relevant signs that might suggest hypertensive disorders or mild pre-eclampsia[64]. The algorithms would then suggest a response: a management plan if the software user was logged in as a doctor or a referral to a doctor and/or higher-level facility if the software user was an ANM[64].

2.4 mIRA project timeline

The mIRA project officially began in late 2018, planned as a three-year project that would include one year of formative research and two years for running the cRCT and accompanying process and cost-effectiveness evaluations. From the outset, the mIRA project's joint funding structure – with LSHTM and Dhulikhel Hospital funded by MRC, UK and PHFI funded by DBT, India – staggered the collaborating institutions' funding start dates and set up disjointed timelines for work in India and Nepal. While MRC required LSHTM to begin spending project funds in October 2018, PHFI would not receive any of the awarded funds from DBT until more than six months later (Figure 2.2), and only after a sizable reduction to the PHFI budget. The PHFI budget included all resources designated to develop the EDSS, which could not begin until funds from DBT were released.

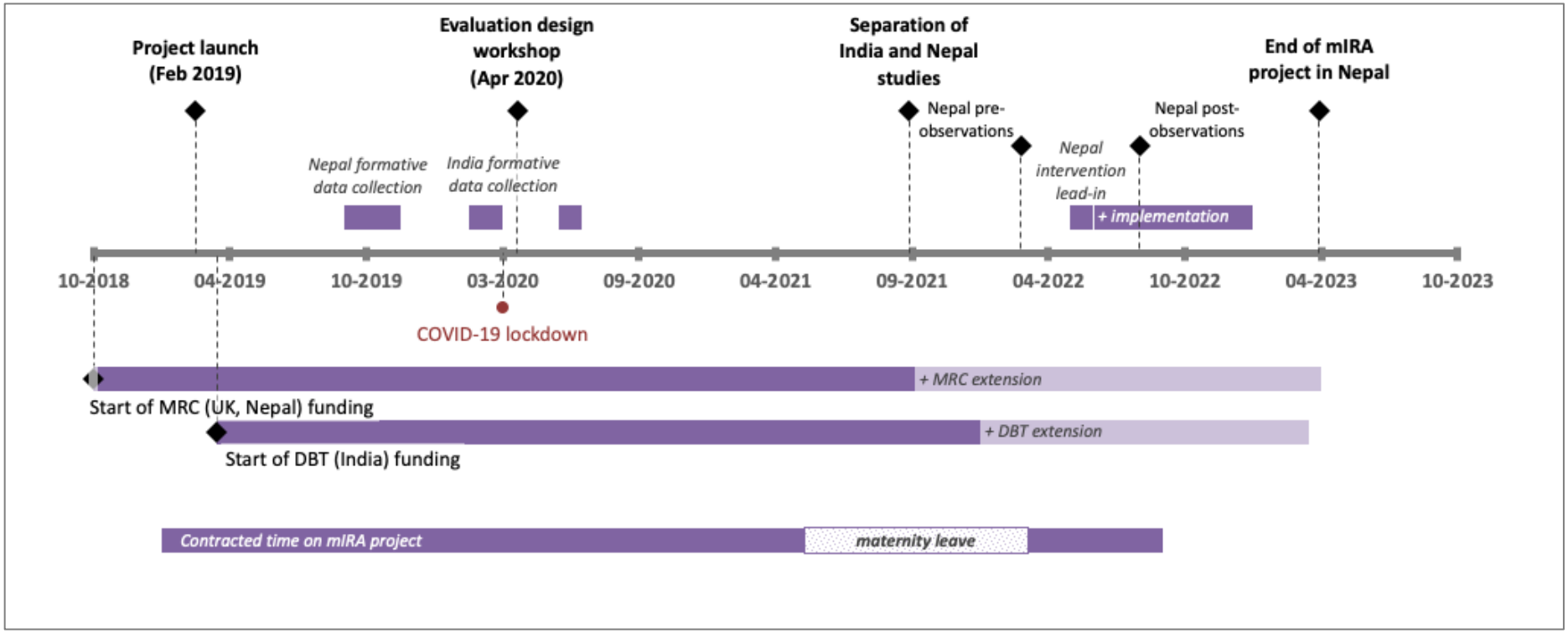

Figure 2.2 Timeline of mIRA project key events

The three collaborating institutions met in Delhi, India in February 2019 for a project launch to begin the formative research phase. However, the project encountered protracted delays in securing approval from the government of Telangana State, India to begin formative phase data collection. The state's Commissioner of Health and Family Welfare, which oversees ANC in Telangana, expressed scepticism about the usefulness of the planned trial and had other priorities in mind for the PHFI researchers. The Commissioner required the PHFI research team to conduct an unrelated investigation into blood testing practices prior to beginning formative phase data collection for the mIRA project. As a result, formative data collection in India did not begin until February 2020 and was shortly curtailed by the national COVID-19 pandemic lockdown on 24 March 2020, resuming several months later (Figure 2.2). The initial interactions with the Commissioner would prove a preview of the unsettled relationship between PHFI and the Telangana State government, where multiple commissioners were appointed and subsequently left (or, in at least one instance, further promoted) over the coming five years, with each commissioner restarting the process of approval for the mIRA project.

Separation of the India and Nepal studies

The software development delays further pushed back the timeline for the proposed multi-country trial and ultimately resulted in the separation of the India and Nepal interventions into independent evaluations. In spring 2021, as I began my 10-month maternity leave, there was still no workable version of the mIRA app available. In late summer 2021, mIRA project co-principal investigators from LSHTM and PHFI took an amicable decision to split the collaborative project into two related but distinct studies. The decision was taken largely due to the divergence in funding periods, where LSHTM and Dhulikhel Hospital (funded by MRC) were due to run out of funds before PHFI (funded by DBT) and would not be funded for the full duration of a trial. PHFI planned to continue with a cRCT in Telangana of the mIRA app, once the software was ready, and state government permissions in place. In Nepal, where local permissions were already in place, Dhulikhel Hospital and LSHTM would conduct a much shorter before-and-after evaluation of the mIRA app, alongside a WHO-developed EDSS. The study in Nepal began in December 2021, with baseline data collection for the process evaluation, and lasted one year. To date (July 2024), the trial that was planned in Telangana has been suspended.

The scope of my PhD shifted to focus on the before-and-after evaluation in Nepal. The original PhD proposed to examine process evaluation indicators from the trial in India and Nepal, taking advantage of the large sample size of the trial – with most clusters and participants coming from India – to enable more

complex quantitative analyses. Chapter 3, describing ANC quality in Telangana, was intended to complement further analyses of evaluation data in India, which did not materialise. The chapter is retained to offer a related perspective on the complexity of ANC quality assessment and provision that informed planning and interpretation of the evaluation in Nepal.

Addition of the WHO EDSS

Following the ongoing delays in the mIRA EDSS software development, and the decision to separate into the two studies (cRCT in India and before-and-after evaluation in Nepal), the Nepal study opted to additionally implement and evaluate another EDSS: the WHO digital ANC module[65]. The change was motivated by concerns about delays in finalising the mIRA EDSS, as well as an interest in learning from and contributing to the developing knowledge base around the WHO app[66,67]. Early iterations of the mIRA EDSS had numerous software 'bugs' and a complicated user interface. It was not clear whether Quad One could produce an improved version quickly enough to enable implementation and evaluation within the timeframe of the research project. Further, Nepal policymakers and collaborating partners expressed reservations about potential scale-up and sustainability of the mIRA EDSS, particularly around future software maintenance by the Indian developers and control over servers hosting patient data – well-founded concerns that plague many digital health efforts[2,68].

The WHO app was viewed by some Nepal stakeholders and members of the mIRA project as a potentially more dependable option for implementation. The WHO ANC app was already functional in 2021 (during these project discussions), though changes were needed to adapt it to Nepal ANC guidelines, and to translate it to Nepali language and incorporate the Nepali calendar. WHO offered guidance on digital adaptation and the decision support logic of the software[69]. The WHO EDSS focussed on facilitating the adoption of the WHO ANC guidelines[63], emphasising screening and routine care components of ANC, with prompts adapted to the capabilities of the health facility (such as the availability of ultrasound) and, like the mIRA EDSS, the scope of care of the particular healthcare cadre. While broadly similar in functionality, the WHO and mIRA EDSS software offered different user interfaces for comparison. Moving from a trial to shorter before-and-after evaluation in Nepal freed some of the project's limited resources to potentially explore differences between two similar tablet-based software systems aiming to prompt healthcare providers to offer quality ANC. Nepal stakeholders were keen to gain insights into which system offered easier and more sustainable implementation.

Outcomes for evaluation

The selection of outcome measures planned for both evaluations in India and Nepal largely reflected considerations for the cRCT in India[56]. Original mIRA project plans for the trial proposed following pregnant women longitudinally to measure whether a woman received selected care components throughout her pregnancy. The focus on diagnosis, and importantly treatment, of pregnancy complications in the proposal called for follow-up measures. Women could be diagnosed with PIH, GDM or anaemia at different points in the pregnancy, and treatment responses would differ based on the timing and severity of the diagnosis. Whether the mIRA EDSS would facilitate improved detection of complications *and* improved response was viewed as essential to understanding the potential health effects of such an intervention.

There were two problems. Firstly, the mIRA project's increasingly shortened timeframe for implementation and evaluation, as software development dragged on, made following women for the duration of their pregnancy unfeasible. Secondly, the intervention setting in India presented care-seeking patterns that threatened to dilute the effects of the intervention over the course of a pregnancy. Formative research for the mIRA project in Telangana found pregnant women sought care from a range of ANC providers, with some ANC visits taking place at the government primary care level facilities planned for intervention and other visits at higher-level facilities or in the private sector. In interviews, women reported large numbers of ANC visits throughout their pregnancies, sometimes double the eight or more visits recommended by WHO. Women in Telangana also travelled, particularly towards the end of pregnancy, to stay in their mother's home, receiving final ANC visits and delivery care in different localities from their usual residence. The intervention planned for government PHCs and sub-centres in Telangana would potentially reach a fraction of the numerous ANC visits women were likely to receive during their pregnancies. Any potential effect of the intervention would be mitigated by care received during the pregnancy from providers not taking part in the intervention. If care from outside providers was of poor quality, then any positive effect from care in intervention facilities could be diluted. There were also risks of contamination between trial arms if women selected for outcome measurement in control facilities received care at intervention facilities during their pregnancy.

While sympathetic to the desire to measure responsive care throughout the pregnancy, I realised the Indian study setting presented a problem of intervention dose for a trial outcome measured at the level of a pregnancy[70]. I proposed a change to a per visit outcome. A proposal to change the level of outcome

measurement added to spirited debates about the purpose of the intervention. The mIRA project team held a multi-day online workshop in April 2020 to discuss the components of the intervention and the outcomes of the evaluation. A few colleagues and I argued that improving the content of care of ANC consultations was a necessary prerequisite to improved content of care over the entire pregnancy, and a per pregnancy outcome was unlikely to detect potential improvements in quality of care. There was understandable resistance to a measurement change, particularly as a per visit outcome was at odds with efforts to capture person-centred care in ANC including services received and experiences of care throughout the pregnancy[71]. Practical considerations for the mIRA project evaluation ultimately took precedence.

The result was a compromise: the primary outcome for the trial became a hybrid per visit, per pregnant woman measure. Based on observations of ANC consultations, the primary outcome for the cRCT would measure the mean number of four selected ANC components[3] delivered per ANC visit, observed over two visits (maximum score of eight)[56]. Pregnant women would be observed at an enrolment visit (not necessarily the woman's first ANC visit, just the visit following consent to participate in the research) and the next routine ANC appointment. Some of the trial's secondary outcomes would be measured only for the enrolment visit[56].

These same primary and secondary outcomes would be used in the before-and-after evaluation in Nepal[72].

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Chapter 3: Measuring the quality of antenatal care in a context of high utilisation: evidence from Telangana, India (research paper 1)

This chapter was conducted as part of the formative phase of the mIRA project in India. The published research paper presents findings from analyses of four primary and secondary data sources from Telangana, India, integrating different dimensions of ANC quality to create a more holistic description of the care pregnant women received. It relates to objective 1 of the PhD (to describe the state of ANC quality in the study setting). The types of data in the analysis – statewide household survey, statewide health service statistics, facility survey, and observations of ANC consultations – are often examined and written up separately, giving a partial view of the multifaceted issue of coverage and quality in ANC. This paper examines how findings from the four analyses build upon or contradict each other and what this means for improving ANC quality measurement. The paper identifies specific areas for improvement in ANC in Telangana and recommends ways to better capture different dimensions of quality, including responsiveness and women's experiences of care.

This chapter was published on 25 November 2022 in *BMC Pregnancy and Childbirth*. The manuscript was published under Creative Commons license (CC BY 4.0) and is included in full. The paper and supplementary files are available at: https://doi.org/10.1186/s12884-022-05200-1

3.1 List of Figures

Figure 3.S2 – Percentage of ANC observations with in which specific symptoms were asked about in the ANC consultation, stratified by facility type [Supplementary material]

Figure 3.S3 – Percentage of ANC observations with components of education, stratified by facility type [Supplementary material]

3.2 List of Tables

Table 3.1 – Number and percentage of ANC visits and components of care received for the most recent pregnancy that ended in a live birth in the five-year survey recall period among women living in Telangana, NFHS-5 (2019–20)

Table 3.2 – Selected ANC services statistics from HMIS reported from public facilities for April 2019 to March 2020

Table 3.S1 – Percentage of ANC consultations in which each component of measuring blood pressure correctly was observed [Supplementary material]

3.3 Citation

The paper presented is minorly adapted from:

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3.4 Research paper cover sheet

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Student ID Number	1402301	**Title**	Ms
First Name(s)	Emma		
Surname/Family Name	Radovich		
Thesis Title	Complex reality, implementation and measurement: Evaluation of an electronic decision support system to improve antenatal care quality in South Asia		
Primary Supervisor	Prof. Oona Campbell		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Pregnancy and Childbirth, as: Radovich, E., Chaudhry, M., Penn-Kekana, L. et al. Measuring the quality of antenatal care in a context of high utilisation: evidence from Telangana, India. BMC Pregnancy Childbirth 22, 876 (2022). https://doi.org/10.1186/s12884-022-05200-1		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I had the initial idea for the paper and conceptualised the study with Dr. Monica Chaudhry and Dr. Clara Calvert. I conducted the quantitative analysis of the National Family Health Survey 2019-21 and the health facility survey. I selected and calculated, with inputs from MC and CC, the indicators for inclusion from the Health Management Information System aggregate data obtained by MC. I also suggested and led the mapping of the different data sources onto the WHO framework to illustrate what they could tell us about different components of quality. I wrote the first draft of the manuscript with inputs from MC and CC, prepared the journal submission with consideration of co-author comments, and led the revisions and responses to peer review feedback process.

SECTION E

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Date	22 May 2024

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RESEARCH Open Access

Measuring the quality of antenatal care in a context of high utilisation: evidence from Telangana, India

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Abstract

Background: Antenatal care coverage has dramatically increased in many low-and middle-income settings, including in the state of Telangana, India. However, there is increasing evidence of shortfalls in the quality of care women receive during their pregnancies. This study aims to examine dimensions of antenatal care quality in Telangana, India using four primary and secondary data sources.

Methods: Data from two secondary statewide data sources (National Family Health Survey (NFHS-5), 2019–21; Health Management Information System (HMIS), 2019–20) and two primary data sources (a facility survey in 19 primary health centres and sub-centres in selected districts of Telangana; and observations of 36 antenatal care consultations at these facilities) were descriptively analysed.

Results: NFHS-5 data showed about 73% of women in Telangana received all six assessed antenatal care components during pregnancy. HMIS data showed high coverage of antenatal care visits but differences in levels of screening, with high coverage of haemoglobin tests for anaemia but low coverage of testing for gestational diabetes and syphilis. The facility survey found missing equipment for several key antenatal care services. Antenatal care observations found blood pressure measurement and physical examinations had high coverage and were generally performed correctly. There were substantial deficiencies in symptom checking and communication between the woman and provider. Women were asked if they had any questions in 22% of consultations. Only one woman was asked about her mental health. Counselling of women on at least one of the ten items relating to birth preparedness and on at least one of six danger signs occurred in 58% and 36% of consultations, respectively.

Conclusion: Despite high coverage of antenatal care services and some essential maternal and foetal assessments, substantial quality gaps remained, particularly in communication between healthcare providers and pregnant women and in availability of key services. Progress towards achieving high quality in both content and experience of antenatal care requires addressing service gaps and developing better measures to capture and improve women's experiences of care.

Keywords: Antenatal care, India, Quality of care, Maternity care

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Background

The last few decades have marked substantial successes in increased coverage of essential maternal and perinatal health services in low- and middle-income countries (LMICs). In particular, coverage of antenatal care (ANC) has risen dramatically, as measured by whether women had four or more ANC visits, which alongside skilled birth attendant coverage, is one of the most widely used summary measures of maternal health programme performance[1,2]. There are concerns that the ANC 4+ visit indicator has focused on advances in mere contact, rather than the process and content of ANC, obscuring large gaps between coverage of services and the quality of care received[1,3]. This coverage-quality gap has been blamed for the persistent burden of maternal and perinatal mortality and morbidity[4,5].

Several studies have combined indicators of ANC contact with capture of the care components received in order to measure 'effective coverage' for pregnancy care[1]. These studies mostly rely on household surveys, such as Demographic and Health Surveys, which use women's self-reports of care components received during the most recent pregnancy that ended in a live birth. This includes some routine elements that should be done at each ANC visit (e.g., blood pressure (BP) measurement), but women are asked only if they received the component at least once. The studies found that ANC 4+ visits and coverage across selected components of care correlated relatively well, as fewer visits meant fewer opportunities to offer/obtain care components[1,3]. But while some LMICs had high coverage and high content of ANC, many did not; perhaps more troubling, some had high coverage but poor content[1]. In India, for example, the National Family Health Survey 2015-16 found that 51.2% of women had at least four ANC visits[6]; further analysis, however, revealed that only 23.5% of all women received adequate ANC which was defined as care delivered by skilled health personnel, registration of pregnancy and first ANC visit within the first trimester, 4+ ANC visits and with appropriate content[7].

New measures are needed to understand the care pregnant women receive[1,3,8,9]. In 2016, the World Health Organization (WHO) released new ANC guidelines, recommending an increase from four to eight or more ANC visits, emphasising person-centred care and well-being, and recognising the complexities of providing and monitoring quality ANC in diverse health systems[10]. The WHO conceptual framework for quality ANC highlights the multiple dimensions of quality, including content and women's experience of care, and various inputs needed to deliver routine ANC, including equipment and competent healthcare providers[9]. Measures reflecting services received

at least once during pregnancy, such as those assessed on household surveys, are limited in assessing whether women were adequately followed throughout their pregnancies[8]. Among screening components, such as for syphilis or anaemia, there are often no indicators for whether women screening positive received adequate treatment, resulting in data gaps for capturing maternal and foetal assessment and appropriate response[9]. Further, few studies consider women's experience of care. Examining these different dimensions and inputs is critical to creating a holistic picture of quality of ANC.

Rethinking ANC quality assessment is particularly helpful in settings with high coverage like Telangana, India where nearly all pregnant women access ANC[11]. In Telangana's ANC programme, pregnant women are expected to receive frequent ANC visits, including two visits in the first trimester to a sub-centre and one to a primary health centre (PHC) to register the pregnancy, provide an obstetric history and receive preventive and screening interventions (such as haemoglobin and syphilis testing). If no risk factors are identified, then pregnant women should have monthly primary care level facility visits and two visits to a higher-level facility with a gynaecologist in the second and third trimester. Women identified with high-risk pregnancies have monthly primary care level visits alongside multiple visits with a gynaecologist at a higher-level facility. The National Family Health Survey 2015-16 showed that in Telangana, 75.0% of women with a live birth in the previous five years had 4+ ANC visits, and among those who received ANC, reporting of selected components, such as BP measured, was nearly universal[12]. Yet these coverage measures do not reveal whether pregnant women received the care components correctly, at the right time and frequency, and with an appropriate response.

This paper takes a multi-dimensional approach to examine quality of ANC in Telangana, India based on four different sources of data.

Methods

Data sources

Four quantitative data sources were analysed in this paper. Two comprised secondary analyses of statewide data: 1) the most recently available National Family Health Survey (NFHS-5) 2019-21 for Telangana; and 2) state health management information system (HMIS) data for 2019-20. Two were from primary data collection undertaken in 2019-20 in the context of formative research for a

quality improvement intervention[13] in selected districts of Telangana: 3) a facility survey; and 4) observations of ANC consultations.

We adapted the WHO quality of care framework for ANC[9], situating the four data sources to show how we were capturing different components of the framework (Figure 3.1).

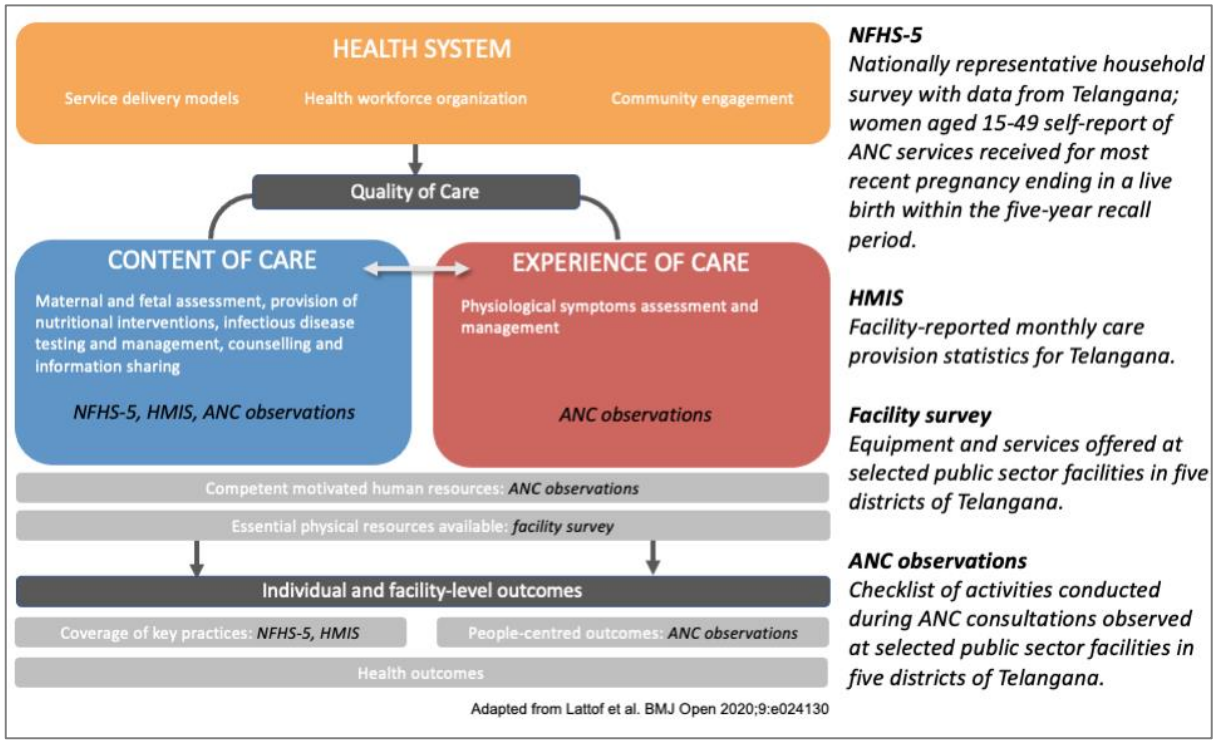

Figure 3.1 Four data sources included in this analysis mapped to the WHO framework for the quality of antenatal care. ANC= Antenatal Care

Data collection

NFHS-5 (2019-21)

The NFHS-5 was a nationally representative household survey using a multi-stage, cluster sampling design and providing national, state-level and district-level estimates of household and individual characteristics and reproductive health measures, amongst other topics. All women aged 15-49 in the selected households were eligible for interview. Data collection in Telangana was conducted from June to November 2019[11]. Questions on ANC were asked of the pregnancy resulting in the most recent live birth in the five years before the survey.

HMIS

India's Ministry of Health and Family Welfare (MoHFW) collects routine HMIS data primarily from public sector healthcare facilities, including monthly service delivery statistics[14]. In Telangana, HMIS data are digitally tracked by auxiliary nurse midwives at sub-centres and reported to their respective PHCs, which upload the aggregated data to the district level. Telangana aggregate HMIS data were obtained from the Commissionerate of Health and Family Welfare (CHFW) for ANC service delivery information for the period of April 2019 to March 2020.

Facility survey and ANC observations

Primary data collection was conducted in randomly selected primary care level health facilities within five districts of Telangana (Medak, Rangareddy, Siddipet, Vikarabad and Yadadri Bhuvangiri). A list of public sector facilities was obtained from the CHFW for each district in Telangana. Facilities <100 minutes driving time from the CHFW office in Hyderabad constituted the sampling frame. The sampling frame was then stratified by the facility level (sub-centres and PHCs) and two PHCs were selected at random from each of the five districts. Under these two PHCs, we randomly selected one associated sub-centre (total of two sub-centres in each district). After obtaining permission from the district health authorities, two trained research scientists visited the selected health facilities, and conducted the facility surveys and ANC observations.

A facility survey was conducted in 19 health facilities: 10 sub-centres and 9 PHCs. During data collection, one PHC selected from Yadadri Bhuvangiri was discovered to have been upgraded to a community health centre and was excluded from this study. The survey used a tailored ANC infrastructure assessment tool, adapted from the Service Provision Assessment facility inventory questionnaire[15]. The survey was administered using paper-based questionnaires by a trained researcher (KRKR) who obtained written informed consent and conducted interviews with the facility manager and the most knowledgeable staff person available for each health service area.

ANC observations were undertaken opportunistically at the selected study facilities; if a pregnant woman attended for ANC on the day the study team visited the facility, then the woman and the healthcare provider were asked to consent to have the ANC visit observed by a clinically trained researcher (RV). ANC observations were guided by a checklist of routine activities based on relevant WHO and MoHFW of India guidelines and on a clinical observation tool previously used to assess routine childbirth care in Uttar Pradesh[16]. The ANC observation checklist covered activities that should be conducted either at the first or subsequent ANC consultations. The checklist was used to

understand the process of care, how was it provided and how clinical notes and documentation of the ANC visit were captured in the client's and facility records. The paper-based facility survey and ANC observation forms were double entered into Microsoft Access to ensure accuracy.

Data analysis

NFHS-5 (2019-21)

All women aged 15–49 with a live birth in the survey's five-year recall period living in Telangana were included in the analysis. For the pregnancy leading to the most recent live birth, we examined women's self-report of the location(s) of their ANC, number of visits, timing (in months) of their first ANC visit, and the components of care received. These components included whether the woman was told about pregnancy complications, had her weight measured, abdomen examined, BP measured, and urine or blood samples taken during any of her ANC visits. We calculated the number of pregnant women who reported four or more ANC visits and those who reported eight or more ANC visits. Women who reported visiting any government health facility or government outreach programme (such as village clinic with auxiliary nurse midwives) were considered to have received ANC from a public sector facility. We additionally examined a subset of women who reported receiving ANC from a public PHC or sub-centre to facilitate comparisons to the other data sources. Less than 0.01% of women with a live birth were missing the number of ANC visits (n=7); these were assumed to have had fewer than four visits. Two women were missing the timing of their first ANC visit and were assumed to have had their first visit after 4 months gestation. There was no other missing data in the analysis. The NFHS uses a multi-stage cluster sampling strategy, which we accounted for in statistical analyses.

HMIS

Due to likely underreporting from private sector facilities[14], we included only public sector service statistics in this analysis. All pregnant women registered for ANC seeking care from a public sector facility were included in the analysis. We extracted statewide service statistics from the 2019-20 report for total number of pregnant women registered for ANC, and amongst pregnant women registered we calculated the proportion who registered within first trimester (up to 12 weeks gestation), received 4+ ANC visits, tested for blood sugar using oral glucose tolerance test (OGTT), received haemoglobin (Hb) tests four or more times in ANC, diagnosed with severe anaemia (Hb<7), tested for syphilis, and diagnosed sero positive for syphilis. Amongst those with severe anaemia or syphilis, we also assessed the proportions who were treated.

Facility survey

We used survey data from 19 facilities, stratified by facility type, to look at two main domains: ANC basic equipment and ANC key services, reporting on the percentage of facilities that had an item within each domain, as well as the mean total score. For ANC basic equipment, we checked for the availability of a total of eight items of equipment required in delivery of routine ANC services: examination bed, measuring tape, height rod, examination light, BP measuring apparatus, stethoscope, fetoscope, and adult weighing scale. The functionality was also checked for five of the eight listed items (examination light, BP apparatus, stethoscope, fetoscope and adult weighing scale). For the ANC key services, or the infrastructure and processes to provide quality ANC, we evaluated whether ten key services were routinely offered and whether their associated equipment and commodities were available, functioning and, if relevant, had valid expiration dates. The services checked included iron and folic acid supplementation, tetanus toxoid vaccination, biochemical investigations (urine protein, blood/urine glucose, anaemia, and syphilis testing), routine measurements (weight, BP), and whether counselling was offered on eight core topics (minimum four visits, birth preparedness, planning transportation for delivery, family planning, breastfeeding, newborn care, postnatal care visits, healthy eating and physical activity). For a facility to be considered to offer an item within the ANC key services, they had to report that they provided the service and, where necessary, had the appropriate equiptment and supplies available.

ANC observations

We used data from 36 observations of ANC visits: 16 at sub-centres and 20 at PHCs. We assessed how well components of ANC were delivered by the healthcare providers by looking in detail at four domains: 1) respectful care (kind greeting, offered a seat, asked woman if she had any questions, discussed physical exam and washed hands with soap if undertaking a physical exam); 2) physical examination (BP, weight, fundal height, pallor, foetal heartbeat, oedema, foetal lie/presentation, pulse rate, respiratory rate and jaundice); 3) current symptom assessment (asked about decreased foetal movement, severe abdominal pain, persistent vomiting, severe difficulty breathing, vaginal bleeding, frequent painful urination, foul smelling vaginal discharge, swollen face or hands, headaches or blurred vision, woman's mental health, palpitations, convulsions/loss of consciousness and fever); and 4) education (informed woman of pregnancy progress, counselled on danger signs, discussed nutrition and healthy eating, discussed next ANC visit details and counselled on birth preparedness).

Within each domain, key items from the observation checklist were identified by two clinically trained researchers. Items were tabulated to assess frequency of performance of routine activities. We excluded items not expected to be done at every visit. We restricted analysis for items that should be performed after 22 weeks gestation[10] to the observations of women who were at 22 weeks gestation or greater (assessment of fundal height, foetal heartbeat and foetal lie/presentation and asking about decreased foetal movement). To judge healthcare providers' performance as an element of quality of care[9], we also examined nine indicators of good practice for measuring BP in the ANC observation tool: asked if patient had tea/coffee, back supported during measurement, feet rested, measurement taken on the left arm, arm rested, sleeve rolled-up, cuff band 1-2cm above elbow, cuff at heart level, and deflation rate no more than 2-3 mm Hg/s[17–19]. We also reported the percentage of ANC consultations where the woman was tested, or referred for a test, for proteinuria, haemoglobin, blood/urine glucose and syphilis.

Results

NFHS-5

We included 5,429 women in Telangana whose most recent pregnancy ended in a live birth in the NFHS-5 (2019-20) analysis. Nearly all women had one or more ANC visits (99.3%), 70.5% had 4+ ANC visits (guideline during part of the survey's recall period) and 20.7% of all women had 8+ ANC visits (the new WHO guideline) (Table 3.1). Nearly three out of four women received all six assessed content of care components during pregnancy (72.7%). Being told about potential pregnancy complications at any point during ANC was the lowest performed component (73.7% amongst all women). The remaining five care components were nearly universal (97-99%). Coverage of contact and content of care components received were similar amongst all women and amongst women who received care at public sector facilities.

Table 3.2 Number and percentage of ANC visits and components of care received for the most recent pregnancy that ended in a live birth in the five-year survey recall period among women living in Telangana, NFHS-5 (2019-20)

	All women with a live birth in the five years before survey (n = 5,429)		Women who attended for any ANC at a public sector facility (n = 3,062)		Women who attended for any ANC at a public PHC or Sub-Centre (n = 651)	
	%	(95% CI)	%	95% CI	%	95% CI
Contact						
1 + ANC visits	99.3	(98.9 – 99.5)	-	-	-	-
First visit at < 4 months pregnant	88.5	(87.4 – 89.5)	87.8	(86.2 – 89.3)	88.8	(85.3 – 91.6)
4 + ANC visits	70.5	(68.6 – 72.3)	71.8	(69.2 – 74.2)	76.7	(72.6 – 80.4)
8 + ANC visits	20.7	(19.0 – 22.5)	20.7	(18.6 – 23.1)	24.4	(20.3 – 29.1)
Content						
Told about pregnancy complications	73.7	(71.5 – 75.8)	74.7	(72.0 – 77.3)	77.1	(72.4 – 81.3)
Weight measured	99.1	(98.7 – 99.4)	99.8	(99.5 – 99.9)	99.6	(98.6 – 99.9)
Abdomen examined	97.3	(96.6 – 97.8)	97.9	(97.1 – 98.5)	98.9	(97.7 – 99.5)
Blood pressure measured	99.0	(98.6 – 99.3)	99.7	(99.4 – 99.8)	99.5	(98.5 – 99.8)
Urine sample taken	98.9	(98.5 – 99.2)	99.6	(99.3 – 99.8)	98.9	(97.7 – 99.5)
Blood sample taken	98.9	(98.4 – 99.2)	99.5	(99.1 – 99.8)	99.1	(97.9 – 99.6)
All 6 above components received	72.7	(70.5 – 74.8)	73.6	(70.8 – 76.1)	76.1	(71.3 – 80.3)

CI Confidence Interval, *ANC* Antenatal Care

HMIS

HMIS monthly reporting for public sector facilities for April 2019 to March 2020 showed high coverage of ANC visits and registration: 84.4% of registered pregnant women had 4+ visits and more than 70% registered the pregnancy within the first trimester (Table 3.2). Haemoglobin tests for anaemia had high coverage; out of the total number of registered pregnant women, there was >100% coverage of testing more than four times, probably due to the discrepancy in service users compared to registered pregnant women (see Table 3.2). Coverage of two other key screening tests in pregnancy was lower. Less than one in 10 registered pregnant women were screened for gestational diabetes using an oral glucose tolerance test and 30.6% of women were tested for syphilis. There were gaps in treatment as well: 22.2% of women testing positive for syphilis received treatment and 40.2% of women diagnosed with severe anaemia did.

Table 3.3 Selected ANC services statistics from HMIS reported from public facilities for April 2019 to March 2020

	Pregnant women registered for ANC (n=758,853)[1]	
	n	%
Contact		
Registered within first trimester	541,828	71.4
4+ ANC visits	640,526	84.4
Content		
Had **blood sugar** tested using OGTT	64,899	8.6
Had **anaemia** tested for 4+ times	834,292	109.9
Of those tested, those diagnosed with severe anaemia	52,632	6.3
Of those with severe anaemia, those treated	21,184	40.2
Had **syphilis** test	232,085	30.6
Of those tested, those diagnosed with syphilis	3,852	1.7
Of those with syphilis, those treated	857	22.2

[1] Number of women registered for ANC at public sector facilities may not reflect the total number of service users, which can include pregnant women who registered before the stated period or who registered at one facility but sought care at multiple public and private facilities, sometimes in different districts, during their pregnancy. *ANC*=Antenatal Care; *OGTT*=Oral Glucose Tolerance Test

Facility survey

The mean scores for ANC basic equipment (out of a total of eight possible) were 4.8 and 5.3 at sub-centres and PHCs, respectively. Overall, only one facility surveyed (a PHC) had all eight items. The highest score in the sub-centres was observed to be seven, which was obtained in two of 10 facilities. The most frequently missed items of equipment in PHCs were a functioning examination light, weight scale and height rod (Fig. 3.2a). No sub-centres had a functioning examination light, and only half of sub-centres had a functioning stethoscope or weight scale.

The mean scores for ANC key services functioning (out of a total of 10 possible routine service components) were observed to be 5.5 and 7.1 for sub-centres and PHCs, respectively. Overall, no facilities surveyed offered all 10 components. The highest score observed in sub-centres was eight, seen in one of the 10 sub-centres surveyed, and the highest score observed in PHCs was nine, seen in two of the nine PHCs surveyed. Counselling on all eight core topics was reported provided in all the facilities. Tetanus vaccination and syphilis testing were not available at any of the sub-centres (Fig. 3.2b). Weight measurement and syphilis testing were available in two of the nine PHCs surveyed. Urine protein testing was available in five of the nine PHCs and in two of the 10 sub-centres surveyed.

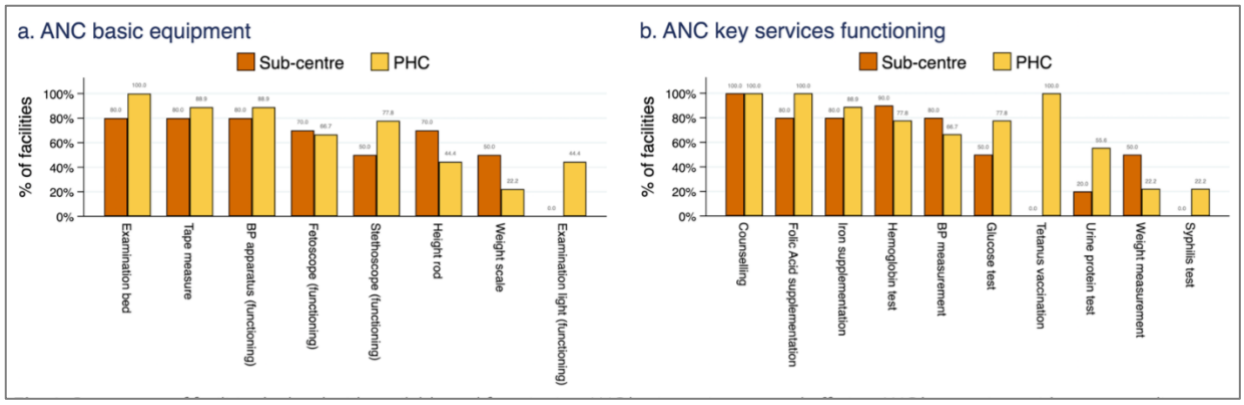

Figure 3.2 Percentage of facilities by level with available and functioning ANC basic equipment and offering ANC key services with corresponding functioning equipment and supplies

ANC observations

Of the 36 ANC observations, two were of women in their first trimester (≤ 12 weeks gestation), 14 in the second trimester (13 to 26 weeks gestation), and 20 in the third trimester (≥ 27 weeks gestation). Twenty-two observations were conducted with women of at least 22 weeks gestation.

For the respectful care domain (Supplementary Figure 3.S1), a kind greeting was observed in 33 of the ANC consultations (91.7%) and the woman was offered a seat in 35 (97.2%). In only 22.2% of the ANC consultations were women asked if they had any other questions. A total of 35 women had a physical examination and, in only one of these, the healthcare provider discussed the steps of the physical exam with the woman. In none of the aforementioned 35 observations did the healthcare providers wash their hands before conducting the examination.

Figure 3.3 shows the percentage of ANC consultations in which each of the 10 assessed physical examinations were conducted. The highest number of physical examinations covered in a single ANC consultation were nine out of 10 (amongst three women). Overall, fewer than 50% of ANC observations had checks undertaken for oedema, pallor, pulse rate, respiratory rate and jaundice. Weight (88.9%) and BP (97.2%) were the two most frequently conducted physical examinations. However, there were some issues in the quality of the BP measurements. Amongst the nine indicators of good practice for measuring BP, no observations scored nine; however, six observations scored eight (Supplementary Table 3.S1). Overall, 22.2% of women were tested, or referred for a test, for proteinuria, 69.4% for haemoglobin and 91.7% for blood/urine glucose. A total of 34 women (94.4%) were referred to another facility for syphilis testing.

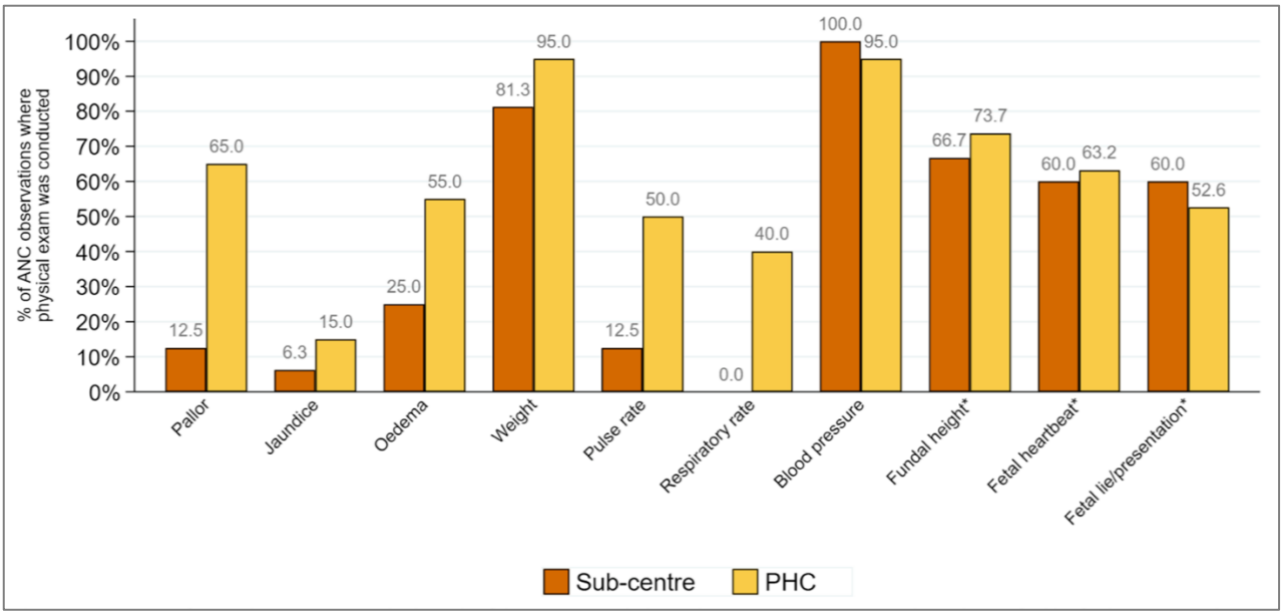

Figure 3.3 Percentage of ANC observations in which each of the 10 assessed physical examinations were conducted, stratified by facility type
**Only includes ANC observations at 22 weeks gestation onwards (n=22)*

Symptom assessment (Supplementary Figure 3.S2) and education (Supplementary Figure 3.S3) were generally done poorly. In very few observations were women asked about symptoms they had been experiencing, and the most commonly asked about symptom in the current pregnancy was decreased foetal movement (63.6%, 14/22 ANC observations among women of at least 22 weeks gestation). Only one woman was asked about her mental health. Nutrition and healthy eating were discussed in 77.8% of consultations, and the next ANC consultation details were discussed in 72.2%. Counselling of women on at least one of the ten items relating to birth preparedness and on at least one of six danger signs was done in 58.3% and 36.1% of consultations, respectively. Women were informed about pregnancy progress in 44.4% of consultations.

Discussion

We analysed four data sources from Telangana that examined different aspects of quality of ANC, finding some important deficiencies in the quality of care despite high levels of utilisation. Analysis of the NFHS-5 for Telangana showed very high statewide coverage of assessed components, though counselling on pregnancy complications was the least performed component of care. Likewise, HMIS data showed high coverage of ANC visits but significant gaps in screening for syphilis and gestational diabetes. The facility survey in selected districts showed moderately equipped facilities. Some key services such as urine protein testing, which should be monitored regularly throughout pregnancy, and syphilis testing, which should be performed at least once during pregnancy, were unavailable in

most of the facilities surveyed. While many ANC services or equipment items were commonly available individually, no facility in our sample offered all 10 components of routine ANC services. In the ANC observations, most women received adequate physical examinations, though some quality issues were noted in performance of BP measurement. However, symptom checking and client education were poorly done.

We found that clinical content of care, in particular maternal and foetal assessments, had high coverage and examinations – where we could evaluate these – were generally performed correctly. Despite high coverage of some important screening assessments (e.g., haemoglobin testing), there were also notable gaps in coverage and service availability (e.g., syphilis testing). This finding was obscured in the NFHS-5 results because women were only asked if they ever had their blood tested, not which specific tests performed. Some assessments that should be performed at every ANC visit, such as BP measurement, had nearly universal coverage in both the ANC observations and in the NFHS-5, which asked only if BP had been measured at least once during the pregnancy. However, other assessments, such as urine testing, had high coverage in the NFHS-5 when asked if urine testing had been performed at least once during the pregnancy, but coverage for urine protein testing, or referral for a test, showed considerable gaps in the ANC observations. This echoes findings from a survey of pregnant women in Kenya which found substantial disparities between receipt of key services at any point in pregnancy and receipt of those services at the recommended frequency[20].

We found that care often lacked the communication between the healthcare provider and pregnant woman that is important to high-quality, person-centred care[21]. The NFHS-5 and ANC observation data showed poor provision of information, with little counselling on potential signs of pregnancy complications. ANC observations showed poor psychosocial and emotional support. Few women in our ANC observations were asked about any current physiological symptoms or their mental health – important components of women's experience of care[9]. Poor counselling in ANC has been documented in other LMIC settings, with calls for better measuring and improving the quality of information provision in ANC[22,23]. The focus on guideline-driven care, particularly with increasing technical content of clinical care[10,24] and emphasis on examinations, can negatively impact interpersonal aspects of quality[21]. Further, busy clinics or those with restricted hours or staff for ANC can often afford little time for meaningful provider-patient interaction[24].

Our findings demonstrate how data sources build upon or contradict one another to provide a fuller picture of the quality of ANC in Telangana, contributing to a growing body of literature on measurement of ANC quality[8,9,21,25]. As others have found, components of ANC provision vary widely in quality and taking multiple data sources together can reveal quality gaps. For example, a study in rural Tanzania found that while pregnant women were highly satisfied by their care in exit interviews, data from observations and facility audits found ANC consultations frequently missed important care components, often due to stock-outs of medications and screening tests[26]. Another study of hospitals in Nepal found poor provision of recommended components during ANC observations; qualitative data from providers and pregnant women echoed these findings, attributing the observed poor performance to insufficient human resources, infrastructure and supplies[27]. Others have noted opportunities for integrating household survey and facility survey data to estimate composite measures of effective coverage of ANC interventions[28].

Indicators frequently drive the focus of improvement efforts[29]. Existing ANC quality measures mainly encompass indicators of content of care and of health system inputs with only a few measures of women's experience of care[8,9]. Our ANC observation tool attempted to address this by examining whether women were asked about current pregnancy symptoms, given an explanation about the physical examination or given an opportunity to ask questions, drawing on components of respectful, person-centred ANC[20]. Given the historic relative emphasis on clinical assessments over counselling in ANC guidelines[10,21], it is unsurprising that we found limited provision of information to pregnant women. Incorporating better measures of women's experience of care will require greater consensus on what matters to women and what can be effectively measured, including through ANC observations, exit interviews with pregnant women, and household surveys[8,9,21].

Improving measurement of the quality of ANC includes opportunities to better assess responsiveness of care. For example, assessment of clinical practice could include whether women were told what their blood and urine samples were for and were given the results of screening tests. This could be assessed by observing ANC consultations or through exit interviews or surveys with pregnant women, although further validation work is needed on whether women can self-report this information. High-quality ANC should be responsive to individual women's needs; where complications are identified, additional indicators on whether women received an appropriate response or treatment are needed.

Our analysis offers multiple strengths in bringing together four different data sources, but we encountered several limitations. Firstly, our data sources cover different time points, reducing some comparability of findings, particularly from the NFHS-5 five-year recall period. The facility survey and ANC observations were conducted in a small number of facilities in the selected five districts. While the facilities were randomly selected, the inclusion criteria for the sampling frame reflected logistical constraints and may not be representative of all PHCs and sub-centres in the districts.

Results from HMIS were hampered by questions about data quality and whether the available denominator – women registering their pregnancy at a public facility – was the most appropriate one. The counts of women extracted from the annual HMIS report (April 2019-March 2020) reflect imperfect numerators and denominators in a setting where pregnant women access care at many different facilities, including within different districts and within the public and private sector. So for example, while a pregnant woman might register at one public sector facility, and be recorded as receiving haemoglobin tests there, she might also receive multiple haemoglobin tests at different public facilities, leading to an overcounting of haemoglobin testing coverage as we observed. Despite this, the HMIS results yield a useful, though imperfect, picture of variability in service coverage.

