Improving intrapartum fetal monitoring in India: is training the answer?

Dr K M Lightly, MBChB Hons, AFHEA

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Contents

List of table and figures

List of abbreviations/acronyms

Abbreviation/acronym	Full name
ACOG	American College of Obstetrics and Gynaecologists
AIIMS	All India Institute of Medical Sciences
BCIAB	Baby cried immediately after birth
BOH	Bad obstetric history
CPD	Continuous professional development
CRF	Case report form
CS	Caesarean section
CTG	Cardiotocograph
CTU	Clinical trials unit
DFID	Department for International Development
DMWH	Daga Memorial Women's Hospital
eLFH	E-learning for health, online health education resource
EFM	Electronic fetal monitoring
ENAP	Every Newborn Action Plan
FBS	Fetal blood sampling
FGD	Focus group discussions
FHR	Fetal heart rate
FIGO	International Federation of Gynaecology and Obstetrics
FM	Fetal monitoring
FM study	Evaluating the impact of an intrapartum fetal monitoring training and quality improvement programme, in a Government tertiary referral hospital in central India, using Kirkpatrick's four-stage evaluation model

FOGSI	Federation of Obstetric and Gynaecological Societies of India
FSB	Fresh stillbirth
GCP	Good Clinical Practice
GHP	Gynuity Health Projects
G/L	Guideline
GMC	General Medical College (Nagpur)
HCW/HCP	Health care workers/professionals
HMIS	Health Management Information Systems
IA	Intermittent auscultation
ICD	International classification of disease
ICMR	Indian Council for Medical Research
IUD	Intrauterine death
INFORM	INduction with FOley catheter oR Misoprostol study
IOL	Induction of labour
IRB	Institutional Review Board
JNMC	Jawaharlal Nehru Medical College
K2	Online CTG training platform
LMIC	Low- and middle-income country
MDT	Multi-disciplinary team
MMR	Maternal mortality ratio
MOLI	“Misoprostol or oxytocin for labour induction” randomised controlled trial
M/M	Misoprostol/Misoprostol
M/Ox	Misoprostol/Oxytocin

MRC	Medical Research Council
MSB	Macerated stillbirth
NICE	National Institute for Health and Excellence
NICU	Neonatal Intensive Care Unit (also known as SCBU)
NND	Neonatal death
PDSA	Plan, do, study, act cycle
QI	Quality improvement
qMOLI study	A qualitative assessment of Misoprostol or Oxytocin for Labour Induction study
RA	Research Assistant
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RCT	Randomised controlled trial
RCOG	Royal College of Obstetricians and Gynaecologists, UK
SB	Stillbirth
SDG	Sustainable development goals
SOP	Standard Operating Procedure
TGCS	Robson's ten-group classification system
TOC	Theory of change
TOLAC	Trial of labour after caesarean
UK	United Kingdom
VBAC	Vaginal birth after caesarean section
WHO	World Health Organization

Publications during PhD

Below is a list of publications related to this thesis.

Weeks AD, **Lightly K**, Mol BW, Frohlich J, Pontefract S, Williams MJ; Royal College of Obstetricians and Gynaecologists. *Evaluating misoprostol and mechanical methods for induction of labour: Scientific Impact Paper No. 68* February 2022: Scientific Impact Paper No. 68 April 2022. BJOG. 2022 Apr 27. DOI: 10.1111/1471-0528.17136. PMID: 35478481.

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Bracken H, **Lightly K**, Mundle S, Kerr R, Faragher B, Easterling T, Leigh S, Turner M, Alfirevic Z, Winikoff B, Weeks A. *Oral Misoprostol alone versus oral misoprostol followed by oxytocin for labour induction in women with hypertension in pregnancy (MOLI): protocol for a randomised controlled trial.* BMC Pregnancy Childbirth. 2021 Jul 29;21(1):537. DOI: 10.1186/s12884-021-04009-8. PMID: 34325670; PMCID: PMC8320158.

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Lightly K, Mundle S, Tripathy J, Deshmukh P, Winikoff B, Alfirevic Z, Weeks A, Kingdon C. EP.0546 Intrapartum fetal monitoring and mode of birth in India: A qualitative study. Category - Hot Topics (Emerging Research/Issues) in Obstetrics, 10 June 2022, https://doi.org/10.1111/1471-0528.10_17178.

Lightly K, Mundle S, Tadas M, Faragher B, Alfirevic Z, Scott H, Weeks A. OP.0059 A mixed-methods evaluation of an intrapartum fetal monitoring training programme in India. Category - Medical Education, 10 June 2022, https://doi.org/10.1111/1471-0528.16_17178.

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Publications currently under peer review

Phan T, **Lightly K**, Ebringer M, Weeks A. Diversifying access to global health research: An evaluation of an online maternal health conference.

Symon A, **Lightly K**, Howard R, Mundle S, Faragher B, Hanley M, Durocher J, Winikoff B, Weeks A. Introducing the Participant-Generated Experience and Satisfaction (PaGES) Index: The development of a novel, longitudinal mixed-methods evaluation tool.

List of collaborators and roles

Katie Lightly (KL) (f) was the UK trial manager for the MOLI study and led the FM, qMOLI and PaGES sub-studies. Her PhD funding came from the MOLI study. She spent seven months in Nagpur to set up these studies and was integral in the overall study conduct. KL is a UK-based obstetrician and gynaecology trainee (year five) with a longstanding interest in global maternal health. She is an Associate Fellow of the Higher Education Authority with extensive teaching experience with undergraduate and postgraduate students, RCOG courses and international webinars. She has previously had teaching experience in Uganda and Sierra Leone and clinical experience in Malawi and Uganda. She was previously Chair of the RCOG Trainee Global Health Group. She is the editor of Volume 15, the puerperium, The FIGO Continuous Textbook of Women's Medicine. She leads the GLOWM Enhancing the Welfare of Women project to develop educational videos and texts for women in low-income settings. She is a steering group member of the GLOW Conference committee.

Roles - KL led all of the work presented in this thesis, from study conceptualisation and design, data collection, cleaning and analysis to write-up.

Andrew Weeks (AW) (m) is a Professor of International Maternal Health Care at the University of Liverpool and Director of the Sanyu Research Unit. He is an honorary obstetric consultant at Liverpool Women's Hospital. He is Chief Investigator for the MOLI study and sub-studies and is responsible for trial design, conduct, analyses and reporting and is also the primary supervisor for this thesis. His primary research interests are the translation of maternity care from high-income to low-resource settings, in particular induction of labour, misoprostol, post-partum haemorrhage and management of labour. He has over 200 publications and currently runs clinical trials in UK, India and Uganda.

Roles – Conception/design, data acquisition/analysis and interpretation and review of thesis drafts/papers.

Hazel Scott (f) is a Professor and Dean of the faculty of medicine at the University of Liverpool and second supervisor. She is a Consultant in Respiratory Medicine and has had numerous leadership roles in medical education, including Associate Postgraduate Dean in Scotland, Director of Medical Education for a large Health Board Director of CPD and Vice President of CPD at the Royal College of Physicians. Her interests are e-learning,

communication skills, simulation and professionalism, and she holds a Principal Fellowship of the Higher Education Academy.

Roles – Conception/design, data acquisition/analysis and interpretation for FM study and review of thesis drafts/papers.

Zarko Alfirevic (m) is an emeritus Professor of Maternal and Fetal Medicine and clinical academic obstetrician. He was the co-ordinating Editor of the Cochrane Pregnancy and Childbirth Group. His interests are intrapartum fetal monitoring, systematic reviews, randomised trials, preterm birth, fetal medicine and high-risk obstetrics. He was initially the second supervisor for this PhD until his retirement in 2021.

Roles – Study conception/design

Shuchita Mundle (f) is a Professor of Obstetrics and Gynaecology and Head of the Department of Obstetrics and Gynaecology at All India Institute of Medical Sciences in Nagpur. She was previously a Professor and Head of Unit at Government Medical College, Nagpur. She has extensive experience conducting clinical trials and coordinating trials with partner institutions, including Daga Women's Hospital, Nagpur. She has a special interest in managing pre-eclampsia in low-resource settings, labour induction, and qualitative research. She has been the principal investigator for several international trials with Gynuity Health Projects and is the Principle Investigator for MOLI and its sub-studies.

Roles – Conception/design, data acquisition/analysis and interpretation. Indian lead for all studies.

Carol Kingdon (f) is a Reader in Medical Sociology from the University of Central Lancashire and an Honorary Research Fellow at the University of Liverpool. Her current role is research manager at Wirral Hospitals. She is a medical sociologist and an experienced qualitative researcher. She has multiple qualitative publications including in the Lancet. Her research interests include unnecessary CS and women's experiences of maternity care.

Roles – Protocol review, data analysis, interpretation and review of qMOLI study. CK coded three transcripts, devised a coding framework and reviewed frameworks and coding throughout the study. She supervised the qMOLI study.

Moushmi Parpillewar Tadas (f) is an Associate Professor and lecturer at Government Medical College. She was the Principle Investigator for the MOLI study and fetal monitoring project lead in GMC.

Roles – Local project lead in GMC for FM study, liaison with department, training design and data acquisition.

Brian Faragher (m) is an emeritus Professor of Medical Statistics from the Liverpool School of Tropical Medicine. He is the MOLI study statistician and provided statistical support for the FM study.

Roles – Conception/design, checked dataset and cleaning, analysis and review of FM study thesis drafts/papers.

Jaya Prasad Tripathy (m) is an Assistant Professor in the Department of Community Medicine, All India Institute of Medical Sciences, Nagpur. He is an experienced researcher with 180+ publications and an experienced qualitative researcher.

Roles – Feedback on protocol, data acquisition/analysis and interpretation for qMOLI study. Led FGDs and transcribed the first two FGDs.

Pradeep Deshmukh (m) is a Professor of Community Medicine and an experienced qualitative researcher at AIIMS Nagpur.

Roles – Design, data acquisition/analysis and interpretation for qMOLI study.

Reena Deva (f) is an Ayurvedic Doctor and research associate. She was an FM study RA and qMOLI RA. She conducted the majority of interviews with women pre and post-IOL.

Roles - She was trained in qualitative research methods, then conducted the semi-structured interviews with women and transcribed and translated the interviews.

Priya Raut (f) is an Ayurvedic Doctor and research associate. She conducted the first two qMOLI interviews.

Julian Winn (m) is a retired healthcare manager, nurse and Honorary Senior Fellow at the School of Health Sciences at the University of East Anglia. He is an expert in realist evaluation and helped to conceptualise and develop the TOC.

Roles – Conception/design of TOC, review of TOC thesis chapter draft.

Hillary Bracken (f) is an experienced qualitative and quantitative researcher from Gynuity Health Projects and was the first Gynuity MOLI trial manager. **Jill Durocher** (f) then took over her role and led the MOLI study trial management and budget. **Professor Beverly Winikoff** (f) leads Gynuity Health Projects.

Roles – Reviewed protocol drafts and attended MOLI Trial Management Group meetings, giving input throughout.

Four research associates in Nagpur were trained and conducted the FM study data collection.

- **Mrs Pushpa Iyengar** – lead RA, responsible for data quality
- **Dr Reena Deva**
- **Mrs Rajeshree Shiral**
- **Miss Aishwarye Kohle**

Lydia Hawker (f) is an academic foundation doctor who spent four months under the supervision of KL and the qMOLI/MOLI team, coding and analysing the IOL aspects of the qMOLI study. A draft of the paper is in progress.

Molly Hanley (f) is an MRES student who KL supervised to analyse the MGBSI/PaGES aspects of the qMOLI dataset, which was presented to the MOLI TMG.

Avni Patel (f) is an MRES student that KL is currently supervising to analyse the PaGES Index data and compare and contrast this with the qMOLI data/RCT Likert scores.

Mira Ebringer (f) is the UK administrator for the MOLI study.

Dot Lambert (f) is the Sanyu Research Manager and gave input to the trial management aspects throughout.

Robbie Kerr (m) is a previous Sanyu Research Unit Academic Clinical Fellow and obstetrics and gynaecology trainee. He helped to set up the MOLI study and originally intended to undertake the UK MOLI Trial Manager role.

Improving intrapartum fetal monitoring in India: is training the answer? K M Lightly

Introduction: Although intrapartum fetal monitoring is a fundamental aspect of intrapartum care worldwide, research on its use in LMIC is lacking. This thesis uses a multi-methods approach to evaluate an intrapartum FM training and quality improvement package in a government hospital in India, informed by staff and patient perspectives.

Methods: This research was conducted in two Government hospitals in central India. The qualitative study involved eight clinician/researcher focus groups and 53 semi-structured interviews with high-risk women before and after labour induction; data was analysed using a framework approach to thematic analysis. A FM training programme was implemented and evaluated using a fixed, parallel, convergent design based on Kirkpatrick's four-stage evaluation model and reflective diary. The prospective cohort data were analysed to evaluate risk factors, outcomes and FM practices. We then outlined an evidence-based theory of change for FM training, that is adaptable to the local context.

Results: The qualitative study developed six themes (in bold). 1. Women preferred vaginal birth as it was **"trouble for two hours [rather than] trouble for two months"**. 2. Women gained **knowledge through experience.** 3. **FM was part of a positive birthing experience [and women] "felt good by hearing the beats".** 4. **Interactions with women, relatives and clinicians** were important. 5. Clinicians felt **FM as per guidelines was "practically not possible",** and 6. **FM and risk** were linked. "Trying for normal" birth without good FM was considered "too risky". Clinicians felt that more FM training and equipment would help.

Clinicians enjoyed the FM training and gained knowledge and confidence. Post-training, they could quantify and describe how cases were managed differently. Of 84 clinicians, 77 (86%) engaged with one session or more. The interactions between the training, co-interventions, relationships, systems and context were paramount. The pre-and post-intervention groups included 2,272 women (2,319 babies) and 1,881 women (1,920 babies), respectively. The mean fetal heart rate (FHR) documentation count during labour increased significantly from 5 to 7.5 ($p=<0.001$); the mean time between the last FHR and delivery fell significantly from 60 to 50 minutes ($p=<0.001$). There were non-significant trends toward increased operative birth rates (42.9% vs 45.5%) and reduced perinatal mortality (4.6% vs 3.7%). Neonatal intensive care unit (NICU) admission rates fell significantly (16.7% vs 10.2%), as did NICU admissions for asphyxia (1.2% vs 0.6%).

The CS rate was 42.5% in this very high-risk population. Fetal indications were the most common indication for operative birth (15.4% of all births), and 13.7% were admitted to NICU. Only 3.4% of NICU admissions were for birth asphyxia and 1.2% for meconium aspiration syndrome. The total perinatal mortality rate, using the Indian definition, was 68.7/1000 (459/6682), of whom 58 were possible/confirmed in-facility intrapartum fresh stillbirths (8.9/1000 WHO definition) and 25 neonatal deaths due to asphyxia.

Conclusion: Women want a healthy baby and "normal" birth, but clinicians feel vaginal birth is unsafe with inadequate FM, and this drives high operative birth rates. "Hearing the beats" and kind communication promotes a positive birth experience for women. FM training is a complex intervention that can improve FM process indicators and some neonatal outcomes. Clinicians enjoyed the training, gained knowledge and confidence, and changed their practice. However, the interaction between training, co-interventions, context, people and systems is essential. For change to occur, training must be embedded within wider interventions so that barriers to implementation are identified and overcome.

Chapter 1 – Introduction

1.1 Introduction overview

This thesis aims to evaluate the impact of introducing an intrapartum fetal monitoring training programme into a tertiary Government Hospital in central India. This is done in the context of staff and patient perspectives on intrapartum fetal monitoring and mode of birth. Therefore, this introduction chapter starts with an overview of global maternal and newborn health in low-and-middle-income countries (LMICs) and the Indian context, followed by global caesarean section (CS) trends and the "too much too soon, too little too late" paradigm. The focus then turns to intrapartum fetal monitoring, fetal monitoring in LMIC and relevant international clinical practice guidelines. It then outlines the existing literature on women's and clinicians' views and experiences on intrapartum fetal monitoring and mode of birth (MOB). Finally, the introduction concludes with an overview of the clinical education and quality improvement literature, focusing on existing studies about fetal monitoring training and interventions that achieve change and the rationale and aims for this thesis.

1.2 Global maternal and newborn health

Birth should be a safe and positive experience for every woman worldwide. However, it is estimated that each year 287,000 mothers die due to pregnancy-related complications, 2.7 million babies die within the first four weeks after birth, and 2.6 million stillbirths occur. (1) (2) (3) Furthermore, 40% of maternal deaths, 1/3 of neonatal deaths and ½ stillbirths occur during labour or the first postnatal day. (4) The vast majority occur in LMIC, where significant barriers reduce access to care, and inadequate quality of care is often provided. (5) However, skilled care and interventions during and immediately after childbirth can deliver a "triple return", reducing maternal deaths, stillbirths and early neonatal deaths. (6)

1.2.1 Maternal mortality worldwide

Every day in 2020, almost 800 women died from preventable causes due to pregnancy and childbirth. (7) Adolescents aged 10-14 face the highest risk of death. (8) Internationally, the maternal mortality ratio (MMR – number of deaths/100,000 live births) has dropped by 1/3 over the past 20 years, but rates are still unacceptably high, at 223/100,000 (80% uncertainty interval 202-255). (7) Reductions in maternal mortality rates have stagnated for the last five years, which is a concerning trend. The estimated lifetime risk of pregnancy-

related death is now 1 in 210. (7) Central and Southern Asia account for 17% of all deaths (7) In 2020, there were 24,000 maternal deaths in India, which is 8.3% of all maternal deaths.

There are huge disparities in MMR between the rich and the poor, with rates in low-income countries at 462 per 100,000 and 11 per 100,000 in high-income countries. The same differences are also seen within countries: wealth is critical for accessing care. Even within countries, there is increasing inequity, with the proportion of maternal deaths rising in the lowest socio-economic quintiles compared to the highest. (9) Pregnancy and birth complications cause most deaths, although some are from indirect causes such as worsening medical conditions or infections, e.g. HIV. Three-quarters are related to the top five causes; severe bleeding (mostly post-partum haemorrhage), severe infection (typically postnatal), hypertensive disorders, birth complications and unsafe abortion. (10) For most women, having a trained birth attendant present at birth can improve outcomes and reduce complications. However, especially for poor women, in rural areas, less than half of births are attended by a skilled birth attendant. (11) Barriers to accessing care include poverty, travelling to facilities, lacking information, poor quality services and cultural beliefs and practices. (12) The new trends in maternal mortality report (2023) highlights key areas which must be prioritised to improve outcomes; greater recognition that collective action is needed to overcome systemic barriers, the lack of access and quality of care for socially marginalised women and girls, intersectoral action from a gender-based and human rights perspective and a multisectoral approach to health system strengthening approach for resilience to climate and humanitarian crises are needed. (7)

1.2.2 Stillbirth – a neglected global tragedy

Stillbirth, the birth of a baby who dies during pregnancy or birth, is “a neglected tragedy”. (13) Each year, 2.6 million stillbirths occur, one every 16 seconds. (14) These losses cause profound, life-changing impacts on women and their families, communities and society. Almost all stillbirths (98%) occur in low-income countries, where they are the hardest to measure, as most do not receive a birth certificate. (1) Stillbirth rates are a marker of quality of care. (14) Significant numbers of the 1.3 million (uncertainty range 1.2 – 1.6 million) intrapartum stillbirths could be prevented by improved care at birth (15), particularly improved monitoring and access to emergency obstetric care. (13) The proportion of intrapartum stillbirths varies significantly around the world, from an estimated 10% in high-income settings to up to 57% in South Asia. (1) Globally, stillbirth

rates are reducing (the current rate is 18.4/1000 births); however, significant improvements are required to meet the Every Newborn Action Plan (ENAP) goal to reduce stillbirths to 12/1000 by 2030, an aim endorsed by the World Health Assembly in 2014. (5)

Global estimates suggest that the commonest causal factors are fetal growth restriction or preterm labour (or both), childbirth complications, and modifiable factors such as maternal infections (attributable population fraction: malaria 8.2%, syphilis 7.7%), non-communicable diseases including nutrition, lifestyle and obesity (10%), maternal age older than 35 years (6.7%), and prolonged pregnancies (14%). Congenital abnormalities only account for 7.4% of all stillbirths. (15)

High-quality stillbirth data is essential to guide strategies to improve outcomes. (16) However, there are several barriers to quality data capture, including the varying definitions used worldwide, differing legal requirements to register stillbirths within and between countries, and large numbers of different classifications without consensus.

1.2.3 Perinatal mortality definitions

The World Health Organization (WHO) and national definitions of stillbirth and perinatal death are often slightly different, including in India. For international comparison, the WHO defines stillbirth as "death before birth, among fetuses that are, by order of priority, of at least 1000 grams birthweight, and/or at least 28 weeks gestation, and at least 35 cm long". In contrast, the International Classification of Diseases (ICD 10) defines stillbirth as the number of deaths in fetuses born after greater than or equal to 22 weeks of gestation or weighing greater than or equal to 500g. One area where there is consensus is on the definition of neonatal death, which is the death of a liveborn infant that dies before 28 completed days of age; early neonatal death is the number of liveborn infants that die up to the first seven days of life, and late neonatal death is between 8 – 28 days. Perinatal mortality definitions also vary because of the inclusion of stillborn babies; perinatal deaths include stillbirths (depending on definition), plus neonatal deaths up to seven days. The extended perinatal deaths also extend to 28 days postnatal, including early and late neonatal deaths and stillbirths. The diagram below outlines the WHO definitions with more clarity.

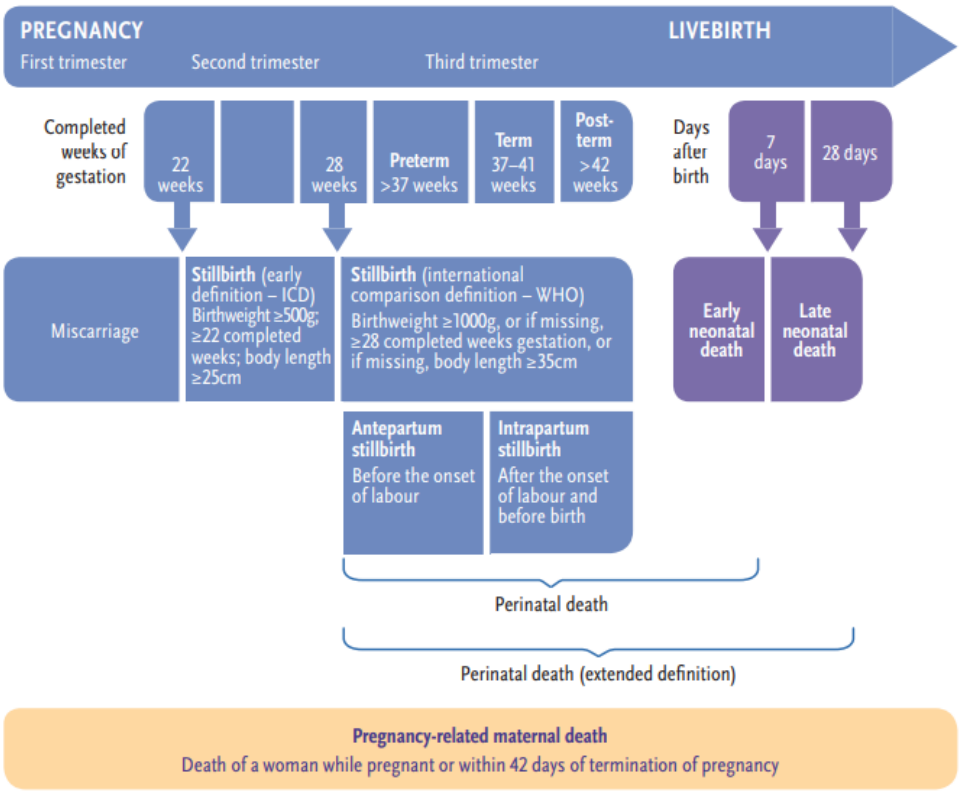

Figure 1 World Health Organization pregnancy outcome definitions. Source WHO (12)

Under India's Health Management Information System (HMIS), stillbirth has been defined as the "complete expulsion or extraction of baby from its mother where the fetus does not breathe or show any evidence of life, such as beating of the heart, or a cry or movement of the limbs".

For Indian sentinel surveillance, the following definitions are used.

> "Early fetal deaths (EFD): An early fetal death is death of a fetus weighing at least 500g (or, if birth weight is unavailable after 20 completed weeks gestation, or with a crown-heel length of 25cm or more)." (sic)
>
> "Late fetal deaths (LFD) (stillbirths): A late fetal death is defined as a fetal death weighing at least 1000g (or, a gestational age of 28 completed weeks or a crown-heel length of 35cm or more)." (sic)
>
> "Fresh stillbirth (FSB) or intrapartum stillbirth are defined as stillbirths occurring after the onset of labour in less than 12 hours before delivery with no skin changes, weighing more than 1000g and more than 28 weeks of gestation, but excludes severe lethal congenital abnormalities." (sic)

> "Macerated stillbirth (MSB) or antepartum stillbirth is a baby born with all the changes which occur in a fetus retained in utero after birth and the death occurred before the initiation of labour. (sic) A "macerated" fetus shows skin and soft tissue changes (skin discolouration or darkening, redness, peeling, and breakdown)." (17)

1.2.4 Global neonatal mortality

In 2020 2.4 million newborn babies died, approximately 6,700 daily, as children are most vulnerable in the first month of life. (3) Improved care has led to reductions in this figure. Still, neonatal deaths are more difficult to prevent, meaning that global under-five mortality is reducing faster than neonatal mortality rates. Nearly half (47%) of all under-five deaths are neonatal deaths. Unfortunately, most children that die within the neonatal period lack good quality care in the first few days after birth. The most common causes of neonatal death are preterm birth, intrapartum-related complications (including asphyxia and "not breathing at birth"), infections and congenital anomalies. (18)

1.2.5 Global health priorities and sustainable development goals (SDGs)

The SDG agenda is a call to action for all to end poverty and inequity, care for the planet and ensure that everyone enjoys health, wealth and justice. It is critical that "no one is left behind". (19) The 17 goals, as outlined in the diagram below, aim to change our world by meeting 169 targets and were adopted by all countries in the United Nations in 2015. Although Goal three is to "ensure healthy lives and promote wellbeing for all at all ages", the other goals are cross-cutting, and progress in the other goals will also improve the outcome for goal three. The SDGs differ from the Millennium Development Goals as the focus is global rather than "developing nations". They are based on values, equity and human rights respect. They focus on sustainable finance, research, innovation, monitoring and evaluation approaches. They aim to strengthen health systems towards universal health coverage through intersectoral actions. (19)

Figure 2 The Sustainable Development Goals. Source SDG website - (10)

In line with the SDGs and the new WHO Global Strategy for Women's, Children's and Adolescents' Health (2016-2030), the global agenda is widening to make sure that women and babies not only survive labour but that they "thrive and reach their full potential for health and life". (20) For the first time, the childbirth experience has been elevated to a "critical aspect" rather than alongside the clinical aspects. WHO defines a positive childbirth experience as "one that fulfils or exceeds a woman's prior personal and socio-cultural beliefs and expectations, including giving birth to a healthy baby in a clinically and psychologically safe environment with continuity of practical and emotional support from a birth companion(s) and kind, technically competent clinical staff". (20) The respectful maternity care agenda is key to ensuring women experience a positive birth. Respectful maternity care (RMC) is defined as "the care organised for and provided to all women in a manner that maintains their dignity, privacy and confidentiality, ensures freedom from harm and mistreatment, and enables informed choice and continuous support during labour and childbirth". (20)

As the number of women giving birth in healthcare facilities has increased globally and the number of births attended by skilled health personnel has increased (now at a record level of 84% (21)), issues around inadequate quality of care are more important than ever. Annually, 5.7-8.4 million deaths are attributed to poor quality care in LMICs, representing around 15% of all deaths. (22) Quality of care is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with evidence-based professional knowledge". (22) Important aspects of quality are that the care is effective (evidence-based for those in need), safe (avoids harm),

people-centred (responsive to individual needs and preferences), timely (reduced waiting times and delays), equitable (quality care for all), integrated (cross-cutting) and efficient (minimises waste). (22) Improving the quality of care is now a key global priority and strategy for improving outcomes.

Summary

Globally maternal and perinatal mortality rates are still unacceptably high, especially in LMICs. Improving care around the time of birth offers a unique opportunity and a "triple return" on this investment, preventing stillbirths and the deaths of mothers and newborn babies. Most of these deaths are avoidable with simple and timely interventions, but political momentum and finances are necessary to ensure countries meet their SDGs and outcomes improve.

1.3 The study context

When considering implementing interventions to reduce global maternal and perinatal death rates, South East Asia is of paramount importance due to the huge population and the volume of morbidity and mortality. Officially known as the Republic of India, India is the second most populous country in the world (population estimate in 2018 was over 1.35 billion), (23) the most populous democracy and the seventh biggest country by area. Every day 67,385 babies are born, that is 1/6 of all global births. India is culturally and ethnically very diverse, with 447 native languages (Hindi and English are the official languages) and varied geographies, rich cultures and traditions. It became a federal republic in 1950, changing from a developing country into a rapidly growing world economy (total GDP of $11.745 trillion) and a world leader in information technology. In this lower middle-income country, poverty has decreased over the last two decades, and GDP per capita is now $8,358 (128th). (24) However, this is at the expense of rising inequity: one in five (21%) live in extreme poverty (<$1.90/day), and 58% are poor (living on <$3.10/day.)