The ANC observations offered invaluable insight into quality of care during a single ANC visit, but both data collection and analysis were challenging. We found it difficult to find the right balance between designing a data collection tool which covered all possible components of ANC and designing something which was feasible for fieldworkers to complete during the ANC observation. Pre-testing revealed the data collector would observe ANC consultations and later finish filling in the tool, as it was too challenging to observe and complete the long checklist. This introduced potential for misclassification or recall bias. Healthcare providers may also have improved the quality of care while under observation, though we note that substantial quality gaps remained. Additionally, analysing the observation data required integrating the results from the checklist with additional information about the woman's stage of pregnancy and previous care received – elements that the tool was not fully designed to address. Each ANC observation was assessed individually by a clinically trained researcher, integrating information available in the woman's handheld ANC card and whether or not it was the woman's first ANC visit at that facility (or any facility). This limited the replicability of the analysis, and the amount of time needed to assess each ANC observation meant that this method would be challenging to do at large scale.

Conclusion

The high coverage of contact with ANC services in Telangana and appearance of high-quality care as measured by receipt of selected care components obscured deficiencies in elements of quality. Some clinical assessments, such as BP measurement, showed consistently high coverage across multiple data sources, but important gaps around counselling, provision of information and psychosocial support remained. Household and facility survey and routine facility data are limited in capturing measures of a pregnant woman's experience of care, but there may be scope for better capture of responsiveness of care provision and communication about the specific interventions and tests provided. Addressing these gaps will require indicators and data to measure progress towards achieving high quality in both content and experience of ANC.

Availability of data and materials

Data from the National Family Health Survey can be accessed from USAID's Demographic and Health Survey program (https://dhsprogram.com/data/available-datasets.cfm). Health Management Information System data are available from the Ministry of Health & Family Welfare, India. De-identified data from the facility survey and antenatal care observations can be requested from Dr Monica Chaudhry (monica.chaudhry@phfi.org).

List of abbreviations

ANC: antenatal care

BP: blood pressure

CHFW: Commissionerate of Health and Family Welfare

Hb: haemoglobin

HMIS: health management information system

LMIC: low- and middle-income country

MoHFW: Ministry of Health and Family Welfare

NFHS-5: National Family Health Survey, 2019-21

OGTT: oral glucose tolerance test

PHC: primary health centre

WHO: World Health Organization

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Contributions

ER, MC and CC conceptualised the study and conducted the data analysis. ER drafted the paper with substantial inputs from MC and CC. KRKR and RV contributed to the development of the tools, conducted data collection for the primary data sources and aided analysis. LPK helped with data interpretation and design of the ANC observation study. AM helped with data interpretation. PJ contributed to tool development and data collection for the primary data sources. OMRC and DP are overall mIRA project co-PIs and, with SM and CC, helped secure funding and contributed to the mIRA project design. OMRC helped design the facility survey and ANC observation studies. All authors reviewed and approved the final manuscript for submission.

Ethics declarations

Ethics approval and consent to participate

Ethical approval for the primary data collection was obtained from Public Health Foundation of India (TRC-IEC-386/18) and London School of Hygiene & Tropical Medicine (17715-1) review boards. Telangana CHFW granted permission for the primary data collection and extraction of HMIS data. National Family Health Survey 2019-21 data was obtained with permission from USAID's Demographic and Health Survey Program. Health facility managers, healthcare providers and pregnant women participating in the primary data collection and women interviewed for the National Family Health Survey 2019-21 provided written informed consent for their information to analysed for research studies. For the extraction of HMIS data from the state report, written consent was not necessary for this type of aggregate operational research; the results did not involve individual patients, and none of the results can be traced back to individual health facilities or healthcare providers. All methods were performed in accordance with the relevant guidelines and regulations.

Competing interests

The authors declare that they have no competing interests.

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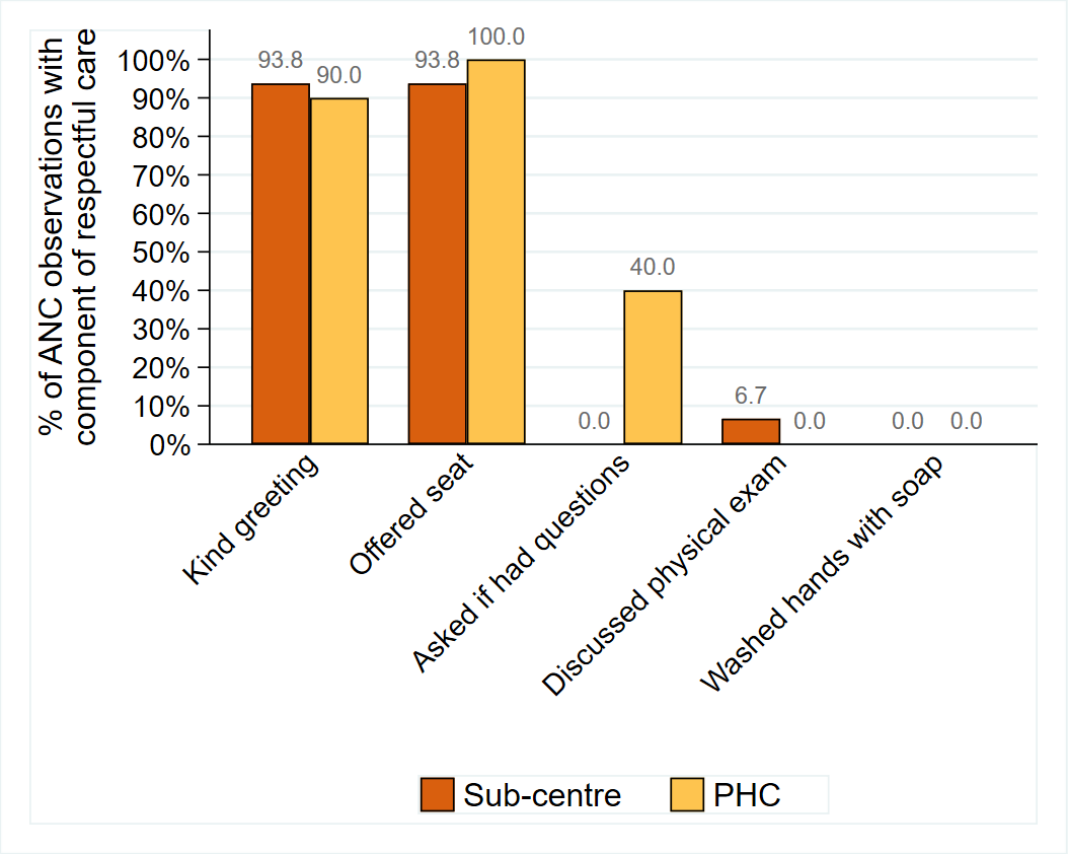
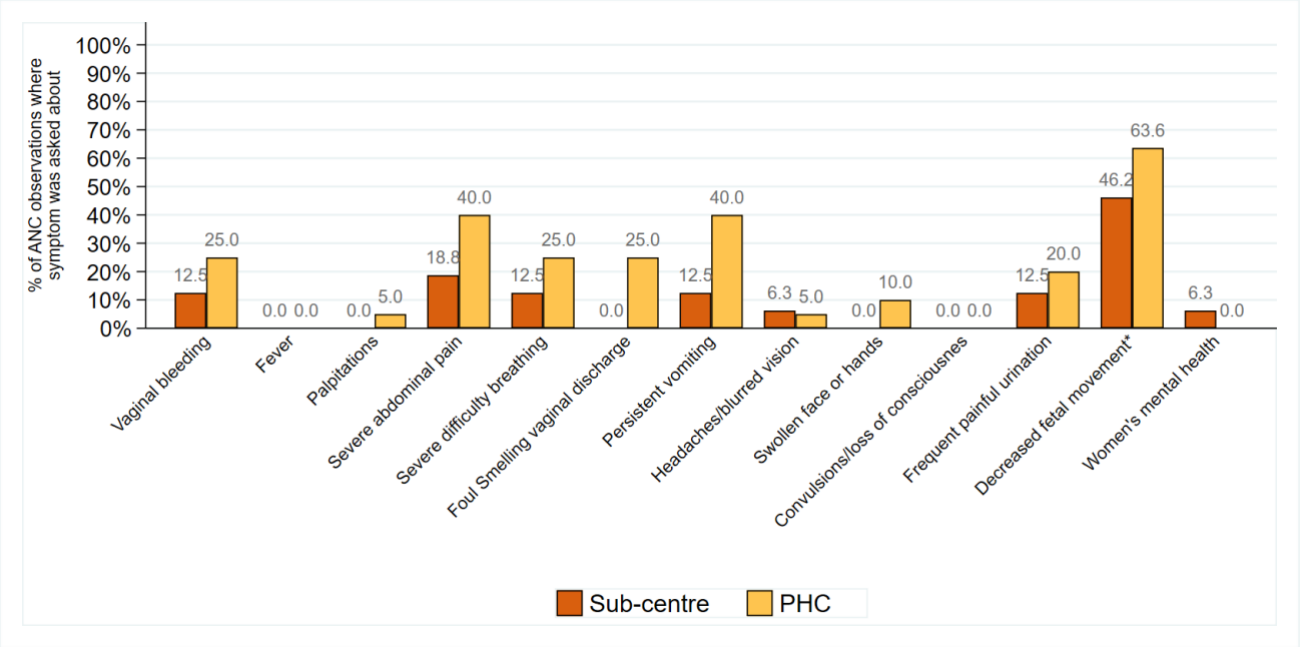
Supplementary Material



Supplementary Figure 3.S1: Percentage of ANC observations with components of respectful care, stratified by facility type

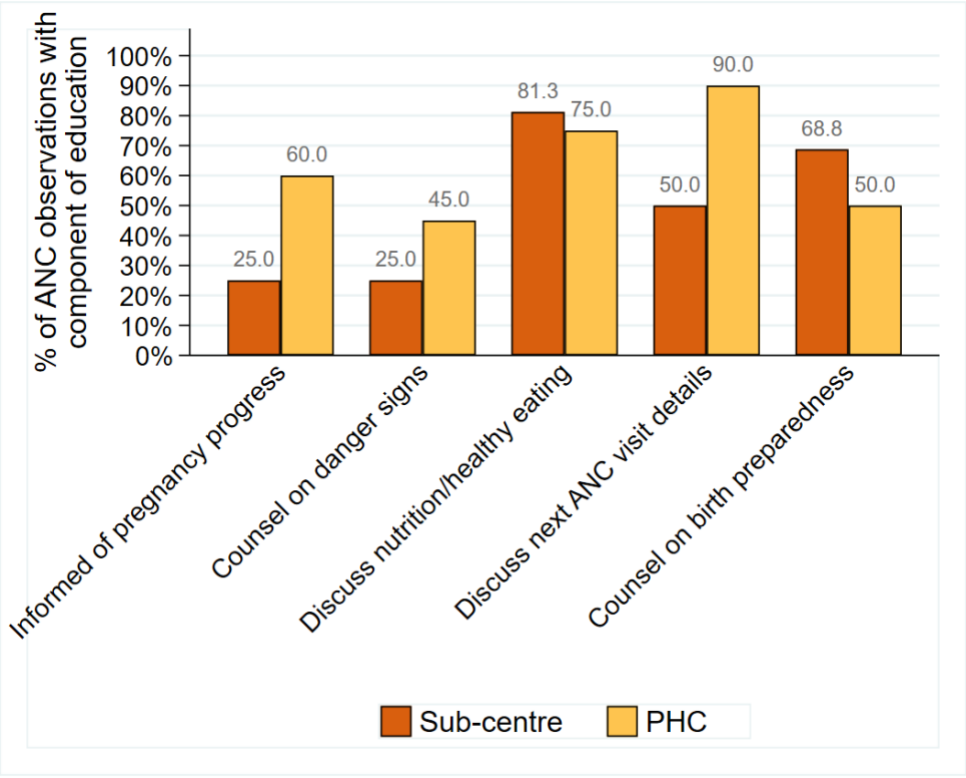
Supplementary Table 3.S1: Percentage of ANC consultations in which each component of measuring blood pressure correctly was observed (N=35, with one ANC observation excluded as there was no physical exam)

Blood pressure component	Percentage with component of blood pressure measured correctly	
	Sub-centre (n=16)	PHC (n=19)
Asked if the patient had tea or coffee	31.3	52.6
Back supported during BP measurement	12.5	15.8
Feet rested	87.5	94.7
Measurement taken on the left arm	81.3	52.6
Arm rested on the table	56.3	79.0
Asked to roll-up sleeve	81.3	73.7
Lower band of cuff positioned 1-2cm above the elbow	87.5	84.2
Cuff at heart level	87.5	94.7
Deflation rate of not more than 2 to 3 mm Hg/s	100	89.5



Supplementary Figure 3.S2: Percentage of ANC observations with in which specific symptoms were asked about in the ANC consultation, stratified by facility type

**Only includes ANC observations at 22 weeks gestation onwards (N=22)*



Supplementary Figure 3.S3: Percentage of ANC observations with components of education, stratified by facility type

Chapter 4: Methods and approach to the evaluation

My empirical papers (Chapters 3, 5 and 6) contain detailed information about the methods used in their respective data collection and analyses. This chapter outlines the methods underpinning how the EDSS intervention was conceptualised, addressing objective 2 of the PhD, and how thinking around the theory of change, which particularly focused on the intervention in India, fed into key areas for investigation in the process evaluation. The chapter adds further detail about the site selection and intervention implementation for the evaluation in Nepal to complement the evaluation protocol (Appendix C) and reflects on some of the ethical considerations for the research. Further, this chapter summarises my role within the mIRA project team, describes the relationship between the PhD and the mIRA project's evaluation in Nepal, and offers reflections on how my identity and background shaped the research.

4.1 Developing the theory of change

All interventions are 'theories incarnate', reflecting explicit and implicit assumptions about how actions will change a perceived problem[1]. A theory explains how and why specific relationships lead to specific events[2,3]. Theories differ in their abstraction from the specificities of a single intervention to theories that seek to explain social phenomena across a range of contexts[2]. An intervention's theory of change is applicable in a specific circumstance but, by testing its constituent elements, can contribute empirical evidence towards higher levels of abstraction[2,4]. A theory of change helps intervention evaluators to understand not just whether, but how and why an intervention has a particular effect. The theory of change can also be useful in generating a more detailed description of the intervention and ancillary inputs, which is necessary for accumulating evidence across evaluations and contexts[1]. While an evaluation might represent an overall test of an intervention's theory of change, evaluations also test mini theories, propositions in the causal chain, that are of particular importance or interest to the evaluators[5].

Developing the mIRA project intervention theory of change was important for clarifying the areas of interest for the process evaluation[1]. Discussions of the theory of change, which I was tasked with leading, began early in the mIRA project, during the formative research phase ahead of the planned trial. Part of the process of developing a theory of change is to bring forward the main ideas and assumptions that go into the making of an intervention[6]. The evolving implementation plans for the mIRA EDSS intervention reflected contextual considerations investigated in the formative

research—with the focus on the intervention setting in India—and highlighted areas of uncertainty about how exactly the intervention would be put in place and how this would function.

A theory of change is sometimes described as comprising both 'implementation theory' (how the intervention activities should happen) and 'intervention theory' (how the activities should generate change)[5]. The process of debating a theory of the mIRA project intervention involved both elements as the details of the mIRA EDSS intervention and its planned implementation took shape and informed theorising about how the intervention's activities would result in the desired outcomes. The theory of change debates and development took place prior to the decision to split the India and Nepal evaluations and to additionally include the WHO EDSS in the Nepal study.[4]

An initial model for how the EDSS intervention would lead to its intended outcomes began based on a Theory of Change approach, which seeks to articulate the relevant theories and assumptions underlying a planned programme via soliciting the views of a wide range of stakeholders[7]. To elicit the mIRA theory of change, I drew from a range of sources to create an evolving understanding about what the intervention would involve and what it was likely to do. I facilitated discussions with mIRA project team members in regular meetings throughout the formative phase and intervention development, seeking to understand the hypothesising about the intervention embodied in the funded proposal and the evolution of this thinking during the project, including in the process of developing algorithm inputs and the EDSS software interface. I reviewed spreadsheets defining the mIRA EDSS algorithm logic to understand what healthcare providers would be asked to input into the app and how different inputs would cue sequences of prompts for more information or recommended courses of action.

An evaluation design workshop in April 2020 resulted in a visual model of a preliminary theory of change of the intervention (Figure 4.1), largely informed by planning around the intervention in

[4] These decisions were taken while I was on maternity leave. I returned to work on the mIRA project in March 2022 as the evaluation was underway in Nepal. After speaking with colleagues and reviewing project documentation on the addition of the WHO EDSS, it was clear that there was an embedded assumption that the two EDSS (mIRA and WHO) would work in the same way and that the supportive infrastructure (training workshop, onsite fieldworker support and monitoring visits) for the intervention was the same.

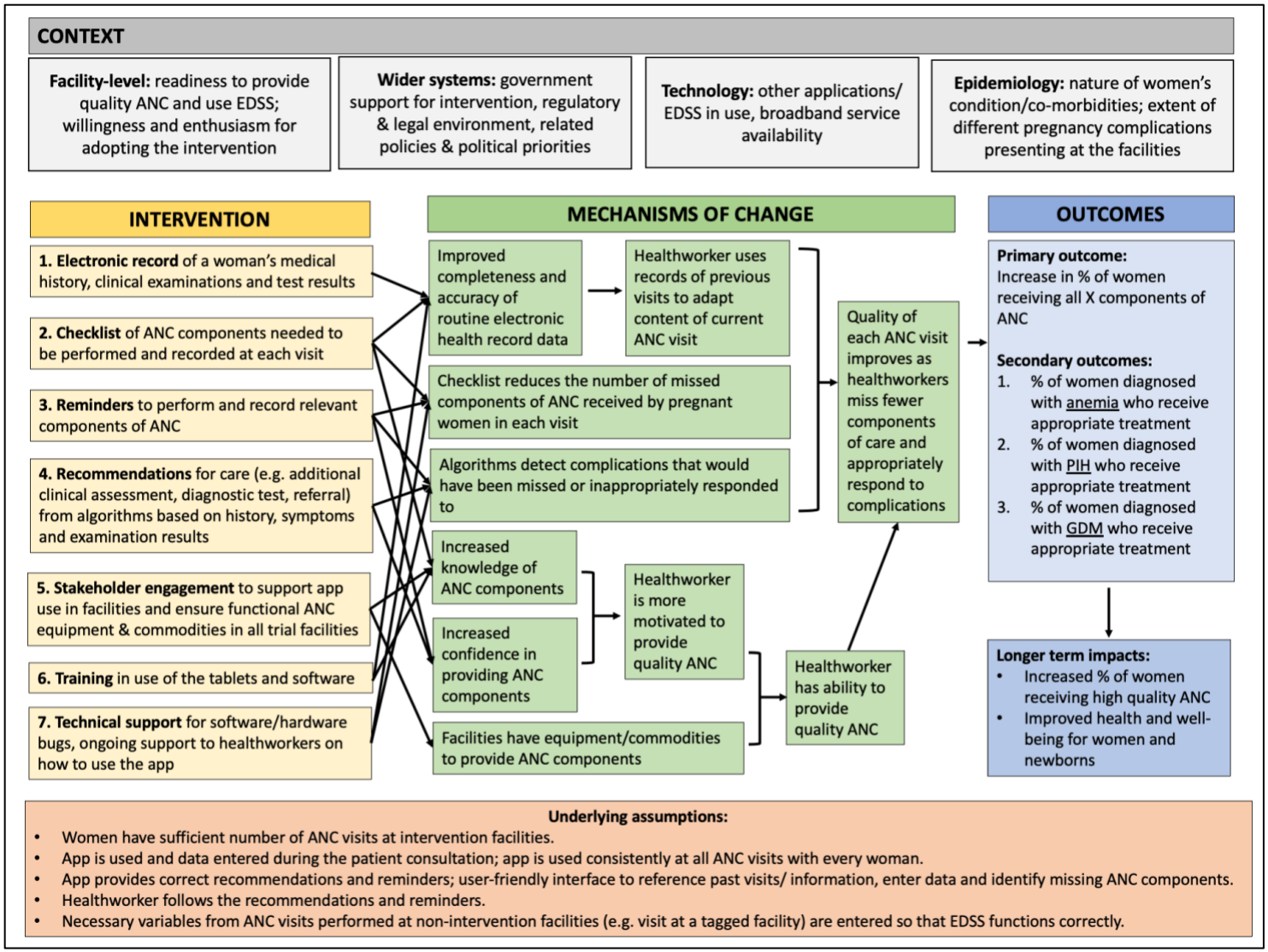


Figure 4.1 Preliminary model of the intervention theory of change, developed via the April 2020 workshop with mIRA project investigators and project staff

India. Figure 4.1 shows that the intervention was understood has having multiple components linked to pathways thought to lead to a change in outcomes. The EDSS was conceptualised to function as both a reminder tool to support performance of all care components in a routine ANC visit and a decision support algorithm to facilitate identification and appropriate response to pregnancy complications. To meet these functions, the EDSS was also a record keeping device. The still-developing software had multiple components: an electronic record of patient information and details from current and previous ANC visits, a structured data entry interface that operated like a checklist of actions to perform during a visit, pop-up reminders and alerts for missing data entry or abnormal values entered, and algorithm-defined recommendations that would appear as pop-ups (such as suggestions to wait and re-measure blood pressure if a reading was high) or as clickable summaries at the end of ANC consultations.

This broad, preliminary theory of change did not encompass all the possible feedback loops, tipping points and emergent outcomes that often characterise interventions that are both complicated and complex[3]. Notably, Figure 4.1 was based on primary and secondary outcomes measured per pregnancy, rather than per visit (see Chapter 2), but there was an underlying assumption that a sufficient proportion of women's ANC visits—a particular concern for the intervention in India—would need to take place in intervention facilities for the intervention to work. The preliminary theory of change articulated assumptions about how the EDSS was intended to be used (during the consultation, consistently at all ANC visits) that fed into defining components of implementation fidelity (see Chapter 5).

The anticipated 'delivery mechanisms' (what would be done to ensure implementation) were still developing[1]. For example, the number and type of healthcare providers who would receive training in use of the tablets and software was yet undefined during the 2020 workshop. There were debates about whether all ANC staff would receive training or whether selected facility staff would attend training workshops and then train their colleagues, potentially introducing a new mechanism of change. The training was envisioned to include hands-on practice using the tablets and EDSS software, but there was also discussion about whether the workshop should additionally include training in routine ANC guidelines, and high-risk pregnancy management. These details were not finalised until after the separation of the India and Nepal studies and beginning of the evaluation phase in Nepal in late 2021.

The preliminary theory of change (Figure 4.1) hinted, via the underlying assumptions and contextual factors, that getting the intervention into practice, to initiate change pathways would be challenging. Yet little consideration was given to how to incentivise initial and ongoing use of the EDSS. Much of the implementation discussions centred on how exactly the tablet with the EDSS software would be handled and incorporated into ANC visits. The uncertainty was greatest for the care settings in India where ANC was understood to be provided by multi-cadre teams, with a pregnant woman interacting with multiple providers during a single ANC visit (i.e., an assembly line approach rather than continuous care performed by one healthcare provider). In Telangana, India, the mIRA EDSS would join an array of electronic and paper-based documentation systems that were poorly integrated and often resulted in duplicate record keeping; formative research suggested that providers felt that they spent too much time on data entry, to the detriment of patient care[8]. The assumption in Nepal was that this was a much simpler arrangement (with more one-on-one care), and there were no existing apps in use.

While most theories of change start at the end point and work backwards[5], the mIRA project started with inputs. The intervention would involve an EDSS used by providers of ANC, but what exactly would the EDSS help providers to do? The formative research in Telangana found some areas for improvement in ANC screening assessments but also important gaps in interpersonal elements of quality care, including counselling[9]. I wrestled with defining the problem the intervention sought to address, how the intervention would solve the problem, and the circumstances where the intervention was likely to work best. I looked to document disagreements in the causal assumptions embedded in the intervention design and to identify important uncertainties for investigation in the process evaluation. I devised a series of questions and hypotheses to elicit the views of team members (Appendix B), looking for consensus on areas where the process evaluation should focus data collection. There was little response from the team outside individuals working on the process evaluation. Team interest in clarifying and refining the intervention theory of change and particularly the mechanisms waned over time as the pressure of finalising a working version of the mIRA EDSS software and concerns about getting the research studies (including the trial) in place took precedence. The result was varying views about how use of the EDSS would generate change in provider behaviour.

Conceptualising EDSS intervention functions

I continued to think about the intervention theory, drawing on abductive reasoning in theorising about causal mechanisms[5] of the intervention and how these might be explored in the process evaluation[11]. In this way, the process evaluation plans, and my thesis, shifted to incorporate approaches and thinking from realist evaluation. Realist evaluation focuses less on gaining consensus among stakeholders and more about the evaluation mapping out potential mini theories about in what circumstances the intervention would work, often done using the heuristic device of Context + Mechanism = Outcome, or CMO configurations[5,12]. For example: more motivated healthcare providers (mechanism), working within well-equipped environments (context), would follow guidelines for care and improve the quality of ANC visits (outcome)[11]. Multiple, and possibly divergent, causal mechanisms are challenging to represent visually[3], so I moved away from a diagram theory of change towards thinking about hypothesised propositions.

I conceptualised the intervention functions being assessed in the outcome evaluation. The data collection tool created to measure the primary and secondary outcomes—the same enrolment visit outcomes planned for the trial were ultimately used in the study in Nepal—endeavoured to straddle the *reminder* and *decision support* functions of the EDSS[13,14]. The outcomes sought to measure the performance of selected diagnostics and, to some extent, the communication of those care components to pregnant women. The performance of selected diagnostics, as part of routine care, focused on the reminder function of the EDSS, and the specific care components were chosen based on their importance in the identification of pregnancy complications (of interest to the researchers and a focus of the funding call). The evaluation outcomes were selected from the pragmatic point of view about the relative rarity of encountering a pregnant woman with a complication that would prompt the decision-support algorithm to recommend a course of action that the healthcare provider could follow (or not).

The intervention development process and selection of outcomes suggested the EDSS intervention was hypothesised to operate primarily through reminders. The embedded assumption was that providers knew what they were supposed to do during an ANC consultation but that they sometimes forgot or took short-cuts. The mIRA EDSS (and the later added WHO EDSS) comprised checklists and pop-ups that sought to remind healthcare providers to perform care components and/or record

[5] The mIRA project theory of change may not embody mechanisms in the realist ontological sense but the development and testing of propositions may yield knowledge about the generative mechanisms at play[10].

essential information. Providing a prompt to action was thought to nudge healthcare providers to perform clinical practices that were already accepted as the norm[15], though it was not clear from the formative research whether this was the underlying problem driving gaps in quality of care. Further, reminders prompt providers to recall key information that they may forget in the midst of providing care, delivering the prompt at a relevant time to enable acting on it[16]. This implied that use of the EDSS during, rather than after, ANC consultations was particularly important for the function of the reminder mechanism. Following a reminder would also require a well-equipped environment, particularly for actions that required equipment or commodities. The mechanism of reminding would prompt healthcare providers, who had the time, skills and required equipment, to perform all guideline-recommended investigations that they already knew to do in every ANC consultation.

However, there was another implicit mechanism of change suggested by team discussions and emphasised in the original project proposal of the EDSS as a device for knowledge provision. The original proposal and some formative research findings, particularly in India, spoke to a desire to increase capacity among lower-level cadres like ANMs to manage some pregnancy complications[8]. This implied that there was a lack of knowledge or skills among ANMs about what they should be doing in ANC for complicated pregnancies, or perhaps a lack of confidence in applying their existing knowledge. The mIRA EDSS – in contrast to the later added WHO EDSS which focused mainly on prompting the performance of investigations rather than managing complications – included algorithms offering sophisticated care recommendations following the identification of a pregnancy complication. The mIRA EDSS sought to provide information that would empower ANMs to perform more care components. The implicit hypothesis was that provision of information and recommendations would operate to empower ANMs with knowledge to perform all care components within their scope of practice.

The EDSS functions, primarily reminders but also knowledge provision and decision support, would rely on use of the tablets and software becoming routinised, that is part of the everyday work of the healthcare providers participating in the intervention. Thinking about how this would happen led me to examine implementation theories to explain what influences implementation processes and outcomes, including the social norms and structural conditions that shape individual behaviour[17]. Normalization Process Theory, one such implementation theory, describes the different kinds of 'work' needed to make an intervention happen[17,18]. It offers a theory that defines the processes necessary to take a new set of practices or behaviours and make them part of the normal way of

doing things. Normalization Process Theory separates this process into three parts: implementation (how the practices are put in place through social organisation), embedding (how the practices become routinised), and integration (how the practices are sustained) that results in normalization of the practices[18,19]. The emphasis of Normalization Process Theory is on individual agency within the social processes through which practices are operationalised in healthcare (and other institutional) settings, making it particularly relevant to the mIRA project's EDSS intervention[19,20]. I used Normalization Process Theory in the thesis to conceptualise what the EDSS intervention was asking healthcare providers to do and to describe the mechanisms, in their social context, that would promote or inhibit this[21]. But I also drew from Normalization Process Theory in thinking about how the mIRA project's process evaluation, including the studies for the thesis, could contribute to understanding this dynamic process in context[20].

4.2 Design of the process evaluation in Nepal

The remaining chapters of the PhD focus on the evaluation of the EDSS intervention in Nepal.

In the decade since the 2015 MRC guidance on process evaluations was published, there has been a movement emphasising the understanding of how an intervention works, why and for whom[1,22]. Complex social interventions are understood to operate through complex causal pathways that react differently in different contexts[22], and what works in one circumstance may not work in another, or may work in rather different ways[23,24]. Process evaluations can offer insight into the workability of interventions in dynamic, complex settings[25]. The role of the process evaluation is increasingly to understand "how implementation is achieved, and how interventions become part of the systems in which they are delivered"[1].

Most process evaluations examine three key features: 1) implementation, 2) mechanisms of change, and 3) context[1,26]. The mIRA process evaluation was informed by the MRC framework for process evaluations of complex interventions[1] and by a theory-driven approach rooted in the philosophy of realist evaluation[12]. The process evaluation was developed to complement the planned cRCT with broadly similar data collection plans in India and Nepal. This was revised following the separation of the cRCT in India to focus on the before-and-after evaluation in Nepal. The protocol (Appendix C) describes the design and methods of the outcome and process evaluation studies in Nepal.

The choice of sub-studies of the process evaluation reflected areas of importance identified by the mIRA project team. Team debates about the theory of change highlighted two issues that became

important concerns of the process evaluation: capturing the details of implementation and the unintended effects of the intervention. While writing the original process evaluation protocol, there was still uncertainty about the specifics of intervention implementation, including how implementation might differ between India and Nepal. The mIRA EDSS was also not yet ready for piloting, so many implementation implications remained uncertain. The process evaluation emphasised documentation of implementation to understand what precisely was being evaluated[1]. What happened during implementation was addressed in several mixed-method data collection approaches: routine monitoring data, notes from debriefing meetings with fieldworkers and longitudinal, ethnographic case studies of facilities. The routine monitoring and facility case studies were designed to capture implementation over time and for the qualitative component, to unpack the role of context in shaping implementation processes[5].

The intervention development process identified concerns about potential unintended effects on paper-based record keeping, particularly the woman-held ANC cards[6], and how the additional work demanded by the EDSS, notably in electronic documentation but also in following the care recommendations, would be incorporated. Two studies in the process evaluation focused on unintended effects: the audit of record keeping and the time-motion assessment. The EDSS intervention created additional record keeping as it was implemented alongside, rather than in replacement of, paper-based ANC records. This was an unavoidable weakness for the time-limited research project, and investigators were keen not to harm paper-based records. The audit of record keeping study looked to capture whether implementation of the EDSS resulted in changes – in completeness and agreement – of these paper-based records and to also examine how documentation in the EDSS compared to paper-based records. The second study of unintended effects, added to the process evaluation through this PhD, looked to capture the effects of EDSS implementation on the workload of ANMs, particularly in ANC direct patient care and related record keeping requirements. The study arose out of concerns about the intervention overburdening ANMs through additional electronic documentation and an interest in how ANMs could incorporate the time burden of the intervention into the context of their workloads.

[6] This concern first surfaced because of plans to use the ANC cards to collect data on the outcomes for the cRCT when the outcomes were to be measured for the entire pregnancy (rather than per visit, which could be collected via observations of ANC consultations). Prioritising the EDSS record keeping in the intervention arm, to the detriment of the completeness of data in the ANC cards, would then potentially underestimate the app's effect on ANC quality. However, there were also concerns about potential negative impacts on paper-based record keeping disrupting continuity of care when women accessed multiple ANC providers.

Selection and description of study sites

In Nepal, DHORCs, PHCCs and Health Posts with at least 40 women attending annually for any ANC and within six hours driving distance from Dhulikhel Hospital in Kavrepalanchok, Sindhupalchowk, Sindhuli and Dolakha districts of Bagmati Province were eligible to participate in the EDSS intervention (29 eligible facilities). All PHCCs and DHORCs were included, and probability proportionate to size was used to select 12 Health Posts. In total, four DHORCs, four PHCCs and 12 Health Posts were selected for the evaluation in Nepal.

Of the 20 facilities in the study, four were 'intensive facilities' (where the longitudinal facility case studies and time-motion assessment were conducted) and 16 were 'normal' facilities. The intensive facilities were purposively selected as those located relatively close to the research base at Dhulikhel Hospital, considered well-functioning by municipal officials, and with the highest ANC volumes among the government facilities included in the evaluation. The four intensive facilities were two PHCCs and two Health Posts; the pairs of PHCC and Health Post intensive facilities were randomly allocated to implement the mIRA EDSS or the WHO EDSS. The 16 remaining facilities were stratified by facility type and paired, to the extent possible, by annual number of ANC registrations (first ANC visits), location, and number of ANMs. Within the pairs, facilities were randomly allocated to implement the mIRA EDSS or the WHO EDSS.

While efforts were made to ensure the WHO EDSS and mIRA EDSS allocated facilities were similar, some differences were noted. ANC patient volume was used to pair facilities but there was variation; the 10 facilities allocated to the WHO EDSS collectively reported 1039 first ANC visits in the year before the intervention (24 to 224 annual ANC first visits per facility), and the 10 facilities allocated to the mIRA EDSS reported 2195 first ANC visits (45 to 749 annual ANC first visits per facility). Following consent to participate in the study, several characteristics were documented in the baseline facility survey (see protocol in Appendix C). Table 4.1 shows characteristics of facilities selected for the evaluation in Nepal. As was noted by the data used to pair facilities, WHO EDSS allocated facilities had fewer ANC patients compared to mIRA EDSS facilities, recording on average fewer first ANC visits in the month immediately before intervention implementation (7.8 vs 21.4, Table 4.1). While ANC services were available in all facilities during normal outpatient clinic hours, five WHO EDSS facilities and one mIRA EDSS facility had weekly designated ANC days where pregnant women were encouraged to attend for their ANC consultations.

Table 4.4 Characteristics of facilities selected for the evaluation in Nepal documented in the baseline facility survey

	WHO EDSS allocated facilities (n=10)*	mIRA EDSS allocated facilities (n=10
Mean number of ANMs (min-max)	2.3 (1-5)	3.1 (1-5)
Mean number of first ANC visits in month before implementation (mix-max)	7.8 (0-22)	21.4 (3-94)
Number of facilities with designated ANC day(s)	5	1
Number of facilities with patient bed for overnight observation	7	7
Number of facilities with laboratory or diagnostic testing available	7	7

*One WHO EDSS allocated DHORC was dropped from the study during the lead-in period due to low numbers of ANC patients.

Intervention implementation

In Nepal, the intervention roll-out consisted of two three-day, in-person training workshops, one each for the mIRA EDSS and WHO EDSS. The workshops included instruction on using the provided tablets and EDSS software, as well as training on measuring and interpreting blood glucose readings using oral glucose tolerance test kits. Workshops were attended by one ANM, selected by the local municipality, from each participating facility. The intention was that the trained ANM would teach other ANMs at the facility how to use the tablet and EDSS.

Following the training workshop, a project fieldworker stayed at each participating facility during a three to four week lead-in period to assist the trained ANM and untrained ANMs in using the tablet and their designated EDSS software. Oral glucose tolerance test kits were also distributed to all study facilities because these kits were not routinely available and were the preferred diagnostic recommended by the mIRA EDSS. During the lead-in period, one DHORC allocated to the WHO EDSS was dropped, without replacement, from the study due to extremely low ANC caseload (<5 ANC patients/year) and a decision was taken to make up the sample size for quantitative data collection from the other facilities.

The two EDSS implemented in the evaluation in Nepal offered broadly similar content and functionality but had distinct user interfaces and originated from different perspectives on decision-support in ANC (Table 4.2). Both included a menu or dashboard of module topics for data entry and incorporated algorithms to offer alerts and/or recommendations in response to data values inputted. The mIRA EDSS, developed through the mIRA project in a process led by PHFI and completed by a Telangana-based software company, addressed routine ANC but included more

detailed diagnostic and treatment algorithms for the detection and management of gestational diabetes and pregnancy induced hypertension[13]. The WHO digital ANC module (the "WHO EDSS") included data and health content consistent with WHO's ANC recommendations[27]. There were small differences in the design, including the portrait or landscape orientation of the app, and structure of the software; the WHO EDSS also required more tablet memory capacity (Table 4.2). All participating facilities received the same make and type of tablets: Samsung Galaxy Tab A 8.0, but WHO EDSS allocated facilities were provided replacement higher-capacity memory cards partway through implementation.

Table 4.5 Summary comparison of features of the two EDSS implemented in the evaluation study in Nepal

WHO EDSS	**mIRA EDSS**
Content: Algorithms for routine ANC check-up and prompts for basic management of complications and referral recommendations	**Content**: Algorithms for routine ANC check-up and more detailed prompts for the management of gestational diabetes and pregnancy induced hypertension
Design: Modular dashboard design using tile windows, orientation is responsive but intended to be used in portrait	**Design**: Modular dashboard design using responsive grids, orientation is in landscape with the navigation menu along the left side
Structure: Data entry form on each page is short (approximately 5 inputs) but each module can contain multiple data entry form pages. Each page has separate 'save' (save data locally) and 'finalise' (sync to the cloud database) buttons.	**Structure**: Modules are divided into sub-modules and the data entry form for each sub-module is on a single page. Each page has separate 'save' (save data locally) and 'submit' (sync to the cloud database) buttons.
Hardware: Requires a tablet with mid-range memory capacity	**Hardware:** Works on tablets with low memory capacity

Visually, the two EDSS were quite different in the design of the dashboard (a menu of modules for data entry) and in the format and length of the data entry form structures (Table 4.2). Figure 4.2 and Figure 4.3 show screenshots of the WHO EDSS and mIRA EDSS, respectively. The WHO EDSS had a more colourful interface (Figure 4.2); the mIRA EDSS was designed to resemble the layout and generally follow the order of content used in Nepal's paper-based ANC card (Figure 4.3).

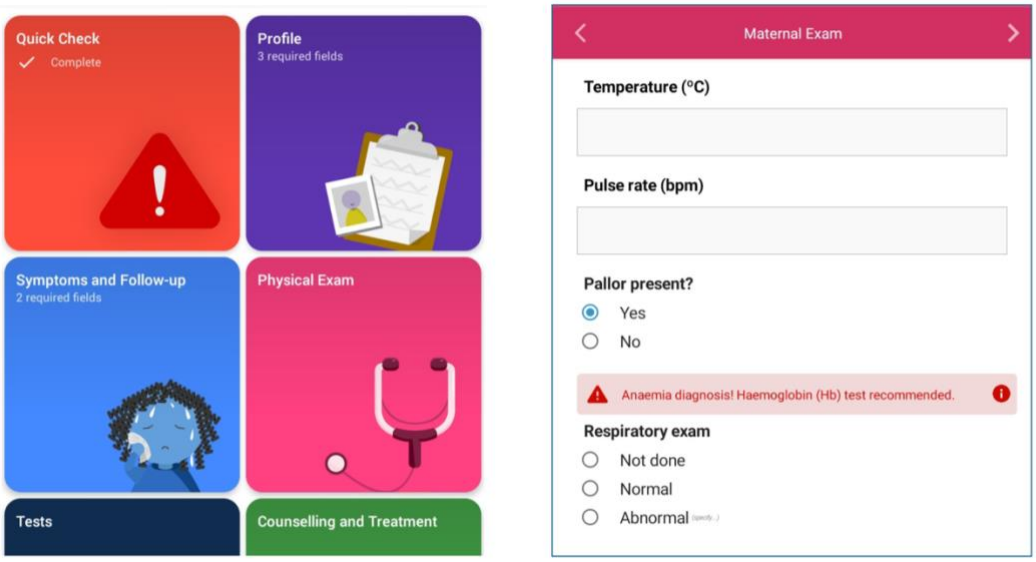


Figure 4.2 Screenshots of the WHO EDSS with the (left) screen showing the dashboard menu of modules for data entry and the (right) screen showing an example data entry form

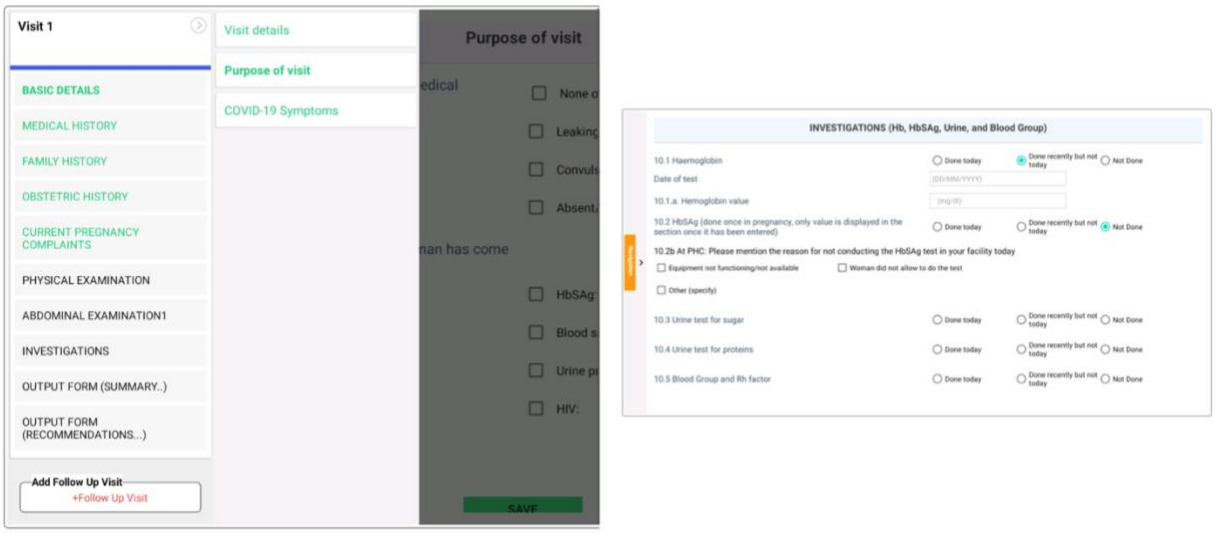


Figure 4.3 Screenshots of the mIRA EDSS with the (left) screen showing the dashboard menu of modules for data entry and the (right) screen showing an example data entry form

4.3 Reflections on ethical considerations

All studies of the PhD were done under the umbrella of the mIRA project, which received ethical approval from LSHTM, Kathmandu University School of Medical Sciences, and Nepal Health Research Council (see Appendix C), and for the formative phase research, from LSHTM and PHFI (see Chapter 3). Decisions about the consent and data collection processes were led by the mIRA project team, where I contributed. I was involved in discussions around ethical approaches to research in the

longitudinal case studies, for which the time-motion data collection was part, in the evaluation in Nepal.

The mIRA project, and the studies of the thesis, drew almost exclusively from facility-based data. Local municipalities in Nepal were approached for permission to conduct research in the selected study sites. Facilities were then consented to take part in the research by speaking with and obtaining the approval and consent of the facility in-charge (usually a doctor in a managerial role). The facility in-charge would consent on behalf of staff to implement the EDSS intervention and for activities in the clinic to be observed. This predominantly included observing ANMs going about providing ANC (see the protocol in Appendix C for full description of data collection activities). ANMs would be individually consented to take part in in-depth interviews and in the intensive observations of individuals done for the time-motion study, but consent for the research project was largely taken collectively. As the facility in-charges (as doctors or senior nurses) clinically outranked the ANMs tasked with providing ANC, professional hierarchies likely exerted pressure on the lower ranked ANMs to cooperate with the research and data collectors in ways that were underexplored in the mIRA project. Additionally, most of the facility in-charges were men and all the ANMs were women, adding a gendered dimension to whether ANMs were voluntarily participating and could truly refuse to take part in the intervention and research. No ANMs refused to take part in the interviews or time-motion data collection for which individual consent was sought. The issue of legitimacy of participation in the intervention by the ANMs – an aspect of this voluntary participation – is explored in Chapters 5 and 7.

The time-motion study, added to the evaluation in Nepal through the PhD, presented challenges for the process of consent and the ethical conduct of research. The time-motion study was conducted in two of the four 'intensive' facilities taking part in the longitudinal case studies; the facility in-charges provided formal consent to participate in the longitudinal case studies, among the other mIRA project activities. The two researchers involved in the longitudinal case studies and time-motion data collection further engaged in informal consenting processes with the ANMs and other facility staff, explaining the research and what the researchers would be observing during the ethnographic data collection[28]. Despite these assurances, the considerable time that the two researchers spent in the four intensive facilities likely blurred the lines of what it means to be actively consenting to participate in research when the researcher becomes a familiar, rather than detached observer[29]. For the time-motion study, the two researchers took individual consent from ANMs to take part in the observations in each round of data collection. However, we also faced the challenge of how to

think about consent for patients attending the facility and interacting with ANMs under observation. The study team emphasised ethical research practice as going beyond formal consent processes[29]. While our institutional ethical approvals did not require individual consent from patients, as they were not the focus of observation, we sought informal, verbal consent from patients encountered (see Chapter 6). But as patients may still feel pressured to agree to the researcher's presence, the study team emphasised sensitivity to the emotional tenor of interactions. This meant that the two researchers involved in data collection were encouraged to stop observations, even though this meant missing data, when they sensed that it was prudent to do so. Doing ethical research for time-motion studies in healthcare settings, as well as ethnographic observation, requires thinking about more than the formal consent process and supporting a culture of ethical conduct among the research team.

4.4 Role in the mIRA project and positionality

This staff PhD began while I was a member of the mIRA project research team and developed from gaps identified in the project where my research interests could bring added value to the overall evaluation. I was substantively employed on the mIRA project from January 2019 to September 2022, with a maternity leave break from April 2021 to March 2022 (see timeline in Figure 2.2, Chapter 2). The mIRA project proposal included both process and cost-effectiveness evaluations to complement the planned trial; however, other than a qualitative researcher in India, no other staff were explicitly assigned to the process evaluation. As my role in the research project was flexibly defined, I saw an opportunity to add a more in-depth process evaluation to the trial through this PhD. The original PhD plans included quantitative analyses to supplement the qualitative investigations led by the researcher in India. Some PhD analyses, notably the assessment of implementation fidelity, were central to the overall research project; another PhD study planned to use secondary trial and process evaluation data for further analysis. The time-motion assessment in Nepal was added, via an LSHTM doctoral travel grant which I obtained, as a separate, complementary study.

The scope of the process evaluation grew, with more project team members joining and contributing to plans. I led the process evaluation workstream, coordinating inputs from team members (from PHFI, LSHTM and Dhulikhel Hospital) into the overall aims, design, and data collection for the process evaluation. When the project split into separate studies in India and Nepal, what was planned for the process evaluation became integrated with the before-and-after outcome

evaluation in Nepal. The PhD scope adjusted accordingly. The secondary analyses of trial data were dropped from the PhD, and the LSHTM and Dhulikhel Hospital team recalibrated to share inputs and leadership of the data collection and analysis plans for the study in Nepal.