The studies outlined in this thesis were conducted in the city of Nagpur, the third largest city in the state of Maharashtra, in central India. Nagpur has a population of 2.4 million. (25) Literacy rates are 92%, and 70% of the population is Hindu, 15% Buddhist and 10% Muslim. (25)

Figure 3 Map of India

1.3.1 Maternal and perinatal outcomes in India

Maternal mortality in India has decreased significantly, aiming for the SDG target of less than 70 per 100,000 livebirths by 2030. The number of deaths of women and girls due to pregnancy and childbirth-related issues was 103,000 in 2000 and is now 35,000 in 2017 (a 55% decrease). (26) However, there are still marked differences between states. Some high-performing states, such as Kerala, have high women literacy rates, engaged governments and medical staff that outperform the targets, whilst others fall behind. Strategies used include demand-side financing and incentivisation. At the country level, Nigeria and India together are estimated to account for over one-third of all maternal deaths worldwide in 2015. India also has the highest number of stillbirths worldwide, with 592,086 in 2015 (1). The published stillbirth rate is 33/1000 total births, based on lower-quality national information systems data, nationally representative retrospective household surveys and other sub-national surveys. (1) This rate is reducing along with

many other countries; there was a 2.4% average annual reduction rate (ARR) between 2000-2015. (1)

Table 1 Maternal and perinatal outcomes in India

Maternal/perinatal outcome	Metric (uncertainty range)	Source
Maternal mortality ratio (per 100,000 live births, 2017)	122	UNICEF (26)
Stillbirth rate (per 1000 births)	33	Lancet series (1)
Neonatal mortality rate (0-27 days, per 1000 livebirths 2017)	20.35 (17.67-23.19)	WHO observatory e-health (27)
Infant mortality rate (between birth and 11 months per 1000 live births, 2020	27.01 (23.98-30.07)	WHO observatory e-health (27)
Under-five mortality rate (probability of dying by age 5 per 1000 live births)	32.63	WHO observatory e-health (27)
% urban population	35.4%	World Bank (28)
Total fertility rate (average number of women to be born to a woman in her lifetime)	2.2	World Bank (28)
Low birth weight rate (<2500g)	15-25%	Ministry of Health and Family Welfare (29)
Literacy rate, adult total (% 15 years+)	74%	World Bank (28)
Contraception prevalence, any method (% married women 15-49, 2016)	54%	World Bank (28)
Adolescent birth rate (per 1000 women, 15-19 years 2018)	12.2	WHO observatory e-health (27)
Life expectancy at birth (years 2019)	70.8 69.5 male, 72.2 female	WHO observatory e-health (27)
Hospital beds (per 10,000 population, 2017)	5.3	WHO observatory e-health (27)
Antenatal clinic – % with ≥ 4 attendances	58%	UNICEF (26)
% individuals using the internet (2020)	43%	World Bank (28)

1.3.2 Sustainable development goals (SDGs) in India

India played a large part in developing the SDGs, and the Indian national strategy is mapped to them; the motto is “leave no one behind”. As 1/6 of the world’s population lives in India, meeting its SDG targets is imperative for global success. There have been significant improvements, but there is still significant variation in and between states. (30) Maharashtra currently ranks ninth of the Indian states for SGDs overall and second for goal three (health and wellbeing). Unfortunately, not all indices are moving in the right direction, and health sector performance has declined in nine of the 21 states. (31)

Multiple initiatives are ongoing in India to improve maternal and neonatal health. The National Health Policy 2017 sets targets for universalising primary health care and reducing infant mortality. (32) The Government of India now offers health insurance for low-income families. The Maternity Benefit Programme offers a conditional cash transfer to protect women from wage loss and access to contraceptive methods and ensure childhood vaccination is prioritised. Beti Bachao Beti Padao (Save the Girl Child, Educate the Girl Child) is a flagship initiative to elevate the status of the “girl child” alongside numerous community women empowerment initiatives. (32)

The LaQyshya Labour Room Quality Improvement initiative was launched by the National Health Mission in 2017. (33) It aimed to reduce preventable maternal and newborn mortality, morbidity and stillbirths associated with care around delivery in the labour ward and labour ward theatres, and ensure respectful maternity care. The three main strategies were realigning labour wards and theatre, ensuring all Government Medical Colleges and busy centres have dedicated HDUs and ensuring strict adherence to clinical protocols and stabilisation before referral.

1.3.3 Challenges to maternal health in India

Among the socioeconomic challenges India faces, with the huge population and disease burden, there are also specific challenges such as gender inequality, child malnutrition and rising air pollution. There is inadequate spending on health in the public sector, and much of healthcare in India is run as a business in the private sector, so it is not always in the best interest of women. There are multi-dimensional effects of poverty on deprivation in health; education, wealth index, caste, religion, and location of residence are all relevant. There are serious staff shortages, although the number of undergraduate and postgraduate places has increased. (30) The role of the midwife in India is negligible, although there is

now some political movement toward developing this role. (34) Still, there are mixed priorities nationally, with misconceptions and anxieties about the role of the midwife and the expectation of care to be delivered by doctors. The global pandemic has further shifted political focus, resources and staff away from maternal and newborn health and its importance is often undervalued. Blame is also a significant issue; maternal death reporting is not anonymised, and institutions and individuals do not want lives to be lost in their hands or documentation of this. It is a frequent occurrence for healthcare workers to encounter physical violence from an angry mob, when fatalities do occur.

Gender inequality is a huge issue for India, which can negatively impact its potential for improvements in outcomes. (30) India is the only large country in the world with a higher neonatal mortality rate in female babies, and the gender difference in survival is 11%. (26) Lower hospital admissions for girl babies and higher under-five mortality reflect community attitudes in some areas. (26) In addition, 34% of all women 15-49 have experienced violence at home since the age of 15 years old, and 31% of ever-married women of the same age range have experienced physical, sexual or emotional spousal violence, with 52% of women and 42% of men believing that wife-beating by a husband is justified. (26) Obstetric violence is a significant issue, with varying reports of abuse and disrespect in the literature from across the country. (35) Reversing this will require a fundamental shift in political, social, cultural and institutional normal and change across multiple sectors, including education, health, employment, nutrition and sanitation. (30) (36)

1.3.4 Study context - "Misoprostol or Oxytocin for Labour Induction" (MOLI) study

Both studies outlined in this thesis are sub-studies from the "Misoprostol or Oxytocin for Labour Induction" (MOLI) study (37), each with separate protocols and approvals. The RCT is a pragmatic multi-centre parallel, superiority, open-label randomised trial in three publicly funded hospitals, comparing oral misoprostol and intravenous oxytocin to augment labour. Participants were eligible for the trial if they were ≥18 years old, pregnant with a live fetus, and had begun induction of labour (IOL) for hypertension with oral misoprostol alone but required a further augmentation agent following the rupture of membranes. To obtain a study size of 520 randomised patients, it was estimated that 1,000 women undergoing IOL with oral misoprostol were required (referred to as the "cohort study") as additional uterine stimulation would not be necessary for all participants following artificial rupture of membranes (ARM). Those who required augmentation after ARM were randomly assigned to receive low-dose oral misoprostol tablets (25 mcg) every two hours

or standard IV oxytocin 30 minutes after membrane rupture. Outcomes included safety, efficacy, acceptability, and cost-effectiveness, and the main RCT results will be published elsewhere. These studies were all conducted by the same multinational team, and the roles of the collaborators are outlined on pages 17-20.

The MOLI project is now more of a research programme, funded by the grant and run by a similar research team (see list of collaborators.) The numerous sub-studies include the fetal monitoring study, qMOLI study, the "Mother Generated Birth Satisfaction Index" (MGBSI), which is now known as the "Participant Generated Experience and Satisfaction index" (PaGES), the health economics evaluation and situational analysis. The full rationale for the FM and qMOLI studies is outlined in chapter two but was brought about to ensure safe induction of labour through high-quality fetal monitoring, as clinicians in Nagpur did not feel the RCT was appropriate without this. KL led the qMOLI study and supervised LH, an academic foundation doctor, to analyse the data and present it as a separate paper. The aims and objectives for the IOL aspects of qMOLI (not presented in this thesis) were to provide a holistic view of IOL through the views, experiences and preferences of women and clinicians. The qMOLI study aimed to assess the priorities, experiences, and acceptability of IOL for women being induced for hypertension in pregnancy, before and after birth, and clinicians' views of the feasibility, usability, acceptability, and barriers to implementing various induction protocols.

1.3.5 Study timelines and impact of the COVID pandemic

The Gantt chart below outlines the timeframes of the FM, qMOLI and MOLI studies. Due to significant governance challenges, all of the studies were delayed. In addition, the studies were also paused due to COVID, resulting in a significant reduction in the role of the FGDs in evaluating the FM training. Throughout the COVID pause, the study team evaluated the COVID situation to determine when it was appropriate to re-start each aspect of the studies; MOLI was re-started first, then qMOLI interviews and then approval to re-start the FGDs was sought last due to the nature and COVID risk of FGDs.

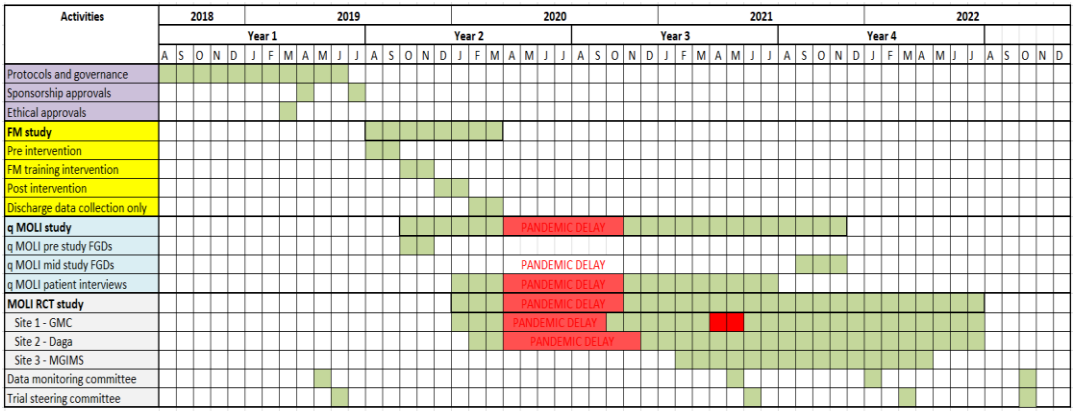

Figure 4 PhD Gantt chart

Summary

India is the second most populous country on earth, has 1/6 of the world's annual births and has the highest number of stillbirths. Therefore, improving maternal and newborn health in India is paramount for meeting the worldwide SDGs. Furthermore, India is such a huge country with such diversity that it is imperative that research is conducted in a setting where it can have maximum benefit. Applying research findings from other settings without fully understanding the context and implementation challenges, risks at best, and, at worst, harms. Both studies outlined in this thesis are sub-studies of a larger work programme to improve labour induction in Government urban hospitals.

1.4 Global trends in caesarean section (CS)

Appropriate caesarean section use is a lifesaving intervention and the most common surgical procedure in many countries. (38) However, rates have risen substantially worldwide since the 1970s and have doubled in the last 15 years. (38) The global CS rate is now 21% (29.7 million/year); this represents an increase of 3.7% each year. There is a large variation between countries (from 0.6% in South Sudan to 58.1% in the Dominican Republic). (38) The average ranges from 5% in sub-Saharan Africa to 42.8% in the Caribbean and Latin America. (39)

Even within countries, there are huge differences in access to CS, up to five times between the highest and lowest economic quintiles. (38) This "too much too soon, too little too late" paradigm highlights the unfair access to CS to those that need it and the lack of evidence-based practices globally. The overuse of CS is a global public health issue of significant international concern. Each year 6.2 million CS are conducted unnecessarily, and projections predict further significant rises. By 2030, 28% of births are expected to be CS,

and the sub-regions with the greatest expected rises include Eastern Asia (44.9%) and Western Asia (34.7%). (39)

1.4.1 What is the optimal CS rate?

Back in 1985, an expert group from the World Health Organization (WHO) and the Pan American Health Organization (PAHO) group met in Brazil to discuss the "unjustified and remarkable" increase in CS rates. This multidisciplinary group made many recommendations about appropriate technology for birth. It highlighted the importance of communication, a woman's right to choose, and the need to use technologies such as fetal monitoring carefully. (40) These experts made the widely quoted statement that there is no justification for any region to have a CS rate higher than 10-15%. (40) This reference range, intended for populations, has been widely interpreted as an optimum CS rate and used in error as a benchmark tool for facilities, regardless of the complexity of the patient load. The debate around the ideal CS rate continues as CS rates continue to rise. However, the WHO no longer recommends an ideal CS rate and instead recommends using Robson's ten groups to understand the complexities within CS rates. (41) There is currently no universally agreed classification for indications for CS, and research is ongoing in this area.

A systematic review of ecological studies found that CS rates were inversely related to maternal and perinatal mortality up to a point (9-16%). (42) However, this relationship disappeared when socio-demographic factors were adjusted. CS rates above 9-16% were not associated with improvements in mortality rates. However, although many citations were searched in this review, only eight studies were included, clinical and demographic aspects were not adjusted for, and data was unavailable on key perinatal and morbidity parameters and psychological and social impacts. The 2014 WHO group determined that instead of striving for particular rates, CS should be used for those "in need" on a case-by-case determination of individual clinicians.

1.4.2 Why are CS rates rising?

The reasons for the rising CS rate are complex and numerous; they are not only medical but fundamental societal, cultural, political and financial matters. The reasons are summarised in the diagram below, ranging from indications for CS and clinical factors, women, family and community factors, health professional factors, and organisational and system factors. (43)

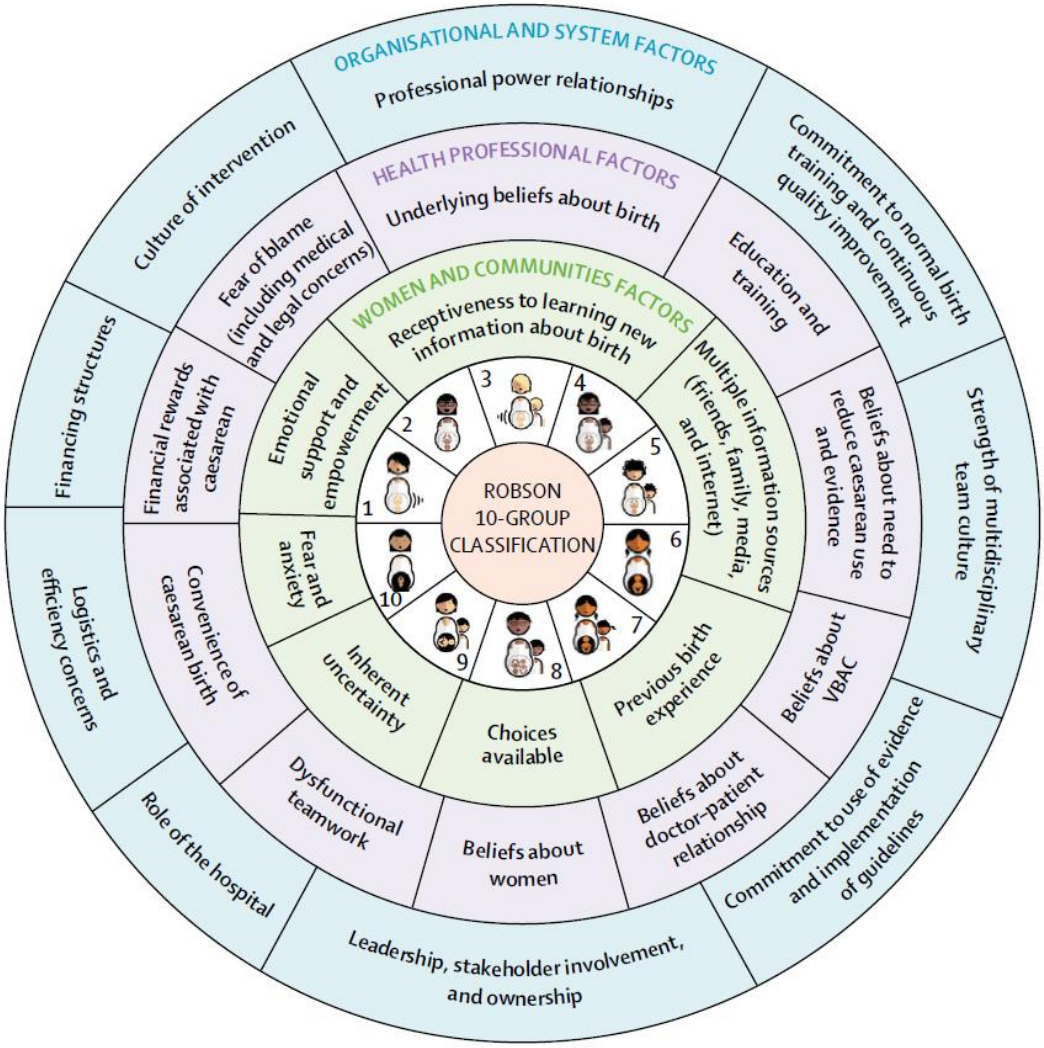

Figure 5 Factors that affect the frequency of CS. Source article (40)

Most women who request CS consider it safer for themselves and their babies. Some fear labour pain, have concerns about long-term pelvic floor effects such as incontinence or sexual function or have had previous traumatic birth experiences. (43) With CS, labour uncertainty is avoided, and timings can be planned. The relative safety of the procedure has increased, as have women's expectations. (44) Society's views are also changing; we often hear of celebrities who are "too posh to push" shared on social media. There are also numerous scandals and horror stories about catastrophic events during labour across the media. This erodes the trust and confidence of women in health care professionals and women's own self-belief that they can give birth vaginally.

Health systems play an important role; in many countries such as India, logistical and financial incentives often favour CS. The fees for CS are typically higher than vaginal birth, without staffing models to support continuous one-to-one care in labour. For obstetric-led

models, the clinicians must run their weekday daily work, including clinics, theatres and ward rounds, whilst simultaneously offering 24/7 one-to-one care during labour. Many units do not work with a staffing model which could support this. Midwife-led continuity models of care have been shown to reduce interventions and improve outcomes and satisfaction. (45) However, implementing this requires system change which is a huge challenge, even in high-income settings.

In settings where private practice dominates, such as Brazil, obstetricians have found CS requires less time and gives higher financial rewards. Therefore rates are as high as 77% in private settings. (46) A quote from a qualitative study summarises many of the issues:

> *"It's almost like the perfect storm. You're going to pay me more, I get to worry less, you're not going to sue me, and I'll be done in an hour." Obstetrician USA* (47)

Litigation and fear of litigation are rising globally; medico-legal issues are almost entirely related to vaginal birth. Society and often the legal profession believe that CS is protective; in courtrooms or even local risk meetings, why CS was not done sooner is frequently questioned. (43) As obstetrics has the highest litigation, even in low-income countries, this feature weighs on the minds of obstetricians and leads to "defensive medicine". Events such as maternal death in labour, intrapartum stillbirth and birth asphyxia are not tolerated by society and risk litigation. (48) Further increases are likely as our culture becomes increasingly litigious. (49)

The art of obstetrics is dying in many settings; young providers are not equipped with skills in vaginal birth, operative vaginal birth, interpretation of intrapartum fetal monitoring, especially CTG (44) and management of obstetric emergencies such as shoulder dystocia. Therefore, CS becomes the default for these clinicians. New generations of obstetricians are completing their training with an understanding that CS is quick, easy and associated with no blame and underconfident in managing labour ward complications and operative vaginal birth. Therefore this problem will perpetuate and escalate without appropriate training, supervision and mentorship.

1.4.3 Risks and benefits of CS

As CS rates rise, there is no clear evidence that outcomes for mothers and babies have improved: (44) (50) indeed, there is evidence of harm. (51) (52) One Swedish study showed cerebral palsy rates have not decreased since the 1950s; despite this increase in CS, this is

especially clear for term infants. (50) CS is associated with increased mortality risk and severe acute morbidity in the index pregnancy. It is also associated with poor outcomes in future pregnancies. (53) Intrapartum CS has a four times higher risk than a vaginal birth, and planned CS has a lower mortality risk than intrapartum CS. (53)

The increased maternal risks associated with CS compared to vaginal birth quoted in the NICE guideline include; peripartum hysterectomy 150 vs 80 women per 100,000, maternal death 24 vs four women per 100,000, length of hospital stay 4 ½ days vs 2 ½ days, placenta accreta 100 vs 40 women per 100,000, uterine rupture 1020 vs 40 women per 100,000. (54) The neonatal increased risks with CS include; neonatal death 50 vs 30 per 100,000 children, asthma 1810 vs 1500 per 100,000 children and childhood obesity 4560 vs 4050 per 100,000 children (54). Other systematic reviews have also highlighted an increase in miscarriage (OR 1.17, 1.03 to 1.32) and stillbirth (OR 1.27, 1.15 to 1.40). (55) However, these rates must be interpreted cautiously, as the comparison of planned and successful vaginal birth vs elective CS does not include the significant number of women who will plan vaginal birth and undergo emergency operative birth. Infants delivered by CS are not exposed to different factors, including drugs, microbiome, physical and endocrine, which can lead to altered immune system development, leading to atopy, asthma, allergy and altered gut microbiome. Emerging research suggests these factors may impact long-term childhood chronic disease development, including autoimmune disease and obesity. The comparison of vaginal delivery vs planned CS is flawed; not all planned vaginal deliveries result in vaginal delivery. However, it is well documented that the risks of operative deliveries are higher. (56)

Benefits of CS include; less urinary incontinence at one year after birth 27,520 vs 48,700 per 100,000 women, fewer third and fourth-degree vaginal tears 0 vs 560 per 100,000 women, and reduced pain on a ten-point visual analogue scale during birth (by seven points) and three days postnatal (by one point), with no differences at four months. (54) Most of the studies described above were in high-income settings, and the risks of CS are far greater in low-income settings. Although the risk of death is low in high-income settings, it is disproportionately high in low-income settings, even as high as 50 times more in Africa. (56) (57) Morbidity also disproportionately impacts women in LMIC. (58) The WHO Global Survey found that the risk of maternal mortality and morbidity index was increased for operative vaginal births and all types of CS. (28)

1.4.4 What can be done to reduce CS rates?

The WHO has released its first-ever non-clinical intervention-based guideline to address the rising CS rates. It highlights the importance of "comprehensive health education, including tailored information and support about childbirth fear, pain relief, and the advantages and disadvantages of caesarean sections". It also recommended mandatory second opinions for CS, audits, evidence-based guidelines, feedback loops and equal financial remuneration for both vaginal and CS birth. (59) As a result, the significance of non-clinical health care interventions such as respectful care, multidisciplinary care, labour companionship and addressing pain and fear have been elevated. In addition, numerous studies have shown potential benefits of midwifery-led care and continuity of care, such as less regional anaesthesia, instrumental birth and pregnancy loss before 24/40 and higher spontaneous vaginal birth and maternal satisfaction. (45) (53) FIGO has also published a position paper about stopping the CS epidemic, recommending equivalent delivery fees for CS and vaginal birth in Government and private practice, obligations to publish CS rates and risk-adjusted CS rates, and the use of uniform classifications such as the WHO-recommended Robson's ten group classification, fully informing women of the benefits and risks, and investment in resources, birth preparation, analgesia, practical skills training and re-introducing operative vaginal birth. (60)

1.4.5 Indications for CS and Robson's criteria

Most of the data on indications for CS before the use of the TGCS highlight that most CS are done for the following indications; previous CS, labour dystocia, fetal monitoring concerns, malpresentation, multiple pregnancy and macrosomia. (61)(62)(63) It is acknowledged that there is no consensus from obstetricians on the indications for CS or how these are applied. As a result, data from different teams are inconsistent, and there are often multiple indications for CS. Comparing overall rates and sub-groups of populations is also flawed, as there are differences between obstetric populations and case mixes. To reduce these inconsistencies and allow comparison of CS rates, the WHO has recommended using the TGCS since 2015 as a global standard for assessing, monitoring and comparing CS rates across nations and institutions. (41) Women giving birth in health facilities are mutually exclusively grouped into ten groups according to their obstetric characteristics (parity, gestational age, previous CS, the onset of labour, fetal lie and presentation and the number of fetuses), as outlined in the diagram below. This permits the assessment of the appropriate CS rates. Groups one to five all have term, singleton cephalic fetuses. Groups

one and two are both nulliparous women who either labour spontaneously (Group 1) or after induction or elective CS (Group 2); groups three and four are the same as one and two, except that they are parous women with no previous CS; and group five is the parous women with at least one previous CS. Groups six to ten are the more specialist groups: groups six and seven are singleton breeches (Group 6 nulliparous, group seven parous including those with previous CS); group eight includes all multiple pregnancies; group nine comprises of those with a transverse or oblique lie, and group ten comprises of all preterm births. (64) The threshold for medically indicated CS has decreased over time.

A secondary analysis of the WHO multi-country survey across 287 facilities in 21 countries found CS, pre-labour CS, and IOL increased across all human-development index groups. (65) Key drivers are increasing interventions in the nulliparous groups and increasing previous CS rates.

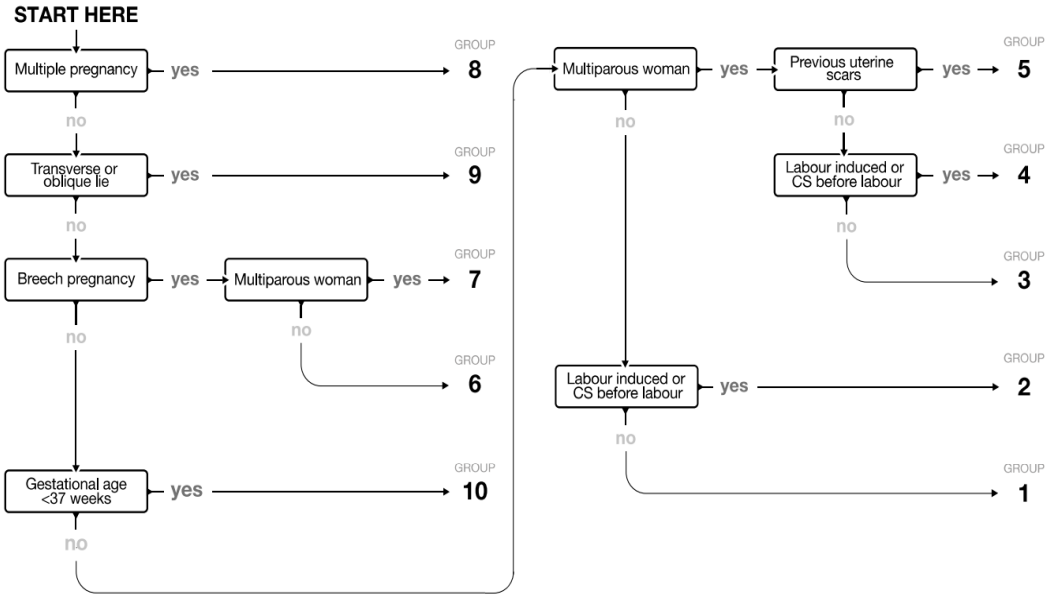

Figure 6 Flow chart for the classification of women in the WHO Robson's ten group.

Source WHO TGCS Implementation Manual (61)

1.4.6 Caesarean section in India

The CS rate in India is 17.8% (28) and rates have risen quickly over the last ten years from 8.5% in 2005-06 (28). In Maharashtra, the CS rate in 2015-16 was 26.3% in urban areas and 15.2% in rural areas. (29) The National Family Health Survey, 2015-2016, collects cross-sectional data, similar to the District Health Survey, across 15 states in India and also showed a CS rate of 17.1%. (31) It drew attention to the marked difference between Government

and private settings; 41.0% in private facilities vs 11.9% in Government. (31) CS rates are higher in urban areas, private hospitals, and in more educated women. (66) Other studies show higher CS rates for primigravidas, higher maternal age, higher BMI, maternal education of secondary school or higher and multiple gestations in India. (67) Although most studies show the most common indications for CS are previous CS, labour dystocia, fetal distress and malpresentation (63), the rates vary between centres. For example, in one hospital in Gujarat, fetal distress was the most common indication for CS (31.2%), with previous CS second (23.9%), malpresentation (breech/transverse) 21.2% and prolonged/obstructed labour (13.7%). (68) A population-based cohort from Eastern Maharashtra demonstrated a CS rate of 20% and the single most likely indication for CS was prolonged/obstructed labour for 63%, and between 6-10% did not have a clear indication. (67) However, this data was taken from the discharge summary, and only one indication was recorded.

More recently, several papers from India use Robson's ten groups to classify CS rates. In one study of 81,784 births in Northern India, the CS rate rose from 22.4% to 25.5% between 2015-2017, and Group five (previous CS) were the biggest contributor (29.4% overall rate.) Group two accounted for 22% and then group one 12.2% overall. (69) The authors calculated a further 0.9% rise annually. Other TGCS analyses from India demonstrated rates of 37.6% (70), 40% (67) and 25.7%. (71)

1.4.7 Women's perspectives on mode of birth

Globally, most women prefer vaginal birth, and these women associate CS with fear and loss of control. (72) (73) Vaginal birth is seen as "natural" and even a "transcendent and empowering" experience or part of a "good mother imperative" or "God's power". (72) (73) However, as CS becomes safer and more accepted by women and society, women's preference for CS is also increasing globally. (74) One meta-analysis found an overall preference for CS in 16% of women, with higher preference rates in middle-income countries (21%). Although, this paper reports MOB preferences rather than requests for CS, which are far lower. (75) Other systematic reviews of MOB preferences quote a median rate of CS requests for nulliparous women in the absence of clinical indication as 9% (76) and 0.3-14% in another. (72) (75) A thematic synthesis of women's MOB preferences included 52 studies, including 24 from LMIC countries. The authors concluded that major factors for some women choosing CS were "deep-rooted fears towards vaginal birth", including pain, injury to the mother or child, and loss of control. The uncertainty of vaginal birth and perceived advantages of CS included planning, reduced anxiety and more fetal safety. Social, cultural,

personal and health system factors all played a role (77) and planned CS was used to ensure the quality of care. (73) A further scoping review on women's MOB preferences and the underlying reasons for their preference outlined six reasons women choose CS; perception of safety, fear of pain, previous experience of birth, HCP encouragement and dissuasion, socio-cultural influences and information access/education. (78)

No studies from India were included in any of the reviews described above. However, a questionnaire survey of 100 antenatal women found most women preferred vaginal birth viewing it as natural and acceptable, and CS could cause more long-term problems. (77) Women gained their knowledge from family and friends. (77) (79) Another study showed that women did not know much about MOB. (80)

1.4.8 Clinicians' perspectives on mode of birth

Most obstetricians also prefer vaginal birth in the absence of risk factors for CS. (81) However, the fear of litigation, perception of CS being a "safe" option for childbirth, obstetricians' convenience, and women's request for CS have all been highlighted in literature reviews. (82) Themes in a Vietnamese study highlight the "mental strain of obstetricians". (83) A Tanzanian study demonstrated that both women and clinicians preferred NVD; however, they both justified the risks of CS to deliver a healthy baby. Clinicians shared they sometimes do CS with unclear indications due to fearing blame and dysfunctional teams. (84) The authors conclude that to improve excessive CS rates, clinicians must recognise their roles as key decision-makers and act to reduce rates. A review of clinicians' experiences of interventions to reduce CS rates highlighted that three key themes were important in determining the mechanisms or resistance to change; their "underpinning philosophy of birth", "social and cultural context", and "negotiation within the system." (85) Some women also describe that clinicians prefer CS due to the "combination of uncertainty, fear, and medical and non-medical information against vaginal birth" and clinicians' fear of blame. (73)

Summary

The "too much too soon" paradigm is very relevant to the Indian context, with rising CS rates and significant potential harms. There are complex medical, social, cultural, political and financial reasons for this. But the existing literature suggests this is not what women want. However, the Indian literature is weak, and no qualitative studies from India were included in any of the multinational reviews. The WHO focus is now not only on surviving

birth but thriving through birth, with the elevation of women's experience to a key factor. Therefore, understanding why CS rates are rising, and women's perspectives on this are important. If a context-specific understanding of drivers does not exist, interventions devised to curb the trend may not be relevant or appropriate.

1.5 Intrapartum fetal monitoring

Intrapartum fetal monitoring is a critical aspect of maternity care globally, and it is universally recommended to assess fetal health throughout labour. However, there are significant controversies around conducting high-quality intrapartum fetal monitoring within clinical practice and literature.

1.5.1 Why is intrapartum fetal monitoring necessary?

Intrapartum fetal monitoring aims to identify inadequate fetal oxygenation so that timely intervention can be undertaken to avoid fetal hypoxic-ischaemic encephalopathy (HIE) and perinatal death. At the same time, it is also important to identify adequate fetal oxygenation so that women and babies are not exposed to unnecessary interventions and iatrogenic harm. (86) Fetal monitoring is fundamental, routine practice internationally and to not monitor fetal health during labour would be universally considered incomprehensible and indefensible. Metabolic acidosis, HIE and intrapartum deaths have decreased in some centres where fetal monitoring during labour has been optimised. (86) However, the evidence for the benefits of intrapartum fetal monitoring methods remains inconclusive.

1.5.2 Adverse fetal outcomes related to intrapartum fetal hypoxia

As fetal oxygenation in cells cannot be measured directly, fetal metabolic acidosis is typically diagnosed using blood collected from the umbilical cord within the first minute of life when the pH is below 7.00, and the base deficit is 12mmol/litre or more, or the blood lactate is above ten mmol/l. (87) Cord pH is routinely measured in many high-income settings after birth or emergency operative birth. However, the equipment is expensive and typically unavailable in most low-and-middle-income settings.

The APGAR score is an accepted tool that should be undertaken on all babies at one minute and five minutes after birth to evaluate the baby's status and response to resuscitation. Five parameters are used: colour, heart rate, reflexes, muscle tone and respiration. A poor APGAR score should not be used as evidence of asphyxia and does not predict mortality or

neurological sequelae. (88) However, the APGAR score is often used as a proxy marker when pH is unavailable. There are many reasons for low APGAR scores, including congenital abnormalities, prematurity, birth trauma, maternal medications, etc. However, prolonged and significant hypoxia will lead to low APGAR scores. Low five-minute APGAR scores are more closely associated with perinatal mortality and neurological complications than low one-minute APGAR scores. (87)

Most babies with metabolic acidosis at birth will have no short or long-term consequences, and it will resolve quickly. Only a small number will have sustained a long or serious enough hypoxia to cause long-term neurological impact or death. Hypoxic ischaemic encephalopathy (HIE) is a short-term neurological condition caused by intrapartum hypoxia/acidosis. It is diagnosed using a combination of metabolic acidosis in cord/neonatal blood, low APGAR scores, cerebral oedema on imaging, and changes in tone/sucking movements/seizures/coma in the first 48 hours of life. Perinatal death and cerebral palsy (typically spastic quadriplegic/dyskinetic) are the primary adverse outcomes clinicians try to avoid using intrapartum fetal monitoring. But despite the huge fear and litigation, only 10-20% of cerebral palsy is due to intrapartum hypoxia. Other causes, such as prematurity, congenital anomalies, infection, medical disorders, antenatal/postnatal hypoxia and birth trauma, are far more common. (87)

1.5.3 Fetal physiology

The fetus is highly adapted to intrauterine life and can maintain a stable environment. It has a higher concentration of haemoglobin (which transports the oxygen) and a higher affinity for oxygen than the mother. The fetal heart pumps deoxygenated blood (low oxygen, high pCO2, low pH) to the placenta via two umbilical arteries. Free oxygen exchange occurs at the placenta's maternal-fetal interface, and the umbilical vein carries oxygenated blood back to the fetus (higher p02, lower pCO2, higher pH). Fetal tissues use oxygen and glucose to create energy in aerobic metabolism, and carbon dioxide is a waste product. In the fetal cells, most CO_2 and H_2O undergo a further reaction, producing hydrogen ions and bicarbonate ions. These toxic hydrogen ions are usually buffered in the cells, and the bicarbonate ion passes into the extracellular fluid. Usually, the fetus is relatively oversupplied with oxygen. Still, when oxygen becomes scarce, the fetus extracts more, centralises circulation to spare vital organs (heart, brain and adrenals) and may conserve energy (less growth and movements). Then it uses anaerobic metabolism; glycogen (from the liver and heart) is metabolised to glucose and lactic acid.

Reductions in oxygen supply are typically grouped into three types: hypoxaemia (reduced oxygen in the blood but normal cell and organ function); hypoxia (reduced oxygen and anaerobic metabolism, in peripheral tissues primarily); and asphyxia (hypoxia involving central organs such as the heart, brain and adrenal glands, which can lead to metabolic acidosis). (89) The fetal response to hypoxia is behavioural, cardiovascular and metabolic. The extent of the injury is determined by whether hypoxic-induced hypotension occurs. (89)

Normal gaseous exchange can be affected at three main points: the mother, placenta and fetus. For the mother, systemic conditions affecting uterine perfusion, e.g. hypotension from sepsis, maternal position, epidural, local factors affecting perfusion to the uterus, e.g. contractions and chronic impairment. For the placenta, fetal circulation can be affected by conditions such as pre-eclampsia, increased placental resistance and slowed blood flow. Finally, fetal reasons include cord compression, fetal bradycardia, fetal arrhythmia, heart block and fetal anaemia.

1.5.4 A brief history of intrapartum fetal monitoring

In the first part of the 20th century, it became routine care to auscultate the fetal heart in labour; (90) therefore, few high-quality studies compare different methods with no fetal monitoring. Continuous cardiotocography (CTG) was developed and widely implemented in the 1960s. Many randomised controlled trials (RCT) were undertaken on low-risk women in the 1960s/1970s, comparing CTG and intermittent auscultation (IA). (91) However, intervention rates, outcomes and clinical practice differed greatly from current practice. Phonocardiography was used for the early CTGs, but the Doppler quickly took over due to issues with signal loss.

1.5.5 Fetal monitoring methods overview

There are broadly two main types of fetal monitoring during labour; intermittent and continuous, and both aim to detect the hypoxic baby. In most low-income settings, the primary method is intermittent auscultation (IA), using a stethoscope (standard or Pinard) or a Doppler. It involves listening to the heart at regular intervals during labour. The frequency of auscultations should increase in the second stage of labour (during active pushing), as a hypoxic injury is more common at this time. Intrapartum continuous electronic fetal monitoring is standard practice in most high-income countries (HIC) around the globe and increasingly in India. Despite the lack of conclusive evidence for this practice,

it is used by most women in the United States of America (92) and high-risk women in the UK. (93)

1.5.6 Intermittent auscultation

The fetal heart can be heard directly by amplifying the sound with a Pinard or fetal stethoscope or indirectly using ultrasound to detect fetal heart movement through doppler shift, e.g. Doppler sonic aid. The Doppler probe emits high-frequency ultrasound waves, which the operator directs through the fetal heart. The sound waves pass easily through soft tissues but are reflected to the transducer by denser structures such as the fetal heart. During atrial and ventricular contractions, the heart's movement changes the frequency of the reflected waves (Doppler shift). If the fetal heart wall moves towards the transducer, the waves are "compressed" to a higher frequency. As the fetal heart muscle is contracted, it moves away from the transducer; the wave is "stretched" to a lower frequency. The Doppler and CTG calculate the difference between the larger ventricular beats and determine how many beats would occur in a minute if the rate were constant. Clinicians should regularly listen for regularity, rhythm, accelerations, decelerations, and fetal movements, then calculate the rate, which should be recorded as a single number. Although not outlined in the literature, the adult stethoscope is often used for intermittent auscultation in India.

The advantages of the Doppler are that it shows a calculated rate, minimal skill is required, waterproof probes exist, and everyone can hear the sound. The disadvantages are that it requires batteries (although a wind-up version exists), it is more expensive, harder to clean, a gel is required (which is an additional cost), and poor signal or misplaced transducer placement can cause doubled or half-counting.

The Cochrane review on IA included three RCTs. It concluded that IA with Doppler (battery and wind up) and intermittent CTG (holding the transducer onto the abdomen and listening, with no paper recording) were associated with higher CS rates with no immediate health benefit to the mother or child. (94) There is not enough available information on the timing of IA (how often, how long and when exactly), which tool is superior and how to train staff in the optimum usage (94) and that, further large, RCTs are required on this topic, especially in low-income settings. A further Cochrane review highlighted that there are no benefits of an admission CTG for low-risk women, and admission CTG rather than IA leads to an increase in the CS rate in this group. (95)

1.5.7 Electronic fetal monitoring

The CTG consists of an electric machine with two transducers. The "cardio" transducer is an external ultrasound which measures the fetal heart rate and is printed as line A on the graph below. The tocodynamometer, an external strain gauge, is usually strapped onto the uterine fundus, which measures the frequency of uterine contractions, but not the amplitude or length. These are displayed on line D below. Typically two belts are strapped around the woman's abdomen using elasticated belts, although wireless, waterproof versions are used in some HIC. Intrauterine pressure catheter monitoring to monitor contractions is not beneficial and is therefore not recommended. (96)

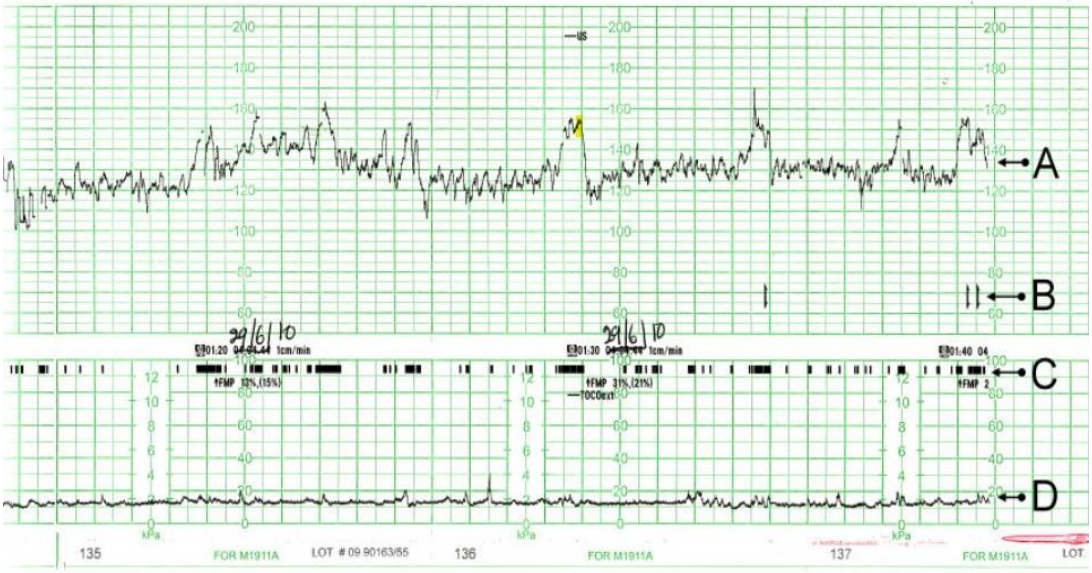

Figure 7 A cardiotocograph. Source website (91)

Other lines on the CTG above are B, which is not present on all CTGs and demonstrates when the woman has pressed a button to show she felt a fetal movement. Finally, line C demonstrates fetal movement, as detected by the CTG machine.

It is frequent for the external transducer to not pick up the fetal heart rate well, often due to maternal position or raised body mass index in labour. If the membranes are ruptured, a fetal scalp electrode (FSE), or internal fetal monitor, can be attached to the fetal head; if there are no contra-indications such as blood-borne infections, extreme prematurity or suspected fetal bleeding disorders (98), and the cervix is open. The FSE is a direct electrocardiogram (ECG) of the fetal heart, which measures the R to R ratio.

1.5.8 Antenatal CTG

Antenatal CTG (during pregnancy) is one of the most commonly used tools to assess fetal well-being in high-risk pregnancies after 26 weeks of gestational age. However, it should not be used for low-risk pregnancies, and there is no high-quality evidence that antenatal CTG improves perinatal outcomes, even in high-risk women. (99) Four features are systematically assessed, including baseline variability, baseline rate, presence of accelerations and decelerations, and uterine activity to determine if the fetal heart is "reactive" or "non-reactive". A non-reactive CTG does not necessarily mean fetal compromise but requires investigation.

Computerised CTG (cCTG) has added software to categorise antenatal CTG traces and alarms in specific scenarios. Computerised CTG provides objective data, reduces variation between observers, and predicts low APGAR scores and cord pH more accurately. It is recommended by NHS England and Saving Babies Lives Bundle to reduce human error, which supports junior health care workers (HCWs) and can prompt seniors to re-think their initial impressions. The Dawes-Redman criteria assess short-term variability, baseline heart rate, accelerations, decelerations, fetal movements, sinusoidal patterns and trace quality. The computer applies the criteria at 10 minutes; then, if they are not met, the analysis re-occurs every one to two minutes until the criteria are met. For example, if the criteria are not met by 60 minutes, it will stop and be classified as not having met the criteria. The cCTG cannot be used if there is any pain/uterine activity.

1.5.9 Intrapartum CTG parameters

Understanding the CTG parameters is essential, but understanding the overall clinical picture is far more important. Individualised management of each clinical scenario is needed, rather than actions in response to specific patterns on the graph. (100) The same four parameters are evaluated on the antenatal CTG, but different patterns are normal in labour, which would not be normal on an antenatal CTG.

Baseline heart rate is the fetal heart rate (FHR) fluctuation around the baseline of 110-160 beats per minute and is controlled by the autonomic (sympathetic and parasympathetic) nervous system. It is influenced by gestation and is ten beats lower at term than 28/40.

Variability is the fluctuation of the FHR around the baseline, typically 5-25 bpm. A normal fetus fluctuates between reduced and normal variability, the periods of reduced variability

lengthen as gestational age increases, and periods of up to 40 minutes can happen at term. The behavioural cycle of the fetus includes the active behavioural state (active sleep and wakefulness) and quiet sleep/quiescence. Cycling between these behavioural states demonstrates that the central nervous system is mature and intact.

Reduced variability (2-4 bpm) can be normal due to fetal quiescence or maternal drugs, or if it continues over 50 minutes/is accompanied by other features can be a sign of hypoxia. Absent variability <2 bpm is more concerning and necessitates a prompt assessment. Variability is more accurately assessed on FSE than on Doppler. By USS, it is less precise and tends to be overestimated. Nevertheless, it is the single most helpful parameter, and normal variability is unlikely to be associated with cerebral hypoxia. (93)

Accelerations. A normal, accelerative trace is good evidence that a fetus is well-oxygenated, and the central nervous system (CNS) is intact. Over 32/40, accelerations are defined as "an increase in fetal heart rate above the baseline of at least 15 beats per minute for at least 15 seconds, where the period from onset to the peak is within 30 seconds." It starts and ends on a stable baseline. Before 32/40, the definition is similar, but with a rise in 10 bpm baseline for 10 seconds.

Decelerations are a temporary decrease in the fetal heart rate below the baseline. FIGO defines it as "a baseline drop of more than 15 beats per minute for more than 15 seconds." During a contraction, uterine vessels are compressed, perfusion of the placental bed is impaired, and the cord and head are also compressed. Decelerations are the parameter with the most difference in classifications – the definition of an early, late, or variable varies globally along with their nomenclature. Early decelerations are benign, uncommon (less than two percent), and caused by head compression. They commence with the contraction onset and return to baseline at the end of the contraction. For late decelerations, the nadir of the deceleration comes after the peak of contractions, and there is often a lag time to return to baseline. Late decelerations are more associated with hypoxaemia and acidosis, particularly when there is a change in the variability or rise in the baseline. In addition, late decelerations tend to be chemoreceptor decelerations, which directly impact hypoxia in the myocardium.

Variable decelerations are the most frequent type and vary in length, morphology and timing with contraction. There is different terminology within different guidelines; however, variable decelerations may have "non-concerning" or "concerning" features.

"Non-concerning/ typical/uncomplicated" decelerations have shouldering (an initial rise followed by a sharp fall, then quick rise), last for less than 60 seconds, and are mediated by baroreceptor reflex via the vagus nerve, caused by compression or mechanical pressure. There is no shouldering for "atypical/concerning" variable decelerations, the drop can be below 60 bpm, and the recovery to baseline may be prolonged. The pathophysiology is a mixed baroreceptor/chemoreceptor mediated response; if prolonged or recurrent, there may be a component of acidosis.

	Normal CTG[a]	**Suspicious CTG**	**Pathological CTG**
Baseline[b]	110-160 bpm	Lacking at least one of normal characteristics, but with no pathological features	<100 bpm
Variability[c,d,j]	5-25 bpm		Reduced/increased variability[c,d]; sinusoidal pattern[j]
Decelerations[e,f,g,h,i]	No repetitive* decelerations		Repetitive* late or prolonged decelerations for >30 min (or >20 min if reduced variability); one deceleration >5 min
Interpretation	No hypoxia/acidosis	Low probability of hypoxia/acidosis	High probability of hypoxia/acidosis

Figure 8 The 2015 FIGO intrapartum cardiotocography classification system. Source – FIGO guideline (87)

1.5.10 Methods comparison

A widely quoted Cochrane review on electronic fetal monitoring during labour included 13 trials and over 37,000 women, but only two of these studies were of high methodological quality. (91) Twelve trials compared continuous CTG with IA and found no difference in perinatal death rate or cerebral palsy. Still, neonatal seizures were halved (RR 0.50, 95% CI 0.31 to 0.80, N = 32,386, nine trials, moderate quality evidence). Continuous CTG was associated with increased caesarean sections (RR 1.63, 95% CI 1.29 to 2.07, N = 18,861, 11 trials, low-quality evidence) and instrumental vaginal births (RR 1.15, 95% CI 1.01 to 1.33, N = 18,615, 10 trials, low-quality evidence). One trial compared intermittent to continuous CTG and found no difference in CS rates or instrumental births. The authors questioned whether future studies should focus on efficacy (intrinsic value of CTG in ideal conditions) or effectiveness (the effect in routine practice.) (91)

The Dublin trial, 1985 (101), was an RCT of 12,964 women randomised to either continuous electronic fetal monitoring (EFM) or intermittent auscultation; both had access to fetal blood sampling (FBS). Women in the EFM group had shorter labours and received less analgesia. CS rates were similar, EFM 2.4% vs IA 2.2%, with higher numbers of babies with a scalp pH of less than 7.2 accounting for this difference. There were more forceps in the EFM group, 8.2% vs 6.3%, due to FM concerns. There were no differences in neonatal deaths (NND)/stillbirths (SB)/low APGAR scores, resuscitation or NICU admission. There were twice as many babies in the IA group with seizures with persistent abnormal neurology at one-year postnatal follow-up. (101)

1.5.11 Adjunctive technologies

When a CTG is normal, it is reassuring that the fetus is coping well. However, the outcome is far less clear when it is abnormal, and the chance of hypoxia is higher, to varying degrees. Therefore, due to the high false positive rates, adjunctive technologies have been developed; fetal blood sampling, fetal scalp stimulation (FSS), and ST wave ANalysis (STAN).

NICE (93) and RANZCOG (86) recommend considering fetal blood sampling (FBS) for some cases when the CTG is abnormal to help determine if the fetus is responding to stress or being compromised. Although the role of FBS is now increasingly being debated and it is used less frequently. A capillary blood sample is taken from the fetal scalp, and the blood gas analyser measures the pH or lactate. The correlation between scalp pH and cord pH after birth is good. However, there is some evidence that capillary blood is affected by the redistribution that occurs in hypoxia and scalp pH/lactate does not always represent the central fetal pH. Meta-analysis shows that when comparing CTG alone to CTG with FBS, there is no decrease in CS; there was an increase in instrumental births but less neonatal hypoxia. (91)

Fetal acoustic stimulation (FAS)/ vibroacoustic stimulation (VAS) is an audio device that buzzes and should elicit an acceleration. It can reduce the incidence of non-reactive CTGs. (102) Guidelines recommend digital fetal scalp stimulation (FSS) to determine fetal well-being when there is “suspected fetal compromise”, and a Cochrane review is ongoing to evaluate its effectiveness. (103)

Fetal ECG monitors the fetal heart’s electrical activity during labour via a fetal scalp electrode (FSE). Hypoxaemia can alter the ECG waveform, especially regarding the PR to RR

intervals and depression or elevation of the ST segment. Seven RCTs, including 27,403 patients, were included in a Cochrane review that found fetal ECG was associated with reduced fetal blood sampling and operative vaginal birth but no difference in caesarean section rates and perinatal outcomes. (104)

Expert systems (ES), applied artificial intelligence decision support software, have been developed to assist interpretation of CTGs, and overcome the low sensitivity (86) and high inter and intra-observer variability. (105) However, a Cochrane review of expert systems in 2015 only found two studies: one was underpowered, and the other did not provide data on relevant outcomes. (105) The INFANT study included 47,062 women randomly assigned to either decision support or no decision support across 24 sites in the UK and Ireland. (106) There were no differences in outcomes between the women and babies in either group. Before the study, the INFANT team had hypothesised that sub-standard care would largely be due to not identifying pathological CTG patterns; however, the INFANT data did not support this. Instead, most sub-standard care was related to inappropriate decisions after recognising the abnormality. (106) The results of the INFANT study are critical, as they suggest that difficult interpretation of the CTG is not the problem, and even artificial intelligence and computer-based interpretation of CTGs do not improve outcomes.

1.5.12 International intrapartum fetal monitoring clinical practice guidelines (CPGs)

It is accepted that healthcare professionals can improve outcomes (107) and resource efficiency (108) by following evidence-based guidelines. CPGs are "statements that include recommendations, intended to optimise patient care, that are informed by a systematic review of evidence and an assessment of benefits and harms of alternative care options". (109) However, guidelines for fetal monitoring are a particular cause of controversy, with some trusts in the UK opting to base their local guidelines on FIGO clinical practice guidelines (110) or others, e.g. physiological (111), rather than the standard practice of adopting NICE (93) recommendations. This is relevant for the Indian setting, as creating high-quality guidelines is expensive and time-consuming. (112) As a result, India does not have its own standard national guidelines. NICE/RCOG guidelines are therefore often informally followed – but this means that implementation is often challenging. (113)

A recently published systematic review demonstrated notable variation between seven national/international intrapartum electronic fetal monitoring guidelines. (114) The Appraisal of Guidelines for Research and Evaluation (AGREE) criteria varied between 25-

89%. The authors concluded that all guidelines were essentially trying to describe similar characteristics with some differences. (114) The authors found mild variations in consensus about actions to be taken when fetal monitoring is abnormal (see table below).

Variable	SOGC (Canadian)	ACOG (American)	NICE (British)	FIGO	RANZCOG (Australian)	GOGS (German)	CNGOF (French)
Acceleration Normal or reassuring (category 1)	Spontaneous acceleration but not required or scalp stimulation	Acceleration present or absent		Abrupt	15 bpm for 15 sex	2 bpm in 20 min	Present
Acceleration Suspicious, atypical, or nonreassuring (category 2)	Absence of acceleration with scalp stimulation	Absence of Acceleration after stimulation				Periodic with every contractions	Present or absent
Acceleration Abnormal or pathologic (category 3)	Usually absent (if present, do not change classification)					None >40 min (unclear significance)	Present or absent
Interpretation or action Normal or reassuring (category 1)	No evidence of fetal compromise	Strongly predictive of normal acid base status May be monitored in routine manner No specific action	All 3 features are normal or reassuring normal CTG, no nonreassuring or abnormal features, healthy fetus Continue normal care	Fetus with no hypoxia or acidosis No intervention necessary to improve fetal oxygen state	Low probability of fetal compromise	All 4 evaluations are normal Action: none	Continuous CTG monitoring
Interpretation or action suspicious, atypical, or nonreassuring (category 2: low risk of acidosis)	Physiological response	Requires evaluation May require ancillary test of fetal well-being like PH or lactate	1 nonreassuring feature and 2 normal or reassuring features Combination features with increased risk of fetal acidosis Action: assess conservative measures	Fetus with low probability of hypoxia or acidosis Correct reversible causes, close monitoring or additional methods to evaluate fetal oxygenation	Unlikely to be associated with fetal compromise when occurring in isolation	At least 1 evaluation criteria suspected and all other normal Action: conservative	Resuscitation, if no improvement for further actions
Interpretation or action Abnormal or pathologic (category 3: moderate or High risk of acidosis)	Possible fetal compromise	Abnormal fetal acid base status Requires prompt evaluation, include resuscitative measures or delivery	1 abnormal feature or 2 nonreassuring features Abnormal and needs conservative measure with further testing Assess conservative measures Offer to take an FBS (for lactate or pH) or delivery	Fetus with high probability of hypoxia or acidosis Action to correct acidosis or delivery	Associated with significant fetal compromise and need further action Identify reversible cause and initiation of appropriate or urgent delivery	At least 1 evaluation criterion pathologic or 2 or more suspicious Action: conservatively and invasive	Immediate further actions if high risk of acidosis or immediate fetal extraction if further action not indicated

ACOG, American College of Obstetricians and Gynecologists; *CNGOF*, National College of French Gynaecologists and Obstetricians; *CTG*, cardiotocography. *DGGG*, German Society and Gynecology and Obstetrics; *FBS*, fasting blood sugar; *FIGO*, Federation of Gynecology and Obstetrics; *NICE*, National Institute for Health and Care Excellence; *RANZCOG*, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; *SOGC*, Society of Obstetricians and Gynaecologists of Canada.

Color codes

	Generally similar consensus
	Some variations in consensus
	Marked variations in consensus

Mohan. Electronic intrapartum fetal monitoring. Am J Obstet Gynecol Glob Rep 2021.

Figure 9 Example of variations in intrapartum fetal monitoring clinical practice guidelines. Source article (111)

Several studies have demonstrated the potential impact of different guidelines on inter- and intra-user variability and outcomes. For example, the use of the FIGO guideline resulted in less inter-observer variability and potentially less unnecessary CS than the French CNGOF guideline. (115) In addition, the FIGO 2015 showed better agreement scores, perceived ease of use and moderate intervention rates than the two previous NICE guidelines. (116) However, the overall prediction of cord acidosis from the last 60 minutes of CTG was poor, and there was high inter and intra-user variability. (117)

The WHO does not recommend continuous CTG during labour due to the lack of evidence that it improves perinatal outcomes. Instead, it recommends IA with Doppler or Pinard for at least one minute, every 15-30 minutes of the first stage of labour and every five minutes in the second stage. (22) WHO recommend noting the numeric baseline rate, the presence of accelerations or decelerations, and listening during and after three contractions if the range is not between 110-160. The guideline development group highlighted that intermittent fetal heart monitoring in labour, with adherence to strict protocols, is essential, irrespective of the method used.

1.5.13 Fetal monitoring in low-and-middle-income countries (LMIC)

Lack of good FM in labour is widespread in most LMICs (118) (119); it is a hallmark of inadequate quality of care. In systems where one-to-one continuous care in labour is unavailable, the frequency of monitoring recommended in the international practice guidelines is highly challenging due to inadequate staffing and high workload. In addition, fetal monitoring technology can be expensive and requires maintenance, power and consumables.

A systematic review and SWOT analysis on intrapartum FM in LMIC concluded that FM must be "simple, affordable, robust, safe, reliable and sustainable." IA and the partograph are the preferred strategies for this, due to reduced stillbirths, lower CS rates and easier implementation. (120) CTG in LMIC increases CS rates but does not improve perinatal mortality. (120) The authors highlight that more studies in LMIC are needed and that they should focus on implementation aspects. Evidence is lacking, and practice is typically guided by culture and high-income practices. Observational studies suggest that admission testing has a greater role in LMIC and can predict adverse outcomes and mode of birth. This is because of the increased frequency of poor outcomes, poor antenatal risk assessment and as a triage tool in heavy workload, low resource settings. Only a few trials

look at CTG use in LMICs. None were identified that evaluated the pragmatic intermittent CTG use in high-risk patients as a tool for diagnosing fetal distress rather than an admission screening or continuous monitoring throughout labour. (120)

A Delphi study on FM in LMIC drew consensus on the key need for an admission test for all labouring women, including history/examination and IA. It also highlighted the importance of FM in the second stage due to the higher incidence of perinatal death. (121) However, experts could not agree on the frequency of FM for high-risk women or monitoring when an abnormal FH was recorded. Overall, Doppler was the preferred FM method. However, CTG was preferred for high-risk women in the second stage.

Tools commonly used in LMICs include a stethoscope, Pinard fetal stethoscope, handheld Doppler and CTG. More recently, papers support the superiority of Doppler over Pinard for IA. (122) In a recent study across seven facilities in India, stethoscopes and Doppler were most commonly used. (123) In this study, there was some use of CTG in the Government Medical College, but whilst 70% of cases had an admission FM with a stethoscope or Doppler, only 27% were monitored more than thrice. Reasons given in this study for the inadequate monitoring were high caseload, too few staff and that it was time-consuming. The paper highlighted that longer-term issues in the Indian setting were a lack of appropriately trained staff and inadequate pre-and in-service training. 77% reported using a stethoscope, and 58% with a Doppler. Still, observations demonstrated equal use of both doppler and stethoscope and no CTG use. Difficulties reported were time to locate FH with a stethoscope, limited expertise and audibility. (123)

1.5.14 Women's perspectives on intrapartum fetal monitoring

Understanding the views and experiences of those directly concerned with any healthcare intervention or technology is paramount. (124) Public and patient involvement from previous studies highlighted that FM is of "critical importance to pregnant women". (125) However, high-quality qualitative research into women's views and perceptions of healthcare interventions is often significantly lacking. A 2017 systematic review on women's perspectives on intrapartum fetal monitoring concluded that "additional and contemporary research on women's views of fetal monitoring during labour is strongly recommended and urgently needed." (126)

Only ten studies were included in the 2017 review, all were from high-income countries (USA, UK, Ireland and Canada), and all except one were conducted in the 1970s/1980s. The key findings are described in the review by four themes: discomfort, anxiety/fear, reassurance and communication. (126) The discomfort was present in all studies and for both CTG and IA. The discomfort was due to the tightness of belts and pressing onto the abdomen; it also related to the restrictions on mobility and moving into the correct position for auscultation. Anxiety/fear was reported in nine studies, primarily related to sounds and alarms from the monitor or from the fetal heart when it slowed. Some women worried, and some were frightened when the machine malfunctioned. Some also worried about the fetal scalp electrode harming the baby. Reassurance and safety were prominent themes and were almost always related to hearing the fetal heart. EFM was strongly linked to safety and security, knowing the baby was alive. The final theme was communication and the provision of information; the CTG was a focus for conversations and enabled husband involvement for some. However, some women found it posed a hindrance, where staff and husbands became focused on the monitor. (126) The only later study included in the review was a sub-study of the INFANT study; the researchers found that anxiety scores were similar across the randomised groups in surveys. The qualitative interviews found that where anxiety was present, it was general anxiety about fetal wellbeing due to several factors, including staff behaviour and communication, rather than the software being studied in the INFANT study. (127)

As part of a doctoral study, Watson conducted an integrative review of women's experiences of intrapartum fetal monitoring. (128) The themes and sub-themes outlined are included below.