Positionality

My approach to the PhD research was shaped by my identity and background, as well as my research philosophy, described below. A description of positionality is considered essential for rigorous, reflexive qualitative research but is rarely incorporated into quantitative research[30]. Yet there is no neutral position from which to undertake research[31]. What and how I chose to research the mIRA project intervention was influenced by my interests, skills and position within the team. Reflecting on positionality is part of the process of decolonising global health research by offering critical reflection on the power imbalances within research teams[32,33]. My role in the mIRA project was the product of my privileged position. Being a white Westerner, from a non-clinical background, employed as a research fellow at LSHTM, I was more able to define my scope of work compared to the other early career researchers on the project from India and Nepal. My positionality shaped the extent of my involvement in creating the intervention and the logistics of research project management and the latitude afforded to me to engage in some conceptual research.

As a non-clinician, based in the UK without language skills in Hindi, Telugu or Nepali, I was only peripherally involved in EDSS intervention development. Early career researchers, particularly at PHFI, were tasked with coordinating the creation of EDSS software algorithms, derived from clinical guidelines and from the inputs of subject expert committees. The mIRA team relied on these early career researchers to locate and review national and sub-national guidelines in India and Nepal, follow-up on questions relating to the “local context”, check on local approval processes, and perform various tasks related to developing the intervention and resolving logistical challenges of doing the research.

As an LSHTM staff member, and a part-time PhD student, my role afforded considerable independence to direct my time and efforts towards reading the wider literature about evaluation and thinking about the theory of change. My PhD supervisor, Prof Oona Campbell, was a co-PI of the mIRA project and supported these more conceptual interests, even when they were not always seen as important within the larger project team, or by the co-PI in India, where logistic concerns were often paramount. But I recognise that my occasional frustration in the lack of engagement in

theorising around the intervention and its evaluation reflected power asymmetries: researchers in high-income settings, relatively free from the time burden of logistical tasks of the doing of research in LMICs, have more resources for conceptual work, inappropriately suggesting that there is not the expertise or interest from researchers based in LMICs[34]. I am keenly aware of how these dynamics, which were apparent in the mIRA project, contribute to systemic inequities in research and publishing[33,34] and believe that theorising work benefits from a diversity of perspectives. Several early career researchers from India and Nepal, working on the process evaluation, were also interested in conceptual work. My more secure position in the LSHTM team, which tended to be less hierarchical than the PHFI and Dhulikhel Hospital teams, enabled me to advocate for the value for this work more freely. As discussed further in Chapter 8, I tried to leverage my position of relatively greater power to promote contributions of fellow early career researchers from Nepal and India in the process evaluation.

My opportunities to spend time in the study settings were limited by COVID-19 pandemic travel restrictions and the duration of my contracted time on the project after returning from maternity leave. I visited the research sites in India and Nepal twice in 2019, once around the project launch meeting and second for training and piloting for the formative research data collection. All other inputs into the data collection and analysis were offered remotely. Data collection for the evaluation in Nepal was undertaken entirely by researchers and fieldworkers recruited and employed by Dhulikhel Hospital. I reflect further on my positionality and how this shaped the resulting research in Chapter 8.

Research philosophy

I wish to briefly reflect on the realist[7] research philosophy that informed the PhD. All research is shaped by ontological and epistemological assumptions that are often implicit yet fundamental to the research questions asked, the approach to analyses and the conclusions drawn[31,36]. Ontology refers to our assumptions about how the world is, and epistemology refers to how we can produce knowledge of it, which together form a research philosophy[31]. Ontological positions offer views about the nature of causation that are important to consider in evaluation research. Positivists think of causality as deterministic event-regularities, whereas critical realists (and scientific realists) think

[7] I recognise there are debates about the ontological nuances of scientific vs critical realism[35], but I agree with the perspective that the basic propositions are similar enough for pragmatic purposes[10]. I use the term "realist" to describe my research philosophy and to refer to the general philosophy underpinning "realist evaluation" as first proposed by Pawson and Tilley[12].

of causality as tendencies, which can be counteracted, that make outcomes possible[37]. Essentially causes (mechanisms) are relatively constant but the conditions (contexts) for their activation less so[4]. A cause can exist even if it only operates in one place, one time[37]. Realists view explanation and evidence as distinct, though we cannot divorce theoretical reasoning from empirical data[4,37]. By this, I mean that generating explanation is related to, but a separate process from, empirical analysis. The role of the researcher informed by realism is to align the explanation of reality with reality itself[4].

Realist evaluation is a type of theory-driven evaluation that emphasises explanation based on a philosophy about the nature of underlying social contexts and structures and of generative mechanisms[10]. The "realistic evaluation" devised by Pawson and Tilley arose out of the research philosophy of scientific realism and a critique of the simplistic positivism of early evaluation research of social programmes employing "a rather mechanical experimental format" with often confusing results[12]. Despite the neat logic of experimental evaluation – make two groups identical on average so that only the intervention causes the outcome – the results rarely give the simple answer promised[12,38,39]. Complex interventions even more so! The accumulator of such evidence throws up their hands in despair lamenting that 'nothing works' or, more commonly, that the inconsistent results mean that 'more research is needed'[38]. That additional research would benefit from a realist approach rooted in explanation.

My realist research philosophy informed the methods and their interpretation in the PhD. Both empirical studies from the evaluation (research papers 2 and 3) reflect a realist approach, particularly to the role and interpretation of quantitative research. The implementation fidelity study (Chapter 5) begins with, and the time-motion study (Chapter 6) focuses on, identifying patterns of events. The quantitative analyses of the PhD aim to describe the existence of patterns: how much, who, where, when, and not to answer questions of how or why. In the implementation fidelity study, explaining the patterns (answering 'why') required qualitative analysis and theorising for causal explanation. The shift from quantitative to qualitative analysis in the study, from describing patterns to exploring causes of the patterns, was informed by a realist research philosophy. The approach was rooted in an understanding that statistical analyses offer evidence for an explanation, not the explanation itself[37]. Qualitative research can produce causal explanation[37,40]. This relates to the role of theorising and abductive reasoning in the interpretation of data where explanation can take the form of narrative[10,37,40]. The empirical evaluation papers provide evidence for the patterning of behaviours in their social context, rooted in

a realist understanding about what different methods offer in producing evidence for, and generating, explanation.

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Chapter 5: A realist approach to implementation fidelity in a mixed-method evaluation of electronic decision support systems to improve the quality of antenatal care in Nepal (research paper 2)

This chapter presents both a conceptual approach and empirical application of a longitudinal, explanatory approach to implementation fidelity assessment through a realist evaluation lens. The manuscript presents findings from an assessment of implementation fidelity in the mIRA project evaluation in Nepal and relates to objective 3 of the PhD (to evaluate implementation and understand the contextual factors and mechanisms shaping fidelity to the EDSS intervention). The mixed-method study used four data sources to examine three components of fidelity: use at the point of care, use for all ANC visits, and quality of data entry. The paper argues that a realist evaluation approach moves beyond an inward-looking question of internal validity used in typical process evaluations to develop more outward-looking explanations for how and why implementation fidelity occurred.

The manuscript was published as a pre-print on medRxiv under Creative Commons license (CC BY 4.0) and is included in full. It has also been submitted for publication in a peer-reviewed journal.

5.1 List of Figures

5.2 List of Tables

Table 5.5 – Completeness of EDSS backend data for all visit entries dated during the implementation period (15 May – 16 Nov 2022) for the mIRA EDSS and WHO EDSS

Table 5.6 – Normalization Process Theory constructs and interpretation of how these mechanisms appeared in our assessment of EDSS implementation fidelity

5.3 Citation

Radovich, E; Karki, S; Das, S; et al. (2024) A realist approach to implementation fidelity in a mixed-method evaluation of electronic decision support systems to improve the quality of antenatal care in Nepal. *medRxiv* 2024.05.07.24306757. https://doi.org/10.1101/2024.05.07.24306757

5.4 Research paper cover sheet

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SECTION A – Student Details

Student ID Number	1402301	**Title**	Ms
First Name(s)	Emma		
Surname/Family Name	Radovich		
Thesis Title	Complex reality, implementation and measurement: Evaluation of an electronic decision support system to improve antenatal care quality in South Asia		
Primary Supervisor	Prof. Oona Campbell		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?			
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If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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Where is the work intended to be published?	Evaluation - https://journals.sagepub.com/home/evi
Please list the paper's authors in the intended authorship order:	Emma Radovich, Sulata Karki, Seema Das, Rajani Shakya, Ona L. McCarthy, Abha Shrestha, Clara Calvert, Oona M. R. Campbell, Loveday Penn-Kekana

Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the study, including the data collection tools for the monitoring visits and software backend data extraction, and developed the three components of implementation fidelity with inputs from the mIRA project team. I conceptualised the realist evaluation approach to implementation fidelity and initiated use of Normalization Process Theory as a framework for understanding the empirical findings. I conducted the quantitative analysis of the monitoring visit data and the software backend data. Prof Oona Campbell made suggestions about how to handle missing data in the quantitative analysis, which I incorporated. I also conducted the qualitative analysis of the monitoring visit fieldnotes. A sample of the monitoring visit fieldnotes were double coded by Loveday Penn-Kekana and Sulata Karki; they offered useful suggestions I used to further refine the analysis and interpretation. Analysis of the longitudinal case studies was led by Sulata Karki and Seema Das with inputs from Loveday Penn-Kekana and myself. I wrote the first draft of the manuscript and prepared the journal submission with consideration of co-author comments.

SECTION E

Student Signature	Emma Radovich
Date	3 May 2023

Supervisor Signature	Oona Campbell
Date	23 May 2024

5.5 Research paper

Title: A realist approach to implementation fidelity in a mixed-method evaluation of electronic decision support systems to improve the quality of antenatal care in Nepal

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Abstract

Background: Understanding implementation fidelity, or adherence to the intervention-as-intended, is essential to interpreting the results of evaluations. In this paper, we propose a longitudinal, explanatory approach to implementation fidelity through a realist evaluation lens. We apply this approach to a mixed-method assessment of implementation fidelity to an electronic decision support system intervention to improve the quality of antenatal care in Nepal.

Methods: The tablet-based electronic decision support system was implemented in 19 primary care facilities in Nepal. As part of the project's process evaluation, we used four data sources – monitoring visit checklists and fieldnotes, software backend data, and longitudinal case studies in four facilities – to examine three components of fidelity: use at the point of care, use for all antenatal visits, and quality of data entry. Quantitative data were analysed descriptively. Qualitative data were analysed thematically using template analysis to examine descriptive findings across the three fidelity components and later to develop and reflect on the causal mechanisms. Findings were

synthesised, drawing on Normalization Process Theory, to understand the processes driving the different patterns of fidelity observed.

Results: Fidelity to point-of-care use declined over time with healthcare providers often entering data after antenatal visits had ended because providers understood the intervention as primarily about record keeping rather than decision support. Even in facilities with higher fidelity to point-of-care use, software decision-support prompts were largely ignored. Low antenatal patient caseloads and the suggestion by fieldworkers to practice back-entering data from previous antenatal visits undermined understanding of the intervention's purpose for decision support.

Conclusions: Our assessment explains how and why patterns of implementation fidelity occurred, yielding more nuanced understanding of the project evaluation's null result that moves beyond intervention vs implementation failure. Our findings demonstrate the importance of discussing intervention theory in terms fieldworkers and participants understand so as not to undermine fidelity.

Keywords: Implementation fidelity, realist evaluation, process evaluation, Nepal, antenatal care

Introduction

This paper reports on the conceptual approach and empirical findings of a mixed-method assessment of implementation fidelity within an evaluation of a digital health intervention to improve the quality of antenatal care (ANC) in Nepal. We propose a longitudinal, explanatory approach to implementation fidelity, drawing on realist evaluation, to examine how fidelity unfolded and why. In doing so we contribute to evidence about intervention implementation in maternal health and deepen understanding of how efforts to ensure ANC quality can be improved[1].

Evaluations are frequently concerned with implementation fidelity, or the consistency with which the intervention was implemented as intended[2–5]. When an intervention is ineffective, process evaluations are often tasked with determining whether it was because it does not work (intervention failure) or because it was not implemented as intended (implementation failure), seeing this as an internal validity question about whether the outcome evaluation was a valid test of the intervention theory[2,5–7]. However, this neat, suggested divide between intervention and implementation failure stems from a positivist view of evaluation. Fidelity assessment in this mode is often about trying to discern the so-called 'true effect' of the intervention[8], and lack of fidelity is frequently blamed for why studies of seemingly the same intervention led to different results in different contexts[4,8].

Our ideas about what implementation fidelity is and how it should be examined are informed by a realist approach to evaluation. Realist evaluation, and more recent perspectives on the evaluation of complex interventions, emphasize explanation – how, for whom and under what circumstances do interventions work[2,9,10]. Evaluations from a realist perspective understand interventions as shaped by their contexts and that these contextually-dependent adaptations may trigger mechanisms leading to desired outcomes or, conversely, unintended consequences[11,12]. We argue a realist evaluation approach to fidelity moves beyond an inward-looking emphasis on internal validity to develop more outward-looking explanation of how and why the intervention-as-intended interacted with its context to produce the process of implementation—and the resulting outcomes—observed. Assessing fidelity requires examining how closely (or not) the implementation process followed what the intervention designers had hoped would happen. A realist understanding of fidelity would see that this is not a binary (fidelity vs implementation failure) but has degrees of consistency and is a process that can change over time and unfold in a non-linear fashion[7,13–15].

We apply these ideas to the Mobile health Integrated Rural Antenatal care (mIRA) research project in Nepal, which aimed to improve the quality of ANC using electronic decision support systems (EDSS) introduced at primary care facilities. EDSS are information systems, often delivered through computers or tablets, that integrate clinical and demographic data to support healthcare providers' decision-making and improve adherence to guidelines via checklists, alerts or information provided at the point of care[16,17]. The mIRA project evaluated two tablet-based EDSS: the newly developed mIRA EDSS[18] and the World Health Organization (WHO) digital ANC module[19], using a two-phase outcome assessment, comparing quality scores pre- and post-EDSS implementation from observations of ANC consultations, alongside a robust process evaluation[20,21]. The mIRA project evaluation results are reported in detail elsewhere[21], but for the most part, the EDSS intervention did not improve quality of care outcomes.

All interventions embody assumptions about how a programme reaches its anticipated outcomes[2,11]. For the EDSS to improve quality of care, we assumed providers would incorporate the EDSS into their workflow so that they could input data into the tablets, respond to its prompts, and make the desired changes to their clinical practice. Project investigators identified three essential components of using the intervention as intended: 1) providers should fill-in the EDSS during consultations with pregnant women; 2) providers should use the EDSS for all ANC visits; and 3) providers should enter sufficient data in the EDSS so that the algorithms generate recommendations and reminders. The three components were based on the idea that point-of-care support improves adherence to guidelines through 'prompts to action' reminding healthcare providers of what they should do in their clinical practice at the time and location of decision making[22,23]. Use at the point of care (component 1) was a vital component in the intervention theory for how the EDSS would improve ANC quality. For example, the EDSS included an alert to perform a dipstick test if the results of a urine protein test were not recorded for each ANC consultation. If the pregnant woman had finished her ANC consultation and left the clinic, then the provider entering information into the EDSS later would be unable to follow this prompt and perform the test. For components 2 and 3, the mIRA EDSS and WHO EDSS were understood to work best if used at every ANC visit to enable the diagnostic algorithms for longitudinal care throughout the pregnancy. Use for all ANC visits would also minimize the need to back-enter data from previous patient contacts, a factor known to hinder EDSS uptake and effectiveness in other settings[16].

This study, as part of the mIRA project's process evaluation, offers a realist assessment of implementation fidelity to the mIRA EDSS and WHO EDSS intervention-as-intended in Nepal. We aim

to give a rationale for widening assessment of implementation fidelity and to demonstrate how we operationalised and analysed these ideas. We do this by 1) describing implementation fidelity over time and between facilities implementing the two EDSS, using the three components of EDSS intervention-as-intended, described above, and 2) developing explanations for how implementation contexts shaped mechanisms that led to observed differences in fidelity.

Methods

Intervention and setting

The mIRA project intervention and evaluation took place in four predominantly rural districts in Bagmati Province, Nepal (Kavrepalanchok, Sindhupalchowk, Sindhuli and Dolakha) between April and December 2022. Twenty facilities—government Health Posts and Primary Health Care Centers and non-governmental Dhulikhel Hospital Outreach Centers—were selected to receive tablets with the EDSS software installed[20]. Facilities were paired by type and reported ANC patient volume for the previous year and then randomly allocated to receive either the mIRA or the WHO EDSS. Following allocation, one facility assigned to the WHO EDSS arm was discovered to have extremely low patient volume (<5 ANC cases/year) and was dropped, without replacement, from the project.

Each facility received a tablet with the allocated EDSS software installed and glucometers to facilitate performance of oral glucose tolerance tests when prompted by the EDSS, as this equipment was not normally present in the facilities. One Auxiliary Nurse Midwife (ANM) from each facility working in ANC was selected by the local municipality to attend a three-day training workshop hosted by Dhulikhel Hospital on either the mIRA EDSS or WHO EDSS. The workshops consisted of training on the purpose of the EDSS and hands-on practice entering data in the EDSS. Participants additionally received training in administering oral glucose tolerance tests.

The trained ANMs were then supported in using their allocated EDSS by an onsite fieldworker during a monthlong lead-in period, during which other ANMs (who did not attend the training) could also receive instruction in EDSS use. ANMs were encouraged to use the EDSS during consultations with real ANC patients. However, due to low patient volume in some facilities, fieldworkers would sometimes encourage ANMs to practice using the EDSS with dummy data or by snapping photos of a pregnant woman's paper ANC card and entering data from past ANC visits. ANMs were expected to continue to complete paper-based records (ANC cards and ANC registers) alongside the EDSS, during the project.

Study design and data collection

The implementation fidelity study used a mixed-method convergent design where quantitative and qualitative data were collected simultaneously[24]. The intent was to offer a more complete understanding of implementation in all 19 facilities, drawing on quantitative and qualitative data from in-person monitoring visits, quantitative information captured in the backend data of the EDSS software, and qualitative data from repeat, unstructured observations and in-depth interviews conducted in four case study facilities[20,25].

Following the supported lead-in period, project fieldworkers visited facilities with a structured checklist to assess functioning of the tablet and EDSS software, whether the EDSS was observed in use on the day and the number of entries on the facility's ANC register for the previous day (or the date of the last register entry). Fieldworkers conducting the monitoring visits were trained by the project's anthropologist (LPK) to additionally document, via free-form notes at the end of the structured checklist, how ANMs described using the EDSS and problems encountered with the tablets or software. The fieldnotes had a dual purpose: firstly, to enable project staff to identify and reconcile problems, for example providing replacement memory cards for tablets. Secondly, the fieldnotes captured whether and how ANMs were using the EDSS based on the fieldworkers' observations and informal conversations with facility staff. Fieldworkers conducted four monitoring visits at intervals of 1-2 months at each facility during the implementation period; however, weather-related issues made it impossible to conduct two (of the four) in-person visits at one facility and one visit at another facility.

We extracted data logged via the EDSS software. The backend data included the facility identification code, the date and number of visit entries logged (to compare to the number of ANC register entries), and values recorded for a selection of non-mandatory fields. Most software fields were mandatory, and those that were non-mandatory were different in each EDSS. We selected three non-mandatory fields in each EDSS, identifying those likely to be relevant in all ANC visits and relevant to the quality outcome measures[20]. The selected fields for the WHO EDSS were: 1) counselling on next visit schedule, 2) was pallor assessed, and 3) was oedema assessed; selected non-mandatory fields for the mIRA EDSS were: 1) any current pregnancy complaints, 2) was urine protein done, and 3) was haemoglobin test done. Several mIRA EDSS facilities experienced software-related difficulties with saving and syncing data to the server, meaning entries were saved locally on the tablet but not visible in the backend data. Software issues were resolved and EDSS entries synced, part-way through implementation for six of the 10 mIRA-allocated facilities. The four mIRA

facilities with ongoing syncing issues are missing an unknown number of visit entries in the backend data; results from these facilities are presented separately.

We conducted longitudinal case studies in four purposively selected facilities, two each implementing the mIRA EDSS and WHO EDSS, to explore changes in ANC provision and facility operations over the course of the intervention[21,26]. Two researchers (SK and SD) conducted repeat observations, formal interviews, and findings validation workshops with facility staff. The researchers documented daily their observations and reflections and transcribed the formal interviews; we also took extensive notes during regular team discussions throughout the data collection period, responding to emerging findings and developing and testing hypotheses[26]. For the purposes of this analysis, we examined evidence in the notes and transcripts on how and why ANMs used the EDSS in the way that they did, based on the three components of fidelity.

Data from all sources were collected simultaneously during the four rounds of in-person monitoring visits and longitudinal case study observations. Initial analyses for this study began during the final phase of data collection for the fourth in-person monitoring visit.

Definitions

Carroll and colleagues' conceptual framework for implementation fidelity, where components are evaluated to understand "whether the result of the implementation process is an effective realisation of the intervention as planned by its designers"[4] offered a useful guide for defining components of fidelity in this study[27]. We mapped our three components to elements of Carroll and colleagues' domain of adherence[4] (Table 5.6). While the framework considers quality of delivery as a moderator of adherence, we considered quality, or how closely EDSS use approached the theoretical ideal of complete data entry enabling full software functionality, as a discrete aspect of fidelity due to the importance of this component in the intervention theory.

Table 5.6 Components of implementation fidelity and their operationalisation in the study

EDSS components of fidelity	**How we mapped to Carroll and colleagues' concepts in the conceptual framework for implementation fidelity**	**Operationalisation of the concept across the data sources**
1. Providers should fill-in the EDSS during consultations with pregnant women.	Content: Timeliness of use of the EDSS, that is at the point-of-care, was considered a crucial 'active ingredient' of how the intervention sought to deliver a change in provider practice.	Monitoring visit checklist: Proportion of ANC consultations with observed use of EDSS, and proportion of facilities with tablet 'ready to use'. Monitoring fieldnotes and longitudinal case studies: Examining point-of-care use vs record keeping after.
2. Providers should use the EDSS for all ANC visits.	Frequency (or coverage): Consistency of use of the EDSS for all ANC visits links closely to the elements that comprise 'dose' in the framework: frequency, coverage and duration. We examine duration via our longitudinal approach using repeated measures.	Monitoring visit checklist and backend data: Proportion of register entries logged in EDSS per monitoring visit. Monitoring fieldnotes and longitudinal case studies: Examining use for every visit vs rationalizing when to use or not use.
3. Providers should enter sufficient data in the EDSS so that the algorithms can generate recommendations and reminders.	Quality: Many fields in both EDSS were marked mandatory (visit entries could not be saved without a value entered), essentially ensuring this component's minimum fidelity. So, we examined whether quality of use of the EDSS went beyond what was mandatory to the scope of EDSS functionality that was enabled.	Backend data: Proportion of selected non-mandatory fields completed out of total number of EDSS entries created, where to be considered complete the field could have any option selected or be marked as 'not done'. Fields with nothing entered were considered incomplete. Monitoring fieldnotes and longitudinal case studies: Examining how providers made use of EDSS functionality or discrepancies between performing tasks/actions and recording them.

For each in-person monitoring visit, we assessed whether the tablet was 'ready to use': the tablet was available, reported functional, reported at least 30% charged (based on estimated battery life needed to record an ANC visit and synchronize files to the server) and connected to either the mobile or internet network. Tablets that were reported unavailable, non-functional, insufficiently charged or with no network connection were considered not ready to use. Tablets insufficiently charged were considered ready to use if there was a functional charging cord available and electricity available at the facility.

Data analysis

We used a modified parallel-databases approach in which the quantitative and qualitative data were analysed independently, using the data to examine aspects of the three fidelity components[24]. Findings from the quantitative and qualitative analyses were brought together during the integration and interpretation stage. Integration of the quantitative and qualitative results involved identifying content areas represented in the multiple datasets and creating a joint display matrix to merge the results for each facility. Descriptive statistics for the related quantitative variables and qualitative data relating to the three core fidelity domains of content, frequency, and quality of EDSS use were arrayed in the matrix. Quantitative and qualitative findings in the matrix were given equal emphasis.

Quantitative analysis

Quantitative data from the monitoring visit checklists and the EDSS backend were analysed descriptively. Analyses were conducted in Stata/SE V.16 (StataCorp, College Station, Texas, USA). No tests of statistical significance were performed as the study was not designed to test for differences in outcomes and the sample sizes were not powered to do so[20].

Analysis of the EDSS backend data included all entries created with a visit date during the implementation period: from the approximate end of the lead-in period through the end of supported implementation for the six Nepali months of Jestha to Kartik 2079 (corresponding to Gregorian calendar dates 15 May to 16 November 2022). No entries were missing visit dates; this was a mandatory field in mIRA EDSS or was created automatically in WHO EDSS. A small number of entries (<5%) were marked as “demo” or test entries and were dropped before the analysis.

Completeness of backend data was assessed for the mIRA EDSS and WHO EDSS separately as a single cross-sectional measure of the proportion of each non-mandatory field completed out of the total number of EDSS entries. Blank variable fields (nothing recorded) were considered incomplete. Anything entered in the field, including ‘not done’, were considered complete.

For the comparison between the previous day’s number of entries on the ANC register and the number of entries logged in the EDSS, we tallied the number of records saved in the backend data for each facility for the designated ANC register date for each of the four rounds of monitoring visits. Some dates on the ANC register included zero entries (no ANC patients attended on that day). Agreement was calculated as an exact match in the number of entries, including zero entries,

recorded in the ANC register and the number of visits recorded in the EDSS for the same date. Analysis comparing numbers of register and backend entries for each facility was done in Excel.

Qualitative analysis

Fieldnotes and interview transcripts from the longitudinal case studies were analysed thematically by SK, SD and LPK (detailed methods for the longitudinal case studies published separately[26]). For the purposes of this study, themes arising from the longitudinal case studies analysis that related to the three fidelity components were extracted and included here.

Monitoring visit fieldnotes were assembled for each facility. Template analysis of the fieldnotes was based on an initial codebook with *a priori* themes based around the three fidelity components. Template analysis is a flexible approach to thematic analysis and tends to define themes from a mix of *a priori* interests and initial engagement with the data before applying the codebook to the full dataset[28]. The initial codebook was developed and fieldnotes were analysed by ER; the monitoring fieldnotes for two facilities were also analysed independently by two research team members (SK and LPK). Themes were compared and refined in a reflexive process intended to increase rigour and deeper analysis. The monitoring fieldnotes were coded and analysed using NVivo.

The data were initially coded descriptively, that is, the codes addressed the initial research aim of describing patterns in the components of fidelity. The research aim of explaining how different patterns arose, shifted the analysis to creating consolidated codes, and re-reading the data to check the codes' interpretive validity, to develop themes of causal explanation[29]. We focused analysis on the contextual factors and mechanisms shaping the process of implementation fidelity[30], rather than the overall outcome of the project's evaluation comparing quality of care measures before/after EDSS implementation, which is reported elsewhere[21].

Integration of results

Analyses were completed concurrently and iteratively, moving between quantitative and qualitative analyses to develop and interpret how patterns of implementation fidelity were shaped by context and mechanisms over time, drawing on theories of implementation[30–32]. The analysis was guided by Normalization Process Theory, a theory of action organised around four key constructs (coherence, cognitive participation, collective action and reflexive monitoring) that describe the different types of work needed to take something new (the EDSS intervention) and make it part of routine practice[31]. The constructs and underlying generative mechanisms of Normalization

Process Theory interact, and implementation fidelity was shaped by mechanisms operating in unique contexts. Using May and colleagues' recent guidance on linking Normalization Process Theory constructs to context-mechanism-outcome configurations[30], we examined how contexts, including organising structures and group processes, affected the dynamics of EDSS implementation. We drew from work conceptualising interventions as events within systems[15] to think about how mechanisms operated within the plasticity of the intervention (the extent to which users could modify intervention components) and how tightly or loosely the intervention was coupled with its implementation context (the level of negotiation users had in interacting with the intervention and the extent of work demanded to adapt the intervention to their contexts)[32].

Monitoring fieldnotes were coded deductively against the four Normalization Process Theory constructs with further themes arising inductively, and these were compared and integrated with findings from the quantitative analyses (ER). Preliminary explanations were reviewed by senior co-authors (LPK and OMRC) in regular meetings to enhance the reliability of findings. Finally, the research team reflected on the validity of the explanations, their plausibility and explanatory power[29].

Ethical approval

The mIRA project, in which this analysis was part, received ethical approval from Kathmandu University School of Medical Sciences (IRC, KUSMS 25/22), Nepal Health Research Council (2695) and the London School of Hygiene & Tropical Medicine (25094-1).

Results

We firstly present descriptive findings across the three components of fidelity, followed by explanations of the mechanisms operating within contexts to shape implementation fidelity.

Table 5.7 shows results from the four in-person monitoring visits. The length of time between monitoring visits increased over the duration of the project, from between 18-38 days between the first two monitoring visits to between 32-105 days for the final two monitoring visits.

Table 5.7 Results of in-person monitoring visits to all facilities

	WHO EDSS facilities (n=9)	mIRA EDSS facilities (n=10)
Monitoring visit 1 (20 May – 2 Jun 2022)		
Number of facilities with monitoring visit	9	10
Proportion of facilities with tablet ready to use	100%	80%
Mean number of days since last sync with server	0.0 (SD*: 0.0)	2.2 (SD: 2.3)
Number of facilities with ANC consultation observed	3	2
Proportion of ANC consultations with observed use of EDSS	100%	100%
Monitoring visit 2 (19 Jun – 28 Jun 2022)		
Number of facilities with monitoring visit	8	10
Range in number of days between monitoring visit 1 and 2	18 – 32	23 – 38
Proportion of facilities with tablet ready to use	100%	80%
Mean number of days since last sync with server	0.1 (SD: 0.35)	5.0 (SD: 9.8)
Number of facilities with ANC consultation observed	3	3
Proportion of ANC consultations with observed use of EDSS	100%	100%
Monitoring visit 3 (18 Jul – 18 Aug 2022)		
Number of facilities with monitoring visit	8	9
Range in number of days between monitoring visit 2 and 3	21 – 56	21 – 49
Proportion of facilities with tablet ready to use	100%	78%
Mean number of days since last sync with server	0.0 (SD: 0.0)	2.3 (SD: 2.7)
Number of facilities with ANC consultation observed	4	4
Proportion of ANC consultations with observed use of EDSS	75%	50%
Monitoring visit 4 (2 Sep – 16 Nov 2022)		
Number of facilities with monitoring visit	9	10
Range in number of days between monitoring visit 3 and 4	35 – 98	32 – 105
Proportion of facilities with tablet ready to use	100%	100%
Mean number of days since last sync with server	0.1 (SD: 0.3)	0.8 (SD: 1.0)
Number of facilities with ANC consultation observed	5	4
Proportion of ANC consultations with observed use of EDSS	80%	50%

*SD = standard deviation

Content: point-of-care use

Across the four monitoring visits, all WHO facilities and nearly all mIRA facilities had the tablet 'ready to use' (available, functional and sufficiently charged) (Table 5.2). Few facilities (20-55% of facilities in each of the four visits) had an ANC consultation during the monitoring visit. Among facilities with an ANC consultation observed, all (100%) were observed to use the EDSS at the point of care during the first two monitoring visits. Point-of-care use reduced to 50-80% for consultations observed in the third and fourth monitoring visits (Table 5.7).

Results from the monitoring visit fieldnotes and longitudinal case studies suggested the EDSS was not understood as a point-of-care tool, so the ANMs used it primarily for record keeping, often entering data after the consultation (Table 5.3). In many instances, providers took a photograph of the pregnant woman's handheld ANC card before she left the facility and entered the information into the EDSS later:

> *"Three ANMs are responsible for ANC check up and all of them uses the mIRA application. I asked one of the ANM staff, who was present in the ANC room, whether they have used mIRA application at the time of ANC consultation, then she replied that they don't use it when they are busy with high patient flow. They just click the photos of ANC card and filled it later in the application."* (Monitoring fieldnotes, 2nd monitoring visit, mIRA facility)

Busy periods with multiple pregnant women attending the facility, including on designated ANC days, were frequently mentioned as reasons why the EDSS was not used or why data was entered later. ANMs working alone struggled to incorporate the EDSS into the consultation, and point-of-care use was achieved when the ANMs worked together to divide the tasks of documentation and conducting the consultation:

> *"Mostly the trained ANM is using the WHO EDSS. We also observe untrained ANM using the EDSS with the help of trained ANM during the consultation. Today (Thursday) is the ANC day, so day is a bit busy. ANMs (3) are working together and they are simultaneously using EDSS and recording as per the variables in the ANC card."* (Monitoring fieldnotes, 1st monitoring visit, WHO facility)

Table 5.8 Synthesis of findings from the longitudinal case studies in four facilities

Fidelity component	How was the EDSS supposed to be used by the ANMs?	How did the ANMs use the EDSS in reality?
Content	One-to-one consultation During ANC consultation at the point of care	• Two or three ANMs worked together to provide ANC; sometimes one ANM dealt with two patients at a time. • EDSS entry sometimes done in the presence of pregnant woman during the consultation, but sometimes after the consultation, either taking a picture of the ANC card or referring to the ANC register, or entering details in the EDSS while the pregnant woman was sent to the laboratory for tests or in the waiting area.
Frequency	All ANC patients in all visits	• EDSS not used in all ANC visits; for example, not used for non-routine patients* or for non-routine visits†, not when expected date of delivery was near, and not when the tablet was not present in ANC room.
Quality	As a decision support system along with record-keeping	• Treated EDSS as more like a record-keeping application. • Low utilization of prompts/pop-up as suggested by EDSS and did not always follow the recommendations. • Entered values (normal and sometimes made-up) in mandatory entry fields just to be able to save and close the visit entry. • Immediately referred pregnant woman to the doctor/higher level provider in case of any minor problems or complications.
*Non-routine patients registered for ANC at another facility. †Non-routine visits are those outside the government-recommended visit schedule, including visits for further investigations or pregnancy complaints.		

Frequency: use for all visits

Table 5.4 shows the comparison in the number of entries recorded in the ANC register for a specific date and the number of entries logged in the EDSS for the same date for four rounds of monitoring visits. For most facilities, fewer than three entries were recorded in the ANC register for the previous date in each round of monitoring visits, and only one facility, in one monitoring visit, recorded more than 10 entries in the ANC register (Supplementary Material, Figure 5.S1). Among all facilities, agreement in number of entries (which included zero entries) varied between 28% to 65% in the four monitoring visits, without a clear pattern over time. In each round of monitoring visits, a substantial proportion (24-58%) of dates saw fewer EDSS entries recorded compared to entries in the ANC register for the same day. Agreement in number of EDSS and register entries was lower among mIRA facilities than WHO facilities for all monitoring visits, except for the mIRA facilities with syncing issues in monitoring visit three. For WHO facilities, there was a small reduction in dates with agreement in numbers of entries documented (78% to 56%) and an increased proportion of dates

with fewer entries in the EDSS compared to the register (11% to 44%) from the first to the fourth monitoring visit.

Table 5.9 Comparison of number of ANC visit entries recorded in the paper-based ANC register and the EDSS software backend data across four rounds of monitoring visits.

	WHO EDSS facilities (n=9)	**mIRA EDSS facilities without syncing issues (n=6)**	**mIRA EDSS facilities with syncing issues (n=4)**	**TOTAL (n=19)**
	n (%)	n (%)	n (%)	n (%)
Monitoring visit 1				
Number of facilities with monitoring visit	9	6	4	19
Agreement in number of EDSS and register entries*	7 (78%)	2 (33%)	1 (25%)	10 (53%)
Zero entries in register and in EDSS	1 (11%)	1 (17%)	0%	2 (11%)
Fewer entries in EDSS than in register	1 (11%)	4 (67%)	2 (50%)	7 (37%)
Monitoring visit 2				
Number of facilities with monitoring visit	8	6	4	18
Agreement in number of EDSS and register entries*	5 (63%)	0 (0%)	0 (0%)	5 (28%)
Zero entries in register and in EDSS	3 (38%)	0 (0%)	0 (0%)	3 (17%)
Fewer entries in EDSS than in register	2 (25%)	5 (83%)	3 (75%)	10 (56%)
Monitoring visit 3				
Number of facilities with monitoring visit	8	6	3	17
Agreement in number of EDSS and register entries*	5 (63%)	3 (50%)	3 (100%)	11 (65%)
Zero entries in register and in EDSS	1 (13%)	2 (33%)	1 (33%)	4 (24%)
Fewer entries in EDSS than in register	2 (25%)	2 (33%)	0 (0%)	4 (24%)
Monitoring visit 4				
Number of facilities with monitoring visit	9	6	4	19
Agreement in number of EDSS and register entries*	5 (56%)	2 (33%)	1 (25%)	8 (42%)
Zero entries in register and in EDSS	2 (22%)	1 (17%)	0 (0%)	3 (16%)
Fewer entries in EDSS than in register	4 (44%)	4 (67%)	3 (75%)	11 (58%)
*Includes both equal number of entries in EDSS as register and zero entries in register and in EDSS.				

The EDSS was rarely used when pregnant women visited the facility for additional investigations, such as ultrasound (USG) scans, or when they were not regular patients registered at the facility (Table 5.3). This aligned use of the EDSS with existing practices on who and what gets documented in paper ANC records:

"The tablet is being used for those cases which is a regular case at the facility but not those come for USG and lab investigation." (Monitoring fieldnotes, 4th monitoring visit, mIRA facility)

"ANC consultation from another ward details are only entered in [EDSS] if ANC card and test reports are brought by the patient, otherwise data is not entered in [EDSS]. Also, their registration is not done in ANC register." (Monitoring fieldnotes, 1st monitoring visit, WHO facility)

For ANC visits that would have been documented in the ANC register, as in Table 5.4, EDSS entry was often limited to the ANM who had received workshop training in using the tablet and software. ANMs described how the availability of the trained ANM, whether due to leave or assignment to non-ANC duties, shaped use of the EDSS and meant that some ANC visits did not get entered:

"In my previous monitoring visit the trained ANM was on leave for one month, and only 1 ANM was there and there was no tablet in health facility. But this time the trained ANM was there with tablet. The trained ANM told me that the tablet was not being used when she was on leave for a month. Since other ANMs does [sic] not show interest in using the tablet with EDSS, she did not [leave] the tablet at health facility. And tablet hasn't been used by anyone else for that period of time. She told me that she is the only one in the health facility who uses the tablet. When I asked her 'why does any other staffs do not use the tablet?' She answered that other staffs doesn't show any interest on using the app and also believed that only trained ANM supposed to use the tablet." (Monitoring fieldnotes, 3rd monitoring visit, mIRA facility)

Quality: scope of EDSS functionality enabled

Table 5.5 shows the proportion of selected non-mandatory fields completed out of the total number of EDSS entries created; completeness was nearly universal (>99%) for all three variables in the WHO EDSS. Completeness for the selected three non-mandatory fields in the mIRA EDSS ranged from 40% to 90%, with only one-third of entries having all three fields completed. The mIRA EDSS non-mandatory fields of urine protein test and haemoglobin test were the least completed variables assessed. These tests require equipment that may not have been available at the facility during the ANC visit, so it was possible to select 'not done' in the EDSS and give stock-out of test kits as the reason.

Table 5.5 Completeness of EDSS backend data for all visit entries dated during the implementation period (15 May – 16 Nov 2022) for the mIRA EDSS and WHO EDSS

	Non-mandatory field	**Value recorded in EDSS**	**Proportion of entries complete**
mIRA EDSS n=848 entries	Current pregnancy complaints	Any option selected/no complaints reported [vs nothing entered]	90%
	Urine protein test	Done/not done [vs nothing entered]	40%
	Haemoglobin test	Done/not done [vs nothing entered]	40%
	All three variables		34%
WHO EDSS n=987 entries	Visit schedule counselling	Done/not done [vs nothing entered]	100%
	Pallor assessed	Yes/no [vs nothing entered]	100%
	Oedema present	Yes present/no [vs nothing entered]	100%
	All three variables		99%

The monitoring fieldnotes and longitudinal case studies suggested ANMs rarely used the prompts or recommendations from the EDSS and in some cases recorded care components without performing them, often out of frustration with trying to fill in all the mandatory fields to save the EDSS entry (Table 5.3). ANMs described the EDSS as something for record keeping, though some noted that the entry form could serve as a helpful reminder to do things. But custom prompts and pop-ups ("toasters") were ignored, and ANMs often did not make use of some of the software's functionality, such as the auto-calculation of gestational age:

> *"She was calculating week of gestation in rough page and copied in ANC card. Completed consultation and filing in ANC card then used WHO app for ANC as this was the client for 4th visit to health facility in 9 mth. Trained ANM used the app and was providing counselling but did not check for the toasters in the application."* (Monitoring fieldnotes, 1st monitoring visit, WHO facility)

Explaining patterns of implementation fidelity

Table 5.6 outlines how Normalization Process Theory constructs appeared in our examination of implementation fidelity. The generative mechanisms underlying these constructs shaped how implementation fidelity unfolded in the different facilities.

Table 5.6 Normalization Process Theory constructs and interpretation of how these mechanisms appeared in our assessment of EDSS implementation fidelity

Normalization Process Theory construct	**How the constructs and their related components appeared in our study**
Coherence (sense-making work): understanding what was different about the EDSS intervention, understanding its aims, understanding what the individual's responsibilities/tasks were in relation to the EDSS and the value/benefits of these activities.	Differentiation: Participating ANMs understood the EDSS as another record keeping practice and did not see it as a tool to support decision making or to change how they provided care during ANC visits. Internalization: Few ANMs spoke of its potential usefulness as a reminder, particularly for counselling topics.
Cognitive participation (relational work): whether key participants (e.g., the trained ANM) drove the new practice forward, whether ANMs believed it was right for them to be involved in the EDSS intervention and how they rethought group relationships.	Initiation and legitimation: Enthusiasm or interest in learning to use the EDSS did not always align with the ANM selected to receive training, and some ANMs who did not receive EDSS training did not view using the EDSS as a legitimate part of their role. Organisational logic and enrolment: Many facility staff saw the EDSS intervention as a time-limited research study that was tangential and duplicative to the government-allocated work of documentation in ANC cards and monthly reporting.
Collective action (operational work): how ANMs operationalised use of the tablet during ANC visits and the resources needed for this.	Interactional workability: Teams of ANMs worked together to incorporate EDSS data entry into the process of ANC consultations and other forms of documentation. Skill-set workability: The EDSS software was not always intuitive to use, and low ANC caseloads meant ANMs had few opportunities to practice and consolidate skills in using the software. ANMs developed workarounds to adapt the EDSS to fit with paper-based record keeping practices, such as entering information about twin pregnancies using '/' marks in relevant variable fields in both the paper records and EDSS.
Reflexive monitoring (appraisal work): ANMs reflecting on whether participation in the new tasks of the EDSS intervention was working, including how the intervention was refined to make it workable in practice, how it affected them and how useful it was.	Individual appraisal: Any potential benefits in decision support could not overcome the increased workload that accompanied increased data entry required by the EDSS. The EDSS was blamed for increasing the length of consultations when ANC patients complained about long wait times. Reconfiguration: ANMs redefined prompted procedures to fit within existing practices, such as only doing oral glucose tolerance tests (provided by the mIRA project intervention and prompted by the EDSS as the preferred action) if the random blood sugar test result was high.

The EDSS was almost universally understood as a record keeping task (Table 5.6), which shaped how the EDSS was used: taking of photos of ANC cards for later data entry, limiting use to routine visits and routine patients to fit with existing norms of documentation in the ANC register, and even in one instance asking the researcher conducting the monitoring visit to assist in EDSS data entry during a busy period. The (in)coherence between the intervention-as-intended and how ANMs made sense of the intervention led to varying fidelity to point-of-care use depending on how the ANC caseload was managed. In smaller facilities with only one ANM allocated to ANC, or where only the trained ANM used the EDSS, simultaneous data entry was challenging, particularly when multiple ANC patients were waiting (negotiating capacity). ANMs snapped photos of ANC cards to input into the EDSS later, seeing participation in the EDSS intervention as simply entering the data and resulting in low fidelity to point-of-care use but higher frequency of visits entered.

In facilities with moderate patient caseloads yet busy ANC days, teams of ANMs worked together to deliver and document care. One ANM interacted with the ANC patient and other(s) did the record keeping, allocating EDSS data entry alongside the paper-based forms in a parallel record keeping system, with both trained and untrained ANMs participating in using the EDSS. In two facilities observed using this approach, fidelity to point-of-care use remained consistently high throughout the implementation period.

Low caseloads of ANC patients hindered incorporation of the EDSS into routine practice. The EDSS software suffered technical problems, but ANMs also had few opportunities to practice using the EDSS, including for adding a follow-up visit for the same patient. Several ANMs still faced skill-set workability challenges at the end of the implementation period (Table 5.6).

Discussion

This study operationalised a realist assessment of implementation fidelity for an EDSS intervention to improve the quality of ANC in Nepal. We incorporated three key features: 1) we saw fidelity not as a binary (fidelity vs implementation failure) but as degrees of consistency with the intervention-as-intended; 2) we analysed fidelity as a process over time; and 3) we proposed explanations for how and why fidelity unfolded in the way that it did. We found fidelity to EDSS point-of-care use declined over time, though this fidelity component was also one of the most challenging to assess via observation. ANMs understood the intervention as primarily about record keeping, resulting in lower point-of-care use and often entering data after ANC visits had ended. Frequency of use for ANC visits aligned to existing paper-based record keeping practices, with ‘non-routine’ interactions

between providers and ANC patients rarely recorded in either the EDSS or ANC registers. Quality of EDSS use (operationalised by completeness of data entry) was lower for the mIRA EDSS compared to the WHO EDSS; however, for both EDSS, and even in facilities with higher fidelity to point-of-care use, prompts and pop-ups were largely ignored.

The 'loose' coupling of the intervention to its implementation context enabled ANMs to negotiate use of the EDSS that at times supported fidelity (e.g., working in teams to use the EDSS at the point of care) or undermined fidelity (e.g., snapping photos of ANC cards for later EDSS data entry)[32]. The taking of photos of the ANC card for later EDSS data entry was an unanticipated modification to the intervention theory that undermined the function of using the EDSS[12,14,20]. Low ANC caseloads at participating facilities meant that even during the monthlong supported lead-in period, ANMs had few opportunities to practice using the EDSS. Fieldworkers suggested photographing ANC cards so that ANMs could practice inputting data in the EDSS, but the suggestion almost certainly undermined the role of the EDSS to be used during the ANC consultation. It also shifted understanding of the function of the intervention from decision-aid – ideally used during interactions with patients when decisions about care were taken – to primarily a record keeping application. This situation demonstrates the importance of discussing the intervention theory in terms that fieldworkers and participants understand, and clarifying the intervention's purpose and allowable adaptations so as not to undermine fidelity to its function[14].

Others have noted the difficulty in defining intervention-as-intended, and our components of fidelity presented very different implementation challenges[13]. Defining fidelity in a complex intervention, like an EDSS, demands teasing out what constitutes essential elements of the intervention's design and what constitutes the mechanisms the intervention was intended to trigger. The EDSS intervention asked healthcare providers to engage in additional record keeping (on top of paper-based records) and to modify how they provided ANC. Healthcare providers were expected to simultaneously provide clinical care, input information in the EDSS, and respond to its prompts. By inputting data *and* following the prompts, (we hoped) providers would deliver more guideline-recommended care components in each ANC visit. How ANMs made sense of the intervention (coherence) was critical to unpacking not just fidelity of the activity but also its intention, capturing the 'spirit' with which the intervention was delivered[30,33]. We understood that how point-of-care use was achieved, whether via teams of ANMs or with providers working alone, was less important than fidelity to the intended function, which was use of the decision-support tool at the point where

decisions about care were being made[2,8,12]. However, as we found, ANMs did not view the EDSS as a decision-support tool, even when used at the point of care.

Our findings echo those from other studies examining implementation outcomes for clinical decision support tools in maternity services in low- and middle-income settings. Similar to a realist evaluation of an antenatal decision-support tool in Ghana, we found shortfalls in the skill-set workability of the intervention and uncertainty about the utility and increased workload associated with using the EDSS, particularly as in both the Ghana project and the mIRA project, the EDSS were implemented alongside paper-based record keeping[34]. A study of an intrapartum decision-support tool in Kenya also found that providers largely used the software for record keeping and reporting, rather than as a clinical support tool[35].