Table 2 Themes adapted from Watson's integrated review of women's experiences of fetal monitoring literature. Source Watson's thesis (125)

Theme	Sub-theme
Provider of extra clinical information	Contractions
	Dilation
	Heartbeat
Communication with others	Birth partners
	Competition for time
	Health professionals
Mechanical medicalisation	Discomfort
	Wires
	Immobility
	Privacy
	Noise
Psychological effects	Reassurance/security
	Anxiety
	Positive/negative feelings
	Control
Influences on attitudes	Prior pregnancy loss
	Income
	Age
Choice and preferences	Decision making
	Information
	Informed consent

A qualitative sub-study of the START study, an Australian RCT comparing CTG with FSE and CTG plus STAN, found that women had similar positive experiences in both groups. (130) Women focused on the presence or not of the FSE, and they perceived STAN as more accurate. However, interviews were conducted weeks into the postnatal period. The themes in this study were reassurance, mobility, discomfort, perception of fetal scalp electrode and overall positive experience. (130) The reassurance was related to the fetal heart sound and helped women to feel relaxed as the baby was safe. Women experienced inaccuracy due to the movement of the abdominal transducer and mobility restrictions and found that the continuous sound from the FSE was more reliable. The FSE allowed women to feel more in control, more relaxed and less worried, as there was less loss of contact once it was on, but they were worried about the scalp clip harming the baby. (130) A mixed methods study about telemetry found it enabled a sense of normality, including being free and in control, enabling and facilitating. It increased perceptions of autonomy, normality and dignity. (131) Women defined normality not in the typical midwifery definition but as being able to do normal things, such as mobilising to the toilet and having privacy and

being able to stand and move, which enabled women to feel more on "an equal footing" with staff, empowered and in control. Findings also highlighted that the maternity unit culture was important and differed between the research sites, with issues in one site related to bad experiences with the technology, including equipment quality, availability, poor recordings and training and an overall more medicalised birthing environment. (131)

Communication and close proximity with staff and companions were more important for women than the method of fetal monitoring used. (132)(133) Even low-risk women often do not feel they are offered a choice about intrapartum fetal monitoring. Many would prefer continuous electronic monitoring, even if they were low risk. (132) However, other studies refute this finding and show women perceive good communication around fetal monitoring. (134) A mixed methods systematic review of women's experiences of continuous fetal monitoring in the antenatal period found that continuous fetal monitoring had high satisfaction and was preferred to intermittent CTG by women. (135) However, it highlighted the sparse and heterogeneous literature and included two studies of women undergoing outpatient IOL. Themes included practical limitations (related to sleep and mobility), positive perceptions (including a preference for continuous monitoring, satisfaction, comfort and reassurance), device implementation (the benefits of home monitoring, communication and confidence with staff) and negative emotions such as anxiety. (135)

A growing body of research is currently ongoing in Tanzania and India to evaluate a new fetal monitoring device, the "Moyo" device (Laerdal, Stavanger) in LMIC, which can monitor intermittently and continuously. One study involved twenty semi-structured interviews with postnatal women that wore the Moyo device throughout their labour. (136) Women found this to be a positive experience, and the device provided much-needed reassurance about fetal wellbeing, "I was relieved to know that my baby was safe." Women felt it improved care due to increased communication and attention from staff; however, they did not fully understand the technology's purpose or limitations. It generated empowerment and shared involvement in fetal monitoring, which elevated the mother's status from the commonly seen scenario where labouring women are perceived to lack knowledge, autonomy and power. (137) The researchers highlight that the role of FM in empowerment and autonomy should be outlined further. (136) A further study of skilled birth attendants using interviews and focus groups highlighted that the Moyo device made it easier to monitor multiple labours at once and reduced stress, and enabled faster

reactions to fetal distress, as clinicians described feeling "overwhelmed" by a high workload, inability to monitor women properly and fear of blame for negative outcomes. (138)

1.5.15 Healthcare professionals' views on intrapartum fetal monitoring

A systematic review and thematic analysis in 2012 included eleven papers from high-income settings (UK, Ireland, USA, Norway) on healthcare professionals' views on fetal monitoring. (139) These studies were more recent than those in the review on women's perspectives (1980 – 2011). They were also of higher quality (with three studies including all three of EPPI-Centre's quality assessment criteria and a further four addressing the 11/12 criterion.) Most research participants were midwives and nurses, with a relatively small number of doctors included. This is important as the doctors are the decision makers about intervention due to abnormal fetal monitoring and primary caregiver in India. The authors highlight four prominent themes: reassurance and safety, technology, communication/education, and midwife by proxy. EFM offered "proof" of fetal wellbeing, with the ability to "hear the fetal heart in the background" and perceived protection against legal action and criticism. Perceptions about the technology varied from scepticism to trust (faith). Many, especially in earlier studies, but not all believed EFM improved outcomes, and some highlighted that they do not always trust the CTG. Earlier studies considered that the technology of CTG was "more authoritative" than IA. Still, clinicians felt CTG led to unnecessary intervention and increased use of other birth technologies such as epidural, oxytocin and centralised monitoring. EFM was more restrictive and uncomfortable for women, leading to increased analgesia requests. Professionals were concerned that EFM was the focus of care and hindered effective communication. They preferred IA as it allows freedom to move, increases closeness with women, and reduces anxiety. However, poor staffing, busy units and departmental culture made implementing this challenging, and there was evidence of the use of CTG even for low-risk women. Four studies highlighted education as an important factor; some felt the training was important, and others focused on the importance of communication and collaboration for decision-making. The midwife by proxy was strongly related to low staffing levels in busy labour wards. The choice of FM modality was primarily based on perceptions of risk, which are diverse and dynamic and vary according to experiences and knowledge. (140)

There are still relatively few later studies on FM methods and preferences. A small South African study of women in the first stage of labour's method preferences found the wind-

up doppler was preferred over the Pinard and short CTG. (141) The reasons cited were the discomfort of the Pinard or the CTG straps resulting in reduced mobility and “being confined to the bed”. One study highlighted how wireless CTG could enhance the ability of midwives to be "with woman" compared to usual CTG and better mobility, which can increase control and reduce unnecessary interventions. (142) A further ethnographic study about centralised fetal monitoring in Australia highlights new FM technologies' unintended, unanticipated and negative consequences. All technologies must be fully evaluated in a research capacity before introduction. (143)

A qualitative study of focus groups in rural Tanzania comparing midwives’ perceptions of the use of the Doppler or fetoscope found midwives chose the Pinard as they had sufficient training and vast experience with it and did not feel familiar with the recently introduced wind-up Doppler. (138) They highlighted the ability of the device to produce a reliable measurement and that the fetoscope was more prone to human error. The Doppler was more prone to instrument errors when it was not properly charged. The convenience of use and comfort of the device was also important, with the ability to "personalise/hide" the measurements with the fetoscope to avoid anxiety for the woman. Still, it caused some pain and was difficult in the second stage. The Dopplers need charging; they are not painful but provide limited privacy. The authors conclude midwives’ preferences for which device to use are based on the level of training, experience, reliable measurements, convenience and comfort during use.

Summary

Although fetal monitoring during labour is paramount to women and clinicians, it is under-researched. This is even more important in LMIC, where perinatal morbidity and mortality are higher, as are the risks of operative interventions. Furthermore, ongoing controversies exist about monitoring methods and how accurately different methods can predict and avert adverse outcomes. However, fetal monitoring with CTG is unlikely to be de-implemented in the current status quo. Therefore, until the technology and positive predictive values of fetal monitoring in labour improve, it is clear that training is an important aspect of optimising the role of intrapartum fetal monitoring to improve outcomes and avoid unnecessary interventions.

1.6 Clinical education and the role of training in maternity care

Training health care workers is ubiquitously recommended to overcome challenges and improve outcomes. However, high-quality and well-funded clinical education research is often lacking. This section outlines relevant clinical education literature and the theory underpinning this research.

1.6.1 The role of training in improving maternity care

Most programmes that seek to improve healthcare capacity in LMIC involve training as a key component. (144) Clinical education is a proactive risk management strategy to avoid errors. Numerous reports into maternity failings recommend training as part of the solution, as errors are frequently due to communication, leadership and teamworking. The UK Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries (MBRRACE) report recommends skills and drills training. (145) The Ockendon report recommends that "staff who work together must train together" and that "trusts must ensure that multidisciplinary training and working occurs." (146) Simulation is now a requirement of several national training programmes, e.g. USA (147) and the UK. (148) Simulation training has improved competency and confidence and reduced clinician anxiety. (149) Training can also improve clinical outcomes (150) and patient-reported quality of care. (151)

1.6.2 Pre-service vs in-service training

Pre-service or undergraduate training is a key point where important teaching and learning are undertaken. For example, many development programmes focus on increasing the number of places in nursing/midwifery schools or the development of accreditation and curriculums to focus on maternity care. In-service training approaches include training and support for existing health care workers to take on additional tasks through task shifting, e.g. teaching midwives ventouse delivery, additional courses/exams for credentialing and support to improve and maintain existing competencies of health care workers (in-service, on-the-job training and supportive supervision. (144) The General Medical Council describes Continuous professional development (CPD) as any learning outside undergraduate/postgraduate training. It is necessary to “improve the safety and quality of care”. (152) The principles of CPD include responsibility for personal learning, reflection, and remaining competent and up-to-date in your scope of practice. Responsibility for

individual and team learning, shaped by your own professional and service needs and impacts, and must be recorded. (152)

There are key differences between pre-service and in-service training. Firstly, doctors' primary responsibility is to care for their patients, not "to be educated". Attending educational activities can be de-prioritised in the face of multiple competing clinical demands. Even if HCW are physically in a training session, their mind may not be focused as they may still be responsible for patients, and the learning can be interrupted at any time. These challenges are ever-increasing as pressures on staffing, budgets, and demands on hospital services grow. Secondly, healthcare professionals, especially seniors, may not identify themselves as learners. This will likely vary according to topic, personality, experience and logistics. Thirdly, the pathways between training and implementing new attitudes, skills and behaviours are poorly understood. Finally, the learning needs will be different within the group. Practising clinicians are at different career stages and have had different experiences and knowledge. Staff would rarely build up brand-new knowledge. Instead, new knowledge must be assimilated into existing knowledge and practice. This is especially important as "unlearning" is far more challenging than learning, and training must address this purposefully.

There are specific challenges to training in obstetrics and gynaecology compared with other specialities. Many of the skills are haptic in nature and often sensitive, leading to potentially reduced opportunities to learn at an undergraduate level. The shared interprofessional care between midwifery/obstetric and nursing staff can lead to difficult interactions between members of the clinical team who may have different perspectives of birth, risk and ideologies. Situational awareness and responsiveness skills are critical, where not only procedural skills but also communication and teamwork are paramount. Surgical training and mentoring are essential components of training. (153) Simulation-based education, interprofessional education and improving surgical training during the undergraduate period are all potential solutions to overcoming some of the challenges. (153) (154)

1.6.3 What does good in-service training look like?

Emergency obstetric training can save lives and improve quality of life. (155) It can also improve HCW knowledge, skills, attitudes and long-term behaviours. (155) However, not all training is equal or effective (156), and many studies do not demonstrate improvements in

clinical outcomes after training. (157) The features known to be relevant for good training in maternity care are multi-professional training undertaken locally at the unit level, with integrated clinical and teamwork/human factors elements, for all staff regularly. (156) Training is now focused on training teams to use local tools and communities of practice rather than improving individual skills and knowledge. (156) The active components for effective training have been described; institution-level incentives to improve training and safety culture, relevant in-house training, non-threatening assessment and training for the entire workforce, self-directed infrastructure changes with local solutions to national problems, realistic training tools that are high fidelity, not high tech and multi-professional teams with integrated clinical and teamwork training. (158)

1.6.4 Models of learning and important concepts in medical education

There are numerous relevant concepts, theories and models for clinical education and clinical education research. A brief overview of some key concepts that are relevant to this thesis and underpin this research are outlined in this section.

"Ripples in a pond" – factors that underpin successful learning

Race described the seven important factors that underpin successful learning as the "ripples in a pond." (159) Good learning starts with wanting/needing (motivation). It is then followed by a non-linear process of doing (practice/repetition), then making sense (time to think), feedback (which cannot be gained until the doing stage), verbalising (helping to make sense) and assessment (assessing own knowledge and understanding, concerning where the learner wants to go). (159)

Maslow's hierarchy of needs

Maslow's hierarchy of needs, although devised in 1943, is still relevant to clinical education today. The pyramid (shown in the figure below) is based on the principle that each of the needs at the pyramid's lower levels must be met to move on to the next level. The first four levels (physiological, safety, belonging and esteem) are considered basic needs. (160) This is especially relevant for clinicians in low-income settings, which may not have been paid, and therefore, even basic needs such as food and rest may not have been met. In addition, there may be no running water or temperature control in the working environment, meaning clinicians could not proceed past the first level.

The concept of “psychological safety” is very important. In many hospitals, where hierarchy and blame culture prevails, if clinicians do not feel safe, they will not risk getting questions wrong or appearing not to know the answer. They will not even try to implement new concepts which may or may not work. Esteem and respect are important for clinicians, both for how they think of themselves and how others consider them. Clinicians, especially senior clinicians, may not wish to be seen as not knowing something and, therefore, may not engage in training. Even if present physically, they may not engage mentally. At the top level, self-actualisation comes from the desire to achieve and not simply mitigate deficiencies, which should be the ultimate aim of education for clinicians.

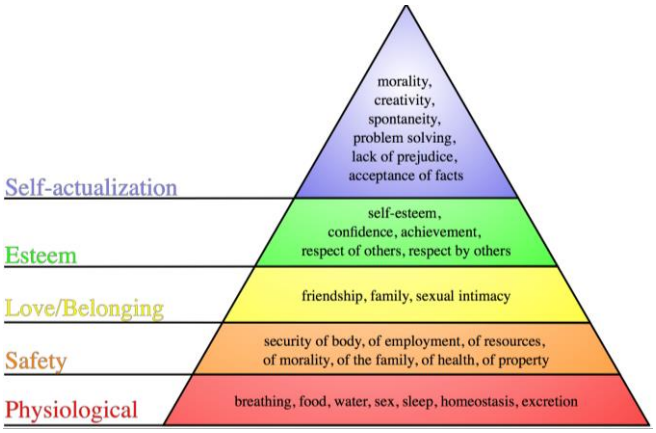

Figure 10 Maslow’s hierarchy of needs. Source website (157)

More recently, the model has been updated to include needs and motivation as key factors throughout each model level. If educators can understand why learners need to gain certain knowledge and drivers for this, such as avoiding HIE and perinatal death, teaching and learning are likely to be more impactful. Transcendence is helping others to achieve self-actualisation and sharing our own self-actualisation through sharing with and educating others. This is part of the role of CTG training leads.

Miller’s prism of clinical competence

Miller’s pyramid ranks clinical competence in the workplace; knowledge is seen at the lower levels, and only “doing” is true competence. Most descriptions include four levels; knows, knows how/understands, shows how and does. Some models also include the two lower levels of heard of and know about. (161) Miller argues that assessment should take place in the workplace as there is more professional authenticity. However, this is not

always possible, especially in rare or emergency situations. Simulation, particularly simulation in situ in the labour ward, offers some potential advantages for higher-level learning and assessment.

Figure 11 Miller's prism of clinical competence. Source website (158)

Bloom's taxonomy highlights that learning occurs on different levels; remembering, understanding, applying, analysing, evaluating and creating. (162) Learning needs to occur in three main domains: cognitive (knowledge), affective (attitude and self) and psychomotor (skills). Much of learning and assessment in wider fields are related to cognition. However, if we are to improve outcomes with such a complex entity as intrapartum fetal monitoring, education must be equally focused on the affective and psychomotor domains. FM is an emotive topic, where opinions are polarised, even amongst clinicians, and clinical decisions in the labour ward are time-pressured, stressful and sometimes made with incomplete information. Assessment of learning must incorporate these factors.

More recently, Miller's pyramid (see figure above) has been combined with Bloom's taxonomy to create Miller's prism of clinical competence. (161) Crucially for clinicians' training, only the "does" triangle represents clinicians' true performance. Even demonstrable improvements in the other levels, e.g. with pre/post-tests, do not necessarily result in changed behaviour and therefore improved patient management and outcomes.

Deliberate/effortful practice

Deliberate practice is the idea that clinicians are not just born with talent, nor does practising something repeatedly without focus help ("give a thousand monkeys typewriters"). However, practising wisely through repeatedly performing tasks and then getting specific feedback, analysis, assessment and review to improve can push learners

towards mastery and becoming experts. (163) To do this, tasks must be broken down into small tasks to become masters. This is partly the concept behind weekly CTG meetings and CS review meetings. These work best when there is wide engagement, and attendance is expected by all team members, from senior to junior, and the aim is to improve and learn and not blame.

Realism and context

Realism highlights that it is often not the intervention (such as training) that causes change but the interpretation and actions taken around it and that operationalisation of an intervention is contextually dependent. Realism typically organises information into context-mechanism-outcome configurations. (164) Context is the overarching principle and can be broadly grouped into four contextual layers. (165)

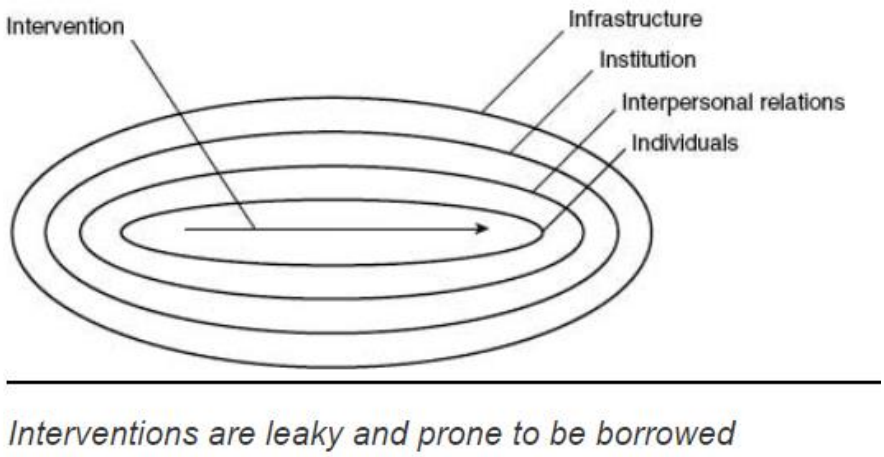

Figure 12 The intervention as a product of its context. Source website (162)

- **Individual capabilities of the key actors** – Do educators have the necessary skills, drivers, time and motivation to drive the initiative?
- **Interpersonal relationships** – Can an intensive enough learning environment be created? Do the leaders and managers "buy in" to the project?
- **Institutional setting** – Does the culture prioritise education and change towards improvement? Does the policy setting support this? Are there adequate resources, time, and finances?
- **Wider infrastructure change** – Is there political support? Does the national environment prioritise and promote change?

1.6.5 Clinical education theory

The clinical education literature is clear that learning situated within a strong basis of theory is essential. The mixed methods literature also highlights that before embarking on research, researchers must consider philosophical debates on the meaning of knowledge and how it is obtained, as well as the underpinning theory. (166) All research is underpinned by philosophical assumptions (whether acknowledged or not), which shape research. Whilst there are supporting and opposing critiques of all theories, theory can give educators and researchers structure to improve their teaching and research. It also allows teachers to understand why learning works and how to achieve desired outcomes. However, although multiple theories aim to explain how adults learn, no one explains the entirety of how healthcare professionals learn. (167) As a result, educators invariably approach training and research in a manner consistent with their underlying theoretical framework. (168) These multiple theories are typically grouped into different approaches to learning and research, each with its own assumptions, definitions, underlying psychological principles, and views on epistemology, ontology and axiology. (169) This is relevant for this thesis, as different perspectives from different stakeholders impact on training, and have different and sometimes contradictory meanings for different stakeholders. A few key concepts are outlined below:

Epistemology (understanding) is the theory of knowledge and how to access it. It is about views/beliefs on the nature of knowledge, learning and teaching and the relationship between the researcher and that being researched.

> *How can I know reality?*
> *What does learning mean to you? What does a good learning encounter look like?*

Ontology (being) studies the nature of being, existence and reality. It can be a framework for representing knowledge and building theory.

> *What is reality?*
> *What strategies do you use to help students reach their learning objectives?*

Axiology (valuing) is about our values and attitudes toward teaching, learning and research.

> *How would someone watching your interaction with students describe it?*

Methodology (acting) is the theoretical underpinning for best practices, how educational values are realised and the process of research.

> *Which activities and materials are used? Which approaches in research should be used?*

In addition to the above approaches to educational research, there are various theories on the behavioural response to education, which have evolved over the years. Broadly speaking, **behaviourist** theories explain knowing as the result of an objective stimulation/response and that all behaviours can be explained without considering external stimuli. Information is transmitted, and learning is passive and tutor-led. **Cognitivism** largely replaced behaviourism in the 1960s and focuses on knowing as the result of mental processing. People are no longer thought of as "programmed animals", such as the infamous example in Pavlov's dogs, but are rational beings where information comes in, is processed and leads to outcomes as a result of thinking. Learning is tutor-led, and learners build on what they already know. **Constructivism** highlights that learning is not simply gathering information; it is an active process whereby new knowledge is constructed on or around existing knowledge and experiences. New information can be assimilated or fitted into existing schemas if it fits with existing understanding. Or accommodated, which involves incorporating a new way of thinking about something, revising existing schema and re-structuring information and ways of thinking. Assimilating this new knowledge can be difficult and stressful, resulting in a change in meaning. (169) "Effective learning is about conceptual change, not just acquiring learning." (169)

Clinicians and researchers have often not received training on sociology and its underpinning concepts. Likewise, clinicians have often not received explicit teaching on how to teach. As a result, they may well be unaware of their own conceptual frameworks, how their own framework fits within learning theory and that understanding this learning theory is key to ensuring the maximum impact of any given teaching programme. Even among medical educators who self-selected to enter a study about their medical education theory, there was "considerable variation in understanding of learning theory". (170)

1.6.6 Research paradigms/worldviews

It is widely accepted that there are several worldviews, each based on assumptions about what can be known and what we believe to be "true". (171) Each worldview is underpinned by its own set of beliefs, which contribute to defining research questions, what is valid

information and what conclusions can be made. In addition, each worldview has its own associated ontology, epistemology and educational theory. These underlying theories can be used as "conceptual lenses" to make sense of complex problems. (171) Some relevant worldviews are briefly outlined below to give an outline of the different worldviews that different people hold. This includes positivism, post-positivism, interpretivism, criticalism, constructivism and pragmatism.

Positivism is familiar to all healthcare professionals, as this underpins a significant amount of what is taught about the human body and pathology. In positivism, a truth/reality is "out there." It is fixed, static and can be known and measured. The researcher and the thing they are researching are separate and can be studied without being influenced by the researcher.

Post-positivism accepts the basic tenets of observation and measurement but recognises that observation is fallible and that all theories can be changed. Furthermore, it is characterised by an understanding that the researcher's background, knowledge and values influence what is observed. (171)

For **interpretivism**, everyone constructs their own reality, which is dependent on many things, and therefore there are multiple realities/"ways of knowing" and no one "ultimate truth". There are multiple realities, as reality is shaped by experience; reality is complex and context-dependent.

In **criticalism**, reality may be objective or subjective. Different groups continually contest the truth, but power relations determine what knowledge "counts".

Constructivism outlines that there are multiple realities, and that knowledge needs to be interpreted to discover the underlying meaning. (Please note the constructivism medical education theory description in section 1.6.5).

Finally, **pragmatists** think that reality is always interpreted, negotiated or debated and that knowledge should be examined by whichever tools best suit the problem.

Summary

Although the underpinning theory and learning models may appear abstract to practising clinicians, this baseline understanding is essential to understanding how and why people

see and understand the world (and knowledge) the way they do. Moreover, this understanding is essential if we are to design research and interventions that contribute to the literature and scholarship of clinical education practice and ultimately maximise the output and impact of training interventions.

1.7 Intrapartum fetal monitoring training and other interventions to effect change in maternity care

Section 1.7 outlines the existing literature and current practice for FM training. The considerations needed to plan FM training and specific challenges are also discussed, with an outline of quality improvement.

1.7.1 Intrapartum fetal monitoring training literature

A systematic review of CTG training was published in 2021 after the completion of the studies outlined in this thesis. It evaluated 64 studies, including 13 RCTs, 40 quantitative non-randomised studies and 11 quantitative descriptive studies. Almost all studies were from high-income countries. (172) The RCTs showed that the CTG training might improve knowledge through improvements in test scores, level two of Kirkpatrick's model; however, this is low-quality evidence. Evidence of CTG training leading to improvements in key maternal and newborn outcomes is also "low quality, inconsistent and limited", and none of the RCTs included assessed these outcomes. In addition, none of the studies outlined any theory, behaviour change or evaluation model. The authors suggest that future high-quality studies focus on intervention designs, clinical outcomes, contexts of sub-optimal practice and mechanisms of change using a theory-guided system-based approach to encourage an understanding of training interventions' impacts through a real-world lens. (172)

A large Australian national pre-and-post study evaluated the impact of introducing a one-day multidisciplinary "fetal surveillance education program" on three and a half million term neonatal outcomes. (173) It is clear in the paper that there were new national guidelines, and this "universal education of the maternity workforce" was an essential component of active guideline implementation. The authors highlight the need for validated and reliable assessment tools and use this assessment annually for appropriate "credentialing" according to work scope. Co-interventions are not explained in detail. This large study found that neonatal death rates were unchanged after the training, but NICU

admission rates increased. However, the study found a reduction in the potentially intrapartum hypoxia-related poor neonatal outcomes, including intrapartum stillbirth rates, HIE, intubation and APGAR under five at five minutes. The emergency CS rate and instrumental delivery did not change. (173) This study highlights the critical importance of national routine data collection of important maternal and perinatal outcomes. Countries can benchmark care, recognise good practice, and understand the impact of interventions on patient outcomes. Few studies have evaluated the impact of national-level training initiatives. (172)

A further Australian study evaluated the impact of the same intervention in one state, Queensland, on HIE rates from 2003-2011. (174) The study showed a statistically significant reduction in HIE rates but has been rated at a high risk of bias. The difference in the coding of HIE could have accounted for some of this reduction, as the ICD-10 codes changed during the study period. Interestingly the interventions are summarised very differently than the paper described previously comparing national outcomes, although are apparently the same intervention of the Australian national RANZCOG guideline in a smaller geographical area. The Victorian Managed Insurance Authority (VMIA) report in 2000 highlighted a substantial number of poor perinatal outcomes related to inappropriate use and interpretation of CTG, which led to updates of the RANZCOG guidelines. The aim was not focused narrowly on CTG but instead to "improve the quality of intrapartum care". (174)

One of the first ever and widely quoted papers evaluated whether training in obstetric emergencies could improve neonatal outcomes. (150) As part of the Clinical Negligence for Trusts in Bristol, UK, a mandatory multidisciplinary PROMPT course was created. This consisted of half a day of CTG training and half a day of six obstetric emergency simulations. Low APGAR and HIE rates reduced significantly, stillbirth rates were unchanged, and CS rates increased. The authors questioned whether the increase in CS was due to "better recognition of intrapartum problems". However, it is not possible to elucidate how much of the improvement in neonatal outcomes was due to the training alone or how much was due to the suite of interventions at the senior and departmental policy level, as well as numerous undescribed interventions which were used as part of the CNST process, as the co-interventions were not clearly defined. The authors highlight the benefit and costs of in-house training and the importance of the critical mass of trained personnel. Where attendance is mandatory, and study leave is allowed for it for all staff,

including new starters. It also demonstrates that increased vigilance of the fetus and training can increase intervention for the mother. (150)

An evaluation of the Denmark national CTG training and “safe deliveries” programme included the implementation of checklists in all Danish units and was described as a “comprehensive national obstetric intervention”. (175) The CTG training consisted of an e-learning program, a one-day face-to-face course, mandatory attendance for all physicians and midwives and a test of competence for all staff. The day course consisted of lectures, plenary discussions, small group-based teaching and a multiple-choice question test. The teaching content was based on the Danish version of the FIGO guidelines and taught by 20 experienced obstetricians and midwives. This historical cohort study of all planned, term, singleton vaginal births (331,282 births) (175) showed that after training, there was a non-significant increase in the numbers of babies with a pH under seven and cooled babies (although the intervention of cooling was used far more widely generally); APGAR scores stayed the same. There was a transient increase in CS rates, which then returned to baseline, and the authors attributed this to the "focus on sub-standard care". Instrumental deliveries also decreased. The authors mention a checklist of vacuum delivery also being introduced, but no details are provided. Therefore, it cannot be known how much the vacuum checklist meant reduced numbers of instrumentals rather than the CTG training.

One Taiwanese hospital evaluated perceptions of patient safety after an annual one-hour training delivered by an obstetrician at the monthly nurses meeting on SBAR handover for an abnormal FH. (176) Small numbers of nurses were included, other interventions were unclear, and this study has a high risk of bias. There were improvements in safety attitudes on the Chinese version of the safety attitudes questionnaire, e.g. teamwork, safety climate, job satisfaction and working environment. Still, there were no differences in five-minute APGAR scores. SBAR, as a tool for communication of abnormal FH, could be useful, but further detail is needed.

A study in Japan studied the impact of introducing a new rule-based grouping on fetal heart patterns, with clear management of each group. (177) They found no difference in CS rates but a significant reduction in the arterial cord pH under 7.15; however, this study was rated as a high risk of bias. A visiting perinatologist conducted weekly training sessions for physicians and nurses over six months.

In summary, the existing literature on FM training, especially in LMIC, is weak. There is no clear consensus on whether it improves outcomes or which training methods to use. In some scenarios, it can impact maternal and perinatal outcomes, but this is unclear, and descriptions of interventions are incomplete and lack necessary detail. Hence, it is currently not possible to determine the "magic ingredients" or best methods of training.

1.7.2 Where/how does intrapartum fetal monitoring learning take place?

Throughout this PhD, we have identified six key occurrences where FM learning takes place: routine clinical practice ("doing it"), interactions with colleagues, formal training sessions, clinical meetings with colleagues, online learning modules and self-directed learning. Unfortunately, the FM published literature does not reflect the full picture of how intrapartum FM is learnt and taught and is focused on specific training sessions primarily, without acknowledging the importance of the apprenticeship aspects of learning.

Routine clinical practice. The daily work of doing intrapartum FM in routine and emergency situations. Reviewing cases and CTGs/FH, making and enacting management decisions, and communicating with women, families and colleagues.

In the labour ward, in the theatre, clinic.

Through **interactions with colleagues** during clinical work. Asking seniors/colleagues for advice, mentoring, supervision and apprenticeship, observing clinical interactions on labour ward and ward rounds, informal feedback, formal feedback such as work placed learning, feedback from adverse events, peer-to-peer learning and feedback.

In the labour ward, in theatre, clinic, hospital offices, phone/email, corridors.

As part of **formal training sessions** focused entirely on intrapartum FM or when intrapartum FM is one topic, within longer sessions focused on wider aspects of maternity care e.g. obstetric emergencies. These can be lectures, small group work, case-based discussions, tutorials, workshops, demonstrations, skills and drills or simulations. These can be standalone training or part of a multifaced intervention, e.g. guideline dissemination. This also includes training the trainer sessions. Trainers can be in-house or experts/leaders.

Classrooms, lecture theatres, seminar rooms, conferences, simulation rooms, labour ward, online courses.

Through departmental **clinical meetings with colleagues** within/close to the clinical environment. MDT CTG meetings, audit meetings, maternal and perinatal mortality meetings, risk meetings, audit presentations, CS review meetings, adverse event meetings, and specialist MDT discussion meetings.

Clinical areas, meeting rooms close to clinical areas.

Online learning packages, typically mandatory full intrapartum FM training courses, which take hours to complete and involve assessment and reviewing cases as a core component, such as K2 and e-learning for health (eLFH).

Home/conference hall/hospital library/clinical areas - computer/phone/tablet/books.

Self-directed learning. Reading books, websites, guidelines, patient information leaflets, YouTube videos, webinars and conferences. This also includes non-mandatory completion of online learning packages such as K2 or eLFH.

Home/conference hall/hospital library/clinical areas - computer/phone/tablet/books.

The existing published literature does not encapsulate the processes of mastery and becoming an expert in CTG. It is not a simple procedure that can be fully taught and learnt in a classroom/online setting, although this training can provide an important baseline understanding. CTG interpretation and response should be "understood as a complex sociotechnical process involving individuals from multiple professions and disciplines, taking place over several stages and in highly pressurised contexts…with many points of failure." (125) Therefore, intervention designs must incorporate this complex understanding when considering how to improve outcomes.

1.7.3 Important factors to consider when planning fetal monitoring training

The aims of training in maternity care

HCW performance is a “broad construct” encompassing “availability, clinical competence, responsiveness (patient-centred care) and productivity (efficiency).” (178)(179). In-service training should aim to improve clinical outcomes (180), typically within the constraints of

limited time, budget and competing clinical demands and priorities. The aim is to convey knowledge which is retained and used in clinical encounters to improve patient outcomes. It may be making the correct decision due to new knowledge, acting more quickly due to confidence and communication, or remembering that a rare condition exists and knowing where to find out more. Better knowledge should mean better clinicians, which results in less patient morbidity and mortality. But there are also other important outcomes, which are more tacit, such as the self-confidence that comes from knowing and understanding and therefore being able to question others' decisions…are we doing the right thing here? The self-worth gained from having the respect of your peers and the pleasure of knowing you have done a good job. These soft traits are harder to teach and measure, but they are paramount, as most healthcare workers have entered their profession to help people and do good. (181)

Who should be trained?

Professionals with various occupational titles in different countries have the competencies required to provide high-quality maternal and newborn health care. In 2018, FIGO and the International Paediatric Association defined skilled health personnel as "competent maternal and newborn health professionals (MNH), educated, trained and regulated to national and international standards. They are competent to (i) provide and promote evidence-based, human-rights-based, quality, socio-culturally sensitive and dignified care to women and new-borns; (ii) facilitate physiological processes during labour and delivery to ensure a clean and positive childbirth experience; and (iii) identify and manage or refer women and/or new-borns with complications." (182) For example, well-educated midwives working to the International Confederation of Midwives (ICM) standards and regulations in well-equipped and enabling environments could provide 87% of essential MNH services. (183)

Context and high-quality educational environments

The local educational and clinical context is key. The annual trainee evaluation feedback report from obstetrics/gynae trainees in the UK highlighted the three important themes for creating a highly educational environment: community, collegiality and criticality. (184) A **community** where education is the priority and offers a sense of belonging. Staff members working in a team become a truly "working community" with a sense of identity, joint ownership, fellowship, safety and trust. **Collegiality** is where employees feel like

colleagues, not staff. They have a shared moral endeavour of mutual learning and respect and work and learn together. **Criticality** is one of the attributes of professionals and reflective practitioners, where there is no right answer, and clinicians exercise judgement on "practical reasoning/wisdom." (184)

Planning effective training

Van den Broeke outlines the steps necessary for planning effective training programmes in LMIC. A summary is outlined below: (144)

- Determine the needs of HCWs to be trained in consultation with HCWs, managers and team members.
- Determine overall objectives, then work out behaviours needed, then knowledge, skills and attitudes needed to achieve the necessary behaviour.
- Determine content to be covered to meet identified needs within the timeframes available.
- Select participants by considering who will benefit, whether training can be multidisciplinary and whether staff with different levels of experience can be trained separately or together.
- Agree on training schedule; can be concentrated, e.g. five days, nine-five pm or spread out, e.g. two hours/week for ten weeks.
- Book a training venue where participants and trainers can work together comfortably without distraction.
- Select appropriate facilitators/trainers or conduct “train the trainers”.
- Prepare training materials, ideally including audio-visual aids. Consider the need for facilitator/participant manuals, mannequins, training plans and scenarios. Consider plans for no electricity/internet.
- Timetable coordination is important and can be done by trainers/another team member who is not teaching.
- Evaluate the programme to determine its effectiveness and make amendments/improvements. (144)

The Academy of Medical Educators outlines the steps to consider for curriculum mapping, which have been adapted for this thesis; see the diagram below. (182) Largely these are similar concepts as outlined by Van Der Broeke, with the inclusion of

assessment. Other considerations not mentioned include consideration of meals/refreshments and breaks, content delivery without overload, certificates/accreditation, per diems for transport/accommodation, safe staffing in units whilst training is ongoing, and relationships and interactions with colleagues.

Figure 13 Factors to consider when planning training, adapted from AMEE curriculum mapping guide (185)

Curriculum/course content

A curriculum is "a sophisticated blend of educational strategies, course content, learning outcomes, educational experiences, assessment, the educational environment and the individual student's learning style, personal timetable and programme of work". (185) There are differences between the declared curriculum (what is assumed students are learning), the taught curriculum (what is taught), and the learned curriculum (what students actually learn). (185)

A three-round Delphi study was conducted with clinicians with CTG training experience and clinical experience from all hospitals in Denmark (186) to define the most important learning objectives for FM training. Literature searching and guideline review highlighted

six key areas that CTG training must cover: physiology, equipment, indication, interpretation, clinical management and communication/responsibility. In total, 40 learning objectives were concluded upon, with CTG interpretation and management ranking the highest. As rated by experts, this high number of learning objectives highlights that CTG is a time-consuming and complex topic to teach and learn. Plus, there is ongoing debate regarding which guideline/classification to use, and with many inter and intra-observer differences, CTG training is highly challenging to deliver.

Format of training

The Delphi authors highlight that the learning objectives are wide and different objectives will need to be taught using different formats of teaching; simulation, small group, classroom and self-taught. (186) The FM training systematic review highlighted that evidence for optimal content and delivery methods was very limited and poorly described. (172)

Costs and resource implications of training

Significant resources are used in training, notably staff time. Therefore, it is relevant to consider cost-effectiveness and returns on investment (net programme benefits/programme costs x 100%). The realities of this are difficult, as the return on investment is in avoidance of harm and liable cases, potentially many years later. Costs include instructor/facilitator costs, including time, travel, and lost productivity; trainee costs – time, travel, and productivity loss; materials cost; facilities cost, including overheads for electricity, equipment, and printing and development costs. A cost-effectiveness analysis of the PROMPT course in Southmead Hospital (6500 births annually) highlighted that the start-up costs were 5574 Euros and then variable costs annually were 143,232 Euros each year; 90% of this is staff costs (trainers and attendees). (187) They estimated this as a cost of 23,000 Euros for the first year per 1000 births and then 22,000 Euros for subsequent years per 1000 births. An evaluation of PROMPT over seven years in Kansas, America, estimated a saving of $7.5 million through avoiding 15 brachial plexus injuries and $26.8 million for six HIE cases avoided. (188)

Assessment

Assessment of learning and testing competence for intrapartum fetal monitoring is a particularly challenging area, and the concept of “competence” in CTG is nebulous and

warrants further study. Tests require substantial development to ensure their validity and reliability (189) due to the nature of the high-level skills assessed and the spectrum of correct responses to different CTG cases. There is a lack of validated assessment for CTG (190), and tests built "in-house", even when based on previous expert tests as in this study, are unlikely to have been developed with enough rigour to measure competency meaningfully. Where the assessment is mandatory, the assessment still has a role in motivation, even if passing the assessment does not prove competency.

Knowledge into practice

Given the focus and literature available on simulation, there is a surprising lack of literature on how simulated performance corresponds with actual clinical performance. (191) There is also some evidence that senior doctors do not perform better in training and may provide less quality care. (192) One study showed that CTG knowledge, interpretation and decision-making skills were positively associated with working in large units and having less than 15 years of experience. (193) This may be because juniors are more familiar and engaged with learning and testing or because seniors are less receptive to training, new standards or care and interventions. It may also be because novices stick to the rules, which may better fit the written assessment format than experts who work by intuition based on experience. (194)

There are many processes, mechanisms and outcomes involved in "training". Each clinician's knowledge and viewpoint are different according to their backgrounds, previous clinical and non-clinical experiences, education and underlying philosophy towards their existing knowledge, teaching and clinical practice. Training is not often one single tick box or intervention, as is commonly perceived. The pathway between an individual being taught something to understand it well, which creates a desire to make an individual behaviour change, to actually making changes to practice and sustaining them. Then extending this to multiple clinicians changing their clinical practice and for these changes to be significant and frequent enough to result in statistically significant changes in patient outcomes are poorly understood. "Knowing" is important, but "doing" is far more important. As it is sustained behaviour change, as a result of educational input, that has the power to improve patient outcomes and experiences.

The challenges of study design

Poor perinatal outcomes are rare, making study design very challenging, as huge numbers of births are needed to be included to show any difference if there is one, such as in the INFANT study. (106) In addition, CTG is just one aspect of intrapartum care; therefore, typically, many factors lead to poor outcomes rather than a simple mistake in interpretation or a knowledge gap. For example, in Each Baby Counts (195), seven contributory factors typically contributed to poor outcomes. These include not following guidelines, staff fatigue, inadequate leadership, poor communication, delays in care such as getting to the theatre, neonatal support, inadequate supervision and loss of situational awareness.

Focusing on CTG misinterpretation as a key cause of harm may overestimate its role in hypoxic brain injuries. Hypoxic injury during labour only constitutes 10% of all cerebral palsy cases. (196)(197) A consensus statement has been developed due to the complexity of the potential causal relationship between intrapartum hypoxia, the correct and timely diagnosis, and action taken to avoid harm and the development of cerebral palsy. However, this has not been used in all previous studies. (194)

Scaling up and sustainability

Scaling up any healthcare intervention is hard; outdated approaches have focused on publication, examples, policy and training. (198) More recent approaches from key organisations include four phases; set up, development of the scalable unit, a test of scale up and full scale. (199) Specific features of interventions are known to determine the adoption rate, such as evidence of superiority, its simplicity and the alignment with the culture of new implementers. (200) Even with the clear benefits of the PROMPT course demonstrated through a series of publications, full scale-up and sustainability have been challenging, and results have been variable. (201)(202)

Due to the nature of clinical education as an intervention, “training” is different when delivered in different settings, with different challenges and contexts and by different people. Therefore, the intervention is likely to vary significantly in different contexts. So even if an intervention works well in one unit, scaling up and rolling out the training across all hospitals would likely have different impacts. Also, once the initial drive and enthusiasm (or funding) decrease, ensuring long-term change in practice is even harder.

1.7.4 Best practice examples of fetal monitoring training from UK practice

In order to fully understand existing fetal monitoring training, KL attended and observed numerous fetal monitoring training sessions across various hospitals in the UK in 2019. The section below shares observations and reflections on training from three hospitals.

Peterborough Hospital

The FM lead and I first met when she stood up and shared how her trust had significantly reduced HIE and neonatal death in her unit, at a CTG training course. We had several meetings, and then I spent a day in the unit, observing handover and having over ten meetings with various cadres of staff. As I spoke to staff, it became clear that the training intervention was far more than simply fetal monitoring training and involved a long journey, through strong leadership, towards a culture of training and teamwork. This journey started with a series of bad reports and outcomes. Postpartum haemorrhage (PPH) was identified as a problem, so new guidelines, protocols and training were implemented. However, this did not change outcomes until a series of human factors training and management decisions were undertaken. Then again, the PPH training was implemented, and rates improved. It highlighted how essential it was to have management buy-in and that "negotiating, negotiating, negotiating" was necessary to gain all of the necessary approvals and buy-in from managers and clinicians to ensure mandatory attendance from all staff, including consultants. New consultants were employed with good leadership and training backgrounds. The unit's culture was transformed, and the staff felt like part of a team.

The training interventions consisted of a daily discussion of cases at handover (for all CS, not just poor outcomes), a weekly two-case presentation CTG multidisciplinary meeting, and all staff attending the day-long CTG Masterclass course. The mandatory midwifery training consisted of four days each year, including CTG, skills and drills, basic life support and human factors. The focus of the CTG training was to anticipate and escalate.

St George's Hospital

At the time of my observation, this hospital was internationally renowned for CTG training. I shadowed the ward round and CTG meeting and spoke with staff, including seniors, juniors and the CTG training midwives. I was told repeatedly that all staff "knew" and were "empowered", even the most junior midwives, as they had all been trained and passed the

test. Midwives discussed cases on the central monitoring themselves, without the expectation of requiring a doctor's opinion or review. There were frequent and detailed conversations about "how is this baby" rather than knee-jerk reactions and interventions in response to CTG patterns. There was a culture of support and leadership. I was told repeatedly that the Consultants were excellent and inspiring, and everyone felt free to challenge each other and even call other consultants if there was uncertainty.

The CTG training intervention consisted of four hours of training, the requirement to pass the test to work in the labour ward, clear fail pathways of one-to-one support and upskilling for those who did not pass the first attempt. FM midwifery presence in the labour ward for training and support most days, weekly CTG meetings and consistent lengthy discussions on cases throughout the day were all key components of the training.

Oxford intelligent auscultation

The midwifery team has won national awards for their "intelligent auscultation" training in Oxford. It consists of a three-hour session, which includes training from expert midwifery trainers (PowerPoint and cases), videos from consultants, and a test. It is compulsory to pass the test to work in the labour ward. Much of the fetal monitoring midwives' time is spent following up and providing one-to-one training for those who do not pass. The training was built around implementing change in practice, but the midwives shared that certain points were harder to embed than others. For example, only undertaking the second listening of the FH “second ears” after the first interpretation had been completed to avoid confirmation bias and that suspicious CTGs (grey zone) were not clinically significant.

1.7.5 Other interventions that can cause change

Training is just one intervention that aims to change behaviour in HCP; other examples are highlighted in the diagram below. (203) Continuous monitoring and local reporting of clinical outcomes have reinforced positive changes worldwide. A Cochrane review highlights that audit and feedback can lead to small but potentially important improvements in practice. (133) (204) This is especially noted when the initial performance is poor. The improvements from audit are greatest when the lead for audit and feedback is a supervisor or colleague, and the feedback is provided multiple times, with verbal and written results, clear action plans, and targets.

A theory-led systematic review of interventions that promote health professional behaviour change included 69 studies. (205) The authors used normalisation process theory, which focuses on actions through four areas; “coherence (what users do to make sense of new practice), cognitive participation (what users do to engage with new practice), collective action (what users do to enact a new practice) and reflexive monitoring (what users do to appraise the effects of a new practice).” They found that interventions that make a normative restructuring in practice and modify peer group expectations and norms through emphasising expectations of an external reference group or a combination of these are most likely to achieve change. They grouped the interventions into three; persuasive, educational and informational and action and monitoring. (205) In low-income countries, a systematic review of interventions aimed at improving the performance of health professionals suggests that supervision and audit with feedback are generally effective, and multifaceted interventions might be more effective than single interventions. (206)

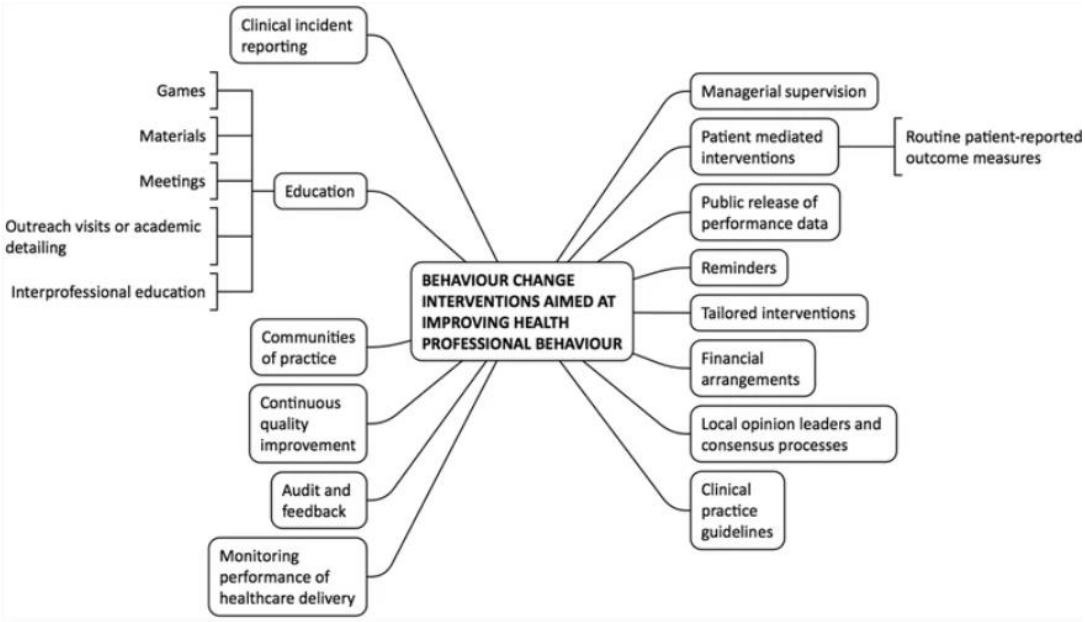

Figure 14 An adapted version of the Cochrane Effective Practice and Organisation

of Care Taxonomy. Source journal (203) and Cochrane (207)

A further systematic review by Rowe et al. focused-on strategies to improve HCP performance in LMIC; most strategies had multiple components and were difficult to compare. (179) Effect sizes for technology-based strategy and only printed materials were minimal. Training or supervision alone had moderate effects (10.3-15.9% improvement),

whereas training and supervision had larger improvements than either strategy alone (28.0-37.5% increase). Some but not all, multi-faceted interventions had large effects, and some interventions, such as group problem-solving and training, appear to be more effective. (179)

1.7.6 Quality improvement

Quality improvement (QI) is "about giving the people closest to issues affecting care quality the time, permission, skills and resources they need to solve them. It involves a systematic and coordinated approach to solving a problem using specific methods and tools with the aim of bringing about a measurable improvement." (208) It bridges the gap between knowledge and practice, what we know we should do, and what is actually done. The Health Foundation outlines necessary key factors: leadership and governance, improvement culture, behaviours and skills and external environment (policy, Government and regulatory bodies). (208) There are a variety of tools and approaches which are based on several similar principles:

- Identify the quality issue
- Understand the problem from a variety of different viewpoints, especially data-driven (process and outcome data)
- Develop a theory of how change could be created
- Identify and test solutions, using data to measure impact and then refine solutions
- Implement solutions and sustain change

The majority of QI approaches were developed in industry. Although they have been used extensively in health care over the last thirty years, no strong literature highlights that one particular approach is better than others. Approaches should therefore be decided according to the context and problem being addressed. (208) Common approaches include the model for health care improvement, lean and clinical microsystems.

The model for healthcare improvement

For this approach, tests of change are carried out continuously with the continuous approach of the plan, do, study, act (PDSA) cycles. (209) The cycles are created by asking three questions:

- "What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in improvement?" (210)

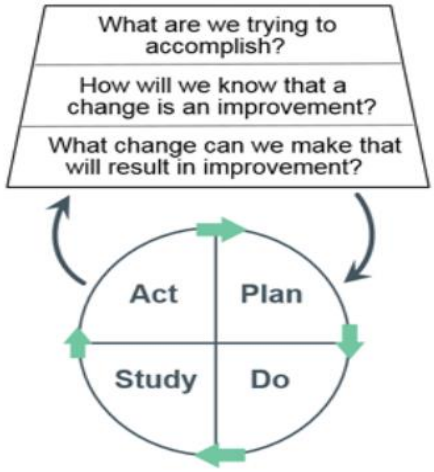

Figure 15 The PDSA model for improvement. Source NHS England (207)

Lean

Lean is a more novel approach developed in Japan's car industry and focuses on the patient's viewpoint by adding "value" for them and respect. (211) There are five steps: defining what adds value to patients, mapping the pathways that deliver care, making these pathways flow better, and allowing patients to "pull value" towards them. Hence, their care meets their needs and then pursue perfection in the future.

Clinical microsystems

Small groups of people that usually work together for a specific group of patients meet to improve their "clinical microsystems" focused on the 5Ps: patients, people, patterns, processes and purpose.

For all QI, the relational aspects profoundly impact their success, and the literature shows how a change is introduced is critical. (211) All healthcare systems are built on a complex system of processes and networks; how this works together largely depends on how well care is delivered. Complex systems are based on relationships, interdependencies and interconnections. There are many relevant factors from politics, communities, local needs and individuals. Change and QI are typically very difficult to achieve. A review of common difficulties encountered across programmes highlighted ten common challenges (212); convincing peers there is a problem, convincing peers this solution is the right one, data collection and monitoring systems, excess ambition and "projectness", organisational

context culture and capacity, tribalism and lack of engagement, leadership, "balancing carrots and sticks", sustainability and side effects. For effective improvement, four elements are necessary; leadership and governance, infrastructure and resources, skills and workforce and culture and environment of improvement. (213)

1.8 Study rationale, aims and overview

1.8.1 Justification for fetal monitoring focus

Annually 2.6 million stillbirths occur; almost all of these (98%) occur in LMIC, and over half occur during labour. (1) Improving care during birth could prevent a large proportion of the 1.3 million intrapartum stillbirths and provide a “triple return”, avoiding stillbirths and neonatal and maternal deaths. (15) Antenatal/intrapartum hypoxia is a key mechanism for birth asphyxia, which can lead to long-term disability and perinatal death. (214) High-quality intrapartum FM is a fundamental aspect of care that aims to identify inadequately oxygenated fetuses during birth, so clinicians can take action, to avoid injury or even death of the baby. (87) However, delivering high-quality, accurate FM remains a significant problem worldwide, with experts rating it as a top research priority (215) and numerous reports and court cases highlighting deficiencies in intrapartum FM leading to avoidable perinatal harm.

There is currently a global epidemic of caesarean sections, leading to the concept of "too much too soon, too little too late," (108) with high rates of unnecessary caesareans in some settings and not enough in others. For example, India’s CS rate is currently 17.8% (28), and rates have risen quickly over the last ten years, from 8.5% in 2005-06. (28) Excess CS leads to excess maternal morbidity and mortality, especially in low-resource settings. (41) Multiple factors have led to this rise (216), and increasing concern for the fetus and changing perceptions of risk are important factors. Fetal concerns are among the most common indications for CS worldwide (62) and, therefore, an important contributor to rising CS rates. However, according to current clinical practice guidelines, significant numbers of these CS are not indicated.

The role of high-quality intrapartum fetal monitoring is even more critical in LMICs, where the burden of perinatal mortality (1) and the risk of interventions such as caesarean (56) are higher. India has the highest number of stillbirths globally, nearly 600,000 annually (1), and the highest number of newborn deaths, 522,000 annually. Yet, very few studies on intrapartum FM have been conducted in low-income settings and even fewer studies on

fetal monitoring training. Moreover, the context, resources, staffing, populations and medical norms are so different from high-income settings that HIC studies for FM are unlikely to be transferable and generalisable to the Indian context.

1.8.2 Justification for fetal monitoring training intervention

Training is widely believed to save lives and avoid harm, and it is a key patient safety strategy ubiquitously recommended to improve the quality of care. In some countries, CTG training and competency are now mandatory for all maternity staff working in labour wards. (217) There are frequent, well-documented failings in CTG interpretation, classification and failure to take appropriate, timely actions regarding CTG abnormalities. (195) (218) Therefore, it seems logical that if deaths occur because of failings in CTG interpretation and actions in response to abnormal CTGs, outcomes could improve if clinicians knew more about CTG and these errors did not occur. We assume that there is a knowledge gap around intrapartum FM, and training could help fill this knowledge gap and therefore improve outcomes.

However, a recently published systematic review of CTG training highlights that the evidence base for CTG training is weak. (172) Randomised controlled trials demonstrated that training might improve knowledge. However, the evidence of CTG training leading to improved critical maternal and newborn outcomes was “low quality, inconsistent and limited”. The authors suggest future high-quality studies focus on clinical outcomes and mechanisms of change using a theory-guided system-based approach, to promote real-world understanding of the issue.

1.8.3 Nature and significance of the local need for change

Piloting and feasibility work for the MOLI project in a large Government Medical College (GMC) in Nagpur highlighted that clinicians felt that intrapartum fetal monitoring was a key challenge in their setting and a barrier to safe labour induction and safe intrapartum care. The clinicians did not feel it would be appropriate to conduct the MOLI study without access to good FM for study patients, and training and equipment were needed. Senior clinicians felt that the CS rate was too high, notably for CS performed for perceived fetal distress. Clinicians felt that improving FM could improve outcomes by avoiding perinatal deaths and harms and reducing unnecessary CS. Clinicians knew that operative intervention for suspected fetal compromise is not indicated for abnormal IA or meconium alone in high-income settings. International clinical practice guidelines recommend that a

CTG be conducted when IA is abnormal or for high-risk women. (87) In contrast, in many LMICs, a decision for operative birth for "fetal distress" is made on the sight of meconium or the sound of a "variable FH" alone.

As part of the MOLI project, two additional CTG machines were planned to be procured for each recruiting site. In addition, a visiting obstetrician from the UK (KL) was identified to train staff in CTG monitoring techniques. This training was planned independent of this doctoral research project at the request of the clinicians in Nagpur, implementing the MOLI RCT. However, due to the global significance and importance of FM and training in LMICs, it was decided to obtain ethical approval and develop the evaluation into a formal PhD research project. This involved training staff in using a two-stage assessment of intrapartum fetal monitoring: intermittent auscultation screening for all women in labour (as per current practice) plus the addition of intermittent CTG as a secondary screening test to further test the initial diagnosis of “suspected fetal compromise” (SFC) (made on abnormal IA/meconium) before operative birth, after exclusion of obstetric emergencies.

The impact of fetal monitoring training has never previously been studied in a “too much, too soon” setting where unnecessary intervention rates are high, nor in a low-income setting where mortality rates are high. It is contrary to much of the existing literature on CTG to propose that increasing CTG use could decrease operative intervention rates. However, this concept chimes with numerous conversations, over many years, with clinicians working worldwide in low-income settings hoping that technology could be the key to improving outcomes. (219) Clinicians working in any context are best placed to understand their own context and how interventions might work. This is especially pertinent where research on this topic is lacking and is typically conducted in well-resourced environments.

1.8.4 Justification for exploring women and clinicians’ views

Although some work has been conducted to understand why CS rates are soaring (38), significant further exploration is required. We can only develop appropriate interventions in a specific context if we understand the setting's specific drivers. Unfortunately, few studies thoroughly interrogate this concept and focus on women’s views. As fetal monitoring concerns during labour are one of the most frequent indications for operative birth, preliminary work highlighted that clinicians in Nagpur felt FM was a particular concern, which training could address. Qualitative exploration could potentially offer a

deeper understanding of the context of the study setting and set the role of fetal monitoring training in perspective.

Women are the focal point of care, yet their voices are often unheard in research and society. Every woman has an expert understanding of her own birth experience, irrespective of her education level or cultural background. Birth is one of life's most defining experiences, so hearing women's voices talking about birth is essential. This work will contribute to understanding and implementing respectful care in labour, in line with the principles of the respectful care agenda, which include treating every woman with respect, providing her with information about what she might expect, asking her about her expectations, and involving her in her care decisions. (108) A better understanding of women's views, ideas and priorities will allow healthcare professionals to consider these for their practice and advocate for their patients. (61) Fetal monitoring methods must be acceptable to women and incorporate their wishes and priorities where possible, as FM is such a fundamental aspect of good intrapartum care. Future development of improved fetal monitoring devices should be designed with women's preferences in mind. It is paternalistic to assume that we know what women think without asking them.

Clinicians deliver the care, and doctors make intrapartum FM and MOB decisions. We aim to improve outcomes and experiences; therefore, understanding clinicians' views is also important. Obstetricians are the gatekeepers to CS rates, so interventions cannot be tailored to address their specific concerns and circumstances without understanding their views.

1.8.5 Aim and objectives

Aim

This thesis aims to use a multi-methods approach to evaluate the impact of applying an intrapartum fetal monitoring training and quality improvement package, in the context of staff and patient perspectives on intrapartum fetal monitoring and mode of birth, in a Government Hospital in India.

Objectives

1. To explore patients' and staff's perspectives of intrapartum fetal monitoring and mode of birth.

    1.1 To explore high-risk patients' perceptions, understanding, preferences, priorities and experiences regarding intrapartum fetal monitoring and mode of birth prior to induction of labour

    1.2 To explore high-risk patients' perceptions, understanding, preferences, priorities and experiences regarding intrapartum fetal monitoring and mode of birth in the first few days after birth

    1.3 To explore clinicians' perspectives on intrapartum fetal monitoring, training on intrapartum fetal monitoring and mode of birth.

2. To apply a quality improvement package for intrapartum fetal monitoring, including training and guideline development, that is both evidence-based and appropriate to the local setting.

    2.1 To evaluate the impact of the intrapartum fetal monitoring training package

    2.2. To understand if the training package is acceptable, feasible and increases knowledge (stages one to three of Kirkpatrick's four-stage training evaluation model)

    2.3 To evaluate the impact of the training on short-term maternal and perinatal outcomes, especially in-hospital perinatal morbidity and mortality rates, and operative birth rates, particularly for suspected fetal compromise (stage four of Kirkpatrick's model).

3. To understand the indications for operative birth, maternal and perinatal risk factors and outcomes and fetal monitoring practices in a Government tertiary referral hospital in Nagpur, India.

1.8.6 Thesis overview

Chapter **one** is the introduction, which includes an overview of the literature around fetal monitoring in LMIC, unnecessary CS rates, women's and clinicians' views on FM and MOB and what is known about FM training.