Limitations

Our assessment of implementation fidelity contributes to more robust evaluation and elaboration of EDSS intervention theory, offering causal explanation about what happened during implementation of the EDSS and why[9], but our study is not without limitations. Due to logistical constraints in collecting data from remote health facilities in Nepal, qualitative and quantitative data were collected at the same time, which limited probing of the fieldworkers' observation notes based on the emerging quantitative findings. In particular, the backend data provided useful insights about unobserved EDSS usage, but as this data was not available until in-person monitoring was nearly complete, we were unable to query with ANMs about the patterns found. There were also discrepancies in the amount of data available from the difference sources for each facility. In the monitoring fieldnotes, some facilities had very detailed descriptions of implementation over time, while others had virtually no additional information documented. The monitoring fieldnotes were not wholly focused on describing implementation, with some recording (often useful) background information about staff changes and numbers of patients attending the facility or about difficulties encountered during the monitoring visit, such as not being able to observe any ANC patients or an inability to check tablet functionality (e.g., due to a forgotten password). We also found divergence between quantitative and qualitative findings that were not always easy to reconcile.

We found it challenging to identify non-mandatory fields in the backend data that could be expected to be relevant for all ANC visits in order to assess completeness of EDSS entries. The resulting non-mandatory fields assessed for the mIRA EDSS versus the WHO EDSS are qualitatively different. This limits the appropriateness of comparing quality or scope of functionality enabled between the two

EDSS. The non-mandatory fields for urine protein and haemoglobin tests in the mIRA EDSS required equipment that may not have been available (though providers could indicate lack of supplies as a reason for not performing the test) and also suggested guideline-informed actions that potentially conflicted with the frequency with which ANMs thought the tests should be performed[21].

We applied Normalization Process Theory as a lens to examine the contexts and mechanisms shaping fidelity. Dalkin and colleagues have argued that Normalization Process Theory's generative mechanisms differ ontologically from how causal mechanisms are conceived within realist evaluation, most notably that the theory's constructs occupy the empirical realm (observable) rather than the real (unobservable)[36]. While we interrogated how contexts influenced the observable actions taken by participants, we were less able to uncover the invisible drivers of action[37]. Missing from this analysis were interviews with healthcare providers that could have probed the reasoning healthcare providers gave—explicitly or implicitly—for their actions and the (lack of) implementation fidelity; however, interviews within the longitudinal case studies were conducted prior to beginning analysis for this study.

Conclusion

Our assessment of implementation fidelity expands the concept through a realist evaluation lens, combining a longitudinal approach to see this as a process and an emphasis on explanation of how and why patterns of implementation fidelity occurred. This leads to more nuanced understanding of the mIRA project evaluation's null result than attributing it to intervention vs implementation failure. We hoped to enhance understanding of how the EDSS intervention was enacted within the complex system of ANC in Nepal and the different kinds of work necessary to implement an EDSS in ways that enhance fidelity to its function. As clinical decision support tools continue to proliferate, more nuanced evidence on the processes driving fidelity can help improve intervention design, optimise implementation within complex systems, and enhance the potential for positive impacts on provider performance and health outcomes.

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Supplementary Material

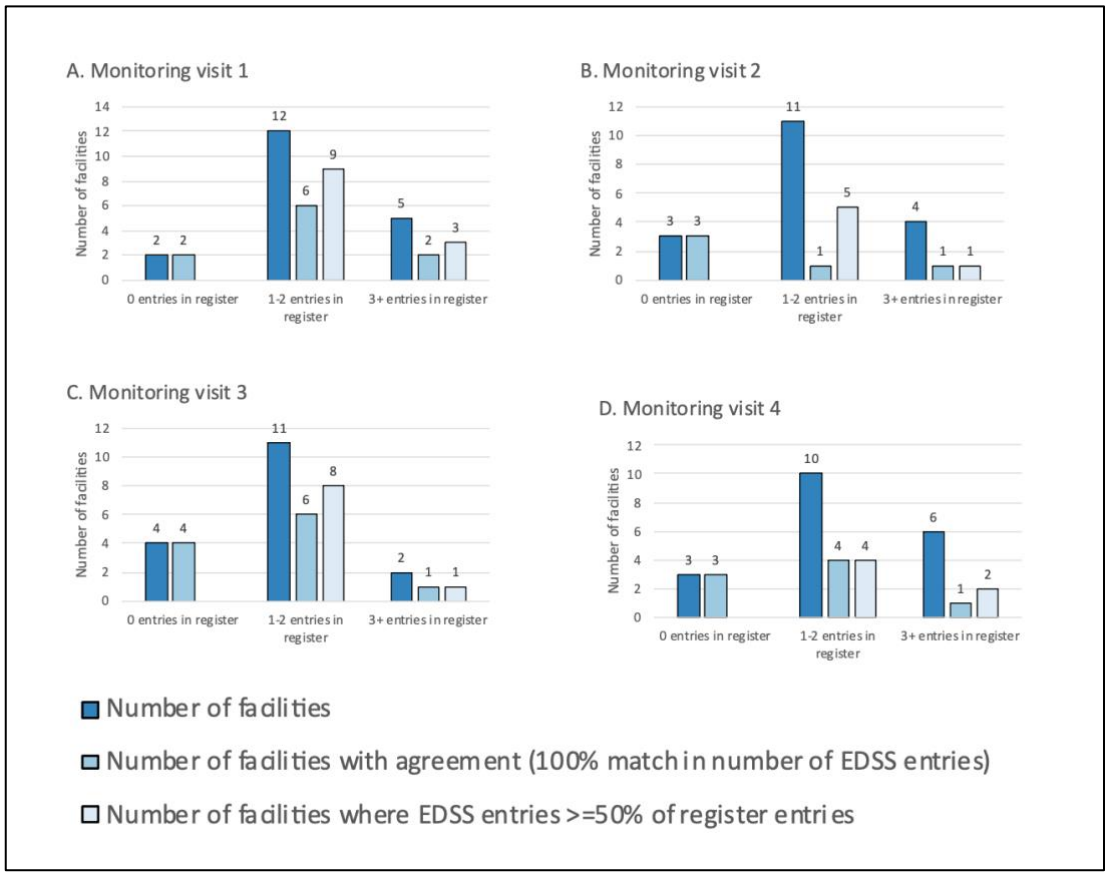

Figure 5.S4 Number of facilities, stratified by number of ANC register entries recorded for each of the four monitoring visits, with agreement in number of EDSS entries and where EDSS entries were greater than or equal to 50% of the number of ANC register entries for the same date

Chapter 6: Workload in antenatal care before and after implementation of an electronic decision support system: an observed time-motion study of healthcare providers in Nepal (Research paper 3)

This chapter presents findings from a time-motion study in Nepal, which was added to the mIRA project process evaluation through this PhD. The study, written up as a manuscript for publication, presents findings from two rounds of observation, before and after implementation of the EDSS, in two facilities, and relates to objective 4 of the PhD (to investigate the consequences of the EDSS intervention on changes in workload in ANC).

The study arose out of concerns about how the EDSS intervention would impact the workload of ANMs. The EDSS aimed to change provider practices during ANC consultations, and by offering more care components would likely increase the time spent on direct clinical care. Implementation of electronic documentation alongside paper-based records (rather than replacing them) was also hypothesised to increase the total amount of record keeping related to these ANC consultations. There were concerns that this potential dual increase in time—particularly from record keeping as this was seen as an unavoidable problem in the intervention—would be difficult for ANMs to incorporate into busy workdays and have potential adverse effects on time spent on other clinical activities. Formative research from the mIRA project in India suggested that the EDSS would add to an already substantial record keeping load. The time-motion study took a perspective that though the EDSS intervention was targeted at ANC, the effects of intervention might be seen more broadly within ANMs' workdays and capturing these auxiliary and unintended effects was important for understanding implementation in context.

6.1 List of Figures

6.2 List of Tables

6.3 Research paper cover sheet

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SECTION A – Student Details

Student ID Number	1402301	**Title**	Ms
First Name(s)	Emma		
Surname/Family Name	Radovich		
Thesis Title	Complex reality, implementation and measurement: Evaluation of an electronic decision support system to improve antenatal care quality in South Asia		
Primary Supervisor	Prof. Oona Campbell		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMC Medical Informatics and Decision Making
Please list the paper's authors in the intended authorship order:	Emma Radovich, Seema Das, Sulata Karki, Christian Bottomley, Ona L. McCarthy, Abha Shrestha, Loveday Penn-Kekana, Rajani Shakya, Biraj Karmacharya, Abha Shrestha, Oona M. R. Campbell, Giorgia Gon

Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceptualised and designed the study and drafted the initial activity categories for the data collection tool. Finalization of the tool, piloting and the first round of data collection were overseen by GG, who along with OLM, coordinated the study while I was on parental leave. I supervised the second round of data collection. SD and SK piloted the observations, inputted into the design of the study and tool, and conducted data collection. I cleaned the data and conducted the analysis. I wrote the first draft of the manuscript and prepared the manuscript for intended submission with consideration of co-author comments.

SECTION E

Student Signature	Emma Radovich
Date	25 June 2024

Supervisor Signature	Oona Campbell
Date	26 June 2024

6.4 Research paper

Title: Workload in antenatal care before and after implementation of an electronic decision support system: an observed time-motion study of healthcare providers in Nepal

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Abstract

Background: Healthcare interventions are shaped by the resources needed to implement them, including staff time. This study, part of a process evaluation, aims to compare time spent on antenatal care (ANC) and related record keeping in two rural primary health care facilities in Nepal, before and after implementation of an electronic decision support system intervention to improve ANC quality that required additional electronic documentation.

Methods: The study is a before-and-after, observational time-motion assessment. Researchers used the WOMBAT (Work Observation Method By Activity Timing) software to observe and record activities performed by auxiliary nurse midwives providing ANC in two rounds of data collection. We summed the observation time (in minutes) spent on activity categories for each day of observation, in each round of data collection. For each auxiliary nurse midwife, we estimated the proportion of total observation time spent on activities and compared these proportions before and after intervention implementation. We also compared the mean minutes per day spent on ANC and record keeping in the two rounds.

Results: Six auxiliary nurse midwives were observed over two data collection rounds (41 total observation days). Prior to intervention, providers spent 7% of their workday on ANC and 6% on related record keeping, and time spent on these activities did not change after intervention implementation. Only one of the six auxiliary nurse midwives demonstrated a statistically significant increase in time spent on ANC and record keeping after implementation. There was considerable day-to-day variation in ANC time, and substantial periods of "non-work" time (on break or not engaged in work-related activity). Non-work time reduced from 42% to 26% in the second round of data collection.

Discussion: Time spent on ANC and related record keeping was low and did not change after implementation of the electronic decision support system. Rural facilities serving few pregnant women meant time on ANC and record keeping was sensitive to day-to-day fluctuations in numbers of women attending for ANC, which may have masked the intervention's effects. However, the large amount of non-work time observed suggests time constraints during the workday were not a major factor inhibiting use of the electronic decision support system.

Introduction

Antenatal care (ANC) provides a platform for health promotion, disease prevention, screening, and treatment of pregnancy-related complications. The World Health Organization (WHO) essential package for ANC emphasises the importance of person-centred, quality care during each ANC visit in order to address the large burden of pregnancy-related mortality and morbidity in low- and middle-income countries (LMICs)[1,2]. The Mobile health Integrated Rural Antenatal care (mIRA) project sought to test the effectiveness of a tablet-based electronic decision support system (EDSS) on improving the quality of ANC in primary-level health facilities in Nepal and India. EDSS use electronic health records to integrate clinical and demographic data with diagnostic and treatment algorithms that provide prompts to improve guideline adherence[3]. In Nepal, where our study took place, a before-and-after study of the custom-built mIRA EDSS[4] and the WHO digital ANC module[5] sought to evaluate the impact of an EDSS intervention on quality of ANC, and to compare the implementation process of the two EDSS designs[6].

Interventions in healthcare environments are constrained by the resources needed to implement them, including staff time. Information and communication technology interventions, including EDSS, often result in changes to work practices in health facilities, enhancing or disrupting existing patterns of work and communication between healthcare providers and patients[7–10]. In pilot projects, EDSS may be implemented alongside paper-based record keeping systems[11], as was the case for the mIRA project. The additional tablet-based record keeping requirement takes up staff time. Further, efforts to improve guideline adherence and ensure high-quality ANC visits can result in providers spending more time on clinical care. It is important to assess changes to workload and their implications for clinical care and record keeping to understand an EDSS intervention's intended and unintended effects.

Time-motion studies are increasingly applied to yield important insights on workload and the effects of digital health interventions in resource-constrained settings[8,11–17]. In its most basic form, a time-motion study consists of an independent observer recording the time it takes for a worker to perform a task and the movements related to it and can offer less biased accounts of how healthcare providers use their time, particularly compared to self-report[18]. Time-motion studies in LMICs have been used to examine the effects of electronic documentation and quality improvement interventions in maternal health[11,19,20]. Studies in Ghana, Tanzania and West Bank, Palestine of time spent on ANC after EDSS implementation found no change in direct ANC clinical care but improved time efficiencies in record keeping where electronic documentation replaced paper-based records[11,20].

In Nepal, primary care maternity services are largely provided by auxiliary nurse midwives (ANMs) in rural settings[21]. ANMs are engaged in a wide range of services; a substantial focus of their role is on provision of ANC. The mIRA project trained ANMs in participating facilities in using the tablet-based EDSS to assist them in providing high-quality ANC. Because ANMs are increasingly involved in such a range of services[22–25], little is known about how ANMs spend their time, including how much of their workday is spent on ANC and related activities.

This study, conducted as part of the mIRA project process evaluation in Nepal, aims to compare change in time spent on ANC, and on record keeping related to ANC, before and after EDSS intervention implementation. To our knowledge, this is the first time-motion study conducted in Nepal.

Methods

The study is a two-phase (before and after), observational time-motion assessment focusing on major work activities performed by ANMs who provide ANC.

Study setting

The mIRA project evaluating the mIRA EDSS and WHO EDSS took place in four districts of Bagmati Province, Nepal at 19 primary-level facilities providing ANC in rural areas[6]. One ANM from each facility attended a three-day workshop at Dhulikhel Hospital in March 2022 to receive training in using their allocated EDSS. It was intended that the trained ANM teach other ANMs at the facility to use the EDSS; all ANMs were eligible to use the EDSS during ANC consultations. Following the training, ANMs received one month of in-facility support in using the EDSS by a trained fieldworker, with full EDSS implementation beginning in May 2022.

As part of the mIRA project's process evaluation, four facilities were purposively selected for qualitative longitudinal case studies consisting of repeat, unstructured observations and in-depth interviews[6]. The time-motion study was conducted in two Primary Health Care Centers with relatively higher ANC caseloads taking part in these longitudinal case studies, one each implementing the mIRA EDSS and WHO EDSS. ANC coverage is high in Nepal; between 2020-2022 nearly 87% of pregnant women in rural areas of Bagmati Province had at least one ANC visit and nearly 79% had four or more ANC visits[26]. Despite high ANC attendance, the participating facilities were in sparsely populated areas serving relatively few pregnant women. Facility-A, implementing the mIRA EDSS, recorded 749 first ANC visits in the year before the study; facility-B, implementing the WHO EDSS, recorded 224 first ANC visits in the year before the study.

Study design, tool development and definitions

The study continuously observed healthcare providers throughout their workdays in two rounds of data collection, conducted before and after EDSS implementation. Each round of data collection was conducted over two weeks, 10-12 days of observation per round. Due to the remote locations of the two facilities, the researchers stayed in nearby villages during data collection. Researchers conducted observation sessions during normal facility open hours when ANC is provided: approximately 10:00 to 16:00, Sunday through Friday (360 minutes per day). Both facilities offered 24hour services for the birthing centre and for emergencies.

All staff involved in providing ANC were eligible for observation; participants included ANMs and one staff nurse with similar duties as an ANM. To the extent possible, the same ANM was observed by the same data collector in both rounds of observation, to control for unmeasured factors that might affect activity recording. In the second round of data collection, we prioritised observing the ANM who had attended the EDSS training workshop. Due to the intense concentration required during data collection, researchers took 5-10 minute breaks after every 60-90 minutes of observation ("observation session") and took at least one 45 minute midday break to eat and rest. Researchers tried to time their breaks alongside those of facility staff and when there were no pregnant women presenting for ANC. Facility-A had a designated break time from 13:00-14:00 each day; Facility-B did not have a set break time.

Unlike other time-motion studies of digital health interventions in ANC[11,20], this study did not base the unit of observation on ANC consultations. This is because of evidence from formative research that ANMs in Nepal work in teams and frequently perform ANC consultations with multiple pregnant women simultaneously, switching between patients when, for example, a patient is sent to the laboratory for blood or urine testing, and resuming the ANC consultation when the patient returns with the test results. Further, there was evidence that some ANC-related record keeping occurred after ANC consultations ended[27]. In this study, the unit of analysis was minutes of the ANM's workday.

As the study focus was on ANC and ANC-related record keeping, priority was given to observing the ANM(s) involved in providing ANC on any given day of observation. The researcher would follow the ANM until the end of the workday or until the ANM was no longer available (attending home visits, for example). If an observation ended before the end of the workday, the researcher would switch to observing a different ANM, again prioritising any ANM involved in ANC provision, or if no ANC was being provided, then the ANM who was engaged in work activities, rather than non-work activity. If an observation ended after 15:00 (with less than an hour before facility closing), the researcher would end data collection for the day.

The study used the WOMBAT (Work Observation Method By Activity Timing) software, which enables automatic time stamps, and the recording of multitasking and interruptions[7]. To develop the activity categories, two researchers took notes during preliminary unstructured observations in Dhulikhel Hospital's obstetrics ward and in a Health Post in Kathmandu district during ANC days to develop the initial framework of actions performed by healthcare providers during ANC consultations. We used the notes, and additionally drew on categorisations used in a time-motion study in ANC in Ghana and Tanzania[11], to group actions into mutually exclusive activity categories with defined scope to improve reliability and consistency in data collection (Table 6.1).

Data quality

SK and SD conducted the observations, one of whom is clinically trained. Prior to the first round of data collection, the two researchers piloted the tool in simultaneous observation sessions over two days at Dhulikhel Hospital's ANC clinic, observing the same healthcare provider, to check inter-observer agreement. Activity coding and sequencing (including the allocation of the primary activity and secondary activity(ies) when multitasking) were reviewed by a third researcher (GG) and minor adjustments to coding suggested. The researchers conducted a second, three-day pilot in a Primary Health Care Center in Lalitpur district to further check inter-observer agreement. Piloting was considered complete when activity categories were coded reliably and only minor discrepancies of <1 minute in time stamp duration remained.

During data collection, the research team met regularly and communicated via a WhatsApp group. Following observations in each facility, in each round, the team debriefed to ensure consistent approaches and refine understandings of activity categories. The research team also discussed and reflected on findings not captured in the data entry tool to refine analysis plans and interpretation.

Table 6.10 Activity categories, associated sub-tasks and definitions

Activity category	Sub-tasks	Description of activities
ANC	Registration	Issuing the ANC registration number, providing ANC booklet, asking and documenting basic personal and contact information of the client into her ANC booklet and register.
	Education and counselling	Educating the pregnant woman on topics such as: danger signs in pregnancy, counselling on diet/nutrition, hygiene, need for immunization, STI prevention, family planning, breastfeeding and birth preparedness. Responding to the pregnant woman's questions about pregnancy or her care (for example when the woman should return for her next ANC visit).
	History taking	History taking- documenting past obstetric history, medical/surgical history, family history of illnesses, calculating EDD/gestational age. Asking about current symptoms or complaints related to the pregnancy.
	Physical examination	General examination from head to toe, handwashing, pallor, looking for signs of oedema and abdominal scars, and the examination of breast and pelvis. Palpation of abdomen, measuring of fundal height, listening to foetal heart sound, checking foetal position presentation, performing ultrasound scan.
	Investigation/referral	Advising client to attend for lab test, reviewing lab reports, discussing lab results with the client, referring client to another facility for lab tests; taking of blood samples; testing for haemoglobin, testing blood samples for syphilis and HIV using rapid diagnostic test kits; checking blood grouping of client. Testing of urine for protein, glucose, etc. using dipsticks, USG referral, reviewing USG report.
	Drug administration	Dispensing medications or supplements (such as deworming, iron or folic acid tablets); writing prescriptions; administering vaccinations to the ANC client, including tetanus diphtheria (Td); counselling on drug side effects.
	Vital signs	Taking and documenting height, weight, blood pressure, pulse, and temperature of the ANC client
	Supervising/delegating/training	Supervising nursing or any paramedical students, training those students during their posting.
	Navigating EDSS	Reading or scrolling through tablet
Record keeping	Client handheld ANC card	Entry into client handheld ANC card
	Paper ANC register	Entry into paper-based ANC register
	Other paper records	Entry into any other paper-based registers (e.g. family planning register, immunization register/card, tally sheet for monthly reporting etc.)
	Other electronic records	Computer data entry (including filling out HMIS)

	EDSS tablet	Entry into tablet (mIRA or WHO EDSS)
Communication	Client: chit-chat	Talking with clients about the weather, family, the pandemic, etc.
	Client: other	Talking with clients about other issues, not directly related to clinical care
	Colleague: work-related	Talking with colleagues or attending to phone calls about client-related matters
	Colleague: chit-chat	Talking with colleagues about non-work issues
Family planning		Provision of family planning commodities, counselling on family planning methods, checking equipment available for family planning (for example autoclaved/sterilized materials for IUCD implant), referring client for family planning services elsewhere, supervising/delegating/training students.
Immunization		Administering vaccinations to children or non-pregnant adults; preparing immunization equipment and materials. Does not include immunizations given to pregnant women.
Admin		Meeting with facility staff (including supervisor or colleagues), cleaning facility/equipment, preparation of examination room.
Non-work		Waiting for any reason, resting, meal or tea breaks, socializing (while not simultaneously doing another activity), attending to non-office/personal phone call or a phone call where subject/reason is not clear
Out of sight		ANC or other work, movement or other activity done elsewhere (out of sight of observation)
Other client services		Newborn health checks, abortion and related actions, conducting deliveries, postnatal care, outpatient services for non-pregnant clients (such as treatment of minor ailments). This includes record maintenance. Maintaining records of safe abortion services, file documentation and compilation, arranging incentive documents, mid-arm circumference measurement of baby, making delivery file, USG of non-ANC client, vaginal examination of non-ANC clients, delivery, post-natal care, dealing medical abortion cases, COVID-19 vaccination, blood pressure measurement of general patient, handling and supporting emergency cases

Data analysis

Analyses were conducted at the level of the ANM as the EDSS was hypothesised to be used differently by each ANM and have differing effects on time use[6]. For each ANM, we summed the total amount of time (in minutes) of observation spent on the activity categories for each day of observation, in each round of data collection. We calculated the proportion of time spent on each activity out of the total amount of observation time for each round. For ANMs observed in both rounds, we used unpaired t-tests to compare differences in daily proportions of time spent on ANC, ANC-related record keeping and non-work activity between rounds one and two (before and after EDSS implementation). For the activities of ANC and ANC-related record keeping, we described the total amount of time (in minutes) spent on specific sub-tasks of the activity (Table 6.1). To compare daily time spent on ANC and ANC-related record keeping before and after EDSS implementation, we calculated the mean number of minutes per day spent on ANC and record keeping for each ANM, among observation days that included that activity, and used unpaired t-tests to compare differences. We also calculated paired t-tests to compare overall differences for all ANMs combined, between rounds one and two, in proportion of time spent on ANC, ANC-related record keeping and non-work activity. Statistical significance was considered at the 5% level. All analyses were conducted in Stata/SE V.16 (StataCorp, College Station, Texas, USA).

The WOMBAT software enabled the documentation of multitasking (doing two or more activities concurrently). We calculated the proportion of total observation time spent multitasking in each round of data collection. For activities with multitasking sequences, time calculations were based on the primary activity to avoid overlapping activity time totals exceeding total observation time. We considered the primary activity to be the first activity in a multitasking sequence or the activity that overlapped with all the simultaneous activities in the multitasking sequence. For example, a five-minute episode of record keeping that included one minute of simultaneous communication with colleagues that began 10 seconds before record keeping and was immediately followed by one minute of ANC history-taking, would be coded as a primary activity of record keeping. Multitasking sequences could include a simultaneous activity that extended beyond the time period of the primary activity.

Across the two rounds of data collection three time-stamped episodes (between 3 and 41 seconds in length) were missing an activity code and were excluded from the analysis. Due to a data collection software issue in round 2, ANM-6 in facility-B had duplicate observation sessions documented for one observation day. While the observation session activity codes and time stamps were similar—

suggesting consistency in coding—they did not match exactly. As it was not possible to determine which of the duplicated observation sessions were more accurate, one observation day for ANM-6 in round 2 was excluded from the analysis. In round 1, ANM-1 at facility-A was observed for less than five minutes and in round 2, ANM-7 at facility-B was observed for less than 13 minutes before both ANMs left the facility to attend off-site trainings for the day. These two observation days, for these two ANMs, were excluded from the analysis.

The data collection software allowed the observer to end an activity independently before the start of the next activity (where this was not coded as multitasking). As the software logged continuously elapsing time, this resulted in a time gap, with some observation time not coded to an activity. Less than 1% of observation time (0.0-1.2% per ANM) was not coded to an activity; we retained all observation time (coded to an activity or not) in our denominators.

Ethics

Ethical approval was obtained from the Nepal Health Research Council (2695), Kathmandu University School of Medical Sciences (IRC, KUSMS 25/22) and the London School of Hygiene & Tropical Medicine (25094-1). We obtained written informed consent from ANMs participating in the study. When ANMs under observation engaged with patients, the researchers explained the purpose of their presence and sought verbal confirmation of permission from the patient to continue the observation. When patients declined permission, or when the researchers decided additional privacy was prudent (for example, when a patient wished to discuss pregnancy termination), the researcher ended the observation session and resumed observation when the ANM was no longer engaged with that patient.

Results

Round 1 data collection was completed in December 2021 in facility-A and in February-March 2022 in facility-B. During round 1, we conducted 11 days of observation in facility-A and nine days of observation in facility-B (Table 6.2a). During round 1, facility-B was closed for three days for public holidays. Round 2 data collection was completed in July 2022 in facility-A and in August 2022 in facility-B. During round 2, we conducted 10 days of observation in facility-A and 11 days of observation in facility-B.

In facility-A, three ANMs were observed in round 1 (ANM-1, ANM-2 and ANM-3); however, one ANM (ANM-1) was unavailable during round 2 so two new ANMs (ANM-8 and ANM-9), who were not

observed in round 1, were observed in round 2. In facility-B, the same four ANMs were observed in rounds 1 and 2 (ANM-4, ANM-5, ANM-6 and ANM-7). Observations were conducted over 2-9 days for each ANM; the six ANMs in both rounds were observed for 4-8 days each (Table 6.2b). The length of observation time of ANMs ranged from 92 minutes to 351 minutes per day, with a mean amount of observation time per day of 242 minutes (standard deviation [SD]: 49) in round 1 and 253 minutes (SD: 49) in round 2. The two EDSS-trained ANMs were ANM-2 in facility-A and ANM-5 in facility-B; both had multiple years' experience at their facilities and permanent contracts (Supplementary Material, Table 6.S1).

Time spent multitasking was 3.8% and 3.7% of total observation time in rounds 1 and 2, respectively (results not shown).

Table 6.11 Total amount of observation time and mean observation time per day of observation by facility and ANM in each round of data collection

A. Total amount of observation time per facility and average amount of observation time per day in rounds one and two										
	Baseline (round 1)					Endline (round 2)				
	Number of observation days	Total amount of observation time (in minutes)	Mean amount of observation time per day (in minutes)	SD[a]	Range (min-max)	Number of observation days	Total amount of observation time (in minutes)	Mean amount of observation time per day (in minutes)	SD	Range (min-max)
Facility-A	11	5475	497	47	(434-562)	10	4949	501	54	(372-553)
Facility-B	9	4915	547	63	(448-679)	11	5200	500	99	(229-623)
TOTAL	20	10389	520	60	(434-679)	21	10149	501	77	(229-623)
B. Total amount of observation time per ANM and average amount of observation time per day in rounds one and two										
	Baseline (round 1)					Endline (round 2)				
	Number of observation days	Total amount of observation time (in minutes)	Mean amount of observation time per day (in minutes)	SD	Range (min-max)	Number of observation days	Total amount of observation time (in minutes)	Mean amount of observation time per day (in minutes)	SD	Range (min-max)
Facility-A ANM-1	9	2136	237	41	(152-294)	0	-	-	-	-
Facility-A ANM-2[b]	8	1710	214	73	(92-286)	5	1348	270	26	(226-290)
Facility-A ANM-3	7	1629	233	50	(132-283)	8	1938	242	35	(159-265)
Facility-A ANM-8	0	-	-	-	-	5	1132	226	40	(167-271)
Facility-A ANM-9	0	-	-	-	-	2	531	266	2	(264-268)
Facility-B ANM-4	5	1429	286	13	(263-297)	4	1206	302	19	(275-321)
Facility-B ANM-5[b]	4	1033	258	83	(159-351)	5	1385	277	21	(242-292)
Facility-B ANM-6	4	971	243	58	(159-289)	5	1168	234	93	(75-302)
Facility-B ANM-7	6	1482	247	69	(121-328)	6	1441	240	63	(114-286)

[a] SD=standard deviation [b] ANM who received training in using the EDSS.

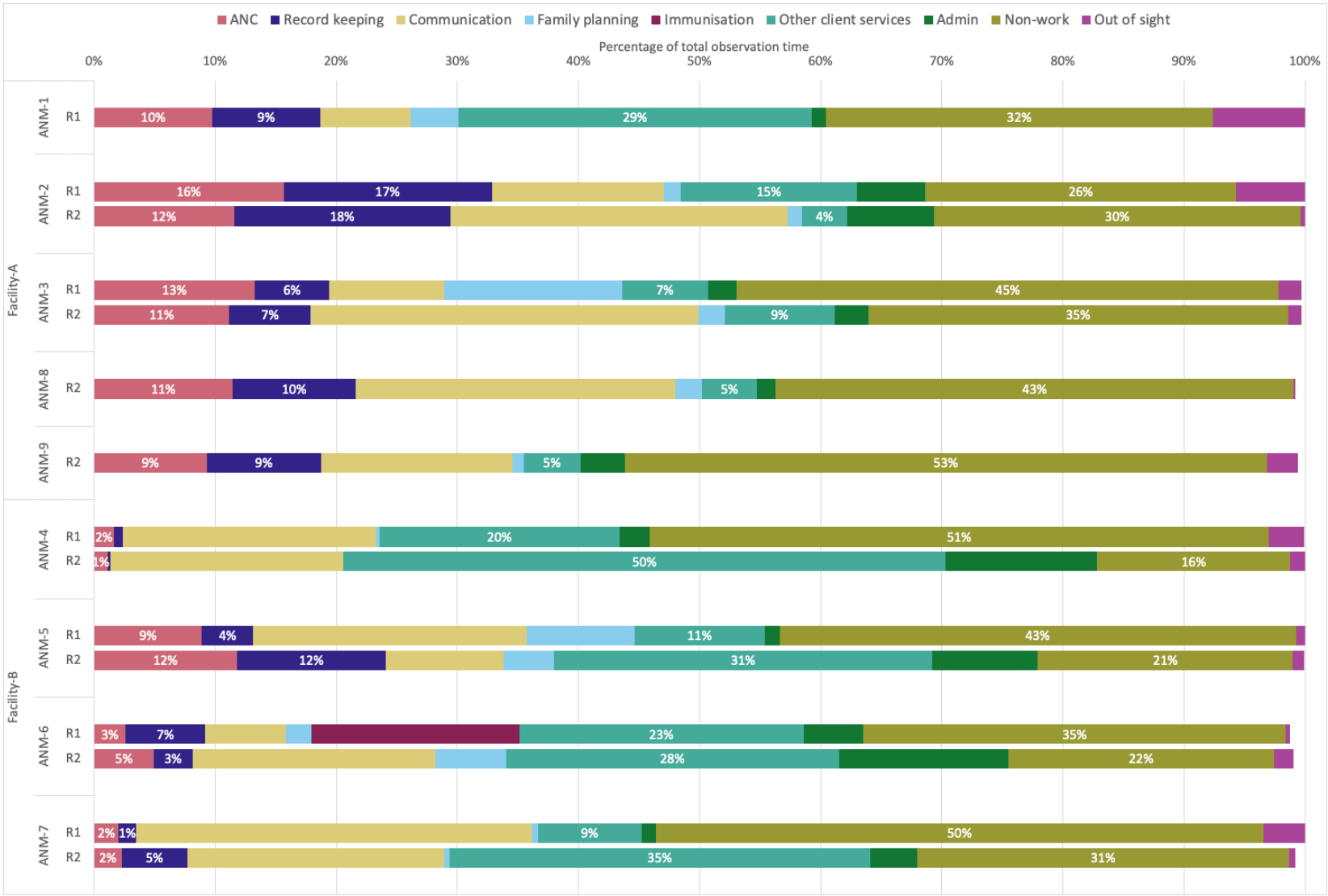

Figure 6.5 Proportion of total observation time spent on activity by ANM in rounds 1 and 2

Table 6.12 Comparison of the overall and daily proportions of ANC, record keeping and non-work activity time among ANMs observed in rounds 1 and 2

			ANC			Record keeping			Non-work		
			A. Proportion of total observation time	B. Mean daily proportion of observation time	p-value (column B, r1 vs r2)	A. Proportion of total observation time	B. Mean daily proportion of observation time	p-value (column B, r1 vs r2)	A. Proportion of total observation time	B. Mean daily proportion of observation time	p-value (column B, r1 vs r2)
Facility-A	ANM-2	R1	15.6%	19.5%	0.335	17.18%	17.9%	0.994	25.7%	24.7%	0.407
		R2	11.6%	11.5%		17.86%	17.8%		30.3%	30.1%	
	ANM-3	R1	13.3%	12.3%	0.777	6.13%	6.6%	0.992	44.7%	46.0%	0.041
		R2	11.2%	11.2%		6.73%	6.6%		34.6%	34.4%	
Facility-B	ANM-4	R1	1.6%	2.8%	0.073	0.74%	1.2%	0.896	51.2%	50.7%	0.100
		R2	1.1%	4.5%		0.26%	1.0%		15.9%	20.7%	
	ANM-5	R1	8.9%	13.0%	0.898	4.24%	4.4%	0.143	42.6%	42.5%	0.035
		R2	11.8%	14.2%		12.33%	14.9%		21.1%	21.1%	
	ANM-6	R1	2.6%	4.5%	0.603	6.54%	8.0%	0.252	34.9%	33.1%	0.666
		R2	4.9%	7.0%		3.18%	3.5%		22.0%	27.1%	
	ANM-7	R1	2.0%	2.6%	0.018	1.45%	1.8%	0.042	50.1%	52.6%	0.064
		R2	2.3%	9.5%		5.43%	9.4%		30.8%	29.5%	

Among all the ANMs observed, the proportion of observed time spent on different activities is shown in Figure 6.1. Across both rounds, between 1.1-15.6% of observed time was spent on ANC, and 0.3-17.9% of time was spent on ANC-related record keeping. In facility-A (mIRA EDSS), the five observed ANMs spent at least 9% of observed time on ANC across both rounds, whereas the three of the four ANMs in facility-B (WHO EDSS) spent less than 5% of observed time on ANC. Across all ANMs, the overall proportion of time spent on ANC (7.4% in r1 vs 7.1% in r2, p=0.849) and on record keeping (6.0% in r1 vs 7.6% in r2, p=0.372) was similar in the two rounds. Among the six ANMs observed in both rounds, there was no evidence of change in the daily proportions of time spent on ANC between the two rounds for five ANMs and evidence of an increase for ANM-7 in facility-B (2.6% vs 9.5%, p=0.018, Table 6.3). There was no evidence of change in the daily proportions of time spent on ANC-related record keeping for five of the six ANMs and evidence of an increase for ANM-7 in facility-B (1.8% vs 9.4%, p=0.042, Table 6.3).

A substantial proportion of observed time was spent on "non-work" activity (which included waiting around, meal or tea breaks, or attending to personal phone calls) (Figure 6.1). For all ANMs, approximately a fifth to half of all observed time was coded as non-work across both rounds. On some observation days, non-work activity constituted the majority of observation time (Supplementary Material, Figure 6.S1). Overall, there was strong evidence for a reduction in the proportion of non-work time (41.5% in r1 vs 25.8% in r2, p=0.034) before and after EDSS implementation. Table 6.3 shows that among the ANMs observed in both rounds, there was evidence that daily proportions of time spent on non-work activity decreased for ANM-3 in facility-A (46.0% vs 34.4%, p=0.041) and for ANM-5 in facility-B (42.5% vs 21.1%, p=0.035); marginally significant reductions were also observed for ANM-4 and ANM-7 in facility-B (p=0.100 and p=0.064, respectively).

The aggregate totals concealed large variations in how ANMs' time was spent day-to-day. The number of minutes spent on ANC varied by observation day, and some observation days included no time spent on ANC (Supplementary Material, Figure 6.S2). ANMs in facility-A, particularly ANM-2 (the EDSS-trained ANM) and ANM-3, had similarly wide ranges in minutes spent on ANC across the observation days. In facility-B, ANM-5 (the EDSS-trained ANM), had a much wider range in minutes spent on ANC across the observation days compared to their three colleagues. Further, there was variation in time use within the workday, with periods of non-work throughout but particularly in the afternoon (Supplementary Material, Figure 6.S3).

Figure 6.2 shows the activities of ANC and record keeping by sub-task. Within ANC, the sub-task of physical examination took up the majority of time spent on ANC for most ANMs. Only three ANMs in round 2 were observed as navigating the EDSS during ANC, including ANM-2 and ANM-5, the two EDSS-trained ANMs (Figure 6.2a). Navigating the EDSS (scrolling through the software or reading prompts) accounted for 16.9% and 5.8% of all ANC activity time in round 2 for ANM-2 and ANM-5, respectively. Within record keeping, filling in other paper records (which included monthly reporting) accounted for the majority of record keeping time for all but ANM-4 in round 1 and ANM-5 in round 2 (Figure 6.2b). In round 2, four ANMs were observed record keeping in the EDSS app. The two EDSS-trained ANMs, ANM-2 and ANM-5, spent a third to two-thirds of record keeping time, respectively, on documentation in the EDSS app.

Table 6.4 shows the comparison of mean number of minutes per day spent on ANC and record keeping in rounds one and two. For all ANMs, mean time spent on ANC and record keeping was less than 60 minutes a day. For ANM-4 and ANM-7, time spent on ANC was less than 20 minutes per day in rounds one and two. There was no evidence for a change in mean number of minutes per day spent on ANC or on record keeping for five of the six ANMs observed in both rounds. For one ANM (ANM-7), time spent on ANC and record keeping increased from 6 to 16 minutes per day for ANC ($p=0.029$) and from 4 to 20 minutes per day for record keeping ($p=0.047$).

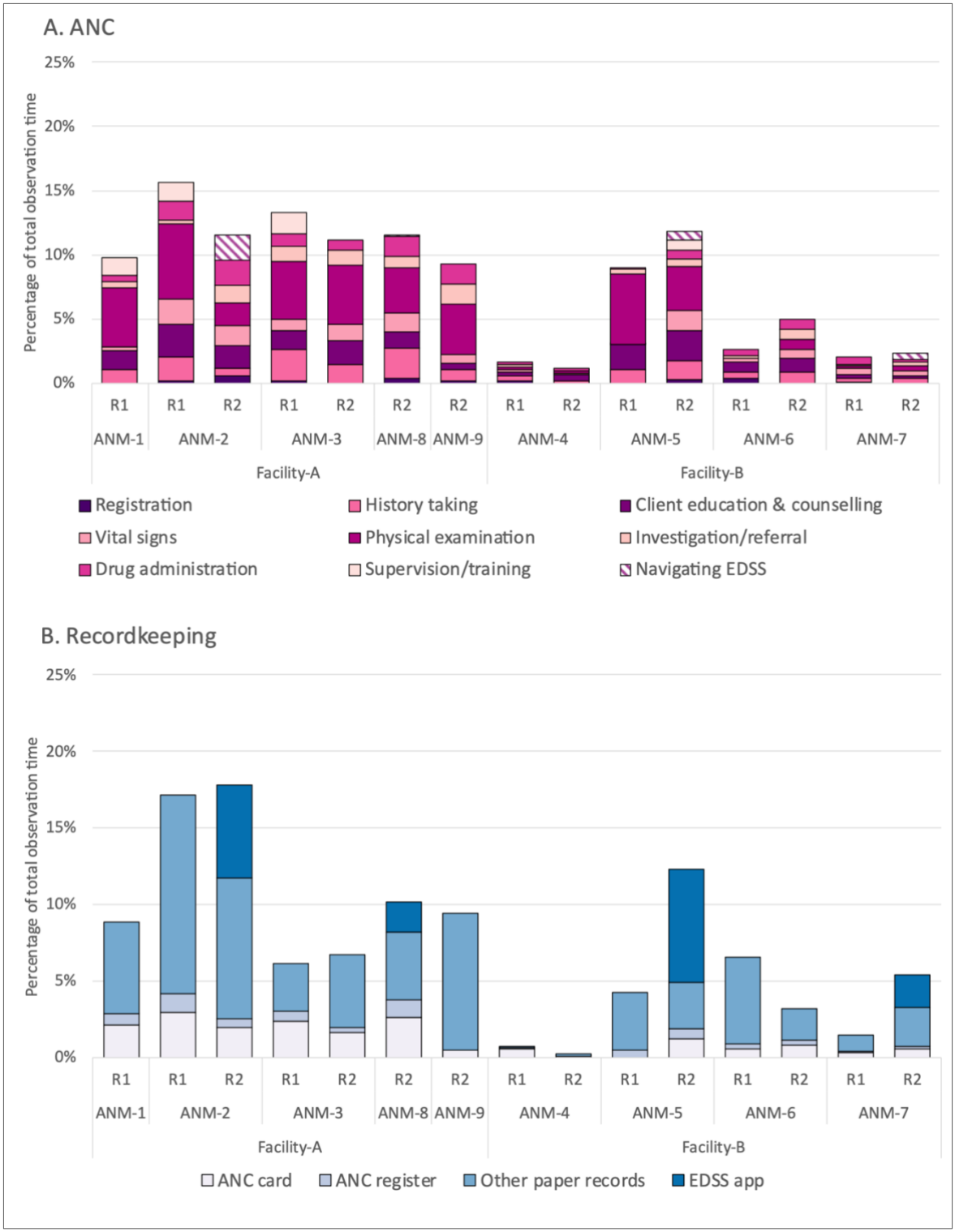

Figure 6.6 Proportion of total observed time spent on sub-tasks for A) ANC and B) record keeping

Table 6.13 Comparing mean number of minutes per day spent on ANC and record keeping in rounds 1 and 2 of data collection

A. ANC

		Baseline (Round 1)				Endline (Round 2)				Difference in mean minutes per day, r1 to r2	p-value, r1 vs r2
		Days of observation that included ANC activities (n)	Mean number of minutes per day	SD	Range (min-max)	Days of observation that included ANC activities (n)	Mean number of minutes per day	SD	Range (min-max)		
Facility-A	ANM-1	7	30	33	(6-101)	-					-
	ANM-2	7	38	28	(1-77)	5	31	5	(25-36)	-7	0.592
	ANM-3	7	31	23	(1-73)	8	27	15	(5-53)	-4	0.707
	ANM-8	-				5	26	12	(15-44)		-
	ANM-9	-				2	25	2	(23-26)		-
Facility-B	ANM-4	3	8	1	(7-9)	1	14	n/a	n/a	6	0.059
	ANM-5	3	31	26	(6-58)	4	41	37	(3-92)	10	0.705
	ANM-6	2	13	10	(6-20)	3	19	16	(4-36)	6	0.658
	ANM-7	5	6	4	(2-12)	2	16	3	(14-19)	10	0.029

B. Record keeping

		Baseline (Round 1)				Endline (Round 2)				Difference in mean minutes per day, r1 vs r2	p-value, r1 vs r2
		Days of observation that included record keeping activities (n)	Mean number of minutes per day	SD	Range (min-max)	Days of observation that included record keeping activities (n)	Mean number of minutes per day	SD	Range (min-max)		
Facility-A	ANM-1	8	24	25	(4-83)	-					-
	ANM-2	7	42	31	(13-102)	5	48	9	(36-60)	6	0.678
	ANM-3	6	17	9	(8-28)	8	16	10	(6-37)	0	0.950
	ANM-8	-				5	23	23	(5-57)		-
	ANM-9	-				2	25	22	(9-41)		-
Facility-B	ANM-4	3	4	4	(0-7)	1	3		n/a	0	0.930
	ANM-5	4	11	7	(4-19)	4	43	35	(2-88)	32	0.128
	ANM-6	3	21	16	(5-37)	4	9	6	(2-15)	-12	0.226
	ANM-7	5	4	4	(1-11)	4	20	14	(0-30)	15	0.047

Discussion

This time-motion study in Nepal examined changes in time spent on ANC and ANC-related record keeping before and after the implementation of a tablet-based EDSS, which was introduced alongside paper-based record keeping. We found ANMs in the study facilities spent a small proportion of their workday on ANC and related record keeping, and this did not change after implementation of the EDSS. ANC took up no more than 16% of any ANM's workday in either round, and ANC-related record keeping was no more than 18%. There was considerable day-to-day variation in the proportion of time spent on ANC, including days where ANMs were observed doing no ANC activity. Substantial periods of the ANMs' workdays were spent on "non-work", or not engaged in any work-related activity or on breaks, and there is evidence that non-work time reduced after EDSS implementation.

Only one of the six ANMs observed in both rounds showed evidence of a change in the proportion of time and mean number of minutes per day spent on ANC and record keeping after EDSS implementation. ANM-7 was observed to have a statistically significant increase in mean number of minutes per day spent on both ANC and on record keeping, though these activities still accounted for less than 10% of the ANM's total observation time. Notably, the two ANMs who received training in the EDSS did not have statistically significant changes in mean time per day spent on record keeping, though this may reflect the high degree of day-to-day variability in ANC and related record keeping activity. However, both EDSS-trained ANMs spent large proportions of their record keeping time on entering data in the EDSS in round 2.

The overall reduction in non-work time between rounds one and two should be interpreted cautiously as this may reflect fluctuations in service demand and is unlikely to be related to the intervention. The large amount of non-work time observed suggests that time constraints during the workday as a whole were not a major factor in the infrequent use of the EDSS documented in other studies[27]. However, non-work time should be considered within the context of variable patient flow, for ANC and other services. For instance, in round 1, the four ANMs at facility-B spent between 8.6-23.5% on other client services and in round 2 spent between 27.5-49.7% of observed time on other client services, which included attending to women giving birth. As part of ethnographic work conducted in the study facilities for the mIRA project process evaluation, we observed that the facilities were often relatively busy with patients (including for ANC) in the morning due to local bus schedules and few, if any, patients attended the facilities in the afternoon[28]. Further, ANMs often

described this non-work time as waiting around for patients to arrive and did not view it as break time. The finding of substantial non-work time is similar to findings from studies in other LMICs, including time-motion studies in India which found ANMs spent considerable amounts of time waiting for patients to arrive on designated clinic days[17,29]. A study of nurses in reproductive and child health clinics in Tanzania, found variation in staff productivity was largely explained by patient flow but that nurses rarely demonstrated the initiative to undertake other tasks (such as filling in health management information system forms) when patients were not present[13].

ANMs spent very little time on ANC. The low proportion of time spent on ANC may reflect how the workload was managed with multiple ANMs involved in ANC consultations, reducing the total amount of time individual ANMs were observed performing ANC tasks. The distribution of daily time spent on ANC between teams of ANMs at both facilities (see Supplementary Material, Figure 6.S2) suggested different ways ANC was managed. ANMs in facility-A appeared to work as more of a team to provide ANC, so when the facility was busy, all the ANMs were busy providing ANC. In facility-B, ANM-5 appeared to frequently do much more ANC compared to colleagues, suggesting that on many days ANM-5 was providing most ANC direct patient care. However, even when spread across multiple ANMs, the low mean number of minutes per day spent on ANC suggested that ANMs spent short periods giving direct clinical care to pregnant women—a finding supported by other studies in the mIRA project[28,30]. The amount of time dedicated to ANC raises questions about whether good quality care can be provided within such short time periods. Our study found no evidence that time spent on ANC changed—though small increases in ANC time were noted for one of the six ANMs—and the overall mIRA project evaluation found no improvement in quality of care after implementation of the EDSS[30]. Our findings on minimal changes in time spent on ANC is echoed in other studies of EDSS interventions in ANC, which found no change in time spent on clinical care in ANC[11,20], though the study in Palestine found improvements in ANC guideline adherence[31] while the study in Ghana, Tanzania and Burkina Faso saw no evidence for improvement in quality of care[32].

Overall time spent on ANC-related record keeping was low, and non-ANC related record keeping was captured under other activity categories, such as family planning, immunization or other client services, limiting our ability to parse the full record keeping workload of ANMs. Our findings about the low proportion of time spent on record keeping should be interpreted carefully due to the design of the data collection tool (and ANC focus of the study) as this stands in contrast to the

substantial literature on the burden of documentation in healthcare. Other studies in LMICs have found a much larger record keeping burden in primary care facilities[33,34], including in ANC[35].

Limitations

The study offers unique insights but was not without limitations. The resource-intensive data collection of the time-motion study design meant spreading observation time over 3-4 ANMs in each around of data collection. The ANM who would be selected to receive EDSS training was unknown during round 1 of data collection, so observation time was distributed across all ANMs, limiting the number of workdays observed for each ANM. Efforts were made to observe the EDSS-trained ANMs in round 2 as much as possible, though these ANMs were sometimes unavailable. The limited days of observation per ANM, alongside the high degree of day-to-day variability, may have masked any potential effects of EDSS implementation on time spent on ANC or related record keeping. However, evidence from other studies in the mIRA project suggested that the EDSS was rarely used and did not significantly change ANC practices, supporting the findings of no meaningful change in time use in this study[27,30].

Due to the intensity of data collection, as well as ANMs going off-site for periods of the day, it was not possible to observe every minute of the workday. This may have underestimated time on some activities. Due to the data collection approach, where observers tried to time their own breaks with that of the ANMs, non-work time in this study may be underestimated. However, priority was given to observing ANMs providing ANC during observation days, and researchers tried to time their breaks when the ANMs were not involved in clinical activities, reducing the likelihood that ANC and related record keeping time were underestimated. Further, for all ANMs, most observation days included at least 252 minutes of observation (70% of normal facility open hours), and more than 80% of observation days included at least 216 minutes of observation (60% of facility open hours).

Before-and-after studies are limited in accounting for other contextual factors that may have contributed to changes (or lack of change) observed. There was a longer than anticipated gap between baseline data collection and the start of EDSS implementation, resulting in more than six months between rounds 1 and 2, though this was a comparatively shorter baseline to endline gap than other studies. The time-motion study in Ghana and Tanzania was completed six months before EDSS implementation and then 17 months after implementation[11]. However, during the six-month gap in this study, there were several staffing changes that impacted data collection, including ANMs returning from or going on maternity leave or being re-assigned to a newly opened surgical ward. As

a result, six ANMs could be observed in both rounds, only two in facility-A. The staffing changes may have impacted the team working and specific tasks of individual ANMs, which we were unable to account for in our study design.

Finally, there is a risk of bias introduced by the Hawthorne effect where ANMs may have changed their behaviour and usual working patterns as they were conscious of being observed. However, others have argued that busy healthcare providers are less able to alter their work patterns even if being observed[16]. We saw no evidence of the participants in our study altering their behaviour to appear more favourable to observers, given the large amount of non-work time.

Conclusion

We did not find evidence that the EDSS intervention substantially changed the amount of time ANMs spent on ANC or related record keeping. ANC and ANC-related record keeping constituted a small proportion of ANMs' time during the workday. Lack of staff time during the workday was unlikely to have been a major factor in the low uptake of the EDSS intervention that was observed in other studies in the mIRA project. However, we found it challenging to conduct a time-motion study in low-volume facilities where time spent on ANC and record keeping was sensitive to day-to-day fluctuations in women attending for ANC and demands from other client services. Future time-motion studies would be more feasible in less remote settings serving larger numbers of pregnant women or in facilities with designated ANC clinic days to focus data collection resources on sampling a greater number of observation days with ANC activity to increase the power to detect potential changes resulting from EDSS interventions.

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Author contributions

ER conceptualised the study, analysed the data and wrote the first draft of the manuscript. GG supervised the study design, piloting and baseline data collection. SD and SK contributed to the

study design and conducted data collection. ER and LPK supervised endline data collection and, with SK and SD, discussed and interpreted findings. CB provided guidance on statistical analyses and along with OLM, SD, GG, SK and OMRC provided substantial inputs on the methods and interpretation of results. AS (Dept of Community Medicine), RS, AS (Dept of Obstetrics), and BK gave additional feedback. All authors reviewed and approved the manuscript.

Supplementary Material

Table 6.S1 Characteristics of healthcare providers observed in the study

		Attended EDSS workshop	Contract type	Qualification	Years of work experience (as an ANM or equivalent)	Years employed at facility	Skilled Birth Attendant (SBA) trained
Facility-A	ANM-1		permanent	ANM	5	<1	yes
	ANM-2	yes	permanent	ANM	5.5	3	yes
	ANM-3		temporary contract	ANM	8	3	yes
	ANM-8		permanent	ANM	unknown	4	yes
	ANM-9		temporary contract	ANM	10	<1	yes
Facility-B	ANM-4		permanent	staff nurse	3	1.5	yes
	ANM-5	yes	permanent	ANM	8	8	yes
	ANM-6		permanent	ANM	8	2	yes
	ANM-7		temporary contract	ANM	7	<1	yes

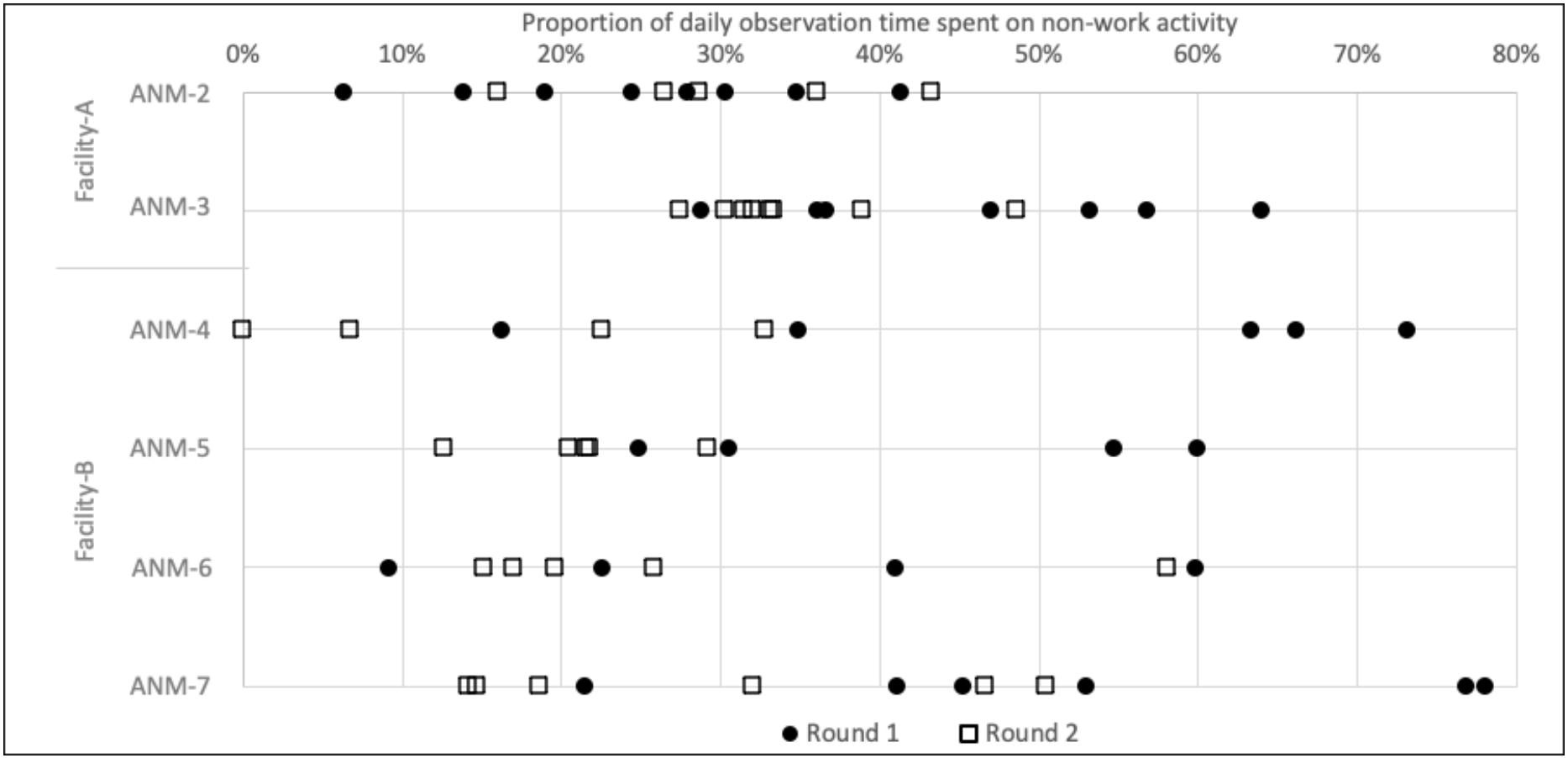


Figure 6.S1 Daily proportion of observation time spent on non-work among ANMs observed in rounds 1 and 2

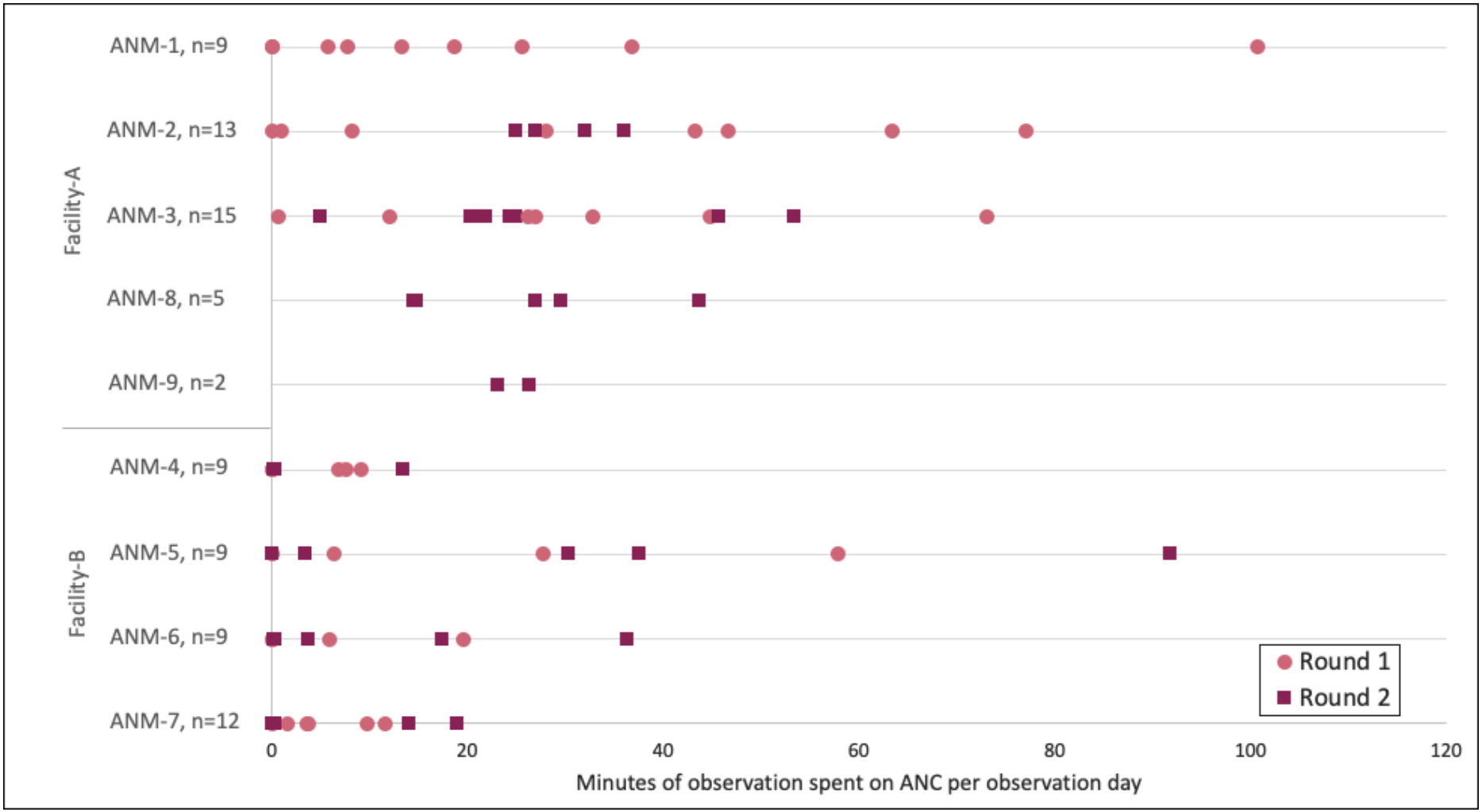
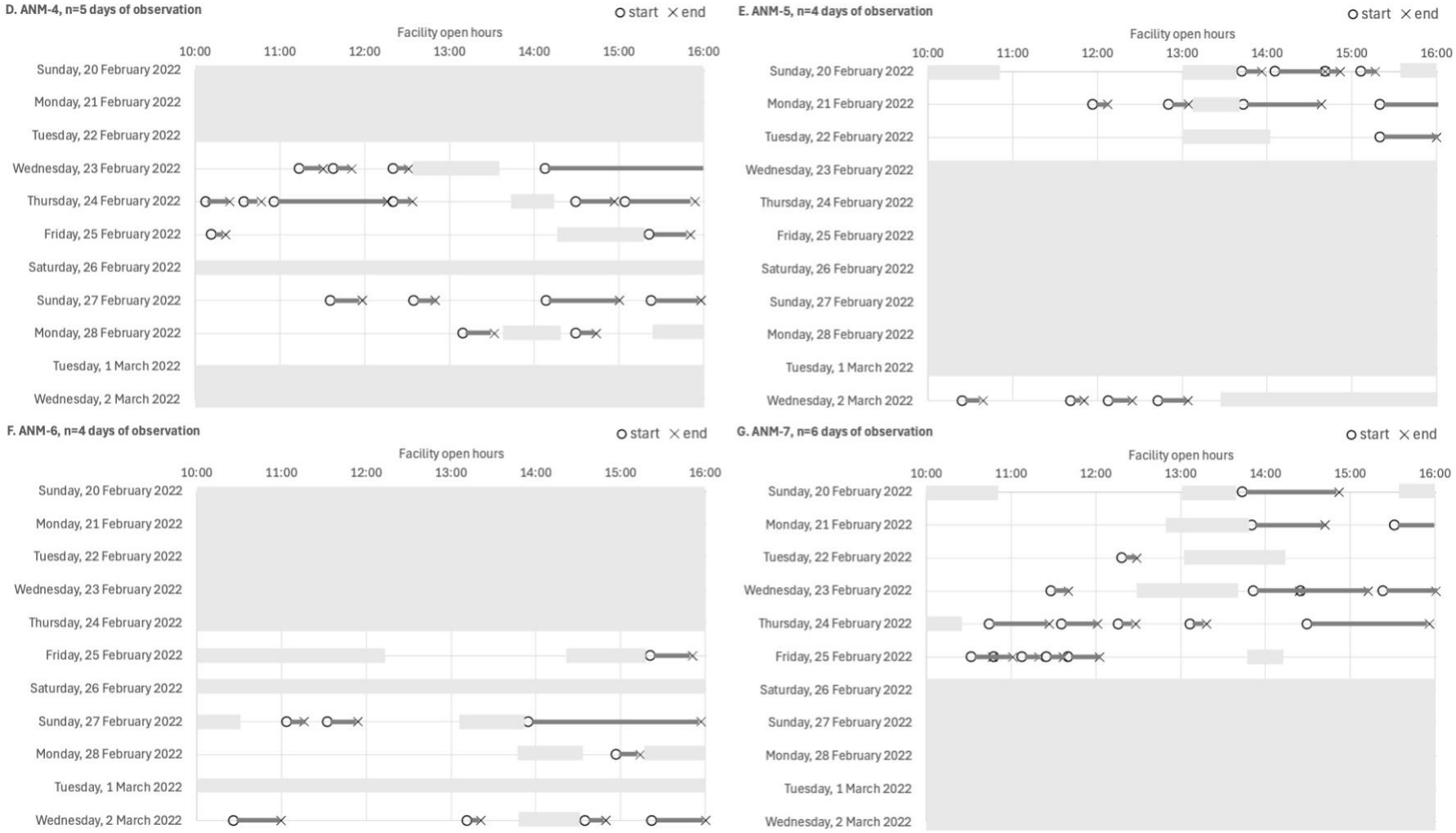


Figure 6.S2 Minutes spent on ANC per observation day by ANM

Figure 6.S3 Start and end times during the workday of non-work activity periods greater than or equal to 10 minutes in duration for all ANMs observed at baseline (round 1) Panel 1 - Facility-A (mIRA EDSS)

Figure 6.S3, continued. Panel 2 – Facility-B (WHO EDSS)



Research checklist: STAMP (Suggested Time and Motion Procedures)

Adapted from Zheng et al. 2011

Area and element	Description (from Zheng et al. 2011)	Section
Intervention		
Type	The system studied (intervention)	Introduction
System genre	Origin or lineage of the system (e.g., commercial product, homegrown system, open source software)	Introduction
Maturity	Time elapsed since intervention, including the amount of time that study subjects have been exposed to the intervention	Methods, Results
Empirical setting		
Institution type	Type of the healthcare facility or facilities where empirical observations are conducted (e.g., academic vs non-academic)	Methods
Care area	Area of patient care services (e.g., inpatient, outpatient, emergency department)	Introduction
Locale	Geographic characteristics (e.g., urban vs rural)	Methods
Research design		
Protocol	Research protocol (e.g., RCT, before and after, after only)	Methods
Duration	Length of fieldwork (e.g., whether all observations are completed within a month, or occur sporadically over the course of a year)	Results
Shift distribution	Clinical shifts observed (e.g., morning, afternoon, night, if applicable)	Methods
Observation hours	Total number of direct observation hours, in addition to how the hours are distributed across study phases or RCT study arms (if applicable)	Results
Task category		
Definition and classification	Definition of tasks and description of all major and minor task categories	Methods
Acknowledgment of prior work	Acknowledgment of task classification schemas previously used in the same or similar settings, and justifications if modifications are made	Methods
New development	Development and validation of task definition and task classification, if no prior work can be leveraged	n/a
Observer		
Size of field team	Total number of independent human observers	Methods
Training	Type and amount of training provided to human observers, including pre-study pilot observation sessions	Methos
Background	Professional background of observers (e.g., residents, nurses, industrial engineering students) and their prior experiences in conducting observational studies in clinical settings	Methods
Inter-observe uniformity	If and how inter-observer agreements are calibrated	Methods
Continuity	Continuity of observers across multiple study phases (if applicable)	Methods

Assignment	How observers are assigned to shadow different research subjects and in particular, research subjects enrolled in different study phases or RCT study arms (if applicable)	n/a
Subject		
Size	Number of research subjects enrolled	Results
Recruitment and randomization	How research subjects are recruited (and randomized, if applicable)	Methods
Continuity	Continuity of subjects across multiple study phases (if applicable)	Results
Background	Background information about research subjects such as clinician type and level of training (e.g., residents vs attending physicians); if conditions allow, other individual characteristics such as gender, age, and computer literacy	Results/ Supplementary Material
Data recording		
Multitasking	If and how multi-tasking is taken into account; in particular, if only the primary task is recorded or all concurrent tasks are recorded	Methods
Non-observed periods	If there are periods of time not covered by independent observers	Methods
Between task transition	If and how transition periods between consecutive tasks are handled	Methods
Collection tool	Device and software used to collect field data, for example, the AHRQ tool, WOMBAT, and the medical work assessment tool developed by Mache et al	Methods
Data analysis		
Definition of key measures	Key measures used in analysis and results reporting, for example, average time spent on ordering activities vs on direct patient care	Methods
Analytical methods	Statistical or other types of analytical methods used to analyze the data	Methods

Chapter 7: Findings and reflections from the mIRA project evaluation

7.1 Introduction

Three further papers from the mIRA project examined the results of the EDSS intervention in Nepal and contain findings that are important for understanding the PhD in context and its contributions to the overall evaluation. The papers, where I was a co-author, include two that are currently under review: a summary results paper, integrating the findings of the outcome and process evaluations (Appendix D) and an audit of record keeping study to assess change in completeness and agreement of paper-based ANC records before and after implementation of the EDSS (Appendix E). The third paper, in preparation, offers key findings and methodological reflections on using multiple methods of data collection in the longitudinal facility case studies, which were central to the process evaluation. This chapter summarises and discusses findings around EDSS utilisation, effects on care provision and effects on record keeping that were captured in these three papers[1–3].

7.2 Summary of the methods in the three papers

A novel approach to assessing the potential of electronic decision support systems to improve the quality of antenatal care in Nepal (Appendix D)

The mixed-method summary results paper brought together findings from the outcome and process evaluations, drawing on eight types of data: 1) pre/post observations of ANC consultations; 2) health facility survey; 3) longitudinal facility case studies and validation workshops; 4) in-depth interviews; 5) monitoring visits; 6) fieldworker debriefing meetings; 7) healthcare provider attitudes survey; and 8) stakeholder engagement and feedback meetings. The data collection methods were outlined in the protocol[4]. The data sources were descriptively and thematically analysed and were integrated using concurrent triangulation to develop explanations about the implementation process and its effects. Using a retrospectively elaborated theory of change, the paper outlined findings around nine themes, aligning to four sequential stages in the theory of change: buy-in, resources, EDSS utilisation and clinical performance.

The impact of digital antenatal care intervention on paper-based recordkeeping: results from an audit of antenatal care records in primary healthcare facilities in Nepal (Appendix E)

As part of the process evaluation, we were interested to capture potential unintended consequences of the EDSS intervention on existing ANC record keeping practices. This paper presents findings from

the audit of record keeping study, which compared individual pregnant women's ANC records before (n=136) and after (n=138) implementation of the EDSS intervention, estimating for selected indicators whether any value was recorded (completeness) and whether the values matched between the different record sources (agreement). The outcomes of completeness and agreement were assessed for the woman's handheld ANC card, the corresponding woman's visit entry in the facility's ANC register, and in the second round of data collection, the visit entry in the EDSS. The woman's handheld ANC card was used as the standard for comparison of agreement.

The implementation realities of a digital antenatal care improvement intervention in Nepal: insights from ethnographic work in primary health facilities (Karki et al., manuscript in preparation)

Longitudinal facility case studies were central to the process evaluation objectives of understanding the process of implementation and the role of contextual factors. The ethnographic work in four facilities – two each implementing the mIRA EDSS and WHO EDSS – involved unstructured observations over the course of three visits to each facility, informal conversations and formal in-depth interviews with facility staff, informal conversations with pregnant women attending for ANC, and validation workshops with facility staff to reflect on initial findings. The ethnographic work sought to develop rich descriptions of the context, and the relationships and structures in which the EDSS was implemented. This paper examines how the data collection methods used in the case studies yielded different insights into ANC service provision and implementation of the EDSS. It draws on street-level bureaucrat theory[5,6] to understand how ANMs adapted ANC guidelines and perceived the quality of care provided.

7.3 EDSS utilisation

There was mixed evidence around whether ANMs believed the EDSS benefitted their work. Despite expressing enthusiasm for the EDSS in reminding them of the steps in ANC consultation and supporting their counselling, ANMs also found the tablets and EDSS software frustrating[1,3]. Using the EDSS was time consuming; both EDSS were slow to load and needed frequent updates to fix software bugs. The software interface required numerous data entry variables, and hardware memory problems (especially in tablets loaded with the WHO EDSS) meant the tablets would often freeze when inputting information. ANMs said data entry in the EDSS became easier with use. Notably, as ANMs became more familiar with the EDSS, they said they no longer needed to read the fields or "wait for the advice to be given by the app"[1]. The healthcare provider attitudes survey, which was administered shortly after the month-long lead-in period to all ANMs and staff nurses

involved in ANC provision (n=43) and based on the NOMAD instrument to capture constructs in Normalization Process Theory[7,8], found overwhelming agreement with statements around seeing the potential value of the EDSS and continuing to support the EDSS[1]. Yet, as was observed in the longitudinal facility case studies, there were discrepancies between what ANMs said (in the attitudes survey and in-depth interviews) and what ANMs actually did[3].

ANMs were unclear about how the EDSS should be used and what it was for. There were particular problems of *coherence*, or the sense-making work people do individually and collectively to operationalise an intervention[9], as was found in the implementation fidelity assessment[10]. ANMs spoke about the potential benefits of the EDSS for reminding, but when observed, ANMs ignored prompts or ticked off actions as complete even when they were not done[3]. Once ANMs became more familiar with the EDSS data entry fields, they saw less use in using the EDSS checklists to guide their ANC consultations and in reading the care recommendations[1]. There was also a lack of worth attributed to the intervention's desired changes in ANC provision (see section 7.4).

There were challenges with integrating EDSS use into existing systems of ANC provision. ANC was organised in different ways in each of the longitudinal case study facilities, and there was no systematic or consistent process for providing care during ANC consultations[3]. As was noted in the implementation fidelity assessment, use of the EDSS was navigated alongside varied ways of managing teams of ANMs and tasks in ANC consultations. Care and record keeping tasks were frequently divided between two or three ANMs, who might be providing ANC to multiple pregnant women at once[3]. The EDSS was not designed to switch easily between women's records and prompts were routinely ignored; the ANM entering data might not be the same ANM providing that element of the examination. The embedded assumptions about how the EDSS would be used – by one provider doing simultaneous care and data entry for one patient – did not match the complex reality of ANC service provision. Many issues around the incorporation of EDSS use were unresolved going into the evaluation as there was limited time for piloting prior to the start of implementation due to software development delays in the mIRA EDSS and the late addition of the WHO EDSS.

7.4 Intervention effects on care provision

The evaluation found that ANMs did not substantially change ANC provision following implementation of the EDSS intervention. While some improvements in the performance of care components were observed, the quality scores remained low, suggesting there was no meaningful change in the quality of ANC (Table 7.1)[1]. Low performance may have reflected infrastructure

factors. Participating facilities largely had the equipment to provide ANC, but some facilities lacked commodities like urine protein tests (41%), haemoglobin tests (23%) or glucose tests (21%)[1], which were necessary for the performance of the care components in the primary outcome measure[4]. The mIRA project provided equipment and commodities for oral glucose tolerance tests as part of the intervention as unlike other tests, like for urine protein, these were not routinely stocked in the facilities. The mIRA project included training on the performance and interpretation of oral glucose tolerance tests as part of the three-day EDSS training workshops. In the outcome assessment, blood glucose test performance showed the largest improvement (Table 7.1, outcome F, 2.6% to 20.6%, p=0.02), which, given that some facilities were missing glucose test kits prior to implementation and then were provided with the materials to perform glucose tests, was perhaps unsurprising.

The measure of responsive care – among ANC consultations where the pregnant woman reported a symptom, the provider took appropriate action – appeared to improve after EDSS implementation (Table 7.1, outcome I). However, as few women reported a symptom (seven in the pre-EDSS observations and five in the post-EDSS observations) and the included symptoms ranged in severity (such as vomiting, decreased or absent foetal movement, or blurred vision), it is difficult to draw conclusions about the effect of the EDSS on responsiveness of care. ANMs continued to refer ANC patients experiencing any complications, even minor ones, to a doctor or higher-level facility, rather than follow guidance in the EDSS to manage minor complications within their scope of practice[3].

ANMs felt they were providing satisfactory ANC for low-risk pregnant women. The standardisation of ANC consultations suggested by the EDSS did not fit with how ANMs made decisions about what investigations and counselling pregnant women needed[1]. While the EDSS, and Nepali and WHO guidelines, suggested more frequent tests, ANMs generally performed the urine protein, haemoglobin and blood glucose tests only during the first ANC visit and did not repeat them unless abnormal results or other symptoms were observed[3]. Further, the EDSS prompted for counselling around pregnancy symptoms and danger signs at every visit, yet ANMs felt information on danger signs was needed only once. The EDSS was not designed to easily account for the wide range of factors ANMs considered when adapting care to what they thought was needed[1]. The longitudinal facility case studies highlighted that ANMs thought the current care provision was sufficient as most of the women seen were without complications:

> *"If women do not have any problems, then what should we explain to them? They are all okay. In the initial visit, we asked about having headaches and blurred*

vision and then counselled them to visit facilities as soon as possible; in the other visits, if they did not complain about any problem, we felt that counselling was not required." (Longitudinal facility case studies, Validation meeting - Facility C)[3]

Table 7.14 Results of the outcome measures from ANC consultations observed pre- and post-implementation of the EDSS, adapted from Karmacharya et al. 2023

Outcomes	**Pre-EDSS** N = 38	**All observations, regardless of whether EDSS was used in consultation**	
		Post-EDSS N = 34	**p-value**
	mean [sd]	mean [sd]	
A. Mean number of the four primary ANC components observed (max 4)*	1.11 [.69]	1.56 [1.21]	0.09
B. Mean number of the selected danger signs the provider tells the women she should return for help for (max 6)***	2.66 [1.77]	1.56 [1.71]	0.01
C. Mean number of the selected symptoms discussed (max 7)**	3.08 [2.10]	1.76 [1.63]	0.01
D. Mean number of 20 components of quality antenatal care delivered in the enrolment visit (max 20)****	8.82 [3.62]	6.94 [3.73]	0.04
	% (n/N)	% (n/N)	
E. Proportion of women who had their blood pressure measured and results recorded	92.1 (35/38)	94.1 (32/34)	0.94
F. Proportion of women who had their blood glucose measured	2.6 (1/38)	20.6 (7/34)	0.02
G. Proportion of women who a urinary dipstick test conducted	7.9 (3/38)	23.5 (8/34)	0.07
H. Proportion of women who a hemoglobin test conducted	7.9 (3/38)	17.7 (6/34)	0.21
I. Proportion of providers who took the appropriate action in response to participants who said they were experiencing selected symptoms	0.0 (0/7)	100.0 (5/5)	-
J. Proportion of participants for whom there was a recording of the diagnostic parameters of hypertension, GDM or severe anemia	0.0 (0/38)	2.9 (1/34)	-
K. Proportion of participants who were *told* by the provider that they had hypertension in pregnancy, GDM or severe anemia	0.0 (0/38)	0.0 (0/34)	-

ANC=Antenatal care; GDM=Gestational diabetes mellitus [sd]=standard deviation

*Components: measurement and recording of blood pressure and the performance of blood glucose, urinary dipstick and hemoglobin tests
**Symptoms that could be asked about or mentioned: nausea, vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain and blurred vision.
***Danger signs: severe vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain and blurred vision
****Components: a) Measurement or performance and recording of: blood pressure, blood glucose, urinary dipstick and hemoglobin tests; b) Symptom check on: nausea, vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain and blurred vision; c) Danger sign warning on: severe vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain and blurred vision; d) Additional components: mention of diet, enquiring about mental health, and writing on women-held ANC card

The flow of ANC patients in facilities further shaped how ANMs provided care and the potential effect of the EDSS. ANMs noted that following all the care recommendations in the EDSS would take too much time. ANMs completed ANC consultations within a few minutes if women did not report problems or complications, in part because women were impatient to finish the visit[3]. The time-motion study found similar paucity in time spent on direct patient care in ANC. There were often time pressures to finish ANC consultations quickly as pregnant women would often arrive together due to local transportation schedules, resulting in busy periods:

> *"It gets busy when the all [sic] patients come at once; then we are busy. Later, when the patient flow is less, they have a lot of time, you might have also noticed they have enough time to chat. We also have free time. I mean, when patients come all at once, they are also in a hurry, they won't even wait."* (Longitudinal facility case studies, in-depth interview with ANM-E - Facility A)[3]

7.5 Intervention effects on record keeping

The evaluation found positive effects of the EDSS intervention, with its understood emphasis on record keeping, on paper-based records in ANC. Despite the increased workload required by the duplicate electronic documentation alongside paper-based record keeping, paper-based record keeping did not suffer and in some cases even improved during the implementation period. The audit of record keeping study found completeness of paper-based ANC records was high before EDSS implementation, except for documentation around tetanus vaccination. There was a general trend towards greater completion of indicators in both the ANC card and ANC register after EDSS implementation, though not all indicators showed statistically significant improvements[2].

Improvement in completeness was largest in the data entry fields for parity and for the date of the tetanus vaccination (among pregnant women's records indicating that a first tetanus vaccination dose had been received) in both the ANC card and ANC register. Whether the pregnant woman had received tetanus vaccination showed no difference in completeness in either the ANC card or ANC register before and after EDSS implementation. Completeness of the field for tetanus vaccination date, which is important for determining whether and when additional tetanus vaccination doses may be required[11], improved in the ANC card (77% to 96%, $p<0.001$) and the ANC register (82% to 99%, $p<0.001$) after EDSS implementation[2]. While the EDSS was not consistently used for all ANC consultations[10], the audit of record keeping study found that when used, the EDSS was less complete compared to the record keeping in the ANC card and ANC register. Among the records examined after EDSS implementation (n=138), completeness was higher for paper-based records

than EDSS records for all indicators except the documentation of the first dose of tetanus vaccination, which was more complete in the WHO EDSS (89% vs 74% in ANC card and 58% in ANC register, p<0.001)[2].

The percentage agreement between the ANC register with the ANC card, among records with a value present in both, increased for all indicators after EDSS implementation. Before EDSS implementation, percentage agreement ranged from 38% (tetanus vaccination date) to 91% (woman's age) before EDSS implementation. Tetanus vaccination date had the largest percentage increase in agreement after EDSS implementation (38% to 57%). Agreement between the EDSS and the ANC card varied from 57% (parity) to 82% (diastolic blood pressure) for the WHO EDSS and from 30% (tetanus vaccination date) to 82% (parity) for mIRA EDSS[2]. Gaps in completeness and agreement in the ANC card and ANC register for indicators around tetanus vaccination, which are often provided on designated immunization days or at different facilities, highlighted the potential benefits of more unified record keeping practices to capture interventions received outside of the routine ANC consultation.

Concerns during intervention development on the potential negative consequences of the intervention on record keeping, particularly the woman-held ANC cards, were not borne out, though this at least partly reflects the low utilisation of the EDSS[3,10]. The time-motion study found little time was spent on ANC record keeping within ANMs' workdays and this did not substantially increase with EDSS implementation, and the audit of record keeping found ANMs prioritised paper-based record keeping over the EDSS. ANMs viewed the EDSS intervention as temporary and the demands of paper ANC record keeping, as a government programme, as more legitimate[3]. Greater integration of the EDSS intervention with other record keeping systems, such as HMIS, might help to address ANMs complaints about the value of the EDSS intervention, as least for record keeping[1].

7.6 Reflecting on the evaluation strengths and limitations

The three papers of the mIRA project evaluation offer a nuanced view of the contextual complexities and intervention design challenges that prevented the EDSS intervention from generating improvements in ANC quality outcomes and the ways in which the system resisted change[12]. The papers add context and learnings for the four thesis objectives. The disappointing, though unsurprising, null results of the pre/post outcome assessment prompted a project decision to contextualise the findings, resulting in an integrated results paper summarising the outcome and process evaluation findings (Appendix D). This shifted the focus of the summary results paper from

description of effects towards explanation, contributing evidence about why the intervention failed to become integrated into systems of ANC provision.

There was often a disconnect between findings from one method of data collection, compared to others. Interviews in the longitudinal facility case studies and the healthcare provider attitudes survey suggested ANMs recognised and appreciated the reminder function of the EDSS, yet this was not seen in observations of EDSS use nor reiterated as valued in the validation meetings held at the four longitudinal case study facilities. The health facility survey captured baseline cross-sectional measures of (mixed) readiness to provide ANC, but the longitudinal facility case studies found facility infrastructure was upgraded or expanded and staffing changed, even during the short implementation period[3]. The contexts of intervention were not static[13]. Some of the differences in findings from different data collection methods may be attributed to temporal changes, such as initial enthusiasm for the intervention waning as technical difficulties made operationalising use of the EDSS frustrating for participants. Other differences particularly between what people said and what they did likely reflected courtesy bias, with ANMs reluctant to express scepticism or less than enthusiastic views about the intervention when directly asked.

The intervention development assumed a simpler arrangement of ANC provision in Nepal than India (see Chapter 4), but this was not the case. This contextual challenge was underestimated in the intervention design and its evaluation in Nepal, perhaps because of the greater attention and resources afforded to formative research in India, where most sites for the planned trial would be, and because of the extent of facility variability in Nepal. Some facilities in Nepal were observed, in both formative and evaluation phase data collection, to model the format of the ANC consultation envisioned by the EDSS intervention (and presumed in the WHO and Nepali guidelines), where one ANM provided the ANC consultation to one patient at a time. However, many facilities did not. The longitudinal facility case studies were particularly important in revealing how teams of ANMs worked to provide and document care components for multiple pregnant women in overlapping ANC consultations and the effect this had on EDSS utilisation[10].

There were few opportunities to explore differential effects of the two EDSS or of contexts of use. The retrospectively elaborated theory of change in the summary results paper (Appendix D) continued the assumption that the two EDSS functioned in the same way. The evaluation undertheorized, and the data collection methods were not oriented to examine, differences in the user interface of the two EDSS or the role of the greater focus on pregnancy complications in the

mIRA EDSS (see Chapter 2). The limited sample size in the pre/post observations of ANC consultations did not allow disaggregation of outcomes by EDSS (mIRA or WHO) or by whether the EDSS was actually used in the consultation. The fidelity assessment found low use at the point of care, which would dilute any overall effect, but it is possible that use of the EDSS during an ANC consultation would operate as a reminder, as ANMs said that it did, and result in some care components being performed more consistently. Both the outcome and process evaluations were limited in examining differences between the mIRA EDSS and WHO EDSS, despite indications of distinct technological challenges (e.g. the tablets running the WHO EDSS requiring new memory cards to address the software freezing or crashing) and implementation processes. The audit of record keeping study was not fully powered to compare differences when stratifying records by mIRA EDSS-allocated and WHO EDSS-allocated facilities; different indicators were available in the WHO EDSS and mIRA EDSS so results were presented separately[2]. Despite low statistical power, statistically significant differences in completeness and agreement among paper-based records compared to WHO EDSS and to mIRA EDSS records were observed, suggesting that the two EDSS may have had differential effects that were not fully examined in the evaluation.

The evaluation papers revealed crucial gaps in the design and implementation of the EDSS intervention. Some of these could have been better anticipated through greater *a priori* theorising about how the intervention would be used and how it would change clinical performance. The retrospective theory of change (Appendix D) was still scant on theorising about the underlying generative mechanisms operating in social contexts. As discussed in the summary results paper, training more than one provider per facility might contribute to greater ownership of the intervention and improve use[1], yet there was still an underlying question of legitimacy of the time-limited research project against government programmes. During the implementation period, Nepal began the rollout of the WHO-recommended 8+ ANC visit schedule[14]. The implementation of the 8+ ANC visit protocol was viewed by ANMs as critically important—and important to document for the local authorities—in a way that the EDSS was not[3]. Additionally, ANMs thought the quality of ANC was largely sufficient, with habitual care practices that were resistant, or resilient, to change. The EDSS intervention, conceptualised as an individual-level intervention, was ill-equipped to disrupt existing systems of ANC provision[12].

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Chapter 8: Discussion

8.1 Introduction

This final chapter offers a summary and interpretation of the thesis findings, building on the discussion points raised in individual empirical studies (Chapters 3, 5 and 6) and on reflections from the overall mIRA project evaluation results (Chapter 7). It begins by summarising the findings around the four thesis objectives, drawing from the research papers of the PhD and elaborating on the logic and linkages between them. The chapter then discusses the contributions of the thesis, including its strengths and limitations, within the broader literature and outlines implications of the findings for future research and programmes.

8.2 Summary of the thesis

This thesis examined the implementation and consequences of an EDSS to improve the quality of ANC in India and Nepal as part of the mIRA project. The PhD described the measurement challenges and status of ANC quality in the intervention setting in India (Chapter 3). It conceptualised how a complex EDSS intervention sought to improve ANC quality and outlined an evaluation approach to assessing the intervention impacts and implementation in Nepal (Chapter 4). It evaluated implementation fidelity within the EDSS intervention in Nepal, leveraging conceptual contributions to a realist approach to the measurement of fidelity (Chapter 5), and investigated the context and effects of the intervention on healthcare providers' time use and workload in ANC (Chapter 6).

Objective 1: to describe the state of ANC quality in the study setting

The objective of describing the quality of ANC was primarily achieved in Chapter 3 (research paper 1) focusing on Telangana, India, but there were also learnings on ANC quality in the study setting in Nepal throughout the research.

Research paper 1 examined dimensions of ANC quality in Telangana, one of the planned settings for the mIRA project trial. The study descriptively analysed four primary and secondary quantitative data sources: the National Family Health Survey 2019-21, statewide HMIS data from 2019-20, a facility survey in 19 Primary Health Centres and sub-centres in selected districts of Telangana, and observations of 36 ANC consultations in these facilities. Data sources were situated in the WHO quality of care framework for ANC to illustrate how the analysis captured different components of the framework. The study found moderate quality of ANC regarding physical examination and some screening interventions (such as for anaemia). There were some gaps in quality that were of

particular interest to the mIRA project's intervention and outcome measurement such as inadequate screening for gestational diabetes or urine protein testing. The study also identified important gaps in counselling, provision of person-centred care, including asking the pregnant woman about current pregnancy symptoms, and in both the provision and measurement of responsive care (such as treatment for complications detected or referral and follow-up for services not available or not provided during a particular ANC consultation).

The complexity of ANC makes improvements in quality of care difficult to achieve and efforts to do so difficult to measure and evaluate. ANC provision needs to respond to both individual women's needs as they change throughout the pregnancy and to what has been provided in previous visits, which complicates conceptualisation and measurement of what is a 'good quality' ANC consultation. Current measures of the content of ANC emphasise clinical investigation and physical examinations, as seen in the indicators available in the National Family Health Survey and HMIS as well as the quality assessment outcomes adopted by the mIRA project. ANC quality measurement could do more to capture the responsiveness of care provision and communication about the specific interventions provided. The challenge in the study setting in India was largely not with ANC coverage or with the performance of many clinical assessments (for example blood pressure measurement or anaemia testing) but with the provision of person-centred, responsive care.

Similar findings on the quality of ANC in the study setting in Nepal were echoed in the literature and in the mIRA project studies. ANC components related to physical examination and screening had higher coverage than those related to counselling, as captured in the Nepal DHS 2022 of care components received at least once during the pregnancy[1]. Some physical examinations, notably blood pressure measurement, were performed in multiple ANC visits in a study done in southern Nepal, yet other screening interventions involving blood and/or urine testing tended to be done only once during the pregnancy[2]. In mIRA project facilities, tests tended to be performed at the first ANC visit and not repeated unless potential complications were suspected[3,4]. The mIRA project evaluation revealed that healthcare providers in Nepal viewed the quality of ANC as adequate and thought the EDSS prompts for more frequent screening and counselling did not correspond with what they thought was needed.

Objective 2: to conceptualise EDSS intervention functions and the pathways leading to improved quality of ANC

Chapters 2 and 4 contributed to objective 2 and depicted the development process of the EDSS intervention and the debates and tensions within the theory of change. Theorising about how the EDSS would work to change healthcare provider performance during ANC visits resulted from reviewing the literature on mHealth and EDSS interventions on quality of care in maternal health; iterative workshops and discussions with the mIRA team; and writing the process evaluation protocol. The theory of change work was undertaken prior to the addition of the WHO EDSS to the evaluation in Nepal. The mIRA EDSS was conceptualised, prior to evaluation, to function around two main mechanisms: reminders and knowledge provision leading to empowerment. The conceptualising of the intervention as largely around reminders, with the corresponding importance of EDSS use at the point of care, and ongoing uncertainty about the implementation process and unintended effects informed the design and focus of data collection in the process evaluation.

While informed by realist notions about causality, the mIRA project evaluation was not a realist evaluation. The focus of the process evaluation was very much on documentation of the implementation process, rather than developing and testing propositions, because there was still considerable ambiguity at the beginning of the project's evaluation phase about how the EDSS intervention would work. Instead, the more detailed theory of how the intervention worked (or did not work), and its explanatory propositions, developed over time via iterative discussions around findings from the longitudinal facility case studies and from emerging data from routine monitoring visits and debriefing meetings with fieldworkers[4]. The incorporation of repeated measures and longitudinal data collection in the mIRA project's evaluation protocol was designed to address some of the initial uncertainty by allowing the research to respond to emerging findings. However, project resources limited the opportunities to collect more or different data during the short implementation period that might have supported further refinement of the intervention theories.

One oversight in the evaluation design was around examining differences between the mIRA EDSS and WHO EDSS. Theorising about intervention functions was done prior to the decision to implement and evaluate two similar, yet distinct EDSS in Nepal. The underlying assumption was that the two EDSS functioned in the same way, though the protocol, revised to incorporate the additional WHO EDSS, emphasised the opportunity to compare the two, including the features and functionality that might influence better uptake. However, comparisons between the two EDSS were not possible in the before-and-after outcome evaluation because it was not powered to do so.

Subsequent findings from the assessment of implementation fidelity, the audit of record keeping and the longitudinal facility case studies suggested that there were differences in the implementation of and responses to the two EDSS that the evaluation design was not fully equipped to explore.

The PhD, and the larger mIRA project, insufficiently theorised about why ANMs would be motivated to use an EDSS in the first place. Motivation, within individuals and teams, is recognised as influencing how well interventions to improve quality are implemented and their associated improvements in service provision[5–7]. There was an embedded assumption that ANMs agreed ANC quality needed improvement and that this would lead to some initial use of the EDSS. The mIRA project did not give enough consideration to the conditions needed to change healthcare provider behaviour and clinical performance[7]. Most attention was given to the logistics of implementation, rather than thinking about the mechanisms the intervention would trigger and, crucially, in what circumstances. EDSS interventions should consider multiple stages of hypothesising about the intervention: firstly, what creates conditions of potential to change behaviour, then, what are the feedback loops that reinforce incorporation of the EDSS, and finally, what is it about the EDSS, operating within enabling conditions, that causes clinical performance and practices to change. More thinking was needed about the problem being addressed and what the EDSS intervention intended to do, yet the practical constraints of working on a tight project timeline meant this theorising took a backseat as the research team moved forward with finalising the evaluation design and starting intervention implementation.

Objective 3: to evaluate implementation and understand the contextual factors and mechanisms shaping fidelity to the EDSS intervention

Research paper 2, in addressing objective 3, proposed a realist approach to implementation fidelity and aimed to apply this to the assessment of implementation fidelity to the EDSS intervention in Nepal. The study saw fidelity as a process over time with degrees of consistency with the intervention as intended. The study used a mixed-method design, analysing quantitative and qualitative data from monitoring visits, backend data from the EDSS software, and fieldnotes and in-depth interviews conducted as part of the longitudinal facility case studies, to examine three components of fidelity to the EDSS intervention: use at the point of care, use for all ANC visits, and quality of data entry. The realist approach to assessing implementation fidelity emphasised explanation and, in applying it to the EDSS intervention, drew on Normalization Process Theory to examine the mechanisms and enabling contexts that drove patterns of fidelity observed. Among the

mIRA project's evaluation papers, this study most visibly incorporated the realist thinking that informed the process evaluation design.

The study found fidelity to EDSS use at the point of care, during ANC consultations, declined over time. Point-of-care use was 100% in the first two monitoring visits, among the few facilities where ANC consultations were observed, but this declined to 50-80% in the final two monitoring visits. Use of the EDSS during ANC consultations was likely undermined by fieldworkers suggesting the back-entry of previous ANC visits in the EDSS. Low ANC caseloads meant there were few opportunities to practice and enact use of the EDSS in 'real life'. ANMs overwhelmingly viewed the EDSS as a record keeping device rather than a device for decision support and changing care practices.