Chapter **two** is the methods for the qMOLI and FM study. The first study, "An alongside qualitative study exploring patients' and health care professionals' expectations and experiences of labour induction with misoprostol and oxytocin for hypertension in pregnancy in India" (q MOLI), was conducted between January 2020 and December 2021, including a pause due to the pandemic. The second study, "Evaluating the impact of introducing a two-stage intrapartum fetal monitoring assessment, using intermittent auscultation and cardiotocography (CTG) in a Government Hospital, Nagpur, India," (FM study), ran between August 1, 2019, and March 14 2020.

Chapter **three** is the results chapter of the FM and MOB aspects of the qMOLI study, which evaluates women's and clinicians' views on fetal monitoring and MOB.

Chapter **four** outlines levels one to three of Kirkpatrick's model (reaction, knowledge gain, behaviour change) for the FM training.

Chapter **five** outlines level four of Kirkpatrick's model, a pre/post longitudinal study of maternal and perinatal outcomes and fetal monitoring process indicators before and after the FM training intervention.

Chapter **six** is an analysis of the prospective cohort study data evaluating risk factors, outcomes, fetal monitoring practices and indications for operative birth.

Chapter **seven** is a proposed theory of change about how FM training could be designed to improve outcomes.

Finally, chapter **eight** is the discussion and conclusion.

Chapter 2 - Methods

2.1 Overview

This chapter outlines the multi-methods used in this thesis, including the multi-methods fetal monitoring training evaluation and qualitative study. Chapter one introduced the key obstetric interventions (intrapartum fetal monitoring, caesarean section and induction of labour) which are principal concerns in global maternal health policy and central to the two studies outlined in this thesis. The first study, entitled "An alongside qualitative study exploring patients' and health care professionals' expectations and experiences of labour induction with misoprostol and oxytocin for hypertension in pregnancy in India" (qMOLI), was conducted between January 2020 and December 2021, including a pause due to the pandemic. The fetal monitoring and mode of birth aspects of qMOLI are presented in this thesis, and the induction of labour aspects are presented elsewhere. The second study, "Evaluating the impact of introducing a two-stage intrapartum fetal monitoring assessment, using intermittent auscultation and cardiotocography (CTG) in a Government Hospital, Nagpur, India" (FM study), ran between August 1, 2019, and March 14 2020. This multi-methods fetal monitoring training evaluation was conducted in a fixed, parallel, convergent design (166) and based on Kirkpatrick's four-stage evaluation model. (220)

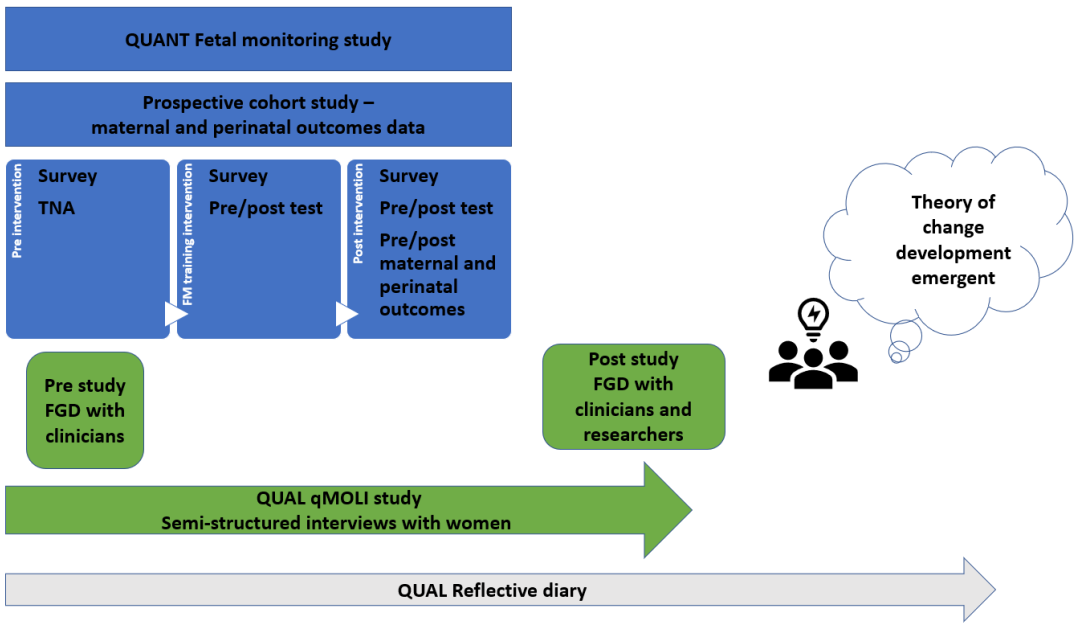

Figure 16 Overall thesis study design

2.2 Theoretical framework and methodology

2.2.1 Rationale for using multi-methods research

Mixed and multi-methods research involves using both quantitative and qualitative approaches to answer research questions. (166),(221) Research has moved on from the initial quantitative to the qualitative paradigm and now to the "third research paradigm" or "third methodological movement". (222) Researchers argue it is a more intuitive way of conducting research that aligns more with our everyday lives. (223) There are numerous definitions of mixed methods research, and there is no high-level consensus on this definition. (223) In Creswell's definition, the author outlines that the researcher

> "Collects and analyses both qualitative and quantitative data rigorously in response to research questions and hypothesis,
>
> Integrates (or mixes/combines) the two forms of data and their results,
>
> Organises these procedures into specific research designs that provide the logic and procedures for conducting the study, and
>
> Frames these procedures within theory and philosophy." (166)

Multiple methods were used to address this research problem. We assumed that combining research approaches would create a more comprehensive understanding of problems and solutions and triangulation of results. (166) We felt it was useful and relevant for this complex and complicated subject (fetal monitoring and birth). In addition, using these approaches can offset the limitations of both sets of methods, and just one approach would not tell the full story of the realities of clinical education. Although more challenging to conduct, as more skills, time and resources are necessary. Multi-methods can deliver more practical solutions and incorporate different worldviews. This is especially useful to bridge the gap in clinical education research between the realities of working in healthcare systems, theory-driven medical education literature, and quantitative-based clinical research. Using one approach alone would limit the explanatory power of this research and its usefulness.

Rationale for research design

A fixed design was used, as both quantitative and qualitative aspects were planned and pre-determined at the beginning of this research. The primary intent of this thesis was for both the quantitative and qualitative aspects to be given equal priority, as the research team believes that both paradigms are of equal importance. For these research questions, both are necessary to understand this research phenomenon fully. The overall methodology for this thesis is multi-methods, as both qualitative and quantitative methods are used to address the different aspects of the thesis aims and objectives and answer wider research questions relevant to the context of intrapartum FM training using both quantitative and qualitative research streams. Furthermore, a Theory of Change development was emergent at the end of this research process and is outlined in Chapter seven to consolidate and describe our understanding of fetal monitoring training and share this understanding with others.

A convergent design was used to evaluate the FM training. We aimed to bring together the quantitative and qualitative aspects to compare and combine results to gain a better understanding through different but complementary datasets. (224) A convergent design was chosen as the design was efficient (due to limited time in India), and different aspects could be supervised separately due to different expertise within the supervisory team. A parallel design was chosen due to the logistics of managing the various study timeframes and the limited time in Nagpur for data collection. Using an explanatory or sequential design

2.2.2 Rationale for qualitative approaches

Increasingly, researchers are using qualitative methodologies to answer research questions that quantitative research cannot answer in obstetrics and gynaecology. (225) They can be used to consider why individuals think or behave the way they do, how they come to understand these complex thoughts and attribute meaning to experiences. (226) A systematic review confirms the increasing amount of qualitative healthcare research in India over the last 20 years (227), but it is not yet used routinely. In this thesis, qualitative methods were used as we aimed to understand views and experiences and hear unheard voices. Depth and detail were needed to understand this complex subject matter fully. Quantitative methods would not have permitted this deep exploration, and surveys alone,

without the time to build rapport with the researcher team, could have risked short and closed responses and missing women's true feelings.

As qualitative research is not widespread in India and staff and patients are unfamiliar with being asked detailed questions about their views and experiences, the research team discussed and decided upon different data collection methods for women and clinicians. Semi-structured interviews were used with women to promote privacy and create a one-to-one rapport between the women and research associates on the infrequently discussed and potentially sensitive topic of birth. A semi-structured format was chosen to ensure the research questions for all study aspects were addressed and encourage free-flowing conversations led by what women felt was important. Focus group discussions (FGDs) with research staff and clinicians were used to promote the group dynamic and discussion, understand collective experiences, and develop a rich understanding of underlying beliefs. The FGDs were planned before and after the training intervention to evaluate the impact of the training and anticipated versus experienced viewpoints of clinicians. There would have been clear benefits of using an ethnographic approach; however, the local team felt that the local ethical review board might oppose this and the ethical issues of having a "foreigner" leading research focused on observations posed ethical challenges.

The rationale for using thematic analysis using the framework approach was that it is suited to large volumes of data and working in teams. (228) It was developed in the late 1980s for policy research and is now used widely in several areas, including health and policy. It aims to create an output that can be used in practice. It allows the evaluation of different experiences and helps identify commonalities and variances before focusing on connections in the data. (229) It aims to draw descriptive and explanatory inferences grouped around themes. (230) This framework approach was adopted because it is not aligned with a specific epistemological, philosophical, or theoretical approach. In addition, the large group of researchers conducting the MOLI study has mixed backgrounds (obstetricians, community medicine and sociologists) with mixed cultural backgrounds (UK and Indian) and experience in qualitative research. Therefore, the structured output aligns with many team members' clinical and quantitative paradigms. (228) As there is minimal published data on which to base a deductive approach and the cultural backgrounds of these researchers and participants differ, the themes were generated through an inductive approach. A purely theoretical study would not have been aligned with the paradigms of

many of the research team and does not produce such structured and implementable outputs.

2.2.3 Rationale for approaches used in fetal monitoring study and using Kirkpatrick's four-stage evaluation model

Quality improvement methodology was chosen to allow the flexibility to build an appropriate, acceptable, and feasible training and quality improvement project led by clinicians on the ground. Pre-specification of all elements was not possible at the protocol stage due to a lack of understanding of the clinical and educational context and the need for flexibility. This was the first project of its kind in this department, and extensive and evolving discussions with key stakeholders were needed. It was unclear what would be feasible and appropriate until each project step evolved. In addition, there was limited literature/guidance on the nature of the ideal CTG training on which to base the planning.

In this case, the process began with clinicians in GMC highlighting intrapartum fetal monitoring as "a problem" and that training could help. The FM protocol represents the first of the PDSA cycles. Standard research principles were used to gain new knowledge, including pre-specification of a research protocol and rigorous data collection, aiming to draw generalisable conclusions relevant to intrapartum FM training globally.

Kirkpatrick's four-stage training model was chosen for this study as it has been widely used for training evaluation in medical education (231) (220) since it was originally designed in the 1950s (220) for business. In addition, it has been used successfully in India (232), other low-resource settings for postpartum haemorrhage (233) and in evaluating CTG training in systematic reviews. (190) Despite all the controversies, CTG and CTG training aim to improve the detection of the hypoxic fetus. Therefore, the overall aim of the study and the majority of outcomes were focused on maternal and perinatal outcomes. In addition, other outcomes were derived from the literature review and through considering the proposed quality improvement change theory, such as process measures, risk factors and documentation. Evaluation models focused on learner outcomes and theoretical constructs would miss the aims of this study, to measure impact on patient outcomes. In the planning phases, a randomised controlled trial was discussed, but this was unfeasible within the budget and time available. An interrupted time series would have been useful, but due to the short time frames of the study and the unknown duration and timings of the intervention, it was not used.

Surveys are a standard part of most training evaluations and involve "the collection of information from a sample of individuals through their responses to questions". (174) We employed closed and open questions to gain a greater understanding of the impact of the training. In addition, we sampled all those attending specific sessions to gain the most feedback at various time points (before/mid/post) intervention to gain insight into the evolving impact over time. It was planned to gain richer data from the FGDs post-training, but this was not possible due to the COVID pandemic.

The whole dataset collated over six months was also analysed as a secondary analysis, as one cohort, to fully understand the population, including rates, risk factors, mode of birth indications, and outcomes, and to identify if fetal monitoring training could have had a significant impact on outcomes. It would have been ideal to have collected detailed data in advance of the study to gain a data-driven understanding of the problem. However, this was not feasible due to logistical and financial considerations. In addition, high-quality datasets with information on risk factors and fetal monitoring from low-income settings are rare.

2.2.4 Rationale for approaches used in the theory of change

The theory of change development was emergent and added as an expansion to this research towards the end of this research process. Reading about realism and realist evaluation in response to the publication of the systematic review on CTG training inspired the work that led to the development of a theory of change about FM training (chapter seven). (234) CTG training is a complex intervention which exists in a complex social world and should be evaluated as such. So, instead of asking "what works" for FM training, we need to understand what works for practising healthcare professionals who work on labour wards (sometimes infrequently) in different contexts and why. A realist evaluation is an emerging research method, which aims to understand why complex interventions work, how, for whom, in what context and to what extent. (235) It has been used for previous patient safety evaluations (236) and may be useful when evaluating CTG training. The intervention of CTG training is multifaced, delivered by different people and implemented in different organisations. Each has its own culture, challenges and assets and therefore creates different social transformations. Realism was used to focus on “what works” rather than simply descriptions, links and explanations from other theories and this research is focused on collective actions rather than individual behaviour. The full explanation of

approaches used and why are all incorporated in chapter seven, as this aspect of the thesis was emergent at the end of the research rather than pre-specified at the beginning.

2.2.5 Philosophical assumptions

An overarching worldview of pragmatism is used throughout this research. As with much-multi methods research (237), it is focused on the problem, real-world practice and "what works". The research question and consequences are prioritised above methods, purist theory and worldviews.

How clinicians learn was predominantly understood through a lens of constructivism throughout this research. If undergraduate students build knowledge from the ground up or from relatively simple constructions, which can be easily adapted, updated, and modified. Currently practising HCW's knowledge, especially among senior and experienced doctors, is already a complex cityscape containing intricate, interconnected architecture. Supporting HCWs to accommodate and assimilate knowledge is difficult and requires thought and attention.

2.2.6 Role of theory

This thesis has been influenced by different theories, including evaluation theory (to understand the necessary criteria for appropriate evaluation) and programme theory (to understand how programmes bring about change). (238)(239) The qMOLI study was informed by some of the principles of grounded theory, with close reliance on the data and themes built from a data-driven inductive approach. The constant comparative methods were used for analysis, and participants were recruited until data saturation. (240) The discovery of new information allowed the adaption of interview schedules and approaches as new theories emerged. However, it is not a grounded theory study. The study never sought to generate sociological theory, is not a theoretical study and has not formally followed grounded theory methods and methodology.

2.2.7 Reflexivity

As Van Maanen highlights how the "confessional tales" of research offer relevant insights into research conduct. (241) This section aims to outline some of my background beliefs and experiences. I came into this research as an obstetrician, passionate about global maternal health, who was keen to learn, teach and gain experiences. I fundamentally believe that clinical education is very important and has the power to change clinicians for

the better. I also believe that women's experiences and how women and clinicians think and feel are important. I find that positivist research, which is focused entirely on measuring and counting, does not reflect the real world well enough to be as useful as it should be in improving outcomes. I strongly believe in evidence-based medicine, but it needs to be shared and conducted in a manner that is meaningful for clinicians. I have seen first-hand (primarily in Africa) the danger of CS in LMIC and the suffering of women. Therefore, I believe vaginal birth is the safest mode of birth, and CS should only be performed when truly indicated in LMICs. I am biased towards believing that most clinicians aim to do their best and have purist intentions to help others (which is flawed) and that obstetrics is a difficult and intricate art requiring far more skills than simply being able to conduct operations well.

Methods chosen in this thesis were underpinned by pragmatism, as I believe that research findings, where possible, should be pragmatic and implementable in clinical practice. As such multi-methods research, bringing together different approaches and different datasets seems more intuitive and "real world". As a clinician aiming to achieve practical changes, purely theoretical or quantitative research approaches are not intuitive. Different team members had different metatheoretical stances, with important post-positivist influences on this research. Across the research group, there are marked differences in research, clinical and cultural backgrounds which had important influences on all aspects of this research. My role as a white, female, non-Indian, non-consultant obstetrician also had a significant impact.

As Coffey and Atkinson highlight, detailed memo writing and reflective diarising throughout the research aimed to ensure transparency and document "part of the transformation of data from personal experience and intuition into public and accountable knowledge". (242) I aimed to acknowledge through reflexive accounting the effect our individual potential biases could have, but recognise this is very difficult to achieve. (243) Whilst accepting that researchers' values, knowledge, and background influence what is observed.

2.3 qMOLI study

2.3.1 qMOLI overview

The qMOLI study was an alongside qualitative sub-study of the MOLI randomised controlled trial. The fetal monitoring and mode of birth aspects of Q-MOLI are presented in

this thesis. The induction of labour aspects has been analysed as a separate workstream (supervised by KL) and will be published elsewhere. It was planned to conduct most of the FGDs shortly after the fetal monitoring training (as well as two before the training/MOLI study). Unfortunately, this was not possible as the FGDs were delayed for over 18 months due to the COVID-19 pandemic.

Full study title

An alongside qualitative study exploring patients' and health care professionals' expectations and experiences of labour induction with misoprostol and oxytocin for hypertension in pregnancy in India.

Short title

qMOLI - a qualitative assessment of Misoprostol or Oxytocin for Labour Induction.

Keywords

"Women's views," "clinicians views,", "fetal monitoring," "preferences," "mode of delivery/birth," "experiences," "intermittent auscultation," "CTG," "India," "qualitative"

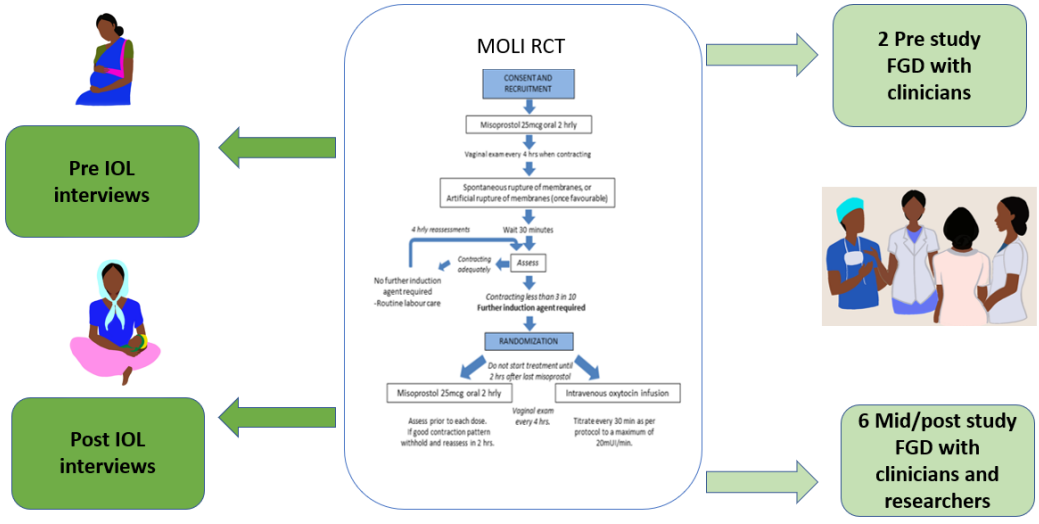

Figure 17 Q MOLI study design

2.3.2 Study setting

This study was conducted in two government hospitals and recruiting sites for the MOLI RCT in Nagpur, India. The first site was the same as the fetal monitoring study, Government Medical College, Nagpur, a government tertiary referral hospital and post-graduate training institution. The second site, Daga Womens Memorial Hospital, was a large Government stand-alone maternity hospital, which accepts lower-risk referrals and refers to the tertiary centre where necessary. There are fewer doctors in this second hospital, and care is primarily delivered by medical officers and trainees undertaking a two-year residency in obstetrics and gynaecology. Some CTG training was planned for the second hospital, but this was not part of a formal research study, and no CTG training had occurred at this site at the time of the first FGDs.

Patient interviews were undertaken in private, quiet rooms adjacent to the labour/postnatal wards. According to patient preference, interviews were conducted in Hindi or Marathi by local research assistants. Focus groups with clinicians were undertaken in private office rooms in non-clinical areas within the hospital. The FGDs were conducted in English and Hindi. Staff were relieved of clinical duties during the FGDs. The researcher's FGD was conducted in a room within AIIMS University, as this is the typical location for RA training and meetings.

2.3.3 Eligibility criteria

Semi-structured interviews

Inclusion criteria

Women recruited to qMOLI were either antenatal (pre-induction of labour) or post-natal, met all of the eligibility criteria to enter the RCT and gave separate consent to participate in the qMOLI study.

Of note, MOLI RCT recruits were antenatal patients with a live fetus, with hypertensive disorders of pregnancy, due to be induced, over the age of 18, who had signed the informed consent form. Women who were excluded from the MOLI study had previous CS, were unable to give informed consent, had multiple pregnancies, had an allergy to misoprostol or other cervical ripening agents than misoprostol.

Exclusion criteria

- Women who were not recruited to the MOLI RCT
- Women who lacked the capacity to make an informed decision
- Women who were distressed/in pain
- Women too unwell to take part in interviews or who needed urgent intervention (in less than two hours), where the time taken to conduct the interview would cause a delay in starting the IOL process and thereby potentially harm the patient.

Focus groups

Inclusion criteria

- Practitioners who were involved in screening, recruiting, randomising and consenting participants to MOLI RCT

(This involves most staff members and members of the research team, including doctors and nurses, working in the labour ward, and some from antenatal and postnatal wards and MOLI research assistants.)

Exclusion criteria

- Staff who did not wish to be included and did not consent to participate.

2.3.4 Recruitment

Women – After a woman was recruited into the MOLI RCT, the MOLI RCT research associate briefly explained the qMOLI study and asked if she was willing to enter the alongside qualitative study if it was clinically appropriate. Next, she was asked to read the qMOLI patient information leaflet in Marathi or Hindi if the patient was willing. The qualitative research associate then further explained the qMOLI study in detail. The research team also explained the study to relatives and staff members and had the opportunity to discuss entering the qMOLI study with whoever she wished, including relatives, friends, staff or legal representatives. If she wished to enter the study, the research associate and participant typically went to a private room to obtain written consent and record the in-depth interview, although some patients chose to stay at the bedside. Where the patient was illiterate, the patient information sheet and consent form

were read aloud to the patient by the research associate. If necessary, a thumbprint could be used instead of a signature.

The consenting process was dynamic according to patient preference but always included discussions on the nature of the study, possible risks, time commitments, data handling, the potential to answer questions and the presentation of written material. Emphasis was placed on the voluntary nature of the trial and that the interview could be stopped at any time without risk to the patient's care. It could take place in a private side room or at the bedside, and she could choose to be interviewed alone or with an attendant. The research team often reflected that women seemed keen to share their experiences but that some requested further reassurance and explanation about confidentiality, the nature of pseudonyms and ensuring that relatives could not access the recordings.

Patients were recruited at two-time points. One group before the induction of labour process and another whilst an inpatient on the postnatal wards (usually day two to four days postnatal). In the pre-IOL group, patients had less than an hour to consider entering the study due to the clinical need to avoid delays in the IOL process. Postnatal patients were given as long as they wished before postnatal discharge (this was hours or even days in some cases) to consider if they wanted to enter the study.

Staff - The focus group discussions were advertised, and information was shared by the MOLI research and clinical team with colleagues. Information leaflets were shared amongst staff via the usual communication routes with doctors (posters/WhatsApp group messages) and at the MOLI launch meetings. Staff were asked to read the information sheet and sign an informed consent form before participating in the FGD.

2.3.5 Sampling

Sampling was purposive and conducted according to a sampling frame defined in the study protocol. The sampling frame was devised according to key factors such as hospital, parity, mode of birth, RCT arm and cadre of staff. Some patients were only interviewed once (either before IOL or postnatally.) Others were interviewed both before and after IOL to better understand individuals' concerns, expectations, and experiences and the changes between expectations and experience. The decisions around which women to interview once or twice depended on the patient's wishes and the research staff's availability.

The interviews were continued until data saturation was met (240) (244) (245) for each aspect of the study (IOL, MOB, FM, MGBSI) hence the relatively large sample.

Pre-IOL sampling frame as specified in the protocol

Table 3 Pre-IOL sampling frame

Criteria	Patients
Primigravida	3+
Multigravida	3+
Social strata	Mixed
Hospital site	2+ from each site

Post-IOL sampling frame as specified in the protocol

Table 4 Post-IOL sampling frame

Criteria	Patients
Misoprostol/misoprostol regime - Vaginal delivery	3+
Misoprostol/misoprostol regime - Caesarean delivery	3+
Misoprostol/oxytocin regime – Vaginal delivery	3+
Misoprostol/oxytocin regime - Caesarean section	3+
Repeat interview of those already interviewed pre-IOL	6+
Social strata	Mixed
Hospital site	3+ from each site

2.3.6 Data collection

All interviews and focus groups were digitally recorded on password-protected recorders following the participants' consent.

Patients – Semi-structured in-depth interviews were conducted face-to-face, in the language of the patient's choice (usually Hindi/Marathi), by two trained research associates. Topic guides were used to guide discussions and ensure key topics were covered but allowed flexibility to discover and elaborate on pertinent data.

Interview guides were developed by the qMOLI study research teams led by KL. After five and ten interviews, they were further reviewed and amended by the qMOLI team via email discussion and consensus meetings. Interview guides were initially written in English, translated into Hindi/Marathi, and then back-translated to ensure accuracy.

Staff – Focus group discussions were facilitated by a senior qualitative researcher and medical doctor (JT). He was familiar with the MOLI and qMOLI studies but not the interviewed practitioners. FGDs were conducted primarily in English, with Hindi, when the participants preferred and often as the dialogue evolved. Interview guides were followed, which were drafted with the protocol, but amended throughout the research process. An additional observer or two was present for note-taking and to ensure that appropriate consent forms were completed (MOLI RA.)

2.3.7 Data analysis

The framework approach (228) to thematic analysis was adopted due to the research team's mixed backgrounds, the research group's relatively large size for a qualitative study and multiple aims.

Stage 1 -Transcription and translation

Interviews and FGDs were transcribed verbatim by the research associate in the local languages. Marathi is rarely used in digital formats as the symbols are typically unavailable on computers. The transcription was therefore done on paper. It was then translated into English in a digital format. Finally, 10% of translations were checked against the voice recordings and paper transcripts by senior native-speaking researchers. Queries that arose throughout the study were dealt with between the RAs and senior members of the team.

Stage 2 - Familiarisation

The research associate took reflective notes before and after each interview, and each interview was discussed with KL at length on the day of the interview, and further notes were taken. Each transcript was checked and edited for typographical errors and sense by KL. Then the RA read through each interview, line by line, with KL to ensure sense, correct meanings and cultural interpretations. Explanatory comments were added in brackets where explanations were required to ensure meaning was appropriately conveyed in written format.

Data was then uploaded into NVivo 12 software for storage and data management. Each interview was re-read at least twice by KL, and notes were taken before coding.

Stage 3 - Coding

Three research team members independently coded three transcripts (CK, SM and KL), and KL coded the whole dataset at that time point (two FGDs and ten interviews), line by line, using inductive open coding. Different codes represented emotions, values, things and more impressionistic/methodological elements. "Other" codes were used to avoid missing any concepts. Detailed memos were written throughout.

Stage 4 – Developing a working analytical framework

CK, KL and SM all drafted an initial draft of a framework separately. The three researchers' provisional frameworks were discussed at length and then merged over multiple iterations and several consensus meetings. Codes were categorised and defined. This provisional framework was reviewed and agreed upon by the wider qMOLI team. It was then applied to the initial ten interviews. The provisional framework was looser for the FGDs at the beginning of the study. The frameworks for the FGD data were finalised much later in the study due to delays and challenges due to COVID, and the interview schedules were slightly different for the pre- and mid-trial FGDs.

Data collection was continued until data saturation and the pre-specified sampling frame was met. A relatively large sample was obtained due to the need to adequately represent the different groups, such as pre-IOL, different MOB and randomised groups, pre/post-randomised patients and some incomplete interviews.

Stage 5 – Applying the analytical framework

The analytical framework was applied to the data, with any queries coded in an "unknown" code. When all data had been coded, the final iteration of the framework was agreed upon by consensus.

Stage 6 – Charting data into the framework matrix

The data were charted in a framework matrix in excel, including quotes, summaries and analysis of each code.

Stage 7 – Interpreting the data

The matrices were discussed further by the research team and mapped into themes. Rigour and transparency were maintained through regular team meetings (monthly/two months), as well as individual supervisory meetings (with AW and CK) to review the study processes and data. Minutes were recorded at the wider team meetings.

2.3.8 Study governance

This study was sponsored by the University of Liverpool, UoL001454 – 4791. The protocol was published on clinicaltrials.gov, NCT04037683.

2.3.9 Ethical considerations

Ethical approval was obtained in Nagpur (19/3/2019, 1756/EC/Pharmac/GMC/NGP) and the University of Liverpool (27/3/2019, 5019).

This study was conducted in accordance with

The World Medical Association Declaration of Helsinki (1996)

International Conference of Harmonisation Good Clinical Practice (ICH GCP)

Indian Council of Medical Research (ICMR) guidelines

Gynuity Health Projects and University of Liverpool Standard Operating Procedures

All research associates were trained in appropriate communication skills and dealing with potentially sensitive birth-related topics. The potential vulnerabilities of this participant group were clearly outlined. They were trained to ensure they knew in what circumstances interviews should be stopped in order to prioritise participant comfort and safety. They also knew that if any issues were disclosed that could cause physical harm to the patient or her child, they would be discussed with the on-call doctor team or research team as appropriate.

2.3.10 Data management

This data was collected and stored in a manner compliant with the Indian Council of Medical Research guidelines, the UK Data Protection Act 2018 and the UK General Data

Protection Regulations 2018. All project staff had to comply with these requirements concerning collecting, storing, processing and disclosing personal information and uphold the Regulation's principles. In addition, all researchers have completed the Good Clinical Practice (GCP) training.

A full suite of data management plans and SOPs have been written, audited and approved for the MOLI RCT by the trial sponsor, the University of Liverpool and these were used for the sub-studies where relevant.

Recordings were made on two password-protected digital recorders to guard against equipment failure. These were anonymised, and attempts were made to avoid using any identifiable data during the interview. Where names/places were occasionally used in the recording, these were changed, e.g. recorded as SXXX. Each participant was given a study number. These recordings were stored securely in a locked room in GMC's research office on password-protected files. Completed audio recordings were transcribed, and copies were sent in encrypted password files. Copies of the data were saved on the M drive, at the University of Liverpool. Data in other forms, e.g. NVivo, tree diagrams and excel spreadsheets, were anonymised and stored in encrypted files on password-protected computers.

The patient consent forms for qMOLI were printed in triplicate; the original copy was filed in the site office in the site file, a copy was given to the patient for their records, and another copy was in the patient's notes. The FGD consent forms were completed by clinicians and research staff and then retained by the research team. In addition, the qMOLI documentation was kept in a separate file, in a separate locked cabinet, in the MOLI site offices, from the main MOLI documentation. Patient consent forms were kept separate from the transcripts to maintain anonymity.