Uncertainty about the intervention theory, including research team debates about how the EDSS would function to change healthcare provider behaviour, potentially contributed to confusion among fieldworkers and participants about the intervention's purpose for decision support. Yet, the EDSS intervention was about record keeping. Any potential change in provider behaviour that might arise from the act of using the EDSS—where data entry fields could constitute reminders of examinations to perform or questions to ask pregnant women or from viewing pop-up reminders or treatment recommendations—relied on the incorporation of the EDSS into the concurrent record keeping process. There could be no decision support, and no hypothesised change in clinical performance, if there was no record keeping in the EDSS. However, even when record keeping in the EDSS was done at the point of care, we found the reminder and decision support functions (the prompts and pop-ups) were largely ignored.

The longitudinal facility case studies revealed a critical disconnect between what the intervention hoped to achieve and the view from healthcare providers that they were essentially providing good quality care already[3,4]. While implementation fidelity was sometimes followed in "form" (point-of-care use), it was not followed in "function" (decision support), but this was shaped by broader systems that saw the current quality of ANC as acceptable and self-organising principles to maintain the status quo, without allowing the intervention to disrupt the system[8,9]. The assessment of implementation fidelity found that higher fidelity, particularly around point-of-care use, could be achieved in some facility settings, but whether use of the EDSS translates into changes in clinical performance seems unlikely without addressing providers' motivation to improve quality.

The study drew on Normalization Process Theory to explain the patterns of fidelity observed. Normalization Process Theory offered a helpful framework of individual mechanisms and collective actions shaping the process of implementation and the effects of this process on the components of implementation fidelity, enhancing the explanatory power of the analysis[10]. But there is a risk that in drawing from Normalization Process Theory constructs, that the view of the data was restricted, allowing the theory to spotlight findings, while keeping other potentially important concepts and mechanisms in the dark[11]. Critiques of Normalization Process Theory include two important elements: 1) that the theory neglects the organisational and relational contexts shaping expressions of agency[12] and 2) that the theory's mechanisms are not the same as causal mechanisms in realist philosophy[13]. This is because the mechanisms of Normalization Process Theory occupy the realm of the empirically observable[13], and observable evidence alone cannot establish causality[14]. While Normalization Process Theory clearly affirms that the mechanisms of the social process of implementation are shaped by structures, it does not claim to explain the relationship between organisational structures and behaviours[12]. The implementation fidelity study identified different outcome patterns and contextual factors that enabled or disabled mechanisms described by Normalization Process Theory. But the theory does not explain *how* contexts affect mechanisms[15]. The application of specific conceptual tools to explain how different social and structural resources governed people's agency and action would have enhanced the analysis. In starting from the outcome (observed patterns of fidelity) and working backwards, the emphasis on Normalization Process Theory made sense because mechanisms are the source of generative explanation. As Raymond Pawson states, "[Mechanisms] are the verbs in the sentence."[8] Normalization Process Theory offered mechanisms suited to explain the effects of the specific EDSS intervention on participants. To explain how contexts shaped the mechanisms identified, we considered wider systems[16], of the ANC consultation and of the service provision setting, and relied on abductive reasoning (the analytical yet inventive thinking required to propose plausible explanations). This required a logical leap from the observable evidence to the theorising of causal explanation that is essential to a realist approach.

Objective 4: to investigate the consequences of the EDSS intervention on changes in workload in ANC

Objective 4 was addressed in research paper 3, which aimed to compare time spent on ANC and related record keeping following implementation of the EDSS in Nepal to examine a potential

[8] Message from Raymond Pawson on 28 May 2024 to the RAMESES (Realist and Meta-narrative Evidence Synthesis: Evolving Standards) email list.

consequence of intervention. In the observational time-motion study, ANMs in two facilities participating in the longitudinal facility case studies were observed throughout the workday in two rounds of data collection to record activities performed and the time taken to do them. The proportion of total observation time spent on each activity was compared before and after EDSS implementation for each of the six ANMs participating in both rounds. The study found ANMs spent little of their workday on ANC and related record keeping, and this did not significantly change after implementation of the EDSS. However, record keeping time somewhat increased after implementation of the EDSS for two ANMs in the study, including for one of the ANMs who received training in using the EDSS. This increase was largely attributable to data entry in the EDSS.

The time-motion study faced limitations in both the generalisability of the findings and in the power to detect changes in time use. The two facilities in the study were selected based on relative convenience for the intensive data collection required for both the time-motion study and the longitudinal case studies, and to include facilities implementing the mIRA EDSS and the WHO EDSS. The facilities offered different patterns of working, which was seen in how much time individual ANMs spent on ANC each day. It was unclear how typical these working patterns were, compared to other facilities in the mIRA project. In one facility, ANMs seemed to work as more of a team to provide ANC so that when the facility was busy, all the ANMs were busy providing ANC; whereas in the second facility, ANMs (particularly the ANM who received the training in using the EDSS) did more ANC work alone. As was seen in the implementation fidelity assessment, the team-based approach to ANC consultations often resulted in higher fidelity as ANMs worked together to incorporate EDSS use into ANC consultations. But the time-motion study had limited power to capture this dynamic. With only two researchers conducting observations, teamwork in ANC involving more than two ANMs could not be fully documented. Further, the study design, in stratifying by ANM, assumed effects of the EDSS on time use at an individual level, rather than within the dynamics of a team, which may have muted the effects of sharing EDSS use across the team.

Low ANC caseloads in rural facilities in Nepal often resulted in small but variable numbers of pregnant women attending each day. This was seen in the time-motion study in the sensitivity of time spent on ANC and record keeping to day-to-day fluctuations in numbers of ANC patients and in demands from other clinical services. The limited resources for data collection meant that the number of days of observation, and the amount of observation time for each ANM, was unable to account for this higher-than-anticipated variability. However, the study findings about the limited

impact of the EDSS on workload in ANC and related record keeping are still likely to be correct, as the implementation fidelity assessment found EDSS use was generally low, and the overall proportion of time spent on ANC and record keeping for most ANMs was minimal.

Original plans for the time-motion study analysis included examining ANMs' self-reported time on activities[17]. Time-motion studies based on independent observation offer less biased accounts of how healthcare providers use their time compared to self-report[18], but perceptions about how time is spent can have important implications for staff satisfaction in their work. For example, a study of nursing unit managers in South Africa found estimates of time spent on direct patient care were similar between direct observation and self-report, but that nursing managers overestimated time spent on administrative duties, potentially reflecting the dissatisfaction they felt about administrative compared to other duties[19]. As the mIRA project had concerns about the actual and perceived impacts of the EDSS intervention, particularly on the burden of record keeping, additional qualitative exploration was embedded in the time-motion study. In the second round of data collection (after EDSS implementation), at the end of one observation day, ANMs were asked to mark a chart with 20 beans to represent relative amounts of time they thought they spent on different activities during the current day. There were chart spaces for direct ANC patient care, paper-based record keeping in ANC and using the EDSS tablets, among other activities. The self-reported time chart was intended as a conversational tool to probe the ANM's views about how they spent time during the workday and to explore how this changed since the introduction of the EDSS intervention. The self-report time chart and follow-on interviews were done to enhance and triangulate findings from the time-motion observations but also to test whether this creative method would provide useful data.

The interviews yielded some helpful insights but ultimately lacked richness and were not included in the write-up of the time-motion study. ANMs struggled to self-report time spent during the workday. The use of beans to represent relative amounts of time, rather than asking about number of minutes per day, was intended to assist thinking abstractly about time use. Instead, the beans were often used to represent numbers of individual patients, rather than how much time was attributed to providing care and/or record keeping depending on what the patient was seeking. Some confusion also stemmed from the activity categories offered, where ANMs seemed uncertain about how to separate direct patient care with record keeping when these were done in tandem. The data collection set-up may have hindered the depth of the interviews as ANMs were asked to complete the self-report chart on their own first and then have a brief follow-up conversation. The

method may have worked better if the interview began by asking about how ANMs structured their day, introducing a level of abstraction in thinking about time use, prior to asking the ANMs to self-report time use during the interview and potentially talk through their thinking as they placed the beans on the chart. The interviews may also have benefitted from being more explicit about the hypotheses being examined, including about whether the EDSS intervention was changing the length of ANC consultations (by changing its content) and how impactful entry in the EDSS was on the record keeping workload.

Some findings from the self-report time chart interviews were incorporated into the longitudinal facility case study findings and other results papers[3,4]. These conversations contributed to understanding how ANMs organised ANC consultations and how they thought about periods of non-work time where they waited for patients to arrive. ANMs complained in the interviews about technical problems with the EDSS tablets freezing or loading slowly, attributing increased time to when the tablet was slow, echoing findings from the implementation fidelity study[20].

8.3 Contributions and limitations of the thesis

The PhD gave a rich account of the evaluation of the EDSS intervention to improve ANC as part of the mIRA project and examined aspects of the implementation and consequences of intervention in Nepal. The thesis offered innovative ways of researching the intervention setting and implementation by integrating multiple data sources to build in-depth pictures of ANC quality and implementation fidelity, and applied a time-motion study design, in a new setting, to deepen understanding of the context of time use and change during the intervention. Throughout, the research emphasised measurement and capture of complex processes, using multiple methods to do so, and the importance of explanation to move beyond description of effects (or lack of effect) to examine how and why they occurred. This approach responded to emerging guidance on evaluation's role to understand the dynamics of intervention within complex systems and to bring greater attention to how and under what circumstances interventions create change[8,21].

Nearly 20 years ago, Penn-Kekana, McPake and Parkhurst asked, how much the maternal health research community had really learned about "getting what works to happen"[22]. Much evaluation research in maternal health continues to be framed by the norms of trials, emphasising standardization and control of contextual nuance, seen in practices such as pre-publishing protocols, trying to isolate the effects of intervention, or restricting intervention adaptation, which raises questions about how well these evaluation approaches respond to the realities of intervention

implementation in complex systems[9]. This perhaps stems from the reliance on randomised control trials as the gold standard in health, and most work on causal complexity in the last two decades originating outside of health research[15]. Controlling for variability in social contexts—in efforts to answer whether an intervention works—removes much of the detail about *how* interventions work[23,24]. While stratifying or studying covariates and interactions can help, evaluation approaches that seek to erase local details about how interventions create change, in what contexts, struggle to evaluate complex interventions involving people and social systems, including quality improvement efforts in maternal health[23,24]. A view of interventions as fixed (or at least desirably so) is at odds with how most interventions are experienced and increasingly how interventions are conceptualised as attempting to change social dynamics within complex systems[8]. The guidance for evaluating complex interventions has changed[21] but, if decades of implementation research in healthcare offer any indication, changing research practice is often slow. This was apparent in the mIRA project's orientation towards older evaluation approaches, where the primacy of the trial was reflected in the project proposal and budget, as well as the relative disinterest of many investigators in understanding the how and why of intervention effects.

Driven in large part by the work of this PhD, the mIRA project's process evaluation applied realist thinking, resulting in a richer description and explanation of what happened in the EDSS intervention. A key strength of the research was the resulting integration of outcome and process evaluation results in Nepal[4]. The outcome and process evaluations began as separate entities, with the major focus of time and resources on the planned cRCT in India and Nepal with a separate process evaluation, which was made substantive by this PhD. The realist thinking infusing the sub-studies of the process evaluation ultimately persuaded the mIRA project team to contextualise and explain the null findings of the outcome assessment in Nepal[4]. My PhD pushed back against a traditional view of process evaluations as primarily about fidelity and determining whether implementation or intervention failure was to blame for null outcome evaluation findings[25]. Implementation vs intervention failure is an unnecessary divide: it is both. An intervention's inability to gain traction during implementation will fail because the intervention is insufficient to succeed in that context.

The thesis highlighted the importance of multiple methods and measures in developing explanations about intervention implementation and effects. Two of the research papers incorporated multiple data sources and methods to compare different aspects of quality of ANC and dimensions of implementation fidelity. Both approaches offered empirical richness alongside methodological

contributions pushing for greater nuance in measurement of complex concepts. The study of implementation fidelity further incorporated measures over time, seeing implementation of the intervention-as-intended as a dynamic process where single cross-sectional measures may offer partial and potentially biased views, depending on the timing of data collection in this process. Repeated observations over multiple days of data collection in the time-motion study sought to capture the day-to-day work of ANMs to contextualise the role of ANC and related record keeping in their workdays. While the extent of day-to-day variability hindered the reliability of the time-motion study findings around changes in time use, considered another way, the variability showed how ANC provision in this context resisted the application of a data collection method that assumed a more constant, consistent system. In capturing, and, importantly, showcasing this variability, the study attempted to uncover how effects of the EDSS should be understood within the context of ANC in the Nepal setting.

My thinking about what the EDSS intervention was and what it might do evolved over the course of the PhD. The mIRA project EDSS intervention might be better understood as seeking implicitly to alter relationships between provider and ANC patient, and between teams of ANC providers, displacing entrenched practices of doing ANC. Interventions asking participants to make different choices—in using a new technology and changing clinical practices—require changes in a participant's reasoning, as well as the resources available to them[7,26]. The mIRA project intervention gave little attention to how to change a behaviour system[7]. The EDSS intervention assumed there was something suboptimal about the interaction between provider and patient in the ANC consultation, and improvement in quality of care could be achieved by systematically modifying a few discrete practices[8]. The ANC consultation is a micro-system. The EDSS intervention focused on this smaller activity, which was set within systems of dynamic provider-ANC patient interaction and of the norms and practices that go beyond the individual participants involved. The mIRA project failed to appreciate the challenge of changing the micro-system in its complex context.

Applying a realist approach in the PhD enabled the beginnings of thinking about conditional causation. More than a complex, yet discrete, intervention, the EDSS was a stone cast into a pond where the fluctuating characteristics of the pond (health facility), the weather and water conditions (participants enacting the intervention), and how the stone was cast (actions of fieldworkers) interacted to shape the ripples produced. Conceptualising an EDSS intervention in this way demands asking what outcomes capture and allow us to better understand the mechanisms and feedback loops created by introducing the EDSS into the systems of ANC[16]. This PhD addressed a few of the

perhaps innumerable, explanatory propositions arising from trying to make sense of what happened in the EDSS intervention. The research offered some ways to understand the relationship between what individuals did during the intervention and the social contexts in which they did them[27].

Much research has grappled with the variable success of quality improvement initiatives and the role of contextual factors in enabling change[5,6,28,29]. The mIRA project may have benefitted from applying an implementation framework to better articulate the context of the intervention, such as the outer and inner setting constructs in the Consolidated Framework for Implementation Research[30,31]. However, it is important to recognise that conceptualisations of context reflect divisions in paradigms and how evaluation approaches understand an intervention and its environment[12,24]. Context encompasses the setting of the intervention, which is often understood as the organisational context in facility-based interventions, but aspects of context may be considered part of the intervention itself where participants in the setting are required to make the intervention happen[12,28,32]. Context for a facility-based intervention like the EDSS includes the qualities and histories of the individuals and teams taking part, in addition to the infrastructure environment; it is a process not just a place[12,28]. Trials still frequently see context as confounders to control, noise of the system as something to be silenced, where interventions effective in other studies can be implemented "across space and time" with predictable results[33,34]. The separation of the Nepal study from the trial in India claimed to shift the work in Nepal to implementation research, but it was not clear if change in the evaluation design fundamentally altered the predominant way of thinking about the role of context and causation. Some elements of context were captured in process evaluation data collection activities, such as by the facility survey or healthcare provider attitudes survey, or were addressed in the overall evaluation design by pairing facilities by type, ANC volume, and number of ANMs, and then randomising facilities to either the mIRA EDSS or WHO EDSS. The research strategy in Nepal was not fully designed to, and did not reveal, contextual patterns in the desired quality-of-care outcomes. The overall evaluation had limited funds to increase the sample size of facilities receiving the intervention or the sample size of sub-studies, including observations of ANC consultations in the before-and-after outcome assessment. The evaluation lacked the statistical power to quantitatively examine patterns of variations in implementation or effects. This meant that the evaluation could not examine patterns of circumstances where the intervention produced different outcomes.

Context shaped the intervention's implementation and effects but also the conditions of the research. A central challenge faced by the mIRA project in Nepal, and a common challenge for

maternal and newborn health care in many settings[35], was the low volume of patients in study facilities. Low ANC caseloads in remote facilities made large-scale data collection unfeasibly expensive: researchers needed to spend several days at each facility to encounter enough pregnant women attending for ANC to meet minimum sample sizes, which also limited the number of facilities we were able to include in the overall evaluation. The small sample sizes limited quantitative analyses. For example, the small number of participating facilities meant that patterns of implementation fidelity were hard to see. While, overall, facilities showed declines in recording all ANC visits in the EDSS over time, some facilities diverged from this. With few facilities and few data points (up to four monitoring visits), these variabilities may simply have been due to chance. A facility demonstrating change in the direction of an indicator may be signalling a new pattern or trajectory or may simply be a blip in the data.

Reflections on positionality

My position within the research team and in relation to the research participants shaped the PhD, resulting in limitations, but also some strengths, of the thesis. The mIRA project (2018-2023) took place during the COVID-19 pandemic. Concerns about COVID-19 exposure during my own pregnancy in 2020-21, and subsequent childcare responsibilities, meant I was unable to immerse myself in the research context. I travelled to India and Nepal twice in 2019 during the project's formative research phase but, crucially, was unable to visit the study sites during intervention implementation in 2022.[9] The research for this PhD, but also for the larger collaborative mIRA project, took place remotely. While I invested in building strong relationships with colleagues at PHFI and Dhulikhel Hospital during those in-person formative phase visits, it took time to build trust and candour. It took time to understand our different perspectives and strengths when nearly all interactions were over Zoom and email. There were also some team members, with whom I worked very closely, but never had the chance to meet in person. Understanding each other, particularly as we came from different disciplinary backgrounds, took time and effort. Further, English was the lingua franca of the collaboration between LSHTM, PHFI and Dhulikhel Hospital, and my inability to speak Nepali prevented me from being able to fully grasp the perspectives of healthcare providers (instead relying on translations of accounts) and the contextual nuances of stakeholder meetings, which were conducted primarily in Nepali. The physical and linguistic distance, and my position as an outsider to

[9] I travelled to Nepal in early 2024 for related research that emerged out of the mIRA project, visiting some of the same facilities that participated in the mIRA project and meeting with mIRA project team members, which has informed many of the reflections presented.

Nepali and Indian culture, almost certainly hindered the depth of my analysis and understanding of the study context.

Writing a thesis and working collaboratively with a multi-country research team created opportunities to think about my role in efforts to decolonise global health research. I invested considerable effort in building equitable research partnerships with colleagues in Nepal and India, including weekly meetings over the course of three years. I strove to understand my colleagues' motivations and expectations, especially within the rigid hierarchies of PHFI and Dhulikhel Hospital which were so different from my experiences at LSHTM. I developed particularly close relationships with a few fellow early career researchers in India and Nepal. I tried to leverage my privileged position, as a white Westerner and as an LSHTM staff member with a secure relationship with the project's LSHTM co-PI, to create space for early career researchers to take leading roles in the project. For example, I worked closely with a colleague at Dhulikhel Hospital to design and lead the audit of record keeping study[36]. I supported professional development of colleagues, including reviewing PhD applications, and have continued to work with several members of the Dhulikhel Hospital team on subsequent research projects. The relationships I developed and the ongoing exchange with these close colleagues granted me access to insights I would not have had otherwise. I tried to capture and recognise these valued contributions in the co-authorship of papers included in this PhD.

My status as both LSHTM staff member and PhD student created tension between managing my role in helping to deliver on the mIRA project and my own research interests. The mIRA project has challenged and allowed me to develop transferrable skills in navigating research partnerships. Despite privately expressed support from peers, the relative security of my position meant that I sometimes stood alone when advocating to project investigators about a particular approach to the research or evaluation. Realist evaluation enthusiasts have embraced being a "disputatious community of scholars"[15], but dissension has its limits in collaborative research projects. Being contentious was not part of the culture of the PHFI or Dhulikhel Hospital teams, and my attempts to influence the research worked best when I did this tactfully. Delivering a large project requires the team to unite around a path forward, even when they may disagree. I worked hard to achieve consensus on the process evaluation protocol, while still incorporating ideas and data collection that were fundamental to my PhD. But I could not own all the decisions that impacted what is and what is not contained within this thesis.

Collaboration has shaped my research. A traditional PhD model seems built on the ideal of an independent researcher offering their unique contribution to the body of knowledge. A staff PhD, and one based on co-authored papers from a large collaborative research project, is at odds with this. Working on a collaborative project means yielding space, including in authorship listings, and seeing your inputs as part of a broader effort. This PhD reflects my work and thinking about evaluation but was done in collaboration with and shaped by the inputs of many others.

8.4 Implications and recommendations

Research and evaluation

Future evaluations of EDSS interventions in ANC should build towards theoretical generalisability. The intention of evaluation research should not be on giving a verdict of a particular intervention as effective or not, but on the development of intervention theory[37]. The principle of multiples in operations research calls for multiple data sources over multiple points in time but also for multiple replications of the intervention in different settings[38]. The replications intend to uncover the extent to which an intervention's effects were unique to a setting or can be generalised[38]. Studying multiple settings is important, but replication alone does not determine the generalisability of intervention effects. Instead, generalisability stems from bridging of case-specific explanation toward the testing and refinement of intervention theory, which specifies contextually contingent mechanisms[15,39]. The literature assembling the evidence for the average effects of EDSS for quality improvement has found the intervention often disappointingly inconsequential, but this offers little insight into when and where EDSS can succeed[40–42]. Though the mIRA project evaluated few facilities, the facilities were neither homogenous nor static[3]. The realist-informed studies in the mIRA project evaluation attempted to unpack what circumstances produced change, emphasising causal explanation about the implementation of the EDSS and understanding these as contextually contingent mechanisms, identified by theory-building work based on empirical observation[15]. Examination of contextual factors has often been given more emphasis in studies replicating interventions that were effective in other settings but then found ineffective in that evaluation, suggesting explanation was considered mostly when explaining why something does not work[43]. Explanation and theory-building must be given equal due in interventions found effective and ineffective. Further research on EDSS in ANC should emphasise development of theory to test and refine understanding of the circumstances for EDSS implementation success and subsequent change in clinical performance.

Interventions do not offer a single theory; they are composed of many ideas about how the different resources introduced trigger different responses from participants that are conditioned by a range of individual and organisational factors[27]. There will always be a variety of outcomes of EDSS interventions, differentiated patterns of success and failure shaped by conditional causation. Outcomes measured in evaluations must reflect theorising, and indicators carefully constructed, so that outcome patterns can be explained[27]. Evaluation designs need to embed these considerations in the outcome evaluation of effectiveness and stop thinking of these as separate considerations only for the process evaluation. Realist trials, which seek to develop empirically-informed middle-range theory about what works in what circumstances, offer a potential approach for evaluation design in maternal health quality improvement research[44,45]. Evaluations should also consider the non-linearity of outcomes, potentially through multiple follow-up measures, as impacts grow or diminish over time[8].

However, research faces a fundamental problem of funding, and particularly the length of funding periods. The mIRA project, like many MRC-funded intervention studies, was initially funded for three years.[10] This is not enough time to develop and pilot an intervention, allow time for implementation, and adequately evaluate and understand its effects, while also doing collaborative work with diverse team members. Interdisciplinary work takes time. Alternative funding structures like the joint UK-India Newton scheme funding the mIRA project, while promising in their decolonised ethos, present real challenges in practice for interdisciplinary teams attempting to forge pathways of consensus in ways of thinking about interventions, implementation and evaluation. The further risk of short studies is that interventions suggesting (or requiring) system-wide change will look infeasible. Recent changes in funding opportunities, including the MRC's intervention development funding scheme, increasingly recognise that the failure of many interventions to produce positive outcomes stems from a rush to evaluate under-developed, poorly theorised interventions[8]. The mIRA project's EDSS would no doubt have benefited from increased resources for intervention development, yet if we continue to think about interventions as events within systems, then even better developed interventions will still often fail within dynamic, changing systems. The key is to focus efforts on better explaining why and how EDSS interventions fail and to learn the circumstances in which they may succeed.

[10] The project received a one-off grant supplement paid to all MRC grantees during the COVID-19 pandemic to offset the impacts of delays and turmoil on ongoing research projects and received a no-cost extension to continue the work beyond the originally planned three-year period.

Programme and Intervention design

Changing record keeping practices and changing clinical performance are separate, though related processes. Efforts to improve ANC quality must find ways to encourage responsive care that moves beyond clinical assessment within a visit to consider longitudinal care[11] (including follow-up on referrals) and patient-centred communication. Improving the quality of ANC consultations cannot ignore the complexity of ANC care-seeking, which mean pregnant women often receive care components from other providers or facilities, which need to be documented to be responded to in subsequent consultations. Good record keeping in ANC is part of this, and electronic records implemented at multiple levels, not just primary care, could help with documentation and communication between providers of ANC services. EDSS interventions in settings without existing electronic record keeping will likely struggle in implementation, and subsequently, in their potential effects on quality of care, if they duplicate rather than replace paper-based records and do little to alleviate the burden (whether perceived or actual) of record keeping. This is especially likely to apply in settings that are busier than facilities in rural Nepal.

However, we need to be realistic about how much an EDSS alone can change. The mIRA EDSS, while focused on risk screening, did seek to address gaps around the quality of counselling and person-centred care identified in the formative phase quality assessment in Telangana[46]. But the EDSS reminder functions, and outcome measures (for the cRCT and also used in the Nepal evaluation), largely targeted behaviours around the physical examination (blood pressure measurement) that had little room for improvement and around screening (urine protein, gestational diabetes, and haemoglobin testing) that tended to be done once routinely and only repeated for ANC patients with other risk indicators[4]. An EDSS is not going to be enough to change behaviours that clash with existing norms of care, particularly if ANMs do not believe ANC requires improvement. However, the time-motion study, as well as the longitudinal facility case studies, raised real questions about the amount of time being dedicated to ANC consultations and whether sufficient time was offered for person-centred care and more in-depth counselling and communication. The contextual constraints around pregnant women's expectations about how long they should spend at the facility to receive ANC and local bus schedules condensing ANC consultations into brief, busy periods meant that there

[11] Importantly, this was a goal of the mIRA project's intervention but was not possible to assess as an outcome within the resource limits of the project (see Chapter 2).

was limited scope to increase the length and depth of ANC consultations[4]. An EDSS can only do so much without a broader intervention to disrupt existing patterns of system organisation.

Evaluating short-term pilots of EDSS interventions may be distorting the evidence base away from learning when and in what circumstances these interventions can succeed[47–50]. ANMs in the mIRA project repeatedly emphasised the time-limited nature of the intervention as part of "a research project" when rationalizing their limited engagement and use of the EDSS[4]. Intervention impacts take time to emerge as feedback loops build[8]. Evaluating even smaller-scale implementation over longer periods of time may help illuminate how use of an EDSS, as both record keeping and decision support, becomes embedded and contributes to change in the dynamics and quality of ANC consultations. But we must also recognise that intervention implementation and scale-up may have more to do with political will that research evidence[51]. Nepal policymakers, even in the absence of evidence for ANC quality improvement, have expressed interest in wider use of EDSS as part of a digital health strategy[4]. Greater government support for rollout in Nepal may help overcome the substantial challenges of EDSS implementation, such as by removing some duplicate paper-based record keeping and integrating with other systems, which could enable looking at what can be achieved around the quality of service provision with better implementation.

8.5 Conclusion

The thesis examined the implementation and consequences of an EDSS intervention to improve ANC quality in Nepal and India, contributing nuanced approaches to measurement of the complex processes of ANC and the intervention to improve its quality. As part of the mIRA project, the thesis offered an argument for how an EDSS intervention should be evaluated and its results understood. I described the state of ANC quality in the intervention setting, finding that improvements in ANC could be gained from more responsive, person-centred care and communication. I conceptualised how the EDSS functioned, as largely through reminders, and the implementation pathways embodied in the intervention that the process evaluation would explore. I evaluated how the organisational context of ANC and the ways the intervention was understood, as primarily about record keeping, shaped how the EDSS was used and the outcomes of fidelity over the course of implementation. I investigated the negligible effect on workload in ANC and related record keeping, contributing understanding as to why the EDSS intervention failed to gain traction and change systems of ANC in participating facilities.

We can learn from evaluations that take and apply realist principles in accessible ways to generate richer, more useful evidence. Yet process evaluations cannot answer all questions about what happened and to whom, in what circumstances and how the intervention had effects; the mountain of data required would exceed even the best resourced evaluations[52]. Evaluators must anticipate what questions to ask among the numerous propositions and implicit theories of an intervention[27,52]. Some effects will remain unmeasured and unexplained. While a step in the right direction, the mIRA project evaluation in Nepal was unable to actually test, rather than just hypothesise, about the mechanisms through which intended and unintended effects occurred[44]. Maternal health research should move away from viewing outcome and process evaluations in separate spheres and apply the same rigour and attention to improving and understanding implementation as evaluating outcomes. The core role of evaluation research is explanation, and this requires embracing complexity in the systems we seek to change and complexity in how we measure and assess this. Contexts matter, not just for what happens in interventions and generating change but also in how research can study this and the context of a research team's interest in doing so.

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Appendix A: Methods for mIRA project systematic review of reviews

To inform the design and evaluation of an EDSS for ANC in India and Nepal, two mIRA project team members – Emma Radovich, LSHTM and Monica Chaudhry, PHFI – conducted a literature review to identify relevant studies to understand implementation factors considered in similar interventions to improve care in pregnancy. A systematic review of reviews was deemed the appropriate evidence synthesis method due to the volume of previously published systematic and non-systematic literature reviews of mHealth interventions that encompassed interventions for care during pregnancy. A review of reviews allows for a rapid, economical summary of evidence from a range of interventions across different settings when the focus of inquiry is on participants providing a particular service yet working at various health system levels[1,2]. In this case, the focus was on healthcare workers providing ANC. Through a systematic review of reviews, we sought to identify primary studies on mHealth interventions targeting frontline healthcare workers in LMICs to improve the quality of ANC. Findings from implementation and outcomes described in the selected primary studies were used in intervention development discussions with the mIRA project team.

Search strategy and selection process

An electronic systematic literature search was conducted on 3 June 2019 in two databases specialising in systematic reviews: Cochrane Library and 3ie Systematic Review Repository using key words and indexing terms (MeSH) around two domains: mHealth and literature reviews (Table A-1). Additional literature reviews were also identified via reference lists of previously identified papers. Search results were imported into the reference management software Mendeley. Duplicates were removed automatically by Mendeley but double-checked manually.

Table A-15 Domains and corresponding search terms for a systematic review of reviews

Domain	Search terms
mHealth	exp Decision Making, Computer-Assisted/ Decision Support Techniques/ Decision Support Systems, Clinical/ exp Medical Records Systems, Computerized/ Diagnosis, Computer-Assisted/ Reminder systems/ Algorithms/ Clinical Decision-Making/ Telemedicine/ Electronic Health Records/ decision-support "mobile health" mhealth
Literature review	Systematic Review/ Review/ review adj3 research systematic* adj2 review* scoping review* literature adj3 review* narrative review* synthesis adj4 evidence synthesis adj4 qualitative qualitative adj2 review meta-analysis realist review evidence adj3 gap*

Relevant reviews were selected based on pre-determined inclusion and exclusion criteria listed in Table A-2. Primary studies included in the eligible reviews were then assessed according to additional inclusion and exclusion criteria (Table A-2), and eligible primary studies were selected for data extraction. We considered mHealth to include interventions delivered on portable digital devices, including laptops, tablets, and mobile cellular phones (with or without 'smart phone' capabilities)[3].

Table A-16 Inclusion and exclusion criteria for reviews and for primary studies from eligible reviews

Inclusion Criteria	Exclusion Criteria
Reviews	
• Reviews of primary studies of mHealth interventions, defined as interventions delivered on mobile phones or handheld computer/tablet devices, that included interventions targeted at healthcare providers. • Reviews of mHealth interventions for antenatal care, but this need not be the focus of the review. • Reviews of studies conducted in all countries or only in LMICs (based on World Bank definition of LMIC). • All types of literature reviews (systematic and non-systematic literature reviews), as well as non-peer-reviewed literature reviews (i.e. grey reports).	• Reviews of mHealth interventions delivered directly to clients/patients only. • Reviews of studies conducted only in high-income countries. • Reviews of short message service (SMS)-only or email-only mHealth interventions. • Reviews of interventions for non-maternity health services or for only intrapartum or postpartum care.
Primary studies	
• All observational and experimental types of study design. • Study was conducted in at least one or more LMIC. • mHealth interventions directed for usage by formal healthcare providers or facility-based interventions. Studies of mHealth interventions for community health workers (CHWs) or traditional birth attendants (TBAs) in home visits were included if they were conducted in India or Nepal. • mHealth interventions for care during pregnancy, including care provided from pre-conception up to and including the intrapartum period.	• Studies of non-maternal health services or for care after childbirth. Studies of family planning or abortion care. • Studies of interventions aimed at non-formal healthcare providers, such as TBAs, or at CHWs, for home visits, if outside of India or Nepal. • Studies of interventions aimed at the registration of vital events or data collection for purely research purposes, and those falling into Labrique and colleagues'[4] categories of: human resource management; supply chain management; or financial transactions and incentives, where there was no additional functionality. (See Table A-3) • PhD theses, or studies not in English. • Primary sources that did not describe implementation, such as the software company websites that had developed the mHealth application.

Due to the large number of interventions comprising multiple functions, further clarification on the inclusion and exclusion criteria for intervention types was mapped against the 12 categories of mHealth interventions developed by Labrique and colleagues[4](Table A-3). Intervention categories selected for inclusion in the examination of primary studies was guided by the potential functions being considered for development in the mIRA EDSS.

Table A-17 Intervention type inclusion criteria for primary studies in the review, mapped against the 12 categories of mHealth interventions

12 categories of mHealth interventions (as defined by Labrique & colleagues[4])	**Intervention types for inclusion in our review**
1. Client education and behaviour change communication	Include only if delivered by a frontline health worker. Exclude if the intervention consists solely of SMS; multimedia messaging service; or interactive voice response.
2. Sensors and point-of-care diagnostics	Include all.
3. Registries and vital events tracking	Include only if delivered by a frontline health worker.
4. Data collection and reporting	Exclude all studies where this is the sole purpose of the intervention.
5. Electronic health records	Include all.
6. Electronic decision support (information, protocols, algorithms, checklists)	Include all.
7. Provider-to-provider communication (user groups, consultation)	Include all.
8. Provider work planning and scheduling	Exclude all studies where this is the sole purpose of the intervention.
9. Provider training and education	Include all.
10. Human resource management	Exclude all studies where this is the sole purpose of the intervention.
11. Supply chain management	Exclude all studies where this is the sole purpose of the intervention.
12. Financial transactions and incentives	Exclude all studies where this is the sole purpose of the intervention.

The database searches were carried out by ER. Following de-duplication, titles and abstracts of reviews were independently screened by two reviewers (ER & MC), and any discrepancies were resolved following discussion. Full text screening of the reviews was completed by one reviewer (ER), applying the inclusion-exclusion criteria. Following final selection of review articles, a list of all primary studies included in the reviews was generated, de-duplicated and title and abstract screened by two reviewers (ER & MC) to identify primary studies meeting the inclusion-exclusion criteria for data extraction. Disagreement or uncertainty about the inclusion of primary studies of interventions was discussed with and decided by a third reviewer (Oona M. R. Campbell). Reasons for exclusion were recorded and are detailed in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram[5].

Study quality

No reviews or primary studies were excluded based on quality assessment as our aim was to explore factors around implementation and evaluation of interventions, rather than to determine the effectiveness of a particular mHealth intervention.

Search results

We identified and screened 405 literature reviews; 12 reviews met the criteria for primary study listing. We screened 182 primary studies, and 30 primary studies describing 18 interventions, met the inclusion criteria (Figure A-1).

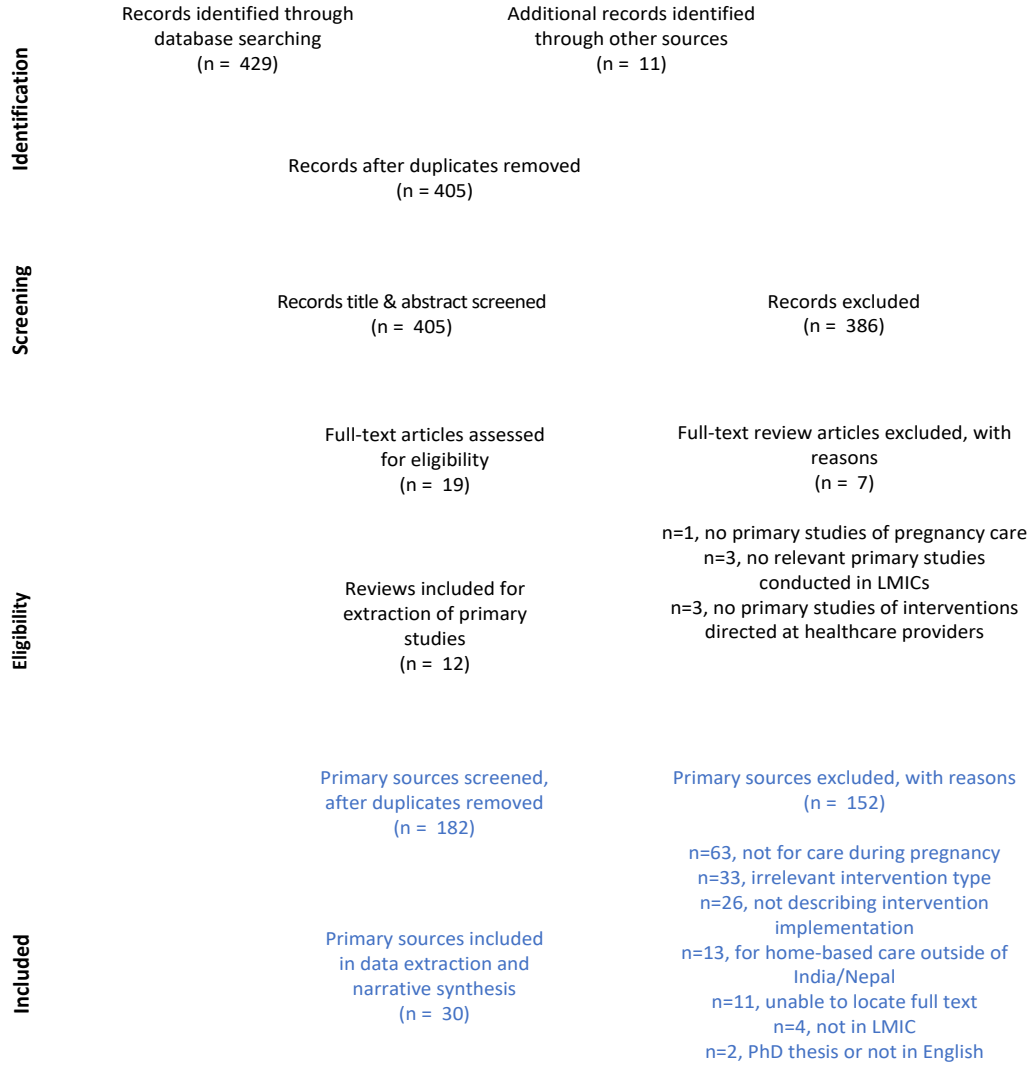

Figure A-7 Search and included results reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) Statement

Table A-4 outlines the scope of the reviews included for the extraction of primary studies.

Table A-18 Summary table of scope of included reviews

Review first author (year)	Aim	Database(s) searched	Search timeframe	Number of individual studies included
Abejirinde (2018)	Review aimed to "build plausible theoretical explanations underlying how mHealth influences the performance of HCWs [health care workers], specifically for delivering maternal health services in LMIC"[6].	PubMed, Web of Science Core Collection, CINAHL, International Bibliography of the Social Sciences (IBSS), and Cochrane Library	1999 to September 2016	23
Adepoju (2017)	Review aimed to synthesise evidence on mobile technology interventions for "improving point-of-care clinical decision-making and the quality of care in Africa"[7].	PubMed, CINAHL, Web of Science Core Collection, Cochrane and K4Health	until 16 March 2016	22
Agarwal (2015)	Review aimed to describe use of mHealth strategies by frontline health workers in LMICs, "critically review the evidence base on the effectiveness of such strategies and identify the gaps in the current knowledge base"[8].	MEDLINE, EMBASE, Global Health, Google Scholar and Scopus	2000 to 2013	42
Amoakoh-Coleman (2016)	Review aimed to assess the "effectiveness of mHealth interventions aimed at health care workers providing maternal and neonatal services in improving maternal and neonatal outcomes in LMIC"[9].	Cochrane Library, PubMed, EMBASE, Global Health Library, and Popline	until 2014	19
Aranda-Jan (2014)	Review aimed to examine "experiences of mHealth implementations in Africa during the last decade, and to identify factors influencing the successes and failures of mHealth projects in Africa"[10].	PubMed and Journal @Ovid	2003 to June 2013	44
Colaci (2017)	Review aimed "to explore the current evidence on the use of mHealth for maternal health interventions in low- and low middle-income countries"[11].	PubMed/Medline, Web of Science and Cochrane Library	2000 to July 2015	19
Feroz (2017)	Review aimed to "assess the effectiveness of mHealth solutions on a range of maternal health outcomes by categorizing the interventions according to the types of mHealth applications"[12].	PubMed, CINAHL Plus and Cochrane	2000 to January 2016	14

Haddad (2019)	Review aimed to "to identify main apps and software that are currently available in mHealth, designed for use by health professionals during antenatal care"[13].	PubMed/Medline, Google Scholar and Google Play platform	Jan 2014 to June 2018	9
Noordam (2011)	Review aimed to analyse "the potential of mobile phones to improve maternal health services" in LMICs[14].	PubMed, Embase, Cochrane Library, Scopus, Science Direct and African Journals Online	Not stated	8
Philbrick	Review aimed to present a "needs assessment and gaps analysis of the current state of the evidence in mHealth" in maternal, newborn, and child health, drawing on a literature review, landscape scan of ongoing mHealth projects and interviews with key informants[15].	Google Scholar, Mendeley, Cochrane Collaboration, Campbell Collaboration, 3IE, GSMA, PubMed, WHO Bulletin, and grey literature from: mHealth Alliance HUB, K4Health, MobileActive.org, and Royal Tropical Institute's "mHealth in Low Resource Settings" knowledge portal	2009 to June 2012	38
Tamrat (2012)	Review aimed to provide an overview of "outcomes, barriers, and strategies of integrating mHealth to improve prenatal and neonatal health outcomes"[16].	Google, Google Scholar, PubMed, Web of Science, Science Direct and ProQuest	2000 to 2010	34
Watterson (2015)	Review aimed to "determine the effectiveness of mHealth tools to increase the coverage and use of antenatal care, postnatal care, and childhood immunizations through behavior change" in LMICs[17].	Google Scholar, PubMed, Embase, PsycINFO, and EBSCO Host	1 January 2000 to 20 November 2014	10

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Appendix B: Internal questionnaire to develop the theory of change

Q1. What are the main problems with the quality of ANC that this intervention is trying to solve?

	Strongly AGREE	Somewhat AGREE	Somewhat DISAGREE	Strongly DISAGREE	Don't know
A) Healthcare providers don't know what routine care components should be provided at each ANC visit.	○	○	○	○	○
B) Healthcare providers don't know how to screen or detect pregnancy complications.	○	○	○	○	○
C) When healthcare providers detect a pregnancy complication, they don't know what to do (where to refer or what care to provide).	○	○	○	○	○
D) Healthcare providers don't record information properly.	○	○	○	○	○

	Strongly AGREE	Somewhat AGREE	Somewhat DISAGREE	Strongly DISAGREE	Don't know
E) ANMs are too reliant on Medical Officers for diagnosis and management of complications that ANM should be handling.	○	○	○	○	○
F) Too many pregnant women are referred upward that should be managed at the primary level.	○	○	○	○	○
G) Medical Officers are not involved enough in providing ANC and should be doing more.	○	○	○	○	○
H) Healthcare providers lack the time to perform all required ANC components.	○	○	○	○	○
I) Healthcare providers don't think it is necessary to perform all ANC components during every visit.	○	○	○	○	○

Q2. Is there another main problem with the quality of ANC (that our intervention is trying to solve) that is not listed above?

Your answer

Q3. How does our intervention solve the above problem(s)?

	Strongly AGREE	Somewhat AGREE	Somewhat DISAGREE	Strongly DISAGREE	Don't know
A) Intervention reminds healthcare providers to perform all routine care components.	○	○	○	○	○
B) Intervention alerts healthcare provider to signs of a potential complication that they otherwise would have missed (e.g. low Hb) .	○	○	○	○	○
C) Intervention trains healthcare providers to perform routine care components correctly via instructions in the app.	○	○	○	○	○
D) Healthcare providers become more knowledgable about ANC from reminders about guidelines in the app.	○	○	○	○	○

	Strongly AGREE	Somewhat AGREE	Somewhat DISAGREE	Strongly DISAGREE	Don't know
E) Intervention reminds healthcare providers to document or record care components better.	○	○	○	○	○
F) Intervention delineates ANC responsibilities more clearly between levels of healthcare providers.	○	○	○	○	○
G) Intervention makes healthcare providers feel more responsible for performing routine care components during every visit.	○	○	○	○	○
H) Intervention inputs and alerts will change the order in which healthcare providers perform ANC components.	○	○	○	○	○
I) Intervention provides recommendations on when and where to refer or not to refer pregnant women with complications.	○	○	○	○	○

Q4. Are there other ways in which our intervention works to solve the main problem with quality of care not listed above?

Your answer

Q5. Under what circumstances do you think the intervention will work best?

- [ ] Young or inexperienced ANMs/staff nurses will be more likely to use the app during ANC visits and show more improvement in quality of care.
- [ ] Healthcare providers who are willing to change the way they organize ANC workflow will be more likely to use the app during ANC visits.
- [ ] Facilities with a lower number of ANC clients (relative to other facilities in the trial) will be more likely to use the app during ANC visits and show more improvement in quality of care.
- [ ] Facilities with good mobile network coverage will be able to use the app more easily and show more improvement in quality of care.
- [ ] Well-equipped facilities, including with lab facilities, will be more likely to use the app and show more improvement in quality of care.
- [ ] Remote facilities that are far from higher-level care and consultant obstetricians/doctors will be more likely to use the app and show more improvement in quality of care.
- [ ] Facilities with low staff turnover will be more likely to integrate the app into their workflow and show more improvements in quality of care.
- [ ] Facilities in areas where district/municipal officials are enthusiastic about the intervention will be more likely to use the app and show improvement in quality of care.
- [ ] Other:

Appendix C: Evaluation protocol for Nepal

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1402301	**Title**	Ms
First Name(s)	Emma		
Surname/Family Name	Radovich		
Thesis Title	Complex reality, implementation and measurement: Evaluation of an electronic decision support system to improve antenatal care quality in South Asia		
Primary Supervisor	Prof. Oona Campbell		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	Figshare as: Radovich, Emma; Penn-Kekana, Loveday; Karki, Sulata; Das, Seema; Shakya, Rajani; Campbell, Oona M. R.; et al. (2023). Assessing the potential of two electronic decision support systems to improve the quality of antenatal care in primary care facilities in Nepal: study protocol. figshare. Preprint. https://doi.org/10.6084/m9.figshare.23685099.v3		
When was the work published?	19 July 2023		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**No**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the overall process evaluation, coordinating inputs from co-authors on the design of the seven data collection activities. In particular, I contributed the emphasis on a realist approach to the evaluation and the use of Normalization Process Theory to examine the intervention's implementation. I drafted the process evaluation protocol and made revisions in response to co-author comments. I contributed to discussions about the primary outcome measurement, which was aligned with the trial planned in India, but the pre-post outcome assessment study was designed while I was on maternity leave. The outcome assessment and related objective (objective 1) was added to the protocol by other members of the study team, but I reviewed and revised the final draft of the combined outcome and process evaluation protocol prior to publication as a pre-print.

SECTION E

Student Signature	Emma Radovich
Date	3 May 2024

Supervisor Signature	Oona Campbell
Date	22 May 2024

Assessing the potential of two electronic decision support systems to improve the quality of antenatal care in primary care facilities in Nepal: study protocol

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Abstract

Introduction

Good quality antenatal care plays an important role in reducing maternal and perinatal mortality, including in high-burden settings like Nepal. Electronic decision support systems (EDSS) aim to promote adherence to evidence-based guidelines. This protocol outlines the outcome and process evaluation of two tablet-based EDSS, the Mobile health Integrated Rural Antenatal care (mIRA) EDSS and the World Health Organization's ANC Reference Application EDSS, on improving antenatal care quality in primary-level healthcare facilities in Nepal. The outcome evaluation aims to assess the effectiveness of the intervention on quality of antenatal care. The process evaluation aims to inform interpretation of outcome results and to improve understanding of the implementation process and intervention effects, addressing the research question: why or how does an EDSS influence quality of antenatal care and in what circumstances?

Methods and analysis

The pre-post outcome and theory-driven, mixed-methods process evaluation will assess implementation fidelity and improvements in the performance of selected antenatal care components, explore the implementation process and contextual factors, and examine causal mechanisms leading to change in antenatal care quality. Data for quantitative and qualitative analyses will be collected at multiple time points, and initial analyses of quantitative and qualitative data completed separately. Results will be integrated using convergent parallel-databases

triangulation to develop explanations about the implementation process—over time and across settings—and the effects observed.

Ethics and dissemination

Ethical approval for this study was obtained from ethics committees at Kathmandu University School of Medical Sciences, Nepal Health Research Council, and the London School of Hygiene & Tropical Medicine. Results will be disseminated through academic publications, stakeholder workshops, conference presentations and reports.

Introduction

Decision support technologies have been implemented in many healthcare settings to address deficiencies in quality of care[1–3]. Electronic decision support systems (EDSS)—information systems integrating clinical and demographic patient data to aid healthcare providers' decision making, and delivered via computers or mobile devices—aim to promote adherence to evidence-based practices through alerts, checklists or information provided at the point of care[3,4]. EDSS can support many types of clinical tasks. These include patient monitoring (such as alerts to changes in patients' physiological conditions or abnormal laboratory results), supporting drug prescribing (such as checking for contraindications), and formulating diagnoses or treatment suggestions[3]. EDSS can be particularly relevant in lower-level health facilities where senior or specialist healthcare providers are not available[2]. However, evidence of the effectiveness of EDSS on quality of care and healthcare provider performance remains mixed[1,3–6]. Some reviews suggest EDSS can have positive impacts on clinical practice, particularly with preventive care reminder systems[3] and when the EDSS is well integrated into workflow[2]. Yet other reviews note that the large amount of electronic patient data required in diagnostic algorithms and high burden of data entry (where the data is not already in electronic records) can adversely impact healthcare providers' enthusiasm for the EDSS, and the accuracy of its decision support[3].

Two EDSS that aim to improve quality of antenatal care (ANC) are the Mobile health Integrated Rural Antenatal care (mIRA) EDSS and the World Health Organization's (WHO) ANC Reference Application[7]. We refer to the latter as the WHO EDSS. Both EDSS use prompts and diagnostic algorithms to improve healthcare providers' adherence to routine ANC guidelines and the detection and management of higher risk pregnancies. The mIRA EDSS was designed in India by Public Health Foundation of India, Dhulikhel Hospital, Kathmandu University Hospital, and the London School of Hygiene & Tropical Medicine and offers bespoke diagnosis and treatment content and pop-up prompts for gestational diabetes, hypertension in pregnancy and anaemia. The WHO EDSS facilitates adoption of WHO ANC guidelines[8], focussing on routine care, with checklists for screening and referral but not treatment of pregnancy complications, and includes facility infrastructure parameters (e.g. whether ultrasound is available at the facility)[7].The two EDSS are designed to be used at all stages of pregnancy, and provide prompts adapted to different gestational ages, missing care components, and the results of screenings or vital signs inputted (e.g., abnormal vs normal blood pressure readings).

EDSS are intended to be used by frontline healthcare providers during all ANC consultations with pregnant women, recording clinical examination and test results. In India, a cluster randomised trial will assess the impact of the mIRA EDSS on quality of ANC compared to usual care[9]. In this paper, we describe the protocol for Nepal where we are conducting implementation research to compare change in ANC quality before/after EDSS implementation and to examine the processes and factors affecting implementation of the mIRA and WHO EDSS. Comparing the two EDSS in Nepal will enable better understanding of the features or software functionality that influence better uptake and the barriers and facilitators to implementation specific to each application.

While many interventions are developed to improve healthcare provider behaviour, few studies examine the possible mechanisms through which interventions act to bring about any observed improvements[6,10]. This planned outcome and process evaluation will fill an important gap in the literature on how EDSS interventions change healthcare worker performance and the quality of maternity care[11]. This paper outlines the protocol for the outcome and process evaluation of the mIRA and WHO EDSS intervention implementation in Nepal.

Aim and objectives

The overall aim of the outcome and process evaluation is to generate evidence to inform interpretation of changes in ANC quality before and after implementation of the mIRA and WHO EDSS intervention in Nepal and to further understanding of the theories underpinning EDSS quality improvement interventions in ANC. The specific objectives of the study are to: 1) assess changes in quality of care following implementation of the mIRA EDSS and the WHO EDSS; 2) document and understand the implementation process and how EDSS become part of the systems in which they are delivered; 3) explore how contextual factors impact implementation and effectiveness of EDSS; and 4) investigate how EDSS change the delivery and quality of ANC.

Methods and analysis

Study setting

The study will take place in four predominantly rural districts in Bagmati Province, Nepal: Kavrepalanchok, Sindhupalchowk, Sindhuli and Dolakha. Most maternity care in the province is provided in government facilities[12,13]. According to the 2022 Nepal Demographic and Health Survey, 94% of women accessed any ANC from a skilled provider and more than 80% of women had 4+ ANC visits[13]. According to formative research by the mIRA project, pregnant women in rural areas sought care at their nearest Health Post, staffed by auxiliary nurse midwives (ANMs), or at

Primary Health Care Centers (PHCC), staffed by ANMs and Medical Officers or at 18 outreach centres (run by Dhulikhel Hospital, and named DHORCS) that are similar in size, staffing and function to PHCCs. In both government facilities and DHORCs, women are provided with handheld paper records for ANC. Nearly all record-keeping is paper based, though some facilities file monthly health management information system (HMIS) reports online to their local municipality or district using laptops. No tablets or EDSS are used for pregnant women's care in any of the facilities.

A total of 20 primary-level facilities, consisting of government Health Posts, PHCCs and DHORCs, in the selected districts will receive tablets with the EDSS software installed. Ten will receive the mIRA EDSS and ten will receive the WHO EDSS. The health facility will select one ANM from each participating facility to attend a training workshop at Dhulikhel Hospital to learn how to use their assigned EDSS. The ANM will then be supported to use the EDSS, and to train other ANMs providing ANC at their facility in EDSS use, during a month-long 'lead-in' period of onsite assistance by a dedicated fieldworker.

Evaluation design

The evaluation is designed to explore how implementation occurred and to examine mechanisms for change in quality of care following implementation of the two EDSS. A pragmatic decision was taken to use an uncontrolled pre/post outcome evaluation design[14] to measure differences in quality of care before and after introduction of the two EDSS due to COVID-19 pandemic-related delays and resource constraints. With the relatively short time scale of approximately 8-9 months between before and after data collection, as well as documentation and triangulation of contextual factors and changes during this period, we believe we will be able to make the case for potential attribution of observed changes to the intervention. The evaluation is not designed to compare quality of care measures between the mIRA and the WHO EDSS as these are expected to operate to improve adherence to guidelines in a similar way. However, we will explore differences in implementation of the two EDSS in planned qualitative data collection, including how ANMs and pregnant women respond to the two software interfaces.

Theoretical approach

This evaluation will take a realist approach, developing testable propositions about the generative mechanisms triggered to bring about change in outcomes[15]. In doing so, we attempt to move beyond describing outcomes ('what works') to an explanatory approach ('why or how does the intervention have its effect and in what circumstances')[16]. We will consider how the EDSS was successful (or not) in these facilities in Nepal and the broad range of factors needed for successful

implementation and integration in other circumstances. This theory-driven approach offers the potential for more generalisable knowledge from the specific implementation of the mIRA and WHO EDSS in Nepal[15,16].

The data collection and analysis will be guided by Normalization Process Theory, which identifies and explains mechanisms that affect the process of implementation and its outcomes[17,18]. Normalization Process Theory categorises the different kinds of work, at the individual and organisational level, necessary for the implementation of an intervention. It focuses on the range of people, situations, times, and places that are involved in all aspects of an intervention's attempt to modify patterns of behaviour in healthcare. The theory has been widely used to investigate digital health interventions, particularly in high-income settings. It recognises that new technologies—such as EDSS software—are not merely tools but are a set of objects, behaviours, and interactions. Normalization Process Theory is particularly useful for examining the mIRA and WHO EDSS because routine use ('normalization') is embedded in the EDSS conceptual framework (Figure A-1). The mIRA and WHO EDSS will work best if used at every ANC visit to enable the diagnostic algorithms for longitudinal care throughout the pregnancy. Routine use will minimize the need to back-enter data from previous patient contacts—factors known to hinder EDSS effectiveness in other settings[3]. Inconsistent use of the EDSS (i.e., for some, but not all ANC visits) can potentially undermine recordkeeping and care practices if providers do not know where to find the most complete record of patient care.

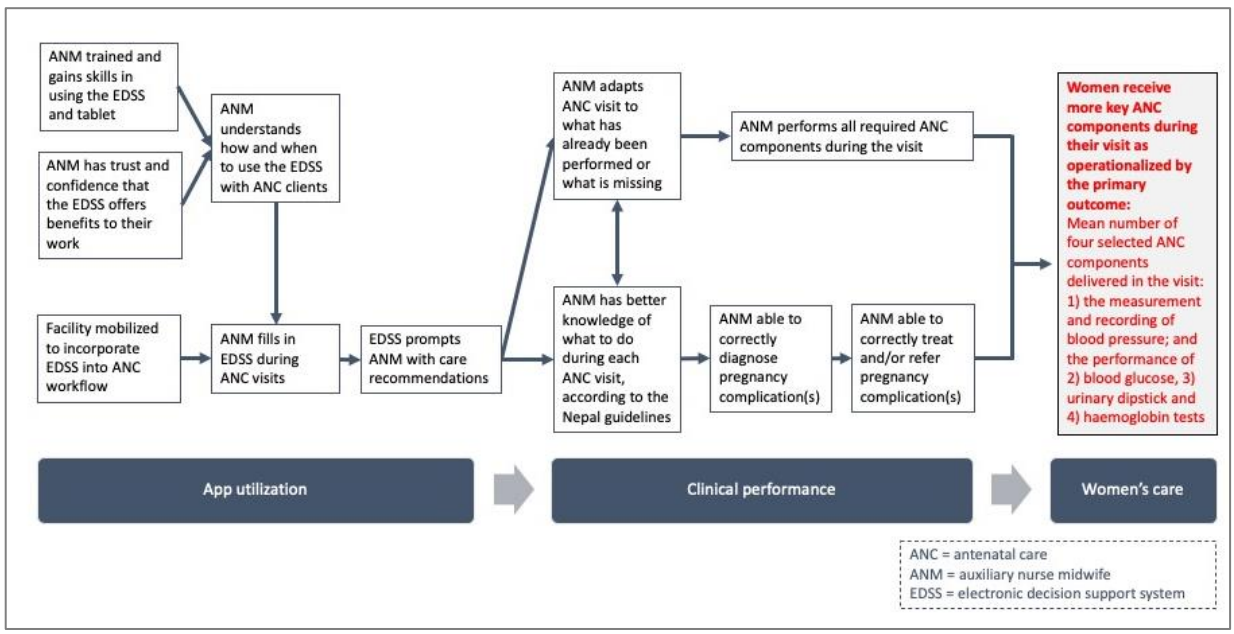

Figure A-1 Conceptual framework outlining the pathways through which EDSS are anticipated to improve the performance of key care components during women's antenatal care visits

Data collection

Eight types of data collection will be undertaken at multiple time points (Figure A-2). These are: 1) a pre-post outcome assessment to evaluate change in ANC quality scores before and after implementation of the EDSS; 2) routine monitoring from repeat, in-person facility visits by research staff and EDSS software backend data will be used to evaluate the frequency and quality of use of the EDSS; 3) a baseline facility survey to document facility characteristics and contextual factors prior to implementation; 4) a healthcare provider attitudes survey at the beginning of implementation to document participants' understanding of and attitudes towards incorporating EDSS into their work; 5) an audit of recordkeeping to examine impacts on record completeness; 6) documentation of debriefing meetings with fieldworkers involved in training and monitoring the intervention to qualitatively examine implementation barriers and facilitators; 7) longitudinal case studies in four facilities, comprising non-participant observations over time as well as in-depth interviews with healthcare providers and facility managers; and 8) a time-and-motion assessment to examine impacts on time spent on recordkeeping and clinical activities.

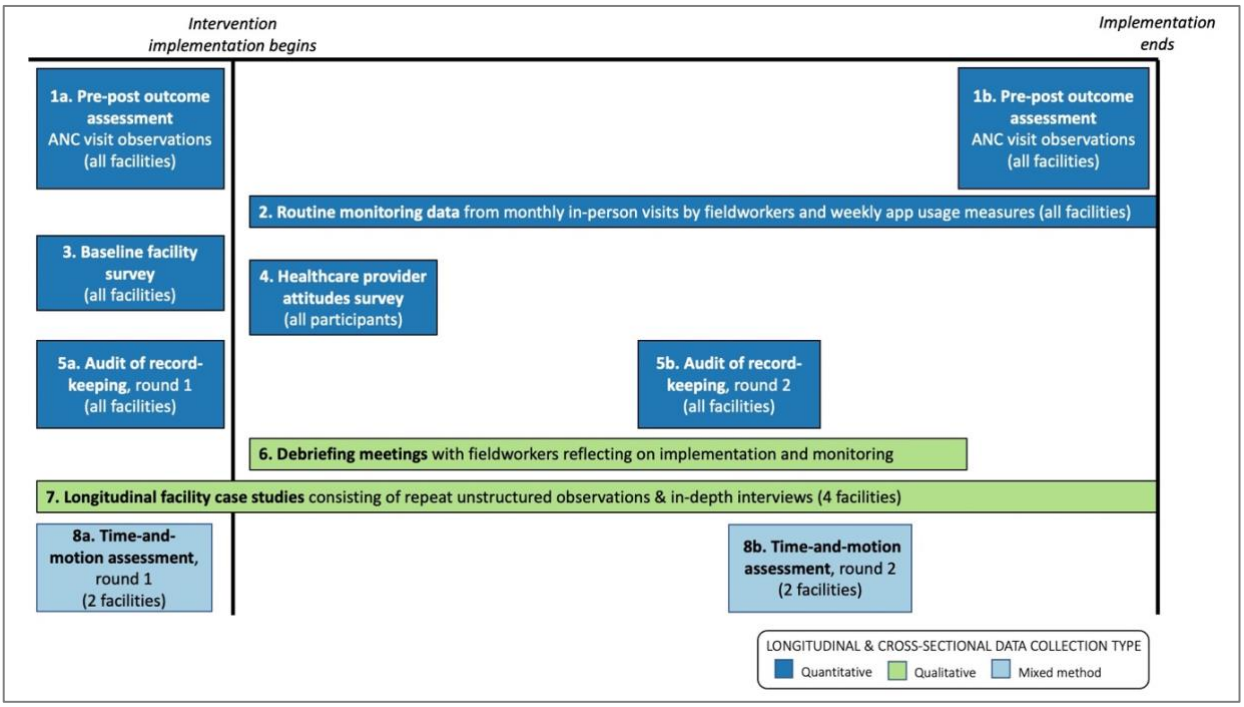

Figure A-2 Diagram of data collection for component studies of the outcome and process evaluation

Table A-1 outlines the data sources and study design details that comprise the outcome and process evaluation.

Table A-19 Data sources and study design details for component studies of the outcome and process evaluation

Data source	Study design	Aim	Participants	Outcome(s)	Sample size
1. ANC visit observations	Quantitative, two-phase (before and after) outcome assessment, comparing ANC quality scores pre- and post-implementation of the EDSS in intervention facilities.	To evaluate the effect of the EDSS on the quality of ANC.	All women 18+ years attending for ANC visits on the day(s) of data collection at all facilities will be eligible for inclusion.	Quality as operationalised by mean number of four selected ANC components delivered by healthcare providers per visit, comparing pre to post EDSS implementation visits. The four selected components are: 1) measurement and recording of blood pressure; and the performance of 2) blood glucose, 3) urinary dipstick and 4) haemoglobin tests.	We will observe at least 60 ANC visits: 30 in mIRA EDSS facilities (15 pre and 15 post) and 30 in WHO EDSS facilities (15 pre and 15 post). This will have 80% power to detect a 12.5% relative increase in the mean number of ANC components.
2. Routine monitoring data	Repeat, cross-sectional assessments of intervention adherence from monthly in-person monitoring visits using a structured checklist and weekly checks of EDSS backend data.	To assess fidelity of implementation of the mIRA EDSS and WHO EDSS over the duration of implementation.	All facilities.	Monthly scores for adherence components (content, frequency, and quality of EDSS use).	Not applicable.
3. Baseline facility survey	Cross-sectional, quantitative survey conducted prior to the start of mIRA and WHO EDSS implementation.	To assess staffing characteristics, infrastructure, and equipment to provide quality ANC to facilitate analyses of the moderating effects of contextual factors on outcomes and implementation.	All facilities.	Proportion of facilities with functional equipment for provision of routine ANC, laboratory testing and medicines for maternal health; numbers of and qualifications of staff; and staff to ANC patient ratio.	Not applicable.
4. Healthcare provider attitudes survey	Cross-sectional, quantitative survey.	To capture healthcare providers' responses to and understanding of the EDSS as potential drivers of implementation fidelity.	All healthcare providers trained in using the EDSS in all facilities	Mean score for Normalization Process Theory constructs: coherence, cognitive participation, collective action, and reflexive monitoring.	Not applicable.

5. Audit of recordkeeping	Quantitative, two-phase (before and after) audit of records, comparing selected data entry fields appearing in paper record sources, and in the second phase, additionally comparing to data entry fields in the EDSS software.	To assess change in the completeness and agreement of pregnant women's handheld records (ANC cards) and facility ANC registers before and after implementation of the EDSS intervention.	All women 18+ years attending for ANC visits on the day(s) of data collection at all facilities will be eligible for inclusion	Proportional difference in 'completeness' (each of the selected variables has an entry in both the ANC card and ANC register) and 'agreement' (data values entered match in both the ANC card and ANC register).	138 women's records in each round are required to detect differences of ≥15% in completeness before and after EDSS implementation, assuming 65% initial prevalence of completeness.
6. Debriefing meeting notes	Secondary qualitative document analysis of notes from debriefing meetings with fieldworkers.	To explore the implementation process and how healthcare providers put the intervention into practice, including contextual factors that help or hinder this process.	All fieldworkers conducting training and monitoring visits.	Not applicable.	Documentation from at least two debriefing meetings.
7. Longitudinal facility case studies	Qualitative longitudinal case studies in four intervention facilities using repeat, unstructured observations and in-depth interviews.	To capture the context in which ANC is provided and emerging changes in implementation, experiences of the intervention, and unanticipated or complex causal pathways, to generate hypotheses about how the EDSS contributes to ANC quality improvement.	Purposively selected facilities located close to Dhulikhel Hospital and considered to be well-functioning by municipal officials.	Not applicable.	Four facilities: two receiving the mIRA EDSS and two receiving the WHO EDSS.
8. Time-and-motion assessment	Mixed method, two-phase (before and after), observational time-motion assessment of major tasks performed by ANM providing ANC.	To investigate change in the workflow, delivery of ANC services and time spent on recordkeeping before and after implementation of the EDSS.	All ANMs providing ANC in two facilities taking part in the longitudinal case studies which have larger ANC caseloads, one each implementing the mIRA EDSS and WHO EDSS	Mean total time in minutes spent on major task categories before and after EDSS implementation (analysis stratified by ANM).	63 observations in each round (126 observation units total per ANM) to detect differences of 20% or greater in mean number of minutes spent on task categories.

Pre-post outcome assessment

The aim of study one is to evaluate the effect of the EDSS on the quality of ANC. An ANC observation tool developed for the trial in India[9], will be used by fieldworkers in Nepal to observe ANC visits and collect data on the number of components of ANC performed during the ANC visit. ANC observation data will be collected before implementation of the EDSS and after implementation at all intervention facilities. All pregnant women aged 18 years or older attending for an ANC visit on the days of data collection will be invited to participate. Quality will be assessed via mean number of four completed ANC components: 1) the measurement and recording of blood pressure; and the performance of 2) blood glucose, 3) urinary dipstick and 4) haemoglobin tests. We will compare pre-post ANC quality scores for mIRA EDSS facilities and WHO EDSS facilities in a combined analysis. The outcome measure is chosen to align with a cluster-randomised control trial of the mIRA EDSS being conducted in India[9], where the four ANC components were selected based on low coverage observed during formative phase data collection[19] and the particular emphasis of the mIRA EDSS to improve diagnosis and treatment of hypertension in pregnancy (blood pressure measurement and urinary dipstick test), gestational diabetes (blood glucose test) and anaemia (haemoglobin test).

Routine monitoring

Study two will use multiple quantitative routine monitoring data sources to assess components of implementation fidelity over time (Table A-2). Implementation fidelity, or the consistency with which the intervention was implemented as intended, is critical to understand whether the outcome evaluation represents a valid test of the intervention theory[16,20,21]. Three essential aspects of fidelity to the EDSS intervention have been identified for investigation: 1) healthcare providers must use and fill-in the EDSS during consultations with pregnant women; 2) healthcare providers must use the EDSS for all ANC visits; and 3) healthcare providers must enter sufficient data in the EDSS so that the algorithms can generate recommendations/reminders.

Table A-20 Components of adherence and operationalisation in the assessment of implementation fidelity in intervention facilities

Adherence component	**EDSS intervention fidelity definition**	**Operationalisation**
Content – extent of EDSS use as intended	1. Healthcare providers must use and fill-in the EDSS during the consultation with the pregnant woman.	• Observed use of EDSS software during ANC consultation (monthly cross-sectional binary measure).
Frequency – incidence of EDSS use	2. Healthcare providers must use the EDSS for all ANC visits.	• Consistency of number of ANC visits recorded in a comparison of paper records vs app data (monthly

		cross-sectional ratio of app to paper-based recorded visits).
Quality – scope of EDSS functionality enabled	3. Healthcare providers must enter data sufficiently in the EDSS so that the algorithms can generate recommendations/ reminders.	• Completeness of data entry in app (weekly cross-sectional proportion of app fields completed).

Intervention facilities will be assigned monthly scores for adherence components over the duration of implementation, categorising facilities by summary measures of the degree of fidelity (high, medium, low/no fidelity) and classifying facilities into implementation fidelity trajectories. Descriptive statistics will be used to examine the distribution of trajectories and degrees of fidelity and how these varied according to facility characteristics and which EDSS was implemented.

Baseline facility survey

We will conduct a survey (study three) in all intervention facilities before implementation of the EDSS using a structured questionnaire based on the Service Provision Assessment inventory of service availability, equipment, and commodities[22]. Data from the facility survey will be used to examine the role of structural quality (e.g., infrastructure to provide ANC) and organisational factors (e.g., numbers of and qualifications of staff) in moderating intervention effects. We will conduct descriptive analyses of intervention facilities and use the data to examine hypothesized moderators on implementation fidelity and utilisation of EDSS, for example the ratio of ANC patients to staff providing ANC.

Healthcare provider attitudes survey

Healthcare providers in all facilities will be invited to complete a self-administered survey questionnaire (study four) following the initial month-long lead-in period of training and intensive implementation support in use of the EDSS. The survey will assess healthcare providers' attitudes about the intervention and their perceptions of readiness to incorporate the EDSS intervention into care processes. The questionnaire is adapted from the NoMAD instrument, which was developed using Normalization Process Theory[23,24]. As this is the first time, to our knowledge, that the instrument has been used in Nepal, we will additionally conduct cognitive interviews with 3-5 respondents to explore how and whether healthcare providers understood the survey questions. Using the survey results, we will compare scores of constructs associated with different levels of

implementation fidelity using t-tests and quantitatively describe construct scores as potential barriers or facilitators to integrating the intervention into facility workflow.

Audit of recordkeeping

The mIRA and WHO EDSS and associated electronic data entry will be implemented alongside existing paper-based record-keeping systems. Due to the additional record-keeping requirements for healthcare providers as part of the intervention, one potential unintended consequence is a change in the completeness and/or accuracy of existing paper-based ANC record systems. We are interested in two outcomes in study five: completeness and agreement between the pregnant woman's handheld ANC card and the facility ANC register for a selection of key data entry variables. We will not assess the accuracy of the patient data entered in the records. In the first round of data collection (before EDSS implementation), we will compare variable completeness and agreement between handheld ANC cards and facility ANC registers; in the second round (after EDSS implementation), we will compare between handheld ANC cards, facility ANC registers and entries in the EDSS software. An individual woman's records (handheld ANC card, ANC register entry and EDSS entry) is the unit of analysis. We will conduct descriptive analyses of percentage completeness and agreement in each data collection round and compare differences in proportions before and after EDSS implementation using matched pair t-tests.

Debriefing meeting notes

Fieldworkers involved in training and implementation have the potential to offer useful insights into how the intervention is received and integrated into facilities and the extent of support required for healthcare providers to use the EDSS software and tablets. Debriefing meetings with fieldworkers will consist of semi-structured discussions around issues related to implementation logistics and contextual factors (such as government policy changes around ANC provision, record-keeping procedures or COVID-19 response, as well as infrastructure or tablet/software issues) impacting the implementation process (study six). Fieldwork supervisors will document the content of debriefing discussions, through meeting minutes or via reports summarizing the meeting. These secondary documentary data sources will be analysed in a theory-driven content analysis drawing from Normalization Process Theory constructs.

Longitudinal facility case studies

The EDSS intervention is a new way of providing care, so it is important to examine how healthcare providers' reactions to and enthusiasm for the intervention and how the processes of implementation change over time. Using four purposively selected case study facilities (study seven),

two each from mIRA EDSS and WHO EDSS sites, we will explore how healthcare providers respond to changes in ANC provision and facility operations over the course of data collection, including other unrelated interventions or initiatives that may happen during the evaluation. Data from the facility case studies will provide a 'thick description' of how the intervention was delivered, maintained, and experienced, offering explanations for observed variation between sites and insight into the interaction between contextual features and components of intervention implementation. We will explore differences in implementation of the two EDSS software to enhance understanding of how an EDSS intervention improves quality of ANC.

At the start of the study, the fieldwork team will reflect on what has been learnt during the project's formative phase and develop a theory of change for how the intervention works. During this process, we will recognise the assumptions we hold about how the EDSS will work in facilities. We will be explicit about these assumptions at the beginning of the fieldwork, put them in the form of hypotheses and then look for information that either confirms or discounts these assumptions. After each period of fieldwork, the research team—consisting of the two Nepali researchers as well as the qualitative researcher based at LSHTM—will debrief and discuss what has been observed during the last piece of fieldwork and how that fits into hypotheses that are generated as the research goes along. At all times we will search for information that confirms or negates our hypothesis generation. At the end of fieldwork, we will present our preliminary findings to the staff at each case study facility, to obtain staff's perspective on what we have found, and ask them for assistance in developing feedback from the four facilities to project researchers. Joint reflection among the team, as well as independent reading and coding of the fieldnotes and later the interview codes will also aim to increase the quality of the research collected. The validation of preliminary results by staff in the facilities will add additional rigour to the process.

Time-and-motion assessment

Embedded within the longitudinal case studies, we will conduct a time-and-motion assessment of ANMs in two higher-volume facilities, one implementing the mIRA EDSS and one implementing the WHO EDSS (study eight). A time-and-motion study consists of an independent observer recording the time it takes for someone to perform a task and the movements related to it; the method has been widely used to assess clinical care and the effects of health information technology[25,26]. The study will continuously observe ANMs over the course of the workday, before and after implementation of the EDSS[26]. Research assistants will be present throughout the ANM's shift, and observation periods will be conducted throughout the day. Research assistants conducting dual data collection in a facility will each follow their designated ANM for the full day of observations.

During the second round of observations, we will also conduct in-depth interviews with ANM to explore perceptions of change in workflow, including self-reported time spent on major tasks and task shifting to other healthcare cadres, following EDSS implementation. The mean number of minutes spent on major task categories will be compared before and after EDSS implementation. Each analysis will be stratified by ANM. We will also incorporate a narrative analysis, combining data from the interviews with ANM, fieldnotes from the Research Assistants and facility floorplans, to describe the process of change in workflow patterns following intervention implementation.

Data integration

The process evaluation analyses will be conducted separately to the pre/post outcome assessment and will inform the interpretation of these data. Data from the process evaluation will be triangulated to develop a more complete picture, and explanation of the implementation process—over time and across facilities—and the effects observed[27]. Quantitative and qualitative data will be integrated using a convergent parallel-databases mixed method design, where data will be initially analysed separately and then combined[28]. We will identify content areas in both quantitative and qualitative data and compare, contrast and synthesise results[28]. We will consider how the data address different levels within the system (such as facility level and individual provider level) and how these enhance and clarify factors shaping intervention implementation. We will draw on Normalization Process Theory to examine individual and collective actions involved in implementation while recognising that these actions and relationships are shaped by the organisational and social contexts in which they occur[29].

By drawing on implementation theory in the data collection and analysis, we aim to move from the specific to the abstract. To do this, we will transition from the identification of patterns and impacts of the mIRA and WHO EDSS observed in specific facilities to more theoretical explanations of how different contextual elements and mechanisms interact to produce specific outcomes. Emerging theories and the relationship of the data to the conceptual literature underpinning the intervention will be discussed and refined at research team meetings throughout the project.

The process evaluation will be used for post hoc explanation[16], though some data analysis will be completed before results of the outcome evaluation are known. Implementation fidelity will be assessed blind to the pre/post outcome assessment to reduce potential bias in classifying facilities into implementation trajectories. Qualitative data analysis, particularly in the longitudinal case studies, will be iterative, moving between data collection and analysis to test emerging theories with final analyses completed after the outcome assessment results are known.

Ethics and dissemination

The study received ethical approval from Kathmandu University School of Medical Sciences (IRC, KUSMS 25/22), Nepal Health Research Council (ref: 2695) and LSHTM (ref: 25094-1). Approval was also given by all municipalities where the intervention facilities are located. The ethical principles of voluntary and informed participation, confidentiality, and safety of participants, including healthcare providers and patients, will be used in all researcher and participant interactions. Written informed consent will be obtained for all interviews, observations, and surveys. Facility managers will provide consent for observations of training sessions and non-clinical areas, and healthcare providers and patients will provide consent for observations of clinical interactions.

Findings will be disseminated via peer-reviewed journals, conferences and seminars with researchers, health programme managers in Nepal, policymakers, and other interested stakeholders. We will host a dissemination and validation meeting with staff from the four facilities in the longitudinal case studies to share experiences, reflections, and findings from the research; policymakers and other researchers will be invited to attend.

Conclusion

This paper reports the design and methods for the outcome and process evaluation of the mIRA and WHO EDSS intervention in Nepal. Results will aid the interpretation of outcomes and knowledge of how an EDSS intervention contributes to changes in quality of ANC. The research will contribute to understanding variation in implementation processes and effects on outcomes, identifying mechanisms of change, and documenting contextual factors that influenced the intervention and its potential transferability to other settings. Results may provide evidence to policymakers and programme implementors in deciding how or whether to expand EDSS to other facilities or settings. Results may also inform further research studies on the design, implementation, and effectiveness of EDSS interventions to improve ANC quality.

Authors' contributions

All authors contributed to conceptualising and planning the outcome and process evaluation studies, designing data collection tools, and applying for ethical approval. ER drafted the protocol. ER coordinated the quantitative studies of the process evaluation with design inputs from OMRC, PJ, SD, SK, RS, OM and AS (Dept of Obstetrics). LPK designed the longitudinal case studies with inputs from SK, SD, and AS (Dept of Community Programs). AS (Dept of Community Programs) and AS (Dept of Obstetrics) served as joint senior authors guiding the overall project and protocol. All authors read and approved the final manuscript for publication.

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Appendix D: Karmacharya et al. (2023) A novel approach to assessing the potential of electronic decision support systems to improve the quality of antenatal care in Nepal

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Abstract

Introduction: Good-quality antenatal care (ANC) is critical to reducing maternal and perinatal mortality in Nepal. Electronic decision-support systems (EDSS) aim to improve quality-of-care through adherence to evidence-based guidelines. Our project assessed the potential of two EDSS (the 'mIRA' EDSS and the World Health Organization EDSS) to improve the quality of ANC in primary-level healthcare facilities in Nepal. This paper reports integrated results of the evaluation.

Methods: We conducted a theory-driven, mixed-methods evaluation in 19 facilities with eight types of data collection: health-facility survey; ANC clinical observations; longitudinal case studies and validation workshop; in-depth interviews; monitoring visits; fieldworker debriefing meetings; healthcare provider attitude survey and stakeholder engagement and feedback meetings. Results from the different data sources were integrated using concurrent triangulation to develop explanations about the implementation process and the effects observed.

Results: We identified nine themes on implementation challenges which hindered the EDSS from generating the desired improvements to ANC quality. Facility readiness and provider confidence in using the EDSS was mixed. It was not always used, or used as intended, and the approach to ANC

provision did not change. EDSS inflexibility did not reflect how staff made decisions about pregnant women's needs, or ensure tests were done at the right time. There was mixed evidence that ANC staff believed that the EDSS benefited their work. The EDSS did not become fully integrated into existing health systems. Engagement of essential stakeholders fell short.

Discussion: Different understandings of, and inconsistent use of the EDSS highlighted the need for increased training and support periods, greater stakeholder engagement, and further integration into existing health systems. Our mixed-method evaluation and novel approach to integrating findings from multiple sub-studies in one paper offers uniquely valuable insights into the many factors needed for successful implementation of an EDSS to improve quality of ANC in Nepal.

Teaser key message: An EDSS alone is not enough to provide quality antenatal care in the Nepalese setting.

Key messages:

- Most antenatal care staff were able to use the Electronic Decision Support System (EDSS), however, most did not use it the way it is intended to be used.
- EDSS implementation is likely to have a greater chance of success if staff understand it to be part of a government package or government research project.
- The findings of this study provide evidence to policy makers, programs managers and researchers on what factors must be considered for effective and sustainable implementation of EDSS in low-resources settings.

Introduction

Nepal has made extraordinary progress in improving coverage of maternal health services, with more than 90% of women reported receiving antenatal care (ANC) from a skilled provider in 2022 (1). Of the 79% of live births delivered in a health facility, 62% of these facilities were in the public sector (1). Home births are around 19% of live births nationally, down from 91% in 1996, with variation by province (1). As the coverage of ANC has increased, improving quality-of-care has become a growing strategic priority for the Government (2, 3).

World Health Organization (WHO) guidance states that all pregnant women should receive essential services throughout pregnancy, including regular ANC visits, preventive interventions, and screening for potential complications (4). Electronic decision support systems (EDSS) are computer-based clinical decision-support tools that integrate clinical and demographic patient data with clinical practice guidelines (5-9). EDSS aid healthcare providers' decision-making and promote adherence to evidence-based practices through alerts, checklists or information provided at the point-of-care (10, 11). EDSS can support clinical tasks such as patient monitoring, drug prescribing and formulating diagnoses or treatment suggestions (10). They can be particularly relevant in lower-level health facilities, which lack senior or specialist healthcare providers (12). However, evidence for the effectiveness of EDSS on quality-of-care and healthcare provider performance remains mixed (10, 11, 13-15).

This paper reports on a novel mixed-method approach to assessing the potential of two EDSS designed for use by frontline healthcare workers with the aim of improving the quality of ANC in Nepal: the mHealth integrated model of hypertension, diabetes and antenatal care (mIRA EDSS) and the WHO digital ANC module (WHO EDSS) (16). A cluster-randomized trial is ongoing in India to evaluate the effectiveness of the mIRA EDSS (17).

Methods

The specific objectives were to: 1) assess the effect of the EDSS on the quality of ANC and implementation outcomes, including acceptability, adoption, appropriateness, feasibility, and fidelity; 2) document and understand the implementation process and how the EDSS became part of existing systems; 3) explore how contextual factors impacted implementation and effectiveness of the EDSS; and 4) investigate how the EDSS changed the delivery and quality of ANC.

Setting

We worked in four predominantly rural districts in Bagmati Province, Nepal: Kavrepalanchok, Sindhupalchowk, Sindhuli and Dolakha. Twenty primary-level ANC facilities were matched based on facility type and ANC client volume and randomly allocated to receive the mIRA EDSS (n=10) or the WHO EDSS (n=10). Following allocation, we dropped one facility (randomized to WHO EDSS) because it had few ANC clients. The remaining sites were government Health Posts (HP, n=12), Primary Healthcare Centers (PHCCs, n=4) and Dhulikhel Hospital Outreach Centers (DHORCs, n=3).

Interventions

The mIRA EDSS was developed by the Public Health Foundation of India (PHFI), Dhulikhel Hospital, Kathmandu University Hospital (DHKUH), and the London School of Hygiene & Tropical Medicine (LSHTM) for use in India and Nepal. It uses prompts and diagnostic algorithms to improve providers' adherence to routine ANC guidelines and the detection and management of higher-risk pregnancies. It offers bespoke diagnosis, treatment-content and pop-up prompts for gestational diabetes, pregnancy-related hypertension, and anemia. The WHO EDSS facilitates adoption of WHO ANC guidelines (4), focusing on routine care, with checklists for screening and referral, but not on the treatment of pregnancy complications. It incorporates a "facility infrastructure parameter" (e.g., whether ultrasound is available) (16).

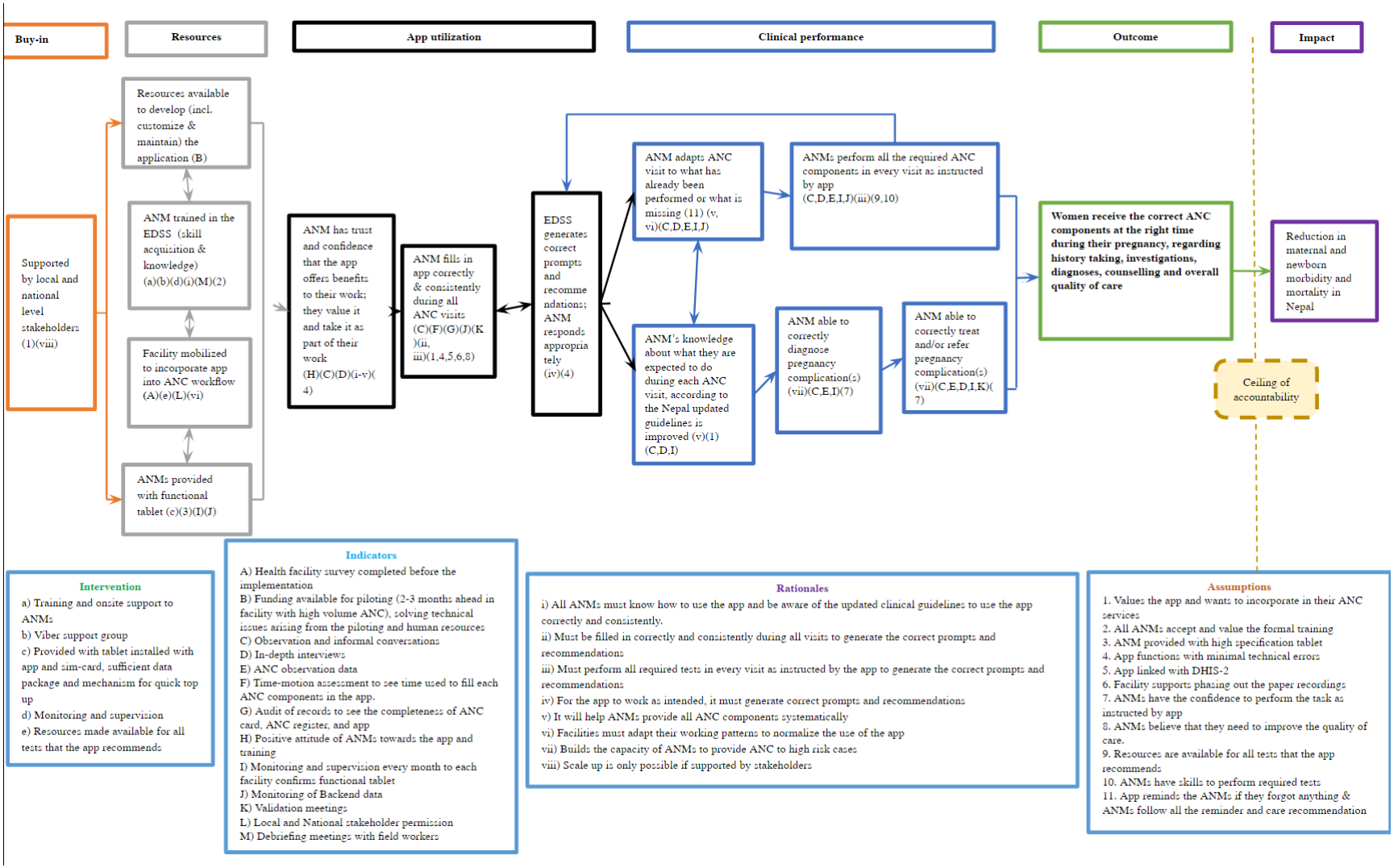
Staff training on the EDSS and tablet provision

Each project facility was given a functional tablet with an EDSS and a sim card for cellular internet to allow the EDSS to be used during power outages. The local municipality selected one Auxiliary Nurse Midwife (ANM) per facility to attend an in-person three-day training workshop in March 2022 on use of either the mIRA or WHO EDSS. ANMs were subsequently supported to use their allocated EDSS by an onsite fieldworker for one month and provided with continued technical support and monitoring visits for the next six months.

Theory of Change

A conceptual framework was developed, based on how we thought the intervention would improve adherence to ANC guidelines and enhance detection and management of pregnancy complications. Post-implementation, it evolved into a Theory of Change (Figure 1(18), and was refined during the course of the project.

Figure 1 Theory of Change



Data collection & analysis

The following data collection methods were used (methodological details are available elsewhere (19)):

1. Health facilities survey: Before the EDSS was implemented in the 19 facilities, we interviewed the facility in-charge and ANMs, and collected data on the availability and functioning of equipment and medicines. We calculated the percentage of facilities with key equipment and medicines available, overall and stratified by facility type.
2. ANC clinical observations: We trained fieldworkers to observe at least 30 ANC visits in each site before and at least 30 after the EDSS was implemented. An ANC quality score was calculated by adding one point for each of the following ANC components provided by the healthcare worker during consultation: 1) measurement and recording of blood pressure; 2) blood glucose test; 3) urinary dipstick test; and 4) hemoglobin test (maximum score of four). We compared mean ANC scores among observations pre- and post-implementation.
3. Longitudinal case studies and validation workshop: We (two researchers, SD and SK) conducted three visits (lasting up to two weeks) in each of four purposively chosen project facilities (two HPs and two PHCCs). One visit was before implementation and two were during, totaling about two months of observation in the PHCCs and about one month in HPs. We subsequently conducted a validation workshop in each facility to review findings with the ANMs and facility in-charge. All the collected observations, informal conversations and validation workshop notes were analyzed using a thematic approach.
4. In-depth interviews: At the end of longitudinal case studies, we interviewed all ANC staff (N=16); data were analyzed using a thematic approach.
5. Monitoring visits: Trained fieldworkers conducted one monitoring visits per month for four months after EDSS implementation. Quantitative data were analyzed descriptively, and field-notes analyzed using a thematic approach. EDSS usage data were generated through use of the EDSS and stored on the server after synching. This 'backend data' was extracted after implementation and analyzed descriptively.
6. Fieldworker debriefing meetings: Fieldworkers participated in weekly debriefings (N=5) while providing onsite support to the sites. One meeting was held separately for mIRA and WHO intervention sites, and the remaining three were combined. Debriefing notes were analyzed thematically.

7. Healthcare provider attitude survey: At the end of onsite support, a self-administered healthcare provider attitude questionnaire was completed by all ANC staff in each intervention site (N=43). Data were analyzed descriptively.
8. Stakeholder engagement and feedback meetings: Periodic meetings were held with local and national stakeholders (four meetings) to discuss the project's progress and to obtain feedback. Around 20 national stakeholders with expertise in maternal health, health informatics, and non-communicable diseases, and around 35 local stakeholders including municipal health coordinators, health in-charge, FCHVs and ANMs were involved. All the meeting notes were analyzed thematically.

Supplementary file 1 summarizes the studies, and methods. These were given equal weight in the analysis using concurrent convergent triangulation (20, 21). Quantitative and qualitative data analyses were initially done separately, then similar content areas in the different datasets were compared, contrasted and synthesized. Where findings diverged, the research team discussed and re-examined results, reflecting on the quality of data and strengths/weaknesses of the different studies, to arrive at the most valid type of interpretation.

Ethical approval

We received ethical approval from Kathmandu University School of Medical Sciences (IRC, KUSMS 25/22), Nepal Health Research Council (ref: 2695) and LSHTM (ref: 25094-1). All municipalities with project facilities also gave approval.

Results

Results are reported in relation to the first four domains of the Theory of Change: buy-in, resources, app utilization and clinical performance (Figure 1) and organized around the nine key messages triangulated by findings from the multiple data collection methods.

Buy-In

1. Engagement of essential stakeholders fell short

In general, all the stakeholders were interested in the EDSS evaluation, valued our novel approach, and considered digital health as a government priority area.

> *"[Integrated Health Information Management System Chief] Government is also considering digitalization in health and therefore you can use Government Integrated Data Centre of web hosting which helps data storage for long term. It*

is necessary to provide complete services for ANC, delivery and postnatal care. [Final National stakeholders meeting].

ANC staff attending stakeholder meetings expressed appreciation for EDSS features including reminders, organized consultation, and minimal writing. At the final local-stakeholders meeting, a few ANC staff recommended implementing this type of EDSS at the national level, and digitizing ANC registers and then integrating into Nepal's District Health Information Software (DHIS-2). The self-administered healthcare provider survey conducted part-way through implementation showed that 98% ANC staff saw the potential value of EDSS and about 95% ANC staff believed that utilizing an EDSS was worthwhile.

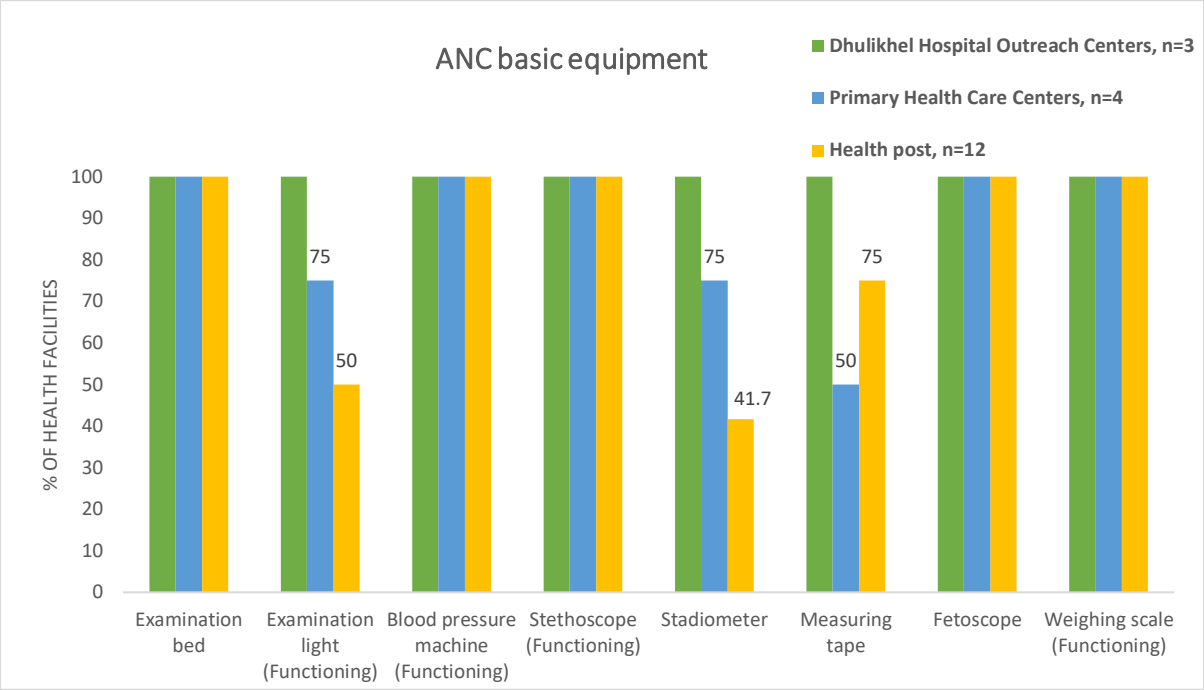
However, although stakeholders were generally positive during meetings, they did not actively engage in the implementation or provide dedicated support to implement EDSS in the facilities. Stakeholders were also concerned about the data security and privacy.