The minimum number of individuals necessary had access to this data for quality control, audit and analysis. Any data transferred to co-investigators, the host institutions or sponsors were anonymised. The backup data will be stored for ten years as requested in the University of Liverpool SOPs on record retention. The data custodian will be the Sponsor, the University of Liverpool. The original data file will be stored in India, as per Indian data protection laws.

Archiving of data will be undertaken in line with the Sponsor's requirements, as detailed in the Sponsor Standard Operating Procedure "Archiving of Essential documents for University Sponsored Studies" at the end of the project. All essential documents will be archived for a minimum of five to ten years after completing the project.

2.4 Fetal monitoring study

2.4.1 Overview

This study aimed to evaluate the impact of an intrapartum fetal monitoring training and quality improvement programme undertaken in a government tertiary referral hospital in central India, using Kirkpatrick's four-stage evaluation model. Quality improvement methodology was used to plan and deliver the intervention. Clinicians' reactions to the training (level one) and behaviour change (level three) were measured with surveys. Knowledge gain (level two) was assessed using pre/post-tests. Maternal and perinatal outcome data were collected prospectively for all births throughout the six months study period. Maternal and perinatal outcomes were analysed using a pre-post design for the training evaluation (level four) and as a prospective cohort study to evaluate the risk factors, morbidity and mortality rates, intervention rates and indications for operative birth in this population. A detailed reflective diary was kept throughout the intervention planning and delivery period. The SQUIRE-EDU 2.0 (246) (standards for quality improvement reporting excellence in education) standards were used to guide planning and reporting.

Full/long protocol title

Evaluating the impact of introducing a two-stage intrapartum fetal monitoring assessment using intermittent auscultation (IA) and cardiotocography (CTG) in a Government Hospital, Nagpur, India.

Short project title

Evaluating a two-stage intrapartum fetal assessment in India. Fetal monitoring study (FM study).

Keywords

"fetal monitoring training," "intrapartum," "cardiotocography (CTG)," "intermittent/intelligent auscultation (IA)," "clinical education research," "Kirkpatrick's four-stage evaluation model," "India"

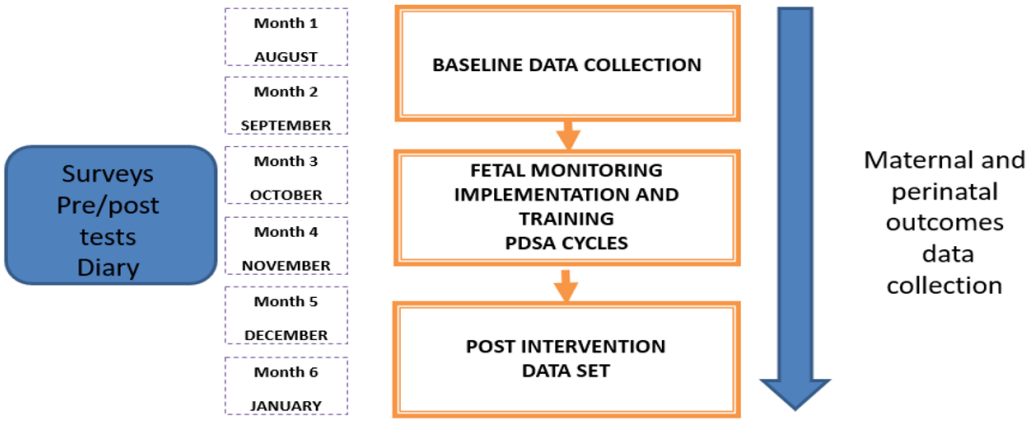

Figure 18 Fetal monitoring study design

2.4.2 Research setting and local educational and clinical context

This study was conducted in a tertiary referral hospital and Government Medical College (GMC) in Nagpur, India. It serves the local population and accepts all referrals of complex patients from across the city (both private and public). In addition, the hospital contains all tertiary facilities for the city, including the adult intensive care unit and tertiary NICU facilities.

Fetal monitoring

In GMC, fetal monitoring involved intermittent auscultation for high-risk and low-risk women undertaken by doctors. One CTG machine was also intermittently available in the high-risk labour ward, primarily for antenatal rather than intrapartum use. A second machine was available for the first few weeks of the study in the low-risk labour ward. However, it malfunctioned and was not fixed or replaced.

Routine data collection

Routine data such as numbers of admissions, operations performed, deliveries and deaths are recorded, and maternal deaths are audited monthly. Before this study, CS rates were

believed to be around 40-45% (247), but accurate data for the whole population was not available.

Clinical care structures and staffing

The obstetrics and gynaecology department had six clinical units led by senior clinicians. A further 25 senior doctors (professors, associate professors, assistant professors and senior residents/medical officers), 60 resident doctors (undertaking their three-year post-graduate qualification to become specialists in obstetrics and gynaecology), interns (first-year doctors), and undergraduate students were in the department. Nurses in the maternity unit gave drugs and completed records but did not typically undertake patient observations/fetal monitoring/remain with women, and there were no midwives. Doctors rotated through the different clinical areas every few months for daytime duties (including the labour ward). In addition, each unit undertook a 24-hour on-call for emergency work and admissions on rotation.

Hospital clinical practice guidelines were not routinely used, and clinical care was directed personally by the head of each clinical unit. Protocols followed vary by unit, e.g. for induction of labour. Clinicians frequently quoted international guidelines such as NICE, RCOG and FIGO. WHO and FOGSI guidelines were rarely mentioned.

There appeared to be strong hierarchies between senior and junior doctors and the residents in different training years. All departmental management decisions were made by the Head of the Department, in collaboration with the Dean of the College, if significant or financial. Staff worked incredibly hard to meet their patient's needs and deliver good patient outcomes. However, the sheer volume of patients and the high-risk nature of patients in the hospital were significant and persistent challenges.

Labour wards

There were two labour wards; one high-risk and one low-risk and mixed antenatal and postnatal wards. Each clinical unit was on call for 24-hour periods and covered all emergency areas including the labour wards, gynaecology and emergency theatres. Typically this was one head of unit (senior Consultant) who led the ward rounds and was called for assistance occasionally and one/two assistant/associate professors or senior residents (equivalent to the registrar/senior registrar/junior consultant) who led most

emergency activities. There were between three to eight residents (equivalent to SHO or junior registrars) who monitored patients, clerked new patients and conducted the majority of deliveries. Each day 50-100 births occurred, and all births were conducted by Doctors.

The focus of clinical activity was the high-risk labour ward, which had several small rooms with between two to eight beds. Each bed was occupied by one or two patients, plus the patient's attendants (relatives) next to the bed. The unwell patients, HDU patients and patients in labour were managed in several of these rooms and were then moved into the larger, lighter delivery room with four delivery beds with stirrups to give birth. Soon after birth, they were then moved to the larger ten-bedded immediate postnatal room. Once stable, patients were moved to the busy post-natal wards, which typically had 50-80 patients/ward and bed-sharing was common. There was often one or no plugs in each of these rooms, one functioning sink for clinicians to wash their hands on the whole ward, there was no piped oxygen and one shared bathroom for the whole delivery suite. If theatre was required, patients were moved down the busy hospital corridor, to the theatre waiting room, until one of the two maternity theatres was available. Typically at least two residents would be undertaking caesareans throughout the day and night.

Teaching practices

Teaching and learning occurred within the team-based structures during clinical work such as ward rounds, clinic, theatre and on-call duties. The “post-graduate activity” occurred daily, where residents typically delivered presentations and received questions and feedback from seniors. Middle-grade doctors supported juniors in preparing these presentations and supervised them. All residents had annual examinations, and passing was necessary for progression. All seniors were respected and considered to be learned teachers. Once residency is complete, there are no further routine post-graduate training sessions or competency requirements, although some seniors attend the "postgraduate activity" daily. Maternal death audit meetings occurred every one to two months, and data was collated by a middle-grade Doctor.

2.4.3 Methodology

Quality improvement methodology was chosen to allow the flexibility to build an appropriate, acceptable, and feasible project, based on the training needs, for the local

setting. A quality improvement hypothesis was devised in the study protocol, using the "Model for Improvement" (210) questions. This was used to build the evaluation as part of Kirkpatrick's four-stage model. Throughout the pre-intervention and intervention period, the plan, do, study and act (PDSA) cycle (210) was used to modify the intervention and co-interventions according to feedback and local needs to address the ongoing barriers to change.

Model for improvement questions within the setting of GMC

What are we trying to accomplish?

- To understand current practice and maternal and perinatal outcomes
- To improve intrapartum fetal monitoring
  - With IA
  - With CTG
- To improve perinatal morbidity and mortality rates
- To reduce caesarean section rates for suspected fetal compromise

How will we know that change is an improvement?

- Improved staff knowledge and confidence in intrapartum fetal monitoring
- Increasing documentation of risk factors for poor perinatal outcomes and intrapartum fetal heart rates
- Streamlining of intrapartum fetal monitoring pathways
- Reducing rates of caesarean section for suspected fetal compromise without worsening fetal outcomes
- Reducing rates of perinatal morbidity and mortality

What change can we make that will result in improvement?

- Development of local guidelines based on international guidelines and expert consensus
- Fetal monitoring training on IA and CTG for all cadres of staff caring for intrapartum patients, that is acceptable, feasible and increases knowledge
- Hands-on labour ward support from a clinician familiar with CTG from the UK
- Regular PDSA cycles to refine processes

2.4.4 Quality improvement change hypothesis

We hypothesised that creating local guidelines and training all relevant staff in intrapartum fetal monitoring would:

- Improve staff knowledge and confidence in intrapartum fetal monitoring using IA and intermittent CTG.
- Improve the quality and documentation of fetal monitoring during labour, which would, in turn, improve perinatal and maternal outcomes.
- Improve the accuracy of the antepartum diagnosis of "fetal distress" and therefore reduce the number of unnecessary caesarean sections conducted for false-positive diagnoses of "fetal distress" whilst ensuring no increase in perinatal morbidity and mortality rates

2.4.5 Development of intervention

Intervention planning

When planning the protocol, KL spent months developing a thorough understanding of existing teaching methods and curricula. Various modes of inquiry were used, including literature searching, personal experience, talking to intrapartum fetal monitoring and medical education experts, observing experts' teaching sessions, talking to clinicians who had undergone training and undertaking the Associate Fellow of the Higher Education Academy qualification. Existing CTG training programmes (full-day workshops on physiological CTG, "intelligent auscultation" workshops and weekly CTG meetings) were attended, and online training packages (K2) were completed. KL also undertook informal observation in two UK hospitals well known for their CTG training excellence (see chapter one). Discussions with their key staff, observing teaching, reviewing local guidelines, training presentations, working patterns and assessment tools added significant value to this understanding. Formal and informal feedback, including surveys, shaped this training programme's format. The informal observations highlighted the importance of the co-interventions of engagement of colleagues, creating a desire to learn, empowering all staff within a department through knowledge and encouragement to speak up about concerns and the criticality of aligning local policies and guidelines to the training, to avoid confusion and potential harm.

Due to the development work described above, a series of sessions, including interactive lectures and case-based discussions, was planned based on existing CTG training in the UK. The lectures were planned to enable the transfer of large amounts of knowledge necessary to larger groups to ensure the whole department received training. Then the smaller group case discussions focused on clinical cases to encourage learning conversations due to the subjective nature of CTGs and the complex labour management plans needed. K2 was also included, as this is commonly used in many UK hospitals to meet the requirements for training, and online learning is used in several of the published research papers. My colleague (RK) had previously liaised with K2, and they had kindly agreed to give access for free as part of this study. The potential for internationally recognised certification as part of K2 was considered meaningful for staff.

The logistics of timings, session planning and location, were not determined until KL arrived in Nagpur. Then plans were made according to feedback from staff in the training needs analysis, pre-intervention survey and training norms within the department.

Planned intervention from protocol

The proposed initial intervention was outlined in a research protocol. The steps included gaining support through discussion and engagement with the Head of Department and senior staff, development of local guidelines adapted from international guidelines, KL to gain a baseline understanding of the department, half/full day series of lectures and workshops for all staff including Doctors and nurses including online lectures on https://physiological-ctg.com/lectures/lectures.html. The sessions were planned to include why we need physiological CTG interpretation, fetal and placental development, fetal monitoring, physiology of hypoxia in labour, acute hypoxia, classification of the CTG, CTG management plan and adjunctive techniques for assessment of fetal wellbeing. These sessions were planned to be a mix of online lectures, lectures by KL and Nagpur clinicians, and interactive and problem-based learning such as group discussions and case studies. In addition, staff received handouts, copies of the local guideline and instructions on where further information/resources could be accessed for their own further self-directed study.

Laying the foundations for the intervention

On arrival in India in July 2019, KL spent the first few months integrating with colleagues and understanding the context whilst the initial pre-intervention data collection was

started. Several meetings with senior staff and departmental presentations about the project were held to engage and enthuse colleagues. A local fetal monitoring research group was created, and the Head of the Department (HOD) was invited to attend these meetings. The research group fed back to the HOD regularly (weekly/fortnightly) throughout the project.

Training needs assessment and local preferences on training format

An informal brief local training needs evaluation was undertaken, and the final document was circulated and discussed within the local FM research group. Training needs assessment is an essential component of planning training. (248) (249) (250) Following this, a pre-intervention survey was undertaken to understand clinicians' preferences regarding the training format and previous CTG training and experience. Based on this, a training intervention was devised based on best practices but suited both culturally and logistically to the local context. Regular shorter sessions of one to two hours were preferred by staff due to the existing teaching arrangements, high clinical demands and the challenges of expecting staff to stay late or attend training outside of regular working hours. Clinicians attending a half-day/full-day session for training was not typically done in GMC and would require re-structuring clinical work and therefore was not feasible.

Local guideline choice

The protocol was planned to incorporate relevant international guidelines into a local departmental guideline. However, as there were no departmental guidelines previously, this was inappropriate. Instead, the HOD facilitated a meeting of all key senior staff stakeholders to review available international guidelines and discuss with KL which would be best applied. There was discussion around which guideline should be used in this setting; physiological CTG was not chosen, as it was not created by a well-recognised body. NICE was discounted as there was no access to FBS, and it was decided to use FIGO guidelines, as they do not recommend FBS and are simpler to understand and disseminate. The senior clinicians felt it was more suited to this context. There was also discussion and consensus-building around the recommended frequency of IA for high-risk and low-risk mothers. The summary table from the FIGO guideline, plus a few lines about the frequency of IA, were put onto one A4 sheet, circulated widely, and used as the basis for the guidance and teaching (see appendix two).

2.4.6 The intervention

Co-interventions (enabling/supporting activities)

Supporting co-interventions were planned and included formal (twelve) and numerous informal meetings, including with the Head of the Department, local and international research groups, senior doctors, junior doctors and some nurses. The one-page summary of FIGO parameters was printed and shared widely. Mobile phone messages (via the WhatsApp social media platform) reminded clinicians about teaching sessions and online learning access. A WhatsApp group was set up amongst middle-grade doctors to facilitate sharing the lactate machine and learning. An open-door policy and trainers' contact details were shared, enabling conversations in and out of classroom questions and discussions and numerous "corridor conversations".

The intrapartum fetal monitoring training programme

The training took place through a series of fifteen face-to-face teaching sessions in October and November 2019. These included five lectures (one of which was delivered by a keynote speaker), five small group tutorials and five clinical teaching sessions in the labour ward. Mixed formats were used in the classroom, including lectures, workshops, case-based discussions, peer-to-peer teaching, quizzes, and informal role-play in the communication of abnormal CTGs. Practical hands-on skills, communication skills, case-based discussions were used in the labour ward. Free access to K2 online CTG e-learning was available throughout the intervention period.

The training intervention was based on fetal monitoring as an integral part of labour ward management. The curriculum included fetal physiology, normal and abnormal intrapartum fetal monitoring parameters as per FIGO guidelines, key definitions and terms, description of CTGs, classification, management of various cases and CTGs, communication of abnormal findings and teaching colleagues. Teaching was primarily delivered by a UK-based obstetric trainee (KL) with a background in global maternal health and an interest in post-graduate clinical education. Train the trainer and weekly departmental CTG sessions were planned (251) in the protocol, but this was unfeasible due to the lack of clinician time and precedence of similar meetings.

Training materials were gathered during the first year of the PhD from experts in the field, the grey literature and liaison with the FM training leads across several UK hospitals. Accessing high-quality CTG cases and images was a particular challenge. Most of the materials used were slides, and images about CTG were shared by Professor Sir Arulkumaran, a world-leading expert, researcher and author on CTG. (252) (253) The intelligent auscultation slides and tests were kindly shared by Wendy Randall, a UK-based consultant midwife, who has won a national award for this IA training programme in the UK and leads the eLFH module on IA nationally in the UK. (251) Each session and test were adapted from this existing material according to the audience, session length, attendance, location and trainees' previous attendance.

The first session was about intelligent auscultation, a form of intermittent auscultation. Although not CTG, IA is the mainstay of fetal monitoring in GMC; therefore, high-quality, accurate, reliable intermittent auscultation is essential, and so was chosen for the first session. The IA training session was based entirely on existing slides and tests, as described above.

The next sessions were large group sessions focused on CTG in the lecture hall, in an interactive lecture-based format containing the basics of fetal physiology, CTG interpretation and parameters for CTG. The large group format allows the knowledge to be shared with large groups of staff to ensure the whole department could be trained within the time constraints. The fourth session was planned again as an interactive lecture, focusing on different parameters and types of hypoxia and decelerations to ensure all parameters were fully understood. The fifth/sixth/seventh sessions were interactive case-based discussions around different CTG traces, focused on applying knowledge to cases, and more aligned with CTG meetings in the UK.

Session eight was a keynote lecture from a visiting Professor from the UK (AW). This Professor is a well-known researcher and obstetrician but does not typically lecture on CTG. Sessions nine to fourteen were case-based discussions and more practical sessions about fetal monitoring in the context of real clinical cases in the labour ward. They included communication, escalation, and partograms. The final session was a large group session in the lecture hall, summarising the learning, focusing on cases, and conducting the post-test. The full study and intervention timelines, training schedule and TIDieR checklist are in appendix two.

Online learning with K2, commonly used for CTG training in the UK, was made available for free. Email links to the learning and reminders, plus WhatsApp reminders, were used. K2 completion would result in an internationally recognised certificate, typically required to practice in many UK labour wards. K2 online learning consists of presentations, interactive cases and competency tests and typically takes six to eight hours to complete.

Equipment

At the beginning of data collection, two handheld lactate monitors were introduced in labour wards/theatres to enable cord lactate samples to be taken when a baby was delivered for suspected fetal compromise. In high-income settings, measuring the cord pH or lactate post-birth is routine practice for all babies delivered with low APGAR scores or by operative birth for suspected fetal compromise. This information is useful for neonatologists to plan care and allows the obstetrician to evaluate and reflect on the management of each case. (254) Therefore it was thought to be a useful aspect of care to promote training and reflection. Training was delivered to middle-grade clinicians on how to use the lactate monitor. The on-call doctor was responsible for monitoring and recording the results in the patient's file and on the paper stored with the lactate meter. Unfortunately, one machine was lost during the study period but was quickly replaced.

2.4.7 Evaluation of intervention

The training was evaluated using Kirkpatrick's four-stage training evaluation model and supplemented with attendance data and note-taking in a reflective diary throughout the planning and delivery of the intervention.

Attendance data

The department's attendance at all meetings was recorded with a common sign-in book, including attendees' names, roles, and signatures. In addition, K2 online learning automatically recorded the length of time, the number of times entered and the test results for each participant. Attendance was summarised in an anonymous format and analysed using standard descriptive statistics.

Kirkpatrick level 1 – reactions

Paper-based, anonymous surveys of clinicians were taken five times during this study: before the training, before and after the keynote lecture, at the mid-point and three weeks after the training. The first four surveys were administered at an organised FM session after piloting within the research team. The post-training survey was carried out ad-hoc in the labour ward rather than after an organised session to gain a more representative sample of clinicians' views. The number of clinicians that declined to take part in the survey was not documented, but was reported to be minimal by the RAs.

The sample was all clinicians who attended the study welcome lecture and training sessions, as we were aiming to evaluate the training. They were typically administered on paper at the end of each training session to gain immediate reactions from the group and a higher response rate. The post-training survey was conducted three weeks after the intervention period, with on-call clinicians on the labour ward rather than immediately pre/post-training, to gain a broader perspective from a wider group.

Kirkpatrick level 2 – knowledge gain

Pre and post-tests were used to assess knowledge gain, as they are relatively quick and easy to use, require few resources to administer and have been used in CTG training practice and literature. However, as clinicians chose a series of frequent, shorter session formats and arrival times varied, assessing knowledge before and after every teaching session was impossible without compromising the training time and relationship with colleagues. Throughout the intervention, nine tests in total were conducted. Three pre-and-post-training (sessions one, two and five) and one stand-alone test were performed three weeks post-intervention. The tests for sessions three and four were also planned as pre/post-tests; however, they were not suitable for analysis in this format due to small numbers, different arrival times and variable form completion. They were therefore analysed as stand-alone tests. Session five was a keynote session with a pre and post-test taken at the beginning and end of the lecture, and attendees classified CTG cases on their phones via online polling. The testing schedule is outlined in appendix two.

The tests were based on existing tests already developed by experts. All except session five were conducted on paper. They varied according to the session content (see appendix two for details)—some questions assessed crucial definitions and parameters. Most related to

the description, classification and planned management/assessment of various CTG cases. The intelligent auscultation test involved listening to audio recordings of fetal hearts as part of cases and making management plans. In the tests, participants were given free text space to describe the fetal monitoring parameters, clinical management and classification of CTG. The researcher marked the tests. Participant anonymity was requested and respected. This meant that results from each test had to be combined, removing any ability to pair at an individual level. The K2 online learning package includes competency assessments from live cases.

Kirkpatrick level 3 – behaviour change

Behaviour change was assessed using questions within the mid and post-training survey, asking clinicians to quantify the number of cases managed differently and describe cases managed differently. Focus groups with clinicians (outlined in the qMOLI methods) were planned for shortly after the training. However, the pandemic delay meant their role had to be more limited than planned.

Kirkpatrick level 4 – maternal and perinatal outcomes (before and after study)

Clinical data on all consecutive deliveries were collected on a standard screening log and case report form for six months from August 1 2019, to February 1 2020. Discharge/NICU data was collected for a further six weeks to account for prolonged maternal or neonatal admissions. The majority of the data was entered at two points by a team of four trained research associates daily, just after birth in the birthing/recovery area (form one, admission) and at discharge (forms two and three) from patient files. All deliveries were screened in the delivery wards and theatres and recorded daily. All files were reviewed again at discharge to ensure data collection was complete. RAs searched for patients with incomplete/missing data on the postnatal wards and records stores. NICU admissions, stillbirths and maternal deaths were recorded alternate daily from admission/death record books. Data was initially entered on paper and then entered into the Research Electronic Data CAPture (REDCap) database. (255) Study data were managed using the REDCap software hosted on Jawaharlal Nehru Medical College (JNMC) server in Belgaum. REDCap is a secure, web-based software platform that supports data capture for research studies. All admission entries were checked at least twice for accuracy and completeness. In addition,

missing data was cross-checked on hospital computer discharge summaries. Lactate data was recorded in the patient file and on paper and stored with the lactate meter.

Risk factors were documented by the research staff as documented in the medical records, rather than strict study definitions. For example, terms such as bad obstetric history (BOH) incorporated concepts such as previous miscarriage, stillbirth or infant mortality. Therefore, where stillbirth/IUD was specifically mentioned, these were recorded as “previous IUD”. However, there likely is a cross-over between the groups, with "BOH" representing a previous IUD for some women.

Outcomes measures

Outcome measures were all pre-specified in the research protocol. Some were maternal and perinatal outcomes, and some were fetal monitoring and training process outcomes, aiming to link the intervention to the outcomes.

Table 5 Fetal monitoring study outcome measures from protocol

Outcome measures - training	Overall numbers and proportion of staff trained • Senior doctors • Residents • Nurses/midwives • Students Improvement in pre-post-test scores Improvement in self-perceived knowledge and confidence about intrapartum fetal monitoring (on Likert score) Staff perceived satisfaction with training Feedback from staff
Outcome measures – intrapartum fetal monitoring	Improved documentation of: • Number of times FHR documented in labour • The average time between the last FHR documented and delivery • Risk factors for poor perinatal outcome • Descriptive data on CTG meetings • The number of cases (CTGs and poor perinatal outcomes) discussed • The proportion of cases where departmental CTG meeting consensus, agreed clinical management aligned with guidelines • The proportion of cases where departmental CTG meeting consensus, agreed alternative clinical management could have improved maternal/perinatal outcome

Outcome measures – maternal	Caesarean section performed for suspected fetal compromise Caesarean section rate overall Operative vaginal delivery rate Maternal length of hospital stay (days) Maternal death
Outcome measures – perinatal	APGAR score seven or below at five minutes Cord blood lactate 4.9 mmol/l or above Neonatal resuscitation required Neonatal intensive care unit (NICU) admission Length of NICU stay (days) Neonatal morbidity (as per NICU discharge summary) Perinatal death before discharge

Reflective diary

A detailed reflective diary was written to understand the broader impacts, details of the interventions and changes to the intervention, and informal feedback throughout the process. This aided understanding of the fidelity of the training, more subtle contextual details and how the intervention changed over time. It also provided important insights into the interaction between the intervention, co-interventions, and context and links between these elements and outcomes. It was an anonymised, personal reflection.

Statistical analysis

Detailed analysis plans were outlined in the study protocol. The anonymised training and questionnaire data were analysed at the unit level using standard descriptive statistics. The free-text responses were summarised using qualitative approaches. Data summary tables of continuous and categorical variables were calculated using standard descriptive statistics for the maternal and perinatal outcomes. Measures were summarised for both assessment times separately using means (with standard deviations), median (with ranges or interquartile ranges (IQRs) as appropriate) or frequencies and percentages; changes between assessment times were summarised using mean differences, median differences, rate ratios or rate differences as appropriate, all with their 95% confidence intervals (CI), as a before and after study. The central limit therum was used for the population characteristics.

During the analysis period, further advice was taken from the study statistician. The Mann-Whitney U test was used to compare mean gestational ages, maternal age, number of FH

recordings and length of stay, as the assumptions of the t-test were not met and the data was significantly skewed and this was a very large sample. For comparison of the parity, the decision to delivery interval and the number of antenatal risk factors, the Kruskall Wallis test was used, as the data is not normally distributed and it is more stable to outliers. The parity and number of antenatal risk factors were ordinal data, with more than two groups. The DDI dataset had notable outliers, meaning that Kruskall Wallis was the most appropriate test, (although testing with the Mann-Whitney U test, did give the same results). T-test was used to compare the means of the birth weights, as this was normally distributed, with similar variance across the groups.

A more detailed analysis was performed to understand better the risk factors and outcomes in the entire cohort. The data were summarised using standard statistical descriptive and grouped where appropriate using standard classifications.

Sample size

The project size was based on consideration of the precision with which changes in important maternal and infant outcomes would be estimated before the study. Unfortunately, there was no detailed information on the population on which to base power calculations. We, therefore, extrapolated from the previous INFORM study (247) undertaken in this setting.

Using INFORM data, CS rates for suspected fetal compromise were in the order of 24%; it was considered that electronic fetal heart rate monitoring could potentially reduce this proportionately by 15% (down to 20.4%). If there were a reduction of 3.6%, then data from 1100 patients before and after the training, with an absolute change in CS rate of 3.6%, would demonstrate significance at the 5% level (95% confidence interval of 0.13% to 7.07% (i.e. of ±3.47%). It would provide evidence suggesting that the relative change in the CS rate of 15% (absolute 3.6%) or greater would be unlikely to have occurred by chance. As this is a longitudinal survey, collecting data for at least two months before and after the intervention was necessary to ensure any changes were related to the intervention rather than other external factors. The percentage of missing data was highlighted for all measures. KL undertook the analysis, which was supervised and checked by Professor Faragher, the MOLI study statistician.

2.4.8 Study governance

This study was sponsored by the University of Liverpool, UoL001457 4835. The protocol was published on clinicaltrials.gov, NCT04084353.

A full suite of data management plans and SOPs have been written, audited and approved for the MOLI RCT by the trial sponsor, the University of Liverpool, and these were used for the sub-studies where relevant.

2.4.9 Ethical considerations

Ethical approval was obtained in Nagpur (19/3/2019, 1755EC/Pharmac/GMC/NGP/) and the University of Liverpool (27/3/2019, 5051).

This study was conducted in accordance with

The World Medical Association Declaration of Helsinki (1996)

International Conference of Harmonisation Good Clinical Practice (ICH GCP)

Indian Council of Medical Research (ICMR) guidelines

Gynuity Health Projects and University of Liverpool Standard Operating Procedures

As per ICMR guidance and discussion with the Institutional Review Board in Nagpur, individual patient and written clinician consent were not required for the FM study. ICMR guidelines state that a consent waiver can be considered: when research cannot practically be carried out without the waiver, when the waiver is scientifically justified, in retrospective studies, where the participants are de-identified or cannot be contacted or in certain types of programme evaluation studies. (256)

2.4.10 Data management

This data was collected and stored in a manner compliant with the Indian Council of Medical Research guidelines, the UK Data Protection Act 2018 and the UK General Data Protection Regulations 2018. All project staff complied with these requirements concerning collecting, storing, processing and disclosing personal information and upholding the Regulation principles. In addition, all researchers completed the Good Clinical Practice (GCP) training.

The only semi-identifiable data on the source document, the case report form (CRF), was the patient's hospital number and date and time of delivery, which was necessary to avoid duplicate entries. The paper CRFs and questionnaires were stored in a locked cabinet in the research office at GMC. Research assistants transferred data onto a password-protected electronic REDCap database and stored it in the GMC research office's computers. The REDCap server was held and managed by JNMC University in Belgaum, India, alongside the MOLI data. Initially, data collection was undertaken on paper CRFs, until the REDCap database was ready, and then data was inputted directly onto REDCap by the RAs on tablets. Tablets were password protected, stored in locked cupboards and backed up onto the Belgaum server regularly.

The minimum number of individuals necessary had access to this data for quality control, audit and analysis. Any data transferred to co-investigators, the host institutions or sponsors were anonymised. A copy of the data will be stored for ten years as requested in the University of Liverpool SOPs on record retention. The data custodian is the Sponsor, the University of Liverpool.

Archiving of data will be undertaken in line with the Sponsor's requirements, as detailed in the Sponsor Standard Operating Procedure "Archiving of Essential documents for University Sponsored Studies" at the end of the project. All essential documents will be archived for a minimum of five to ten years after completing the project.