Resources

2. Facilities had mixed levels of readiness to employ the EDSS recommendations

The health facility survey confirmed that all facilities had access to electricity but that 25% of HPs lacked internet connectivity, which we redressed via the sim cards. Most facilities had the eight key equipment components (Figure 2), but some were missing the urine protein test (41%), the hemoglobin test (23%) or the glucose tests (21%). When we introduced the EDSS, we provided all facilities with a glucometer, glucose strips, and 75-gram glucose, as this was not a standard component of ANC provided by the government. No EDSS tablets were lost or broken during the project, although one charging cord was replaced.

Figure 2: The percentage availability of basic equipment needed for ANC provision in project facilities before implementation of the EDSS, stratified by facility type



3. Training ANC staff in using the EDSS did not necessarily lead to confidence in using it

Some staff found the EDSS slightly difficult to use at first, but most formally trained staff were able to use it and were confident they would improve with continued use:

> *"ANM said in the beginning, it takes a lot of time for us to fill in. Due to continuous filling in the app, my eye hurts. We have to fill in the questions by spending a lot of time, now it is a little easier for me personally. When asking about history, I can ask without looking one by one, and I don't have to wait for the advice to be given by the app, I do not need to read. Now it has become easy." [HF-7, longitudinal study-field notes]*

We observed that many staff who were not formally trained were not interested in using the EDSS and some conveyed that they needed formal training to feel a sense of responsibility [Longitudinal study-field notes, In-depth interviews].

> *"[Trained ANM said] after training, they feel like it is their responsibility and might think of it as their own work as well. I feel like other staff think it is only the responsibility of staff who took the formal training." [HF-8, In-depth interview]*

Others found the onsite support beneficial and learned to use the EDSS [Longitudinal study-field notes]. A few ANC staff said that they would be more conscientious in using the EDSS if incentives were provided. A small financial incentive was provided in one health post at the request of the

facility in-charge and ANC staff; however, we did not observe greater engagement with the EDSS at this facility during longitudinal study.

Factors such as low ANC volume (<40 ANC consultations per year in most health posts), staff on leave, and a local election (during the onsite support phase, and which required 1-2 ANC staff from each facility to work for elections) impacted the EDSS training. In facilities where ANC volume was low, staff said there were not enough opportunities to use the EDSS during onsite support:

> *"[ANM said] trained ANC staff were on leave, and since then EDSS was not used. We haven't worked on the tablet. We didn't get an opportunity to use the EDSS due to low ANC flow." [HF-17, Monitoring visits]*

High staff turnover affected at least one facility and impacted the readiness of the health facility to use EDSS, although there were efforts made to ensure that an EDSS-trained staff was present.

EDSS utilization

4. ANC staff did not always use the EDSS and did not always use it as intended

Backend data showed mIRA EDSS was used with only 37% of ANC clients (29 EDSS entries out of 79 ANC register entries for the same dates) and WHO ANC EDSS in 81% (43/53). The monitoring visits, the longitudinal study, and the fieldworker debriefings confirmed that ANMs did not always use the EDSS at every visit and in the presence of pregnant women. Instead, the ANMs photographed the ANC cards or wrote notes, which they would later enter into the EDSS after women left the facility at the end of the day or on another day.

> *"[The ANM mentioned] that they clicked the picture of an ANC card during busy hours and filled the data into EDSS when they were free." [HF-6, Monitoring visit-field notes]*

Sometimes ANMs copied the information from the ANC card when a woman left the facility for a laboratory test, or copied information from the ANC register:

> *"[The ANM said] they write the notes in a separate paper of medical history, family history, obstetrics history, investigations, and chief complaints and enter data later in EDSS after working hours during free time." [HF-2, Monitoring visit fieldnotes]*

The monitoring visits and longitudinal study revealed that some ANC staff felt that the EDSS was too time-consuming to use in the presence of women. The EDSS was more likely to be completed during

the consultation, when there were two or more ANC staff, with one staff member doing the examination, while the other filled in the EDSS.

> *"[ANM K said] first they fill up the register, and then examine the patient. One of us examines the patient and then we fill in the tablet. If we are alone, we examine the patient first, finish up everything and use the tab." [HF-9, In-depth interview]*

5. There was mixed evidence that ANC staff believed that the EDSS benefits their work

During in-depth interviews, ANC staff emphasized that the EDSS reminded them to organize the care through a checklist for history-taking, husband details, danger signs, and pregnancy complaints. All the ANC staff expressed that they were guided by the EDSS to provide a systematic ANC consultation, and some of ANC staff also expressed that the EDSS had guided them to perform more counselling:

> *"[Trained ANM said] One thing is that it has helped us to go step-by-step through the ANC consultation process." [HF-7, In-depth interview]*

> *"[ANM G said] I think this has guided me do more counselling. [HF-8, Validation workshop]*

ANC staff identified problems with the EDSS during the monitoring visits and longitudinal study, which meant that we had to update the software frequently. It became clear after implementation that the WHO EDSS required a higher specification tablet than the ones used in the facilities. Technical issues encountered included pages 'hanging' and responding slowly, and for the WHO EDSS, miscalculating Nepali dates. These discrepancies, though ultimately resolved, created frustration, and eroded the ANM's trust in the EDSS.

> *"ANM said that the app is slow when we entered the investigation details in it and therefore time consuming. Also, it freezes and stops responding." [HF-8, longitudinal study-field notes]*

6. Inadequate integration of EDSS with existing health systems impaired its utilization

The organization of ANC hindered adequate utilization of the EDSS and its potential to improve clinical performance. The health facility survey showed that most of the health posts lacked laboratory and ultrasound services, so women were referred to PHCC, or higher centers, to perform tests and screening, which interrupted the flow of the visit. At the same time, women attending PHCC only for tests or screening did not receive full ANC consultations and were not recorded in the EDSS [Longitudinal study-field notes].

Most ANC staff prioritized paper-based ANC records systems over the EDSS, explaining that the EDSS was for a short-term research project and was not integrated with monthly reporting systems. Paper-based records were seen as long-term, government work, and therefore more important to complete. The EDSS was not linked to DHIS-2 (a routine health information system), which, had it been, ANC staff felt would have decreased their reporting workload and increased EDSS use.

> *"[MDGP said] if it can be made a government-owned program it will be continued and integration of software with DHIS-2 will be helpful for reporting." [HF-7, longitudinal study-field notes]*

Clinical Performance

7. Use of the EDSS during the consultation did not guarantee that ANC tests were done at the right time

The EDSS was intended to prompt ANC staff to perform tests for pregnant women as required, per trimester or at each ANC visit. Observations of ANC before and after implementation suggested the mean number of the four primary ANC components (measurement and recording of blood pressure and the performance of blood glucose, urinary dipstick and hemoglobin tests) improved, but this could have been due to chance (1.11 before and 1.56 after implementation, p=0.09) (Supplementary file 2). Improvements in performance of the urinary dipstick test (7.9% to 23.5%, p=0.07), hemoglobin test (7.9% to 17.7 %, p=0.21), and blood glucose test (2.6% to 20.6%, p=0.02) were also observed before and after EDSS implementation.

The EDSS asked ANC staff to do more frequent tests as per the Nepali and WHO guidelines, but these were not part of their usual practice. Evidence from the longitudinal case study, in-depth interviews, monitoring visits, and validation workshops showed ANMs generally did tests during the first ANC visit and did not repeat them unless abnormal results were observed or they were advised by doctors to repeat them. Newer ANC staff (who might have been trained in newer guidelines) followed practices of older staff in the facility. ANC staff also explained they limited tests out of concern for women's financial conditions, as women were required to pay a small amount for tests in some facilities.

> *"[In-charge mentioned] No protocol for performing the test once. It was practiced for so long, in this facility, and might be same in the facilities with the similar settings. Also, women don't have enough money to do tests frequently so if normal values of test results, then tests are not repeated. Sometimes, we also make decision based on clinical judgement such as checking for blood pressure, edema, signs and symptoms of other risk conditions." [HF-7, Validation workshop]*

In the longitudinal study, we observed five instances where ANC staff had not performed a test in previous visit, and the EDSS reminder led them to perform the test. Also, ANC staff were trained to administer oral glucose tolerance tests to detect gestational diabetes using test kits we provided. Only one oral glucose tolerance test was logged during the ANC observations, although the longitudinal study and monitoring visits showed that ANC staff initiated and performed the test for most clients.

Among ANC observations where patients reported experiencing vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain or blurred vision), the proportion of providers who took the appropriate action in response improved from 0.0% (0/7) before EDSS implementation to 100% (5/5) after (small numbers because only women reporting symptoms were included from among 72 ANC observations). However, the mean number of these symptoms (plus nausea) discussed decreased from 3.08 pre-implementation to 1.76 post-implementation ($p<0.01$) (Supplementary file 2).

> *"[ANM J said] Since we have explained danger signs during the first entry, so we don't need to do it again in every visit and therefore it was marked as no symptoms observed in the section of EDSS." [HF-9, In-depth interview]*

8. ANC staff did not substantially change approach to ANC provision

We observed some examples of change in provision; the ANC observations showed that even though there was space in the ANC card to record height, it was not measured or recorded before EDSS implementation. After, ANC staff started measuring and recording height, entering it in the EDSS and onto ANC cards.

However, not all the required ANC components (as instructed by EDSS) were performed in every visit. It was noted in the longitudinal study that ANMs referred clients to a doctor rather than follow the EDSS recommendation, and that most ANC staff focused on providing basic ANC. The longitudinal study, monitoring visits, and validation workshops all showed staff tended to refer more complicated ANC consultation (either to medical doctors of the facilities or to the nearby higher center). The health facilities survey showed that all selected PHCCs, DHORCs and two HPs had at least one doctor, and most of the project facilities were close to higher centers, that were easily accessible to pregnant women. In general, observations and interviews suggested that most of the ANC staff were satisfied with their own ANC practice. Most staff seemed to have adequate training and knowledge to provide ANC for low-risk women, however, they were always eager to acquire new skills and knowledge.

"[ANM H said] I am satisfied with my practice. I think we are following the government's guidelines. The government has told us to give medicines, and we have been following its instructions. We are doing the investigation that has been decided, and that is what we are practicing. So, I think it is sufficient while providing ANC because the guidelines given by the government are followed accordingly" [HF-8, In-depth interview].

The times and days ANC was provided also affected opportunities to change behavior. In all facilities, ANC flow was high between 10am-1pm, and ANC staff felt pressure to provide ANC quickly and found it difficult to use the EDSS. The health facility survey showed that seven health facilities had a designated ANC day, and only one of them had ANC days twice a week. While ANC consultations were provided on non-ANC days, pregnant women were generally asked to attend on ANC days. On these ANC days, ANC flow was high:

"[ANM C said] the EDSS required more time than usual, if we do it from the start to counselling, it takes one hour for a patient. And then, ANC clients become impatient. Therefore, ANC was organized as per ANC clients demand" [HF-7, In-depth interview]

In a validation workshop, one in-charge mentioned that re-organizing or adding ANC days was difficult, as they had different tasks for each day of the week, and this would impact on other services provided at the facility on other days. A few of the ANC staff also said that use of the EDSS reduced their interaction with pregnant women.

9. Inflexibility of EDSS design did not reflect how ANC staff made decisions about pregnant women's needs

The EDSS was designed to provide all women with the same information at all visits and other content was standardized as per the national protocol and WHO guidelines. However, ANC staff adapted consultations to be more personalized to pregnant women's specific conditions and their needs at the time of consultation, considering their family and economic conditions. Most ANMs felt that counselling and information about danger signs was only needed once, unless women complained about the problems.

The ANC observation data indicated that the mean number of the selected danger signs (severe vomiting, vaginal bleeding, severe headache, decreased or absent fetal movement, severe abdominal pain and blurred vision) the provider told the woman she should return for help decreased from 2.66 (pre EDSS) to 1.56 (post EDSS) ($p = 0.01$). Monitoring and longitudinal visits

showed that many of the ANC staff marked counselling sections as complete in the EDSS rather actually providing counselling to pregnant women as suggested by the EDSS.

ANC staff stated that they believed they provided care that met women's needs. If women looked fine and had no complaints, and considering the woman's personal issues such as transportation, family issues/household chores, weather, and economic condition, staff provided a quick ANC visit. If women reported any problems, then staff said they provided counselling accordingly, and immediate referral. There was a small decrease in the mean number of 20 counselling related components from pre (8.82) to post (6.94) implementation of EDSS (p=0.04) (ANC observations, Supplementary file 2). In the in-depth interviews, ANC staff said they worried that if counselling was delivered while referring to the EDSS, pregnant women might think that they did not have enough expertise.

Discussion

Summary of main findings

Guided by our Theory of Change and mixed-methods approach, we identified nine themes that deepened our understanding of how the EDSS was used, and highlighted the complexities and challenges that prevented the EDSS from bringing the desired ANC quality improvements. We found that essential stakeholders were not sufficiently engaged, and that facilities had mixed levels of readiness to employ the EDSS recommendations. The ANC staff who were trained in using the EDSS were not necessarily confident using it. Also, ANC staff did not always use the EDSS, or use it as intended. There was mixed evidence that ANC staff believed that the EDSS benefited their work, and evidence of inadequate integration of EDSS with existing health systems. Use of the EDSS during the consultation increased use of some tests but did not guarantee that ANC tests were done at the right time, and ANC staff did not substantially change approach to ANC provision. The inflexibility of EDSS design did not reflect how ANC staff made decisions about pregnant women's needs.

Interpretation of findings

The different understanding of the EDSS and how it is intended to be used highlights the need for broader training and increased support periods. Healthcare providers were using this EDSS for the first time; a three-day training for one person in each facility, with one month of onsite support appeared to be insufficient to generate a sense of responsibility among staff to use the EDSS and an appreciation of its potential. The literature suggests that change is more likely with longer trainings (22, 23) and implementation periods (24, 25), though time constraints meant our project was

implemented for a short period (six months). Failing to formally train all staff can limit accountability (8, 26). Performance-based incentives have been shown to increase job satisfaction and improve practices (27), within direct incentives such as encouragement, recognition and support being highly desired and valued by staff (8). The effectiveness of financial incentives as a mechanism to promote behavior change has been mixed (28); we did not observe meaningful changes in one facility where all staff were provided with a small incentive.

ANC staff held mixed views about the benefits of EDSS on their work, despite expressing positive views towards the EDSS in initial interviews and surveys. The perceived benefits, such as guidance in organizing care through pop-ups and reminders, the detailed history taking and counselling section, may have been negated by the increased workload generated by dual documentation (the EDSS and paper-based records). This finding aligns with digital health studies conducted in African countries (25, 29). In our project, it was not possible to completely replace the paper ANC records for the short project period. Nor did the EDSS aid monthly indicator reporting; a link to routine data monitoring might have made the EDSS more appealing to staff as it would potentially decrease their workload. Future development of the EDSS must satisfy these needs and expectations of staff to increase the potential for its success (30).

In general, ANC staff believed that they were providing quality ANC even prior to the EDSS implementation, which could explain why we did not observe a change in their approach to ANC provision. Our project was conducted during a transition period, where the official guidelines were moving from four to eight recommended ANC visits. This shift had not been effectively communicated in all facilities, and staff did not always think that eight visits they were asked to do via the EDSS were practical for women. ANC staff believed that they were providing patient-centered care regarding contextual factors (ANC client needs, and their social and economic condition), and organizational factors (workload, staff turnover, health system, supervision). This included providing counselling based on perceived need and mostly during the first visit, with birth preparedness and emergency readiness during the last visits. A similar pattern was confirmed in ANC observations in a national health facility survey (31). A positive influence of the EDSS was on history-taking practices, observed during ANC consultations, which is a similar finding to a study conducted in Ghana (24). We also found slight improvements in performance of screening tests. On the other hand, contextual difficulties with digital decision support systems have been shown to surpass their perceived usefulness(8), with similar findings reflected in our project.

The EDSS design did not reflect how ANC staff made decisions about pregnant women's needs. This inflexibility affected how staff used the EDSS, making it difficult to facilitate the desired change in ANC staff behavior. The EDSS emphasis on standardization made it less of a decision-support tool, and more of a guideline-adherence tool. Personalized care should allow ANC staff to make informed decisions considering each woman's needs at all visits. Standardization, on other hand, guarantees that all women receive the same information for each visit. It takes more time to understand the individual client circumstances and needs. Future EDSS development could take adaptability and personalization into account.

Several contextual factors that we were unable to fully account for in the evaluation design may have impacted implementation. The COVID-19 pandemic and software development delays meant the training and implementation period was shorter than originally planned. Additionally, unresolved software issues may have affected the usability and functionality of the EDSS. Changes in guidelines from four to eight ANC visits and municipality political leadership, upgrading of facilities and technical difficulties may also have disrupted use of the EDSS.

Finally, inadequate integration of EDSS with existing health systems impaired its utilization. The EDSS recommended more tests than what was done in usual practice. Despite assumptions and official policy that all ANC care is provided free, some tests were not free, and meant some women might not be able to afford repeat tests suggested by EDSS. Adequate supplies, and considering service fees, are fundamental to realize the benefits of EDSS and normalize its use in daily work (25). Our small-scale project did not link across different health facilities, which could have contributed to greater use of the EDSS and more continuity-of-care as pregnant women attended different facilities during the antenatal period. Active participation of government is essential in considering the needs and priorities of the health system and integration of national strategies to increase the sense of acceptance and recognition among the ANC staff (6). A study reported that the strong commitment and support from the government is essential to promote sustainability and scale-up (32).

Strengths

This is the first time this type of digital intervention has been implemented in ANC in Nepal. We demonstrated that ANMs, with training, have the technical skills to use mobile digital technology to support consultations. Our novel, mixed-method approach allowed us to triangulate qualitative and quantitative data, and provided an in-depth appreciation of the multitude of contextual factors influencing EDSS implementation. The longitudinal study, in particular, offered unique and valuable insight into how the EDSS was perceived by ANC staff and incorporated in their workflow, and why.

Limitations

Implementation and evaluation of the EDSS was conducted in a small number of facilities, without a comparison group, limiting the conclusions we could draw from the findings. The small sample size for some studies, notably the ANC observations, limited further analysis and stratification, for example comparisons between mIRA and WHO EDSS facilities or adherence to guidelines in first vs follow-up ANC visits.

Conclusions

There are indications that the EDSS can improve some aspects of quality-of-care, however we demonstrate that the EDSS alone is not enough to improve the quality of ANC provided. Health workers' responses to interventions are complex (33). This project provides evidence to inform policy and future research on digital health interventions. Future EDSS development and implementation could maximize EDSS potential by considering: the financial implications on the care receiver; health system resource allocation; staff workload; alignment with the needs of staff and clients; intensive training on EDSS use and content to all ANC staff and continuous support and supervision from government. Before scale-up can be considered, further research is required to evaluate the effectiveness, financial implications and sustainability of an optimized EDSS in the Nepali context. This project demonstrated the benefit of employing multiple methods in understanding implementation successes and failures.

Declarations

Author contributions: All authors contributed to conceptualizing and planning the studies. SD wrote the first draft, with guidance from OLM and input from ER and SK. OLM cleaned and analyzed the pre-post outcome data with statistical inputs from CC. SD and SK analyzed the qualitative data from the longitudinal case studies, interviews and meeting notes with guidance from LPK. ER analyzed the monitoring data and provider attitude survey with inputs from SD and SK. SD analyzed the facility survey. RS coordinated data acquisition for the overall project. ER designed the quantitative studies of the process evaluation with inputs from OMRC, SD, SK, RS, OLM, CC and AS (Dept of Obstetrics). LPK designed the longitudinal case studies with inputs from SK, SD, and AS (Dept of Community Medicine). ER, LPK, SD, SK, RS, OLM, OMRC, CC and AS (Dept of Obstetrics) developed the data collection tools. BK and OMRC, as co-Principal Investigators, had overall project supervision and provided feedback on manuscript drafts. All authors read and approved the final manuscript for publication.

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Appendix E: Das et al. (2024) The impact of digital antenatal care intervention on paper-based recordkeeping: results from an audit of antenatal care records in primary healthcare facilities in Nepal

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Abstract

Background: Antenatal care (ANC) plays a vital role in the reduction of maternal and perinatal mortality and morbidity. Accurate recordkeeping is important to providing high-quality ANC. The mobile Health integrated model of hypertension, diabetes and antenatal care (mIRA) project aimed to improve ANC quality in Nepal through tablet-based electronic decision support system (EDSS). As a part of the intervention, electronic data entry was implemented alongside existing paper-based ANC records, adding an additional record-keeping requirement for ANC providers. This study aims to assess the impact of introducing EDSS on the completeness and agreement of existing paper-based ANC records.

Methods: The study was conducted in four rural districts in Bagmati Province, Nepal in 19 primary health facilities. We examined pregnant women's records before (n=136) and after (n=138) EDSS implementation. For selected indicators in the ANC card and ANC register, we estimated the percentage completeness (any value recorded) and agreement (whether values matched) before

and after EDSS implementation. We also reported completeness of the indicators in the EDSS and calculated agreement between the ANC card and what was recorded in the EDSS. Chi-square or fisher's exact test, as appropriate, were used to assess whether there was evidence of differences in completeness before and after implementation.

Results: Completeness of paper-based ANC records was high before implementation (>90%) for all indicators, except tetanus toxoid vaccination. There was a trend towards indicators being more complete after EDSS implementation for both paper-based ANC records. There was >15% improvement in completeness of tetanus toxoid vaccination date records in both paper-based ANC records after EDSS implementation. Agreement between the ANC card and ANC register increased slightly in all indicators after implementation. The completeness of variables in the EDSS was low, ranging from 38.2 % to 88.7%.

Conclusion: The EDSS did not negatively impact on paper-based ANC recordkeeping. The EDSS implementation resulted in general improvements in completeness and agreement of paper-based ANC records. The relatively low levels of completeness in the EDSS suggests that any large-scale implementation will need to consider how to integrate digital and paper-based records to decrease the data entry burden on ANC providers.

Keywords: Digital health, Antenatal care, electronic decision support system, recordkeeping, quality improvement

Background

The reduction of maternal mortality remains a high priority, with Sustainable Development Goal 3 setting a target to reduce the global maternal mortality ratio to <70/100,000 live births by 2030[1]. Antenatal care (ANC) plays a vital role in the reduction of maternal and perinatal mortality and morbidity[2]. ANC is aimed at ensuring all pregnant women receive screening tests, have early detection and prevention of complications, and adequate management of pre-existing maternal diseases and monitoring throughout the pregnancy[3,4]. However, in some settings such as Nepal, there is high coverage of ANC services but a gap remains in the quality of care provided[5].

Accurate and complete recordkeeping is important in ANC for ANC providers to know what care components are needed and to ensure continuity of care over different ANC visits during pregnancy[6]. Medical recordkeeping is critical to assuring the quality of care[7]. Records aid in assessing and managing an individual patient's care and also contribute to monitoring and improving service delivery[7,8]. In Nepal, pregnant women's handheld ANC card and facility ANC register are the basic source of information for mother and child health conditions. Both ANC cards and ANC registers record women's health information and details of ANC visits (as well as delivery and postnatal care). Pregnant women keep their ANC card with them and are asked to bring it to every ANC visit to be filled in by ANC provider. The ANC card allows a woman to understand their progress, and next appointment date[9]. The ANC register is the facility-based register where ANC providers record every ANC visit; it includes fewer information fields than the ANC card. These two documents aid in the systematic recording of information during each ANC consultation.

This study is part of the process evaluation of the mobile health integrated model of hypertension, diabetes, and antenatal care (mIRA) project. The mIRA project implemented and compared two electronic decision support systems (EDSS) with the aim of improving quality of ANC in primary healthcare facilities in Nepal[10]. The first EDSS, the mIRA EDSS, was designed by the Public Health Foundation of India (PHFI), Dhulikhel Hospital, Kathmandu University Hospital (DHKUH), and the London School of Hygiene & Tropical Medicine (LSHTM)(9). The second EDSS, the WHO EDSS, was developed by the World Health Organization (WHO) to facilitate the adoption of the WHO ANC guidelines and was subsequently customized to Nepal[11]. Both EDSS provided checklists, prompts and diagnostic algorithms, based on national protocols, to improve adherence to routine ANC guidelines and facilitate the detection of pregnancy complications. The mIRA EDSS additionally included algorithms for management of higher-risk pregnancies. ANC providers were expected to

use the EDSS during ANC consultations with pregnant women, recording clinical examinations and test results in the EDSS.

The EDSS (mIRA EDSS or WHO EDSS) and associated electronic data entry was implemented alongside existing paper-based ANC records during the research project, adding additional record-keeping requirements for ANC providers as a part of the intervention. With the addition of electronic recordkeeping, one potential unintended consequence could be a change in completeness and/or agreement of existing paper-based ANC records. While a study conducted in Brazil finds the reliability of women's self-reported questionnaires with ANC records[12], there remains a lack of research exploring the impacts of additional electronic recordkeeping (EDSS). Thus, the objective of this study was to assess if there was a change in the completeness and agreement of the ANC card and ANC register before and after EDSS implementation. The study also aimed to examine completeness of the data in the EDSS, and the level of agreement between the ANC card and the EDSS.

Methods

Study setting and design

The study was conducted in four rural districts in Bagmati Province, Nepal in 19 primary health facilities, participating in the mIRA study. Facilities included government Health Posts, government Primary Health Care Centers (PHCCs), and Dhulikhel Hospital Outreach Centers (DHORCs), which are non-governmental clinics similar in capacity and structure to PHCCs. The 19 health facilities were paired by facility type and randomly allocated to receive a tablet with the EDSS software: ten with the mIRA EDSS and the remaining nine with the WHO EDSS[13]. This was a two phase cross-sectional (before and after implementation) sub-study of the mIRA process evaluation[10] with data collection before implementation conducted December 2021 to March 2022 and data collection after implementation conducted June to August 2022 (three months after EDSS implementation).

Participants

All pregnant women aged 18 years and above who had attended a participating health facility for a regular ANC consultation during the data collection period were approached (until required sample size was met) for consent and inclusion in the study. Pregnant women attending facilities only to get a blood test or ultrasound services were excluded from the study.

Sample size

A sample size of 138 pregnant women's records in each round of data collection (before and after EDSS implementation) was estimated to provide adequate power (80%) at the significance level of 0.05 to detect the difference of ≥15% in completeness before and after EDSS implementation, with an assumption of 65% initial prevalence of completeness. This initial prevalence of completeness was based on an analysis of data from handheld ANC cards that were extracted in the pilot phase of the mIRA study; two key fields (date of last menstrual period and estimated delivery date) were completed in 60-65% of the ANC cards.

Definitions and data collection tool

We conducted a rapid literature review and referred to the United Kingdom's National Health Service (NHS) guidelines[14] to identify recordkeeping dimensions and approaches to assess impacts of EDSS implementation on the quality of paper-based ANC records and to develop our data collection tool[9,12,15]. Another dimension of data quality --accuracy-- could not be assessed in our study due to logistical constraints in comparing the paper-based records to a gold-standard of observations of the care provided.

We selected indicators that were common to both the ANC card and ANC register as well as some additional indicators common in the EDSS and ANC card. Nine indicators on the ANC card and seven indicators from the ANC register were selected. The following indicators were available in both the ANC card and ANC register: 1) date of ANC register, 2) ANC registration number, 3) woman's age, 4) last menstrual period (LMP) date, 5) parity, 6) whether the first dose of Tetanus Toxoid Diphtheria (TD) vaccination was received and, if so, 7) TD vaccination date. The pregnant woman's weight at their first ANC visit (in kilograms) and blood pressure measurement (systolic blood pressure/diastolic blood pressure) for that day's visit were additionally available in the ANC card. All nine selected indicators from the ANC card were also available in mIRA EDSS; however, three indicators -- date of ANC registration, the pregnant women's weight at their first visit and TD vaccination date -- were not present in WHO EDSS (See additional file).

The outcomes of completeness and agreement were measured across the three data sources: ANC card, ANC register and EDSS record. Completeness referred to whether any value for the selected indicators was recorded in the ANC card and ANC register, and in the EDSS record (second round of data collection only). Completeness was a binary indicator, with any value recorded for the selected indicators coded as 'yes' or 'no'. Agreement referred to whether the value recorded for each selected indicator exactly matched what was recorded in the ANC card and ANC register, before and

after the implementation. Additionally, an agreement between the ANC card and the EDSS indicators were compared separately.

Data collection

The first round of data collection was carried out between December 2021 to March 2022, and the second round of data collection was carried out between June to August 2022 after approximately three months of EDSS implementation. In each facility, a research assistant was stationed for up to seven days and consented eligible pregnant women attending for ANC visits. The research assistant took a photo of the pregnant woman's ANC card or, time permitting, directly extracted the information into the paper-based data collection tool, while the woman was still at the facility and then extracted the same woman's information from the facility's ANC register at the end of the same day. In the second round, the research assistant additionally extracted data from the EDSS tablets on the day of in-person data collection in a facility. For women missing an EDSS entry, the first author (SD) checked the data that was stored in software (backend data) for the same woman on the same date of the ANC visit after one week of data collection, to account for later data entry in the EDSS after the woman's ANC visit. To ensure that data of same women was obtained, women's name, phone number, place, date of visit and husband name were linked across the three data sources. Following each round of data collection, data from the paper-based data collection tool was entered into kobo toolbox (www.kobotoolbox.org) by the research assistants. Direct data extraction into kobo toolbox was not possible because of the lack of tablets for data collection.

Data quality and management

We piloted and modified the data collection tool and trained the research assistants before data collection. Regular check-ins of research assistants were done to monitor any problems with data collection and to assure the quality of data. During the second round of data collection, about 10% of the paper-based data collection forms were checked against the photos of the ANC card and ANC register. Unfortunately, cross-verification of data extraction was not done in the first round of data collection because of the unavailability of photos of the ANC card and ANC register. However, cross-verification in the second round of data collection showed <5% error in extracted data when compared to photos of the ANC card and ANC register. After entering the data in the kobo toolbox, kobo entries data were again cross-checked with paper-based data collection forms; minimal errors were corrected.

Data analysis

The data obtained was cleaned and coded to facilitate data analysis. The statistical analysis was performed using Statistical Package for Social Science (SPSS) version 24 (IBM, NY, USA). For completeness, we calculated the number and percentage of records with any value recorded for the selected indicators in the ANC card and ANC register before and after implementation. We used chi-square tests to assess the evidence for differences in the completeness of the ANC card and ANC register before and after EDSS implementation for date of registration, TD vaccination first dose, and first ANC visit weight. For remaining indicators, we instead used Fisher's exact test to look at evidence for changes in completeness due to small numbers. Similarly, difference in completeness of indicators for the paper-based ANC records and each EDSS were also computed using Fisher's exact test due to the small numbers.

For agreement, we calculated the percentage of women where the value matched for selected indicators from the ANC cards and the ANC register. We also calculated agreement between the ANC card and what was recorded in the WHO EDSS and mIRA EDSS. The ANC card was selected for the agreement standard based on formative research where ANC providers primarily depend on information provided on the ANC card to guide their actions. A study conducted in Brazil was additionally utilized as a reference[12]. Agreement was only calculated for women where there was a value entered in both data sources. For two of the indicators – any TD vaccination received and most recent blood pressure - agreement was not calculated because both were 'yes' or 'no' responses and were recorded differently in the EDSS compared to the ANC card and therefore values couldn't be matched.

Results

A total of 136 records were collected in the first round and, in the second round, 138 records were collected (76 records from mIRA EDSS facilities, and 62 records from WHO EDSS facilities). Before implementation, majority of women's record were of aged 20-25 years (46%), followed by 26-30 years (32.4%), and the lowest for >30 years (9.6%). ANC register record showed similar distribution: 20-25 years (44.1%), 26-30 years (30.1%), >30 years (8.8%). After EDSS implementation, a slight variation was observed in paper-based ANC records. The lowest age group was >20 years, accounting approximately 10% of the records, while the highest age group was 20-25 years with approximately 45% of the records. after EDSS implementation, about 28% of the records represented to first ANC visits, whereas most of the records (72%) were for follow-up visits.

Completeness

Before EDSS implementation, completeness of ANC cards was above 90% for all indicators, except for first TD vaccination and TD vaccination date (Table 1). The proportion of completeness varied from 73.5% (TD vaccination first dose) to 100% (women's age). This was similar to the selected indicators of ANC register where percentage of completeness varied from 61.0% (first TD vaccination) to 96.3% (women's age). As shown in Table 1, there was either no difference in completeness or some evidence of improvement in completeness after EDSS implementation. There was more than a 15% improvement in the completeness of first TD vaccination date records after EDSS implementation in both paper-based ANC records (77.0% to 96.4% [p<0.001] for ANC card and 81.9% to 98.9% [p<0.001] for ANC register). For both paper-based ANC records, parity increased in completeness after implementation (92.6% to 99.3% [p=0.005] for ANC card and 81.6% to 92.0% [p=0.011] for ANC register).

Table 1 Completeness of selected indicators of ANC card and ANC register before (N=136) and after EDSS implementation (N=138)

	ANC card completeness n (%)				ANC register completeness n (%)			
Indicators	Before	After	% differences	p-value	Before	After	% differences	p-value
Date of ANC registration	127 (93.4)	130 (94.2)	+0.8	0.778	127 (93.4)	135 (97.8)	+4.4	0.072
ANC registration number	130 (95.6)	137 (99.3)	+3.7	0.065	126 (92.6)	132 (95.7)	+3.1	0.289
Woman's age	136 (100.0)	137 (99.3)	-0.7	1.000	131 (96.3)	136 (98.6)	+2.3	0.280
Last menstrual period (LMP) date	134 (98.5)	137 (99.3)	+0.8	0.621	126 (92.6)	135 (97.8)	+5.2	0.044
Parity	126 (92.6)	137 (99.3)	+6.7	0.005	111 (81.6)	127 (92.0)	+10.4	0.011
TD vaccination received (first dose)	100 (73.5)	111 (80.4)	+6.9	0.174	83 (61.0)	91 (65.9)	+4.9	0.398
[a]TD vaccination date	77 (77.0)	107 (96.4)	+19.4	<0.001	68 (81.9)	90 (98.9)	+17.0	<0.001
First ANC visit weight (KG)	131 (96.3)	132 (95.7)	-0.6	0.777	Not included[b]	Not included[b]	NA	NA
Blood pressure measurement (current visit)	127 (93.4)	134 (97.1)	+3.7	0.167	Not included[b]	Not included[b]	NA	NA

[a]TD vaccination date was calculated out of total TD vaccination first dose received.

[b]First ANC visit weight and blood pressure measurement was not available in ANC register.

Table 2 Completeness of selected ANC indicators after implementation of WHO EDSS (N=62) and mIRA EDSS (N=76)

	Records from WHO EDSS facilities				Records from mIRA EDSS facilities			
Indicators	ANC card n (%)	ANC register n (%)	WHO-EDSS n (%)	p-value	ANC card n (%)	ANC register n (%)	mIRA-EDSS n (%)	p-value
Date of ANC registration	56 (90.3)	62 (100.0)	Not included[b]	<0.001	74 (97.4)	73 (96.1)	66 (86.8)	0.102
ANC registration number	62 (100)	61 (98.4)	55 (88.7)	0.006	75 (98.7)	71 (93.4)	66 (86.8)	0.017
Woman's age	62 (100.0)	62 (100.0)	55 (88.7)	<0.001	75 (98.7)	74 (97.4)	66 (86.8)	0.006
Last menstrual period (LMP) date	62 (100.0)	62 (100.0)	55 (88.7)	<0.001	75 (98.7)	73 (96.1)	66 (86.8)	0.013
Parity	61 (98.4)	58 (93.5)	55 (88.7)	0.051	76 (100.0)	69 (90.8)	65 (85.5)	<0.001
TD vaccination received (first dose)	46 (74.2)	36 (58.1)	55 (88.7)	<0.001	65 (85.5)	56 (73.7)	29 (38.2)	<0.001
[a]TD vaccination date	43 (93.5)	34 (94.4)	Not included[b]	0.050	64 (98.5)	56 (100.0)	29 (100.0)	1.000
First ANC visit weight (KG)	58 (93.5)	Not included[c]	Not included[b]	NA	74 (97.4)	Not included[c]	65 (87.8)	0.025
[d]Most recent blood pressure	62 (100.0)	Not included[c]	55 (88.7)	0.013	72 (94.7)	Not included[c]	55 (72.4)	<0.001

[a]TD vaccination date was calculated out of total TD vaccination first dose received.

[b]Date of ANC registration, TD vaccinate date, first ANC visit weight were not available in WHO EDSS.

[c]First ANC visit weight and most recent blood pressure measurement was not available in ANC register.

[d]Women's blood pressure on visit day of data collection

Table 3 Agreement of values of indicator of ANC register with ANC card before and after EDSS implementation

	Before EDSS implementation		After EDSS implementation	
Indicators	% value present in both ANC card and ANC register	% ANC register value matched with ANC card	% value present in both ANC card and ANC register	% ANC register value matched with ANC card
Date of ANC registration	87.5	69.9	92.0	78.3
ANC registration number	90.4	86.0	94.9	89.9
Woman's age	96.3	91.2	97.8	92.0
Last menstrual period (LMP) date	91.9	82.4	97.1	87.0
Parity	78.7	75.7	91.3	83.3
TD vaccination received (first dose)	58.8	[a]NA	63.8	[a]NA
[b]TD vaccination date	44.1	38.2	63.0	57.2

[a]TD vaccination first dose given (yes/no)

[b]TD vaccination date was calculated out of total TD vaccination first dose received.

Table 4 Agreement of values of indicator of WHO EDSS & mIRA EDSS with ANC card before and after implementation

Indicators	WHO EDSS		mIRA EDSS	
	% value present in both ANC card & WHO EDSS	% WHO EDSS value matched with ANC card	% value present in both ANC card and mIRA EDSS	% mIRA EDSS value matched with ANC card
Date of ANC registration	Not included[b]	Not included[b]	84.2	64.5
ANC registration number	88.7	75.8	85.5	73.7
Woman's age	88.7	67.7	85.5	80.3
Last menstrual period (LMP) date	88.7	72.6	86.8	78.9
Parity	87.1	56.5	85.5	81.6
TD vaccination received (first dose)	69.4	[a]NA	52.6	[a]NA
[c]TD vaccination date	Not included[b]	Not included[b]	38.2	30.3
First ANC visit weight (KG)	Not included[b]	Not included[b]	82.9	69.7
[d]Most recent blood pressure				
Systolic blood pressure	88.7	77.4	75.0	59.2
Diastolic blood pressure	88.7	82.3	75.0	59.2

[a]Recorded differently in the EDSS compared to the ANC card and therefore values couldn't be matched
[b]Date of ANC registration, TD vaccinate date, first ANC visit weight were not available in WHO EDSS
[c]TD vaccination date was calculated out of total TD vaccination first dose received
[d]Women's blood pressure on visit day of data collection

Table 2 shows the completeness of indicators after EDSS implementation, comparing the ANC card, ANC register and each EDSS, stratified by whether the records were from facilities implementing the WHO EDSS or from facilities implementing the WHO EDSS. The indicators were more complete in the paper-based records compared to EDSS records for both the mIRA EDSS and the WHO EDSS, except for the first dose of TD vaccination which was more complete in WHO EDSS (88.7%, compared to 74.2% in ANC card and 58.1% in ANC register, p<0.001). Compared to the ANC card and ANC register, indicators in the mIRA EDSS were less complete than in paper-based records, and completion was lowest for first TD vaccination received (ANC card=85.5%, ANC register=73.7%, and mIRA EDSS=38.2%, p<0.001).

Agreement

Table 3 shows agreement between values recorded in the ANC card and the ANC register for each indicator, before and after EDSS implementation. The percentage agreement of ANC register with ANC card ranged from 38.2% (TD vaccination date) to 91.2% (women's age) before EDSS implementation, and slight improvement was observed across all indicators after EDSS implementation. Only women's age showed >90% agreement before and after EDSS implementation. TD vaccination date showed the largest percentage increase in agreement before and after implementation (38.2% to 57.2%)

Agreement between the WHO EDSS and the ANC card varied from 56.5% (parity) up to 82.3% (diastolic blood pressure) (Table 4). Agreement between the mIRA EDSS and the ANC card ranged from 30.3% (TD vaccination date) up to 81.6% (parity) (Table 4). Both systolic and diastolic blood pressure had 59.2% agreement in the mIRA EDSS compared to 77.4% and 82.3%, respectively, in the WHO EDSS.

Discussion

To our knowledge, this is the first study evaluating the completeness and agreement between paper-based ANC records and electronic records in Nepal. We found indicators in the ANC card and ANC register showed high completeness before EDSS implementation, and there was a general trend towards indicators being more complete after EDSS implementation. Levels of agreement were relatively high between the ANC card and ANC register for most indicators, with a few exceptions, including parity and TD vaccination received. The percentage agreement of indicators in ANC register compared to ANC card slightly increased after EDSS implementation. Completeness and agreement

of indicators in both EDSS were low, suggesting that recordkeeping in the ANC card and ANC register was prioritized.

It is unsurprising that we found high completeness of the paper-based records due to the central role they play in the healthcare system. The government of Nepal provides cash incentives to pregnant women on completion of required/protocol ANC visits and institutional birth, as documented on the ANC card[16]. The ANC registers are mainly used by ANC providers to calculate numbers for monthly reporting (for example, the monthly number of first ANC contacts, the monthly number of pregnant women completing protocol ANC visits, and number of TD vaccine doses given)[17].

We found that implementation of the EDSS led to improvements in both completeness of, and agreement between, the ANC card and ANC register; however, we also found lower levels of completeness in the EDSS compared to the paper-based records and lower levels of agreement between the EDSS and the ANC card indicators. As the EDSS were designed to provide reminders and prompts to the ANC providers during ANC consultations[13]**,** the EDSS may have prompted ANC providers to additionally fill in additional items in the paper ANC records explaining improvement in completeness after EDSS implementation[18]. Also understood the intervention as about recordkeeping[13], which may have increased providers' attention towards the paper-based records[19].

There are several possible reasons for the comparatively low completeness of, and agreement with ANC cards, and the data entered into the EDSS. Firstly, the EDSS were implemented as part of a time-limited research project, and not a government initiative, potentially explaining why ANC providers did not prioritize filling these in. Government-initiated work is perceived as a legitimate part of their duties, and healthcare providers prioritize it[13]. The EDSS were not linked with the government District Health Information System, and hence did not help ANC providers in monthly reporting. A study conducted in India also recommended that the monthly reporting system should be added to electronic health records to avoid duplication of efforts[20]. Secondly, in the mIRA EDSS it was possible for the user to skip to the next section and avoid entering data for all fields resulting in low completeness. Potentially, relatively low IT literacy may have led to lower utilization of EDSS and influenced completeness and agreement. A study conducted in low-resource setting hospitals in Ethiopia suggests that computer literacy is associated with better use of electronic records[21]. In addition, the quality of the EDSS with respect to the ease of use and functionality may have

impacted its use[22]. Enhancing the completeness and agreement of data in EDSS requires sufficient technical support and practice, and regular monitoring of data by government authorities[20].

We did observe slightly different patterns for one of the indicators: TD vaccination. This indicator had particularly low completeness in both the ANC card and ANC register, which was lower than expected, with results from the Nepal Health Facility Survey 2021 suggesting that 93% women aged 15-49 who had recently given birth were immunized with TD vaccination[23]. Although there was some variation by age with women aged 35-49 years having lower levels (82%)[23]. The low completeness in the paper-based ANC records in our study may have been because women missed ANC visits to receive the dose at the designated time[24]. ANC providers also use outpatient cards and/or the ANC register for documentation of services received in early pregnancy, later copying data to the ANC card[13,19]. This might lead to instances where first dose TD vaccination provided in first trimester was either missed or incorrectly copied to other records. However, there was a some improvement in recording of TD vaccination in paper-based records after EDSS implementation. For instance, in the facilities where the TD vaccination was provided on the designated day[23], the immunization register was used to record the TD vaccination status, which could affect completeness and agreement. If a pregnant woman forgot to bring her ANC card on the immunization day, during their next ANC consultation, the TD section in the EDSS would have reminded the ANC providers to update TD vaccination status in the paper-based ANC records, and in the EDSS[20].

Understand the imperatives and priorities of healthcare providers is crucial for long-term sustainability[25]. ANC providers have to document the same information in two paper records along with additional electronic records increasing the recording burden. Due to workload and time constraints, ANC providers might have missed or less prioritized recording in EDSS. ANC providers copying the records into the EDSS after women left the facility, relying on their memory or other paper-based ANC paper records[19]. Moreover, the use of EDSS wasn't consistent for all ANC visits, indicating that it was not prioritized[19]. A study conducted in Gambia explored that documents were often incomplete and inaccurate due to healthcare providers seeing documentation as an unnecessary task, and time-wasting[9]. Further efforts to introduce electronic recordkeeping should replace or limit the additional burden of paper-based recordkeeping. Easing the burden of recordkeeping and ensuring its relevance would be helpful in motivating ANC providers to see documentation as important task and part of assuring quality of care[7]. Electronic records can be designed to link with different health facilities which could make it easier to transfer information from one facility to another, enhancing easy access of records and continuity of care[20].

Furthermore, ensuring interoperability and user-friendly interfaces is essential for optimizing the utilization of electronic records[25].

Limitations

The results of this study contribute to future implementation of EDSS in low-resource settings, although some limitations can be found. Despite the small sample size for stratified analysis by EDSS, we found meaningful and statistically significant differences in indicator completeness between the paper-based records and each EDSS. Our study was unable to examine accuracy due to logistic constraints to using observations of care as a 'gold standard' for comparison, and further research is important to assess the accuracy of health information in different forms of recordkeeping. Similarly, we were unable to cross-verify data extraction during the first round (before EDSS implementation) data collection, though we note there was a negligible amount of error in second round (after EDSS implementation) data collection. Data entry from the paper-based tool to kobo toolbox for analysis may have introduced error, though quality checks and management aimed to minimize this.

Conclusion

The introduction of EDSS did not have a negative impact on paper-based ANC records. The additional recordkeeping required by the EDSS intervention resulted in general improvements in the completeness and agreement of ANC cards and ANC registers. However, completeness for the selected indicators in the EDSS tended to be lower than that of the paper-based records. Large-scale EDSS implementation should consider how to integrate electronic and paper-based records to decrease the documentation burden on healthcare providers, and the standard of records should be audited on regular basis. Digital records are widely used in high-income countries to improve documentation accuracy, enhance patient care, and provide better organization and access to data. The increasing implementation of electronic health records in low-resource settings increases the demand for evidence to understand the feasibility and impacts of digital health interventions in real-world settings.

List of abbreviations

ANC: Antenatal Care
WHO: World health organization
EDSS: Electronic Decision Support System
mIRA: Mobile health integrated Rural ANC
LMP: Last menstrual Period
TD: Tetanus Toxoid Diphtheria

Declarations

Ethics approval and consent to participate

This study was performed according to Declaration of Helsinki ethical principles for medical research involving human subjects. The ethical approval was obtained from Kathmandu University School of Medical Sciences (IRC, KUSMS 25/22), Nepal Health Research Council (ref: 2695) and LSHTM (ref: 25094-1). Approval was also obtained from all municipalities where the project facilities were located. Written informed consent was obtained from all the health facilities, auxiliary nurse midwives included in study prior to extracting data from ANC register, and ANC card. Written informed consent was also taken from all the pregnant women to use the ANC card, and click the pictures of ANC card prior to enrollment in the study. All the snapped pictures of ANC card were de-identified and deleted after extraction of data. The snapped pictures were stored in password protected storage that was accessible to research team only.

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Authors' contributions

SD and ER led the conceptualization and planning of the study with inputs from all co-authors. SD wrote the manuscript. SD developed the data collection tool with the inputs from ER, SK, and RS. SD, SK, RS performed the data acquisition. SD cleaned the data with inputs from SK and RS. SD analyzed data with guidance from ER, OM, and CC. OMRC, ER, LPK , AS (Dept of Community Programs), AS (Dept of Obstetrics), and BMK provided overall supervision and feedback on the manuscript drafts. All authors read, provided feedback and approved the final manuscript for publication.

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