2.4.11 Patient and public involvement (PPI)

During the study development of the MOLI RCT, a scoping exercise was carried out to assess the potential for the MOLI trial. Fourteen doctors and 23 women who had undergone labour induction were interviewed at Government Medical College. Most doctors (12/14) and women (22/23) would welcome a change to a misoprostol/misoprostol regimen, but only if it did not increase the risk of CS and intrapartum fetal monitoring was adequate.

Ms Uma Sharma, a local consumer representative, sits on the MOLI Project Steering Committee, and reviewed and gave feedback on the study protocols and case report forms. The surveys were discussed at length with research assistants (as they spent the most time with patients during the previous INFORM study) and clinicians that have previously worked in Nagpur. Ideally, further PPI work would have been undertaken before these

studies. However, as PPI is not common practice in India and due to logistical issues, this was not possible.

2.4.12 Funding and support in kind

Funding for the MOLI RCT and these sub-studies is provided by the MRC/DfID/Wellcome Trust Joint Global Health Projects Fund (ref MR/R006/1801). In addition, this funding provided KL's salary as the MOLI UK trial manager, PhD fees, transport and accommodation, and the CTG machines and consumables. However, the funders had no role in this research's design, implementation, interpretation or reporting.

The University of Liverpool sponsors the MOLI RCT and sub-studies, as defined by the UK Policy Framework for Health and Social Care Research.

Chapter 3 – Results 1

Intrapartum fetal monitoring and mode of birth in India: A qualitative study exploring the views and preferences of women and clinicians

This chapter is the first of four results chapters. It presents the findings of the FM and MOB aspects of the qMOLI study. The findings offer context to the results presented in chapters four, five, six and seven.

3.1 Background and aims

Currently, there is very little literature available on clinicians' or women's understanding, preferences, priorities and experiences for FM and MOB from around the world and none from India, as outlined in Chapter one. This chapter aims to explore the views and preferences of women and clinicians on intrapartum fetal monitoring and mode of birth in two settings in India. Fifty-three semi-structured interviews were conducted pre or post-induction of labour (or both), with women recruited to the "misoprostol or oxytocin for labour induction" RCT. In addition, eight focus groups were conducted with different cadres of clinicians and researchers. As described in Chapter two, a framework approach to thematic analysis was used for data interpretation.

3.2 Participants

3.2.1 Semi-structured interviews with women

In this study, 53 semi-structured interviews were conducted with 45 women, including 19 pre-IOL and 34 postnatal interviews. Eight women were interviewed both before and after birth. Interviews were conducted according to the pre-specified sampling frame, including different parities, mode of birth, social strata, hospital, repeated interviews and RCT groups.

Pre-natal interviews were conducted immediately before the induction of labour. More pre-birth interviews were conducted at the second hospital site (12 vs seven participants) and among nulliparous women (14 nulliparous vs five multiparous.) The women were all

under 30, most were term, and the social strata were mixed across low and middle socio-economic groups.

Post-natal interviews were conducted during the post-natal admission, between days one to six post-birth. Of the postnatal interviews, 20/34 women had a CS, and 14/34 had a vaginal birth (none had an operative vaginal birth). More were conducted in the first site (20 vs 14 participants) and nulliparous women (27 nulliparous vs seven multiparous women.) Social strata were mixed; most women were term and under thirty years old. Of the twenty women who had CS, the most common indications were failed induction of labour (8/20) and concerns over fetal wellbeing (8/20; fetal distress/meconium-stained liquor.) Other indications included suspected disseminated intravascular coagulopathy (a serious complication of pre-eclampsia), transverse lie or prolonged first stage of labour.

In the interviews with women, the use of different fetal monitoring methods was described; 48/53 adult stethoscope, 38/53 Doppler, 21/53 CTG and four described sonography use. The sonography was included as a code from the transcripts, where it was difficult to determine ultrasound from other FM methods. Where it was clear ultrasound and not an FM monitoring technique was used, this was coded separately.

Table 6 Interview participant characteristics for pre-and-post birth interviews with women

Pre-induction Interview Participant Characteristics (n = 19)		**Post-induction Interview Participant Characteristics (n = 34)**	
Characteristics	Number	Characteristics	Number
Location		**Location**	
GMC	7	GMC	20
Daga	12	Daga	14
Age		**Age**	
18-25	13	18-25	21
26-30	6	26-30	12
>30	0	>30	1
Socioeconomic Class		**Socioeconomic Class**	
Low	9	Low	14
Middle	8	Middle	11
High	0	High	1
Unknown	2	Unknown	8
Parity		**Parity**	
Nulliparous	14	Nulliparous	27
Multiparous	5	Multiparous	7
Gestational age		**Gestational age**	
<37 weeks	1	<37 weeks	4
37 weeks+	18	37 weeks+	30
		Mode of birth	
		Vaginal	14
		Caesarean	20
		Day Postnatal at interview	
		0 – 1	7
		2 – 3	17
		4 – 5	10
		Number of interviews	
		1	26
		2	8

3.2.2 Focus groups with clinicians and MOLI research staff

Eight focus groups were conducted with different cadres of clinicians and research staff across two sites (n=83). The first two FGDs were conducted during the FM study intervention months and before the MOLI study recruitment. These were mixed cadres of clinicians, including senior and junior Doctors in GMC and mixed doctors and nurses in Daga. Due to hierarchical differences and usual working practice differences between institutions, clinicians and the research group felt this was appropriate.

The six further FGDs were conducted between September-November 2021 due to the COVID-19 pandemic delay. Different cadres were interviewed separately. Originally, It was planned to interview Daga senior and junior doctors separately, but this was not within the department's norms and, therefore, not done. Also, all RAs from both sites were

interviewed together, as there were only five in each site, and they all worked together closely and sometimes across sites.

Table 7 Focus group participants

FGD No	Location	Timing	Participants	No	Duration (min)	Date
1	Site 1	Pre	Doctors - senior and residents	13	49	Oct-19
2	Site 2	Pre	Mixed - senior doctors, residents, nurses	13	44	Nov-19
3	Site 2	Mid	Nurses	16	38	Sep-21
4	Site 2	Mid	Doctors - senior and residents	10	33	Sep-21
5	Site 1	Mid	Doctors – senior	8	36	Oct-21
6	Site 1	Mid	Nurses	6	30	Oct-21
7	Site 1	Mid	Doctors – residents	7	42	Oct-21
8	AIIMS	Mid	MOLI research associates	10	70	Nov-21

3.3 Themes overview

The data was analysed and summarised in six themes, as outlined below.

1. Women's views about mode of birth: "trouble for two hours, or trouble for two months"
2. Women's knowledge and understanding; knowledge through experience
3. Fetal monitoring was part of a positive birthing experience: "felt good by hearing the beats"
4. Interactions with women, relatives and clinicians
5. Fetal monitoring as per guidelines was "practically not possible"
6. Relationship between fetal monitoring, mode of birth and risk

The figure below provides a summary of the six themes. Appendix one is a comprehensive table demonstrating a summary of the themes, sub-themes and illustrative quotes. Throughout the text describing the themes below, frequently used phrases found throughout the dataset repeatedly are also included within the text in quotation marks to ensure descriptions remain close to the data. First, a theme overview is presented for each theme, and then a description of each sub-theme is presented.

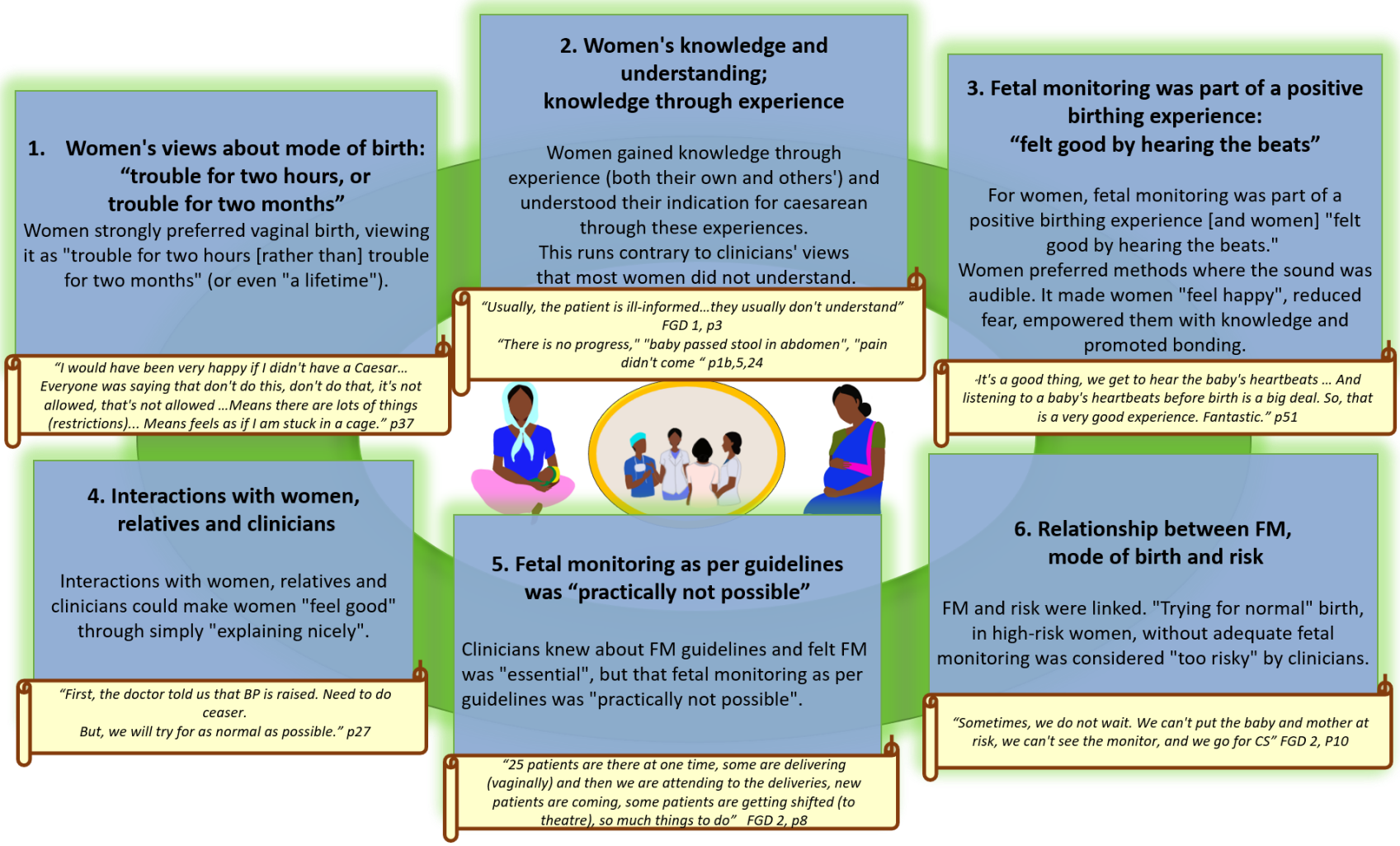

Figure 19 Themes, sub-themes and key quotes

3.4 Women's views about mode of birth: "trouble for two hours, or trouble for two months"

Theme overview

Most women simply described their birth as "good", although pain and "traas" (trouble/pain) was often described. The vast majority of women preferred a vaginal birth, which was important for them; the only exceptions were a couple of women who preferred a CS to avoid labour pains. Women felt that they had to "bear the pain". However, this was only for a short, temporary timeframe. After delivery, they could mobilise, go home quickly, do their household work and have no future concerns related to their birth. Most women expected normal birth. For CS, women felt no discomfort during the birth, but post-birth, there was a "lot of pain" and trouble "traas", which lasted for months or even longer. Worries for women who had CS did not dissipate after birth, as happens after a normal birth. Instead, there were many restrictions on moving, eating and leaving home, and women could not conduct their usual tasks in the home and had to rely on help from others.

> *"I would have been very happy if I didn't have a Caesar. But, now I had a Caesar. Everyone was saying that don't do this, don't do that, it's not allowed, that's not allowed, sit like this, sit like that, don't eat this, don't eat that. Means there are lots of things (restrictions)... means feels as if I am stuck in a cage."*
>
> *Postnatal woman (P37)*

Feelings (priorities/importance) about birth

Before birth, women had many questions in their minds about the process of labour and birth and whether the mother and baby would be ok. Many felt scared and afraid about these uncertainties, especially when CS was needed. After birth, these worries were quickly forgotten. Women that had vaginal deliveries often felt good and were happy to have birthed vaginally and quickly. However, many with CS reported more negative feelings, primarily due to the CS. This included pain, trouble/"traas," restrictions and the reliance on support from others. Some expressed it would have been better if they had had a vaginal delivery. Whereas others felt "let it be" and that their mode of birth was out of their hands.

Experiences of birth

For the majority of women, the delivery "was good". Overall, if the woman was well and the baby was well, women were satisfied with their birth experience. This is true for both

CS and vaginal delivery, and birth is often simply described as "good", even on probing. Some women could remember in great detail what happened, whereas others did not recall much. Pain and trouble “traas” were frequently mentioned before and after birth. There were no reports of personal physical/sexual violence or abuse within the dataset.

Mode of birth preferences: “Trouble for two hours or two months”

Almost all women preferred normal delivery; this was very strong throughout the data. However, the labour pains were very severe and caused "suffering" until the delivery. It was a “one-time” pain which was temporary. After the delivery, the woman was well and healthy, and there was no pain/”traas”. Women said they could walk on the first post-natal day, leave the hospital on the third day and slowly undertake their household responsibilities. There were no further worries about issues in the future, and she was "good for her whole life". Clinicians also knew that women preferred normal birth.

For CS, there was no "trouble/pain/problem" at the time of CS and “not much trouble” for the first few days. But afterwards, there are "months" (descriptions varied between two to ten months) or a "lifetime of trouble"; the "tension" does not go away. The "troubles" described include more pain, restrictions on mobility and movement (sitting, walking, leaving the house) and what can be eaten. Women needed help from others for months, and for some, there was difficulty feeding the baby and giving it "proper attention". Despite these negative perceptions, those that had CS would also do as the doctor recommended for future deliveries.

Mode of birth expectations

The majority of women expected to have a vaginal birth. Some women had no MOB expectation, and only one described an inner feeling that CS would happen. A few others had been told previously they would have a CS, typically in private institutions, which affected their expectations for their mode of birth. Even when counselled in the Government hospital that vaginal birth was possible, the previous conversations with clinicians regarding CS weighed heavily in these women’s minds.

3.5 Women's knowledge and understanding; knowledge through experience

Theme overview

When women were asked about their experiences rather than their knowledge directly, the majority could describe the fetal monitoring methods used in their labour and explain the indication for their CS. Clinicians and the women believed they were not knowledgeable, whereas knowledge and understanding actually existed. On direct questioning, women (especially primigravidas) frequently used the expression "I don't know" throughout the interviews. In the pre-trial FGDs, clinicians also felt that women did not know and could not understand.

Women's understanding of birth was gained through talking with and witnessing relatives and friends' experiences around birth, previous deliveries, watching other women's experiences on the labour ward and their own experiences. This understanding about birth did not primarily come from direct conversations about birth, as these conversations were thought to instil fear. Only a few women searched on the internet/YouTube; one described relevant learning in formal education, and a few reported health care providers educating them.

> *"The counselling part is very much neglected in our setup. Usually, the patient is ill-informed. Because they don't understand, mostly the kind of class we get here, they usually don't understand these things."*
>
> *FGD 1, P3*

> *"There is no progress," "BP is raised," "baby passed stool in abdomen", and "pain didn't come."*
>
> *Postnatal women (1B, 2, 5, 24)*

Women's knowledge of methods and reasons for fetal monitoring

Most women only knew about the FM methods they had personally experienced, but they could recognise the tools used and describe them. The majority understood that the clinicians were listening to check that the baby was well. Some knew that the rate could be high or low, and sometimes interventions such as CS were needed because of this. However, when asked direct questions about their knowledge, women often said, "I don't know". Women felt that it was important that "they know". To hear the heartbeat clearly, contributed to the feeling of "knowing." Some women, particularly those where the fetal

heart was only monitored using an adult stethoscope, provided important negative cases for the relationship between “hearing” and “knowing”, as women said, "only the Doctor knows".

Women’s knowledge about birth

Women hear information from relatives, e.g. mother/mother-in-law/sisters and other women that have given birth, e.g. neighbours/friends/other in-patients. However, details are rarely shared, particularly about the delivery itself. For example, a woman simply says, "it was normal". Women are broadly aware of normal delivery and CS; only a small number mentioned forceps/ventouse. A minority of women had seen normal birth on the internet, but many avoided this to avoid getting frightened. Only one participant exemplifies knowledge gained through formal education, and information gathering from health care professionals on labour and birth was not mentioned throughout. However, this was not a formal question within the interview schedule.

Women’s knowledge about their indication for caesarean section

Whilst some women did not know the indication for their CS, far more could clearly explain the CS indication. Indications included "meconium-stained liquor", "high BP", "no labour pains", "no labour progress", “transverse lie”, “low fetal heart”, and "the head is stuck". These indications broadly match the indications recorded by the RAs from the patient’s records and demonstrate understanding of the indication for CS.

Others on the labour ward

A notable number of women described strong emotional reactions in response to seeing "fearful experiences" in the labour ward; these appeared to be pivotal experiences for some. “Fearful experiences” included seeing other women in "agonising pain," vaginal deliveries, vaginal examinations, episiotomies, CS, screaming, shouting, crying and other elements of labour experience. These experiences made women feel "very scared" and, for some, that NVD was "too long" and "too painful to bear". Due to these experiences, some even considered that CS could be better.

Previous delivery experience (multiparous women)

There were nine descriptions of previous deliveries; all were normal vaginal births (women with previous CS were excluded from the RCT). They primarily described good experiences. Most had spontaneous labours, "pain from home", and described where they delivered. It

was very painful, but the description of duration varied. Only one woman described a negative birth experience, as she had a preterm delivery, was given medicine to delay birth and was in pain for days. Overall, descriptions of birth experiences were good; "the pain came", "delivered", and there were “no problems”.

Clinicians’ perspectives on women’s knowledge

Clinicians felt that women did “not know” or “understand” due to the “class” of women who attend the Government hospitals. “Detailed counselling” was not undertaken. Some clinicians felt that if more time was spent counselling a particular woman, she would be more worried and concerned there was something seriously wrong with her/her baby.

3.6 Fetal monitoring was part of a positive birthing experience: felt good by hearing the beats (it felt good to hear the beats)

Theme overview

For almost all women, "knowing the baby is well and good" through "check-ups" was a good thing. This positive experience was especially memorable when women "heard the heartbeats." A few women described it as "the best thing, " making them feel "happy." When women "can also listen", they can also "hear and know" actively, which for some, reduces fear and makes them feel calm. It also empowered women to "know" and "understand" how the baby is without relying on communication with clinicians or relatives. This is likely to be especially important for these high-risk pre-eclamptic women throughout labour, as many had uncertainties, questions and anxieties, and in settings where perinatal mortality is high.

Although some did not recall clearly, most women could describe but not name the fetal monitoring methods used (handheld Doppler, adult stethoscope and intermittent CTG). Most described the frequency of monitoring and patterns clearly, although descriptions of the time intervals varied. They realised that someone (Madam/Sir) had conducted the monitoring, but their role was unclear.

> *"It’s a good thing, we get to hear the baby’s heartbeats. All that is known is that the baby moves while in the womb. Baby moves, baby moves, but the baby’s heartbeats could not be heard. And listening to a baby’s heartbeats before birth is a big deal. So, that is a very good experience. Fantastic."*
>
> *Postnatal woman (P51)*

Women's experiences of fetal monitoring (perceptions of what was done)

When prompted and shown the possible instruments, most women recalled and described the methods used for fetal monitoring during their labour: adult stethoscope, Doppler or intermittent CTG. However, most did not know the names, and some did not recall fetal monitoring at all. Doctors used stethoscopes "by applying to ear," and only they "could hear and understand." Doppler was a "machine" that was "rotated on the abdomen", making a "thak" sound. CTG was described as "that round-round machine." Many also knew the frequency of monitoring and that it was done regularly. Although there were varying descriptions of the timeframes, there was a clear pattern, which increased when "the pain" started. The role of the staff that undertook the monitoring was often unclear, as all staff (including doctors and research associates) are referred to as "Madam/Sir." However, study recruits undoubtedly received additional fetal monitoring above routine care due to their participation in the RCT. Multigravidas also confirmed this by describing that the fetal monitoring was not like this in their previous delivery.

Mentions of fetal monitoring independent of the interview guide

Frequent "check-ups" was perceived as good by almost all women and part of being well cared for. Checking the heartbeats was mentioned as part of "check-ups" on admission and throughout induction. "Check-ups" also included more generic assessments by clinicians, such as measuring blood pressure and sometimes abdominal examinations, vaginal examinations and other tests, e.g. ECG and sonography. This sub-theme includes data where FM was mentioned at points in the interview without prompting by the RA's questions, as per the interview guide.

"Hearing the beats"

Women liked the sound and experience of "hearing the beats," especially when it was very clear. For many, it was a very positive experience described as the "best thing" that made them feel happy. In addition to the pleasure of hearing the sound, many other important elements were brought about specifically through hearing the sound. Hearing the sound out loud helped women feel that the baby was safe and well, and for some, reduced fear and made them feel calm. Hearing the beats also made women feel they "know" and "understand" how the baby is and that it is well. As both women and clinicians listen and hear the beats, the evidence is plain for all to hear. It does not rely on the intermediary (typically the clinician but sometimes the relative) to communicate that all is well. It is an

active process that enables the woman to be empowered and autonomous, and where women can take ownership; "we can also" "take part in", to "know" and "understand." This contrasts with many other obstetric interventions, which are typically done to a woman, where she is a passive recipient of interventions**.**

How could fetal monitoring have been better?

Overall, women liked everything about fetal monitoring, and there were only a few negative comments about "pressing" on the abdomen with various methods. However, when asked about things that could have been better about FM, some women responded with more general aspects of their experience that they did not like, e.g. wishing doctors had acted sooner, or labour had started spontaneously. This suggests that women could voice negative views on their experiences if they existed.

Feelings and importance

Women universally stated that FM "felt nice/good". Several described it as making them "feel happy". Some women expressed this was their first time hearing the heartbeat, which they were "excited" about. This is especially important at this time, as many women had many concerns, such as, how is my baby? How will the delivery go? Will we both be ok? For some, these were questions, for others, fears and anxieties. Knowing that the baby's heartbeat was there and the baby was well and checked properly was important and reassuring.

"Hearing the beats" may also promote bonding between mother and baby, as it generates the feeling and understanding of "one life within us" and excitement about the new baby. The most important thing for these women is the baby. It is important to women that the baby is well and also that they know how the baby is. The fear of the baby dying or becoming unwell is present until the baby is in their arms. When asked what was important for them about fetal monitoring, most answered about it specifically, but some also liked other aspects of monitoring during IOL, such as checking BP.

Fetal monitoring methods preferences

Women prefer Doppler and CTG over stethoscopes (Pinard was not used). Key features are hearing the beats clearly and understanding the heartbeat themselves. Some women highlighted that the sound was clearer and easier to differentiate with CTG, which is why

they chose CTG. Some liked being shown the beats on the machine and seeing the screen/numbers. Several women highlighted that they did not like “pressing on the abdomen”, primarily with the stethoscope, but one reported the same issue with the Doppler. The stethoscope was the least preferred method, as it could not be heard, and only the doctor could understand.

Clinicians’ perceptions of women’s views and experiences

Clinicians also knew that women listening to their baby’s heartbeat could make women "feel good" and was important to them. Clinicians felt that when women hear the heartbeat and are told "all is well", they know "our baby is safe." They feel some "security," "satisfaction", and "reassurance" despite all of the pain. They are "curious" about their fetal well-being and feel they have had a "proper check-up." Although in one FGD, participants mentioned women being concerned that something was wrong. Clinicians agree that the Doppler/CTG is probably better than the stethoscope from women’s perspectives, as they both "can also listen". This will reduce "apprehension" and make women feel they are “looking at me properly”.

3.7 Interactions with women, relatives and clinicians

Theme overview

Women were often told the heartbeats "were good" or "the baby is well"; this simple communication had the power to make women feel good. Women valued clinicians for "talking nicely" and "explaining nicely". Women and clinicians echoed the same simple conversations about delivery "give a pill (induction medication) to try for normal" and "detailed counselling is not undertaken".

"Don’t take a risk" and "yours will be Caesar" was often heard by women in private settings during the referral journey. This led to the Government hospital clinicians finding it challenging to persuade women that normal delivery was safe. Women clearly remember points from the discussions about "danger", "risk", and potential death or harm to the baby. Both women and clinicians describe how, during labour, women cry out for caesareans to rescue them from labour pains. Some relatives also persuade the medical staff to conduct caesareans to end the suffering.

Interactions about fetal monitoring

There were numerous interactions outlined by women about fetal monitoring. Many recalled being told that the baby's heartbeats "were good" or "the baby was well", which made women feel good and positively impacted them. How clinicians communicated was also important. Women valued clinicians "talking nicely" and "explaining nicely."

Interactions about birth

Women outlined numerous interactions around the mode of birth. Many included "giving a [induction of labour] pill" to "try for normal" birth. However, if "BP was raised" or "pain doesn't come", CS will be done. Several women had been told in the private or referring institution that "yours will be CS." "Yours will be normal" was more of a plan for induction leading to vaginal birth than an assurance about the mode of birth. However, some reassurance was also given; "all is well, don't worry". Conversations about risk, danger, the potential for death, and serious complications for mother and baby were also evident in this high-risk group.

CS requests in labour

There are multiple reports of women requesting CS during labour from both women and clinicians; sometimes, the relatives ask Doctors too. However, all of the requests from the women interviewed were based on being unable to bear the terrible pain or fear after seeing other women deliver. So they were really asking for CS as a rescue from the pain or fear rather than a mode of birth preference. MOB preferences were clearly NVD throughout the data, pre- and post-birth for most women.

Family and relatives

Relatives and family members were pivotal in all aspects of life. At birth, their influences extended to decision-making, experiences, support, advice and knowledge gain. The family advise and reassure, sometimes scold. They typically prefer normal delivery, too, although there were some reports of relatives pleading with doctors to do CS to "end the pain". They advise throughout pregnancy but do not discuss the specific details around delivery. Relatives who had delivered, such as sisters, cousins and some friends, had previously discussed delivery. However, many women had not discussed it with anyone. Women had also seen their relatives' postnatal struggles first-hand at their homes.

Clinicians' perspectives on interactions with patients

Clinicians felt the types of patients who come to the government hospital are "not well informed" and "do not understand". The class and caste systems still operate in Indian culture. Women attending government hospitals are likely to be poorer and of a lower class, as more affluent women would choose to deliver in a private institution. In India, the health care system is more patriarchal, and both women and clinicians feel that the doctor knows best and will do right by them; therefore, the doctor makes the decisions. There are very few instances throughout this dataset where this seems to create issues for either party. Therefore, detailed counselling is not undertaken, as the patient is not expected to contribute to the decision-making. The patient journey typically involves private and public settings. Clinicians also describe that patients had already been told that they would have a CS during their referral journey. Therefore, persuading someone to have a normal delivery could seem risky. There is a reference to detailed counselling in Western settings highlighting differences in practice, but it may or may not be because of the Western influences in this study.

3.8 Fetal monitoring as per guidelines was "practically not possible"

Theme overview

Clinicians felt that fetal monitoring is important and "should be done," but the practicalities of the clinical environment made delivering high-quality monitoring unachievable. They were aware of recommended frequencies and distinguished between high-risk and low-risk women. However, it was "practically not possible" to monitor as per guidelines; clinicians "don't look at the clock and do it", and the maximum frequency "is hourly". Doctors conduct fetal monitoring (there are no midwives). There was a very high ratio of patients to staff, so doctors faced competing demands between managing emergencies, conducting deliveries, and operating in the theatre. It becomes inevitable that routine monitoring is not prioritised compared to these other time-pressured activities. Staff felt that multiple CTG machines and printers would be needed to help due to delays in fixing broken equipment and high patient load. Junior Drs would need to be trained and seniors informed about CTGs due to the risk of over-diagnosing fetal distress. Seniors have to be "tolerant", manage the heart rate and avoid panic and "Hungama" [not directly translatable but includes chaos, drama, adrenaline rush, and excitement…].

"25 patients are there at one time, some are delivering (vaginally) and then we are attending to the deliveries, new patients are coming, some patients are getting shifted (to the theatre), so much things to do."

FGD 2, P8

Fetal monitoring guidelines, practices and norms

Clinicians felt that fetal monitoring was important and "should be done." They were aware of recommended frequencies from the guidelines. They aimed to monitor high-risk women and women in active labour more frequently, according to the "severity" of the case. Doctors, not nurses, did intrapartum fetal monitoring, primarily with an adult stethoscope, Dopplers, and sometimes CTG. Dopplers were used more in one hospital over the last few years, and the resident doctors had their own. Typical monitoring frequency was meant to be every 30/15 minutes in high-risk women and hourly in low-risk women. However, most clinicians felt that the recommended frequencies of fetal monitoring were "practically not possible" and that clinicians "don't look at the clock and do it." Reported frequencies varied between FGDs from thirty minutes/hourly/two to three-hourly. Doctors described multiple competing demands making fetal monitoring "a challenge".

Hospital system barriers to quality fetal monitoring

The high patient load was frequently mentioned throughout the FGDs as the main barrier to high-quality intrapartum FM and change. There were so many patients with not enough "manpower". Although the doctors were highly skilled, there was a very high ratio of patients to staff, so doctors faced competing demands between managing emergencies, conducting deliveries, and managing new patients and those who needed theatre. These time-pressured activities inevitably take priority over the routine monitoring of patients. In addition, clinicians highlighted insufficient staffing/equipment/infrastructure to do the fetal monitoring. For example, CTG machines break and are not repaired; there are not enough printers and machines for this "high-load" environment. Therefore, a practice that had "existed for ages" was unlikely to change as per the latest guidelines. New staff, varying competencies and lack of experience of new residents were also challenging.

Clinicians' previous experiences with fetal monitoring

Clinicians discussed their experiences of fetal monitoring, including admission CTGs in a previous hospital and how admission CTGs could be used to predict stillbirth and guide misoprostol dosage. They also highlighted that seniors have to manage the situation when

the fetal heart is abnormal, to avoid "panic" and "Hungama" chaos. This demonstrates the potential for an emotional reaction from healthcare workers to abnormal fetal monitoring and the importance of team leaders managing and avoiding this. Finally, there are occasional references to the "foreign person", which may or may not be related to the UK-based teachers and Western influences in this study.

3.9 Relationship between intrapartum fetal monitoring, mode of birth and risk

Theme overview

“Waiting/trying for normal” birth in high-risk women was considered “a risk”; therefore, fetal monitoring, mode of birth and risk are inherently linked. *C*linicians described not being able to put the mother and child at risk, so instead, “we go for CS”. Continuous patient monitoring (including dynamic risk assessments, assessing the maternal and fetal condition and progress with examinations) was a critical concern for clinicians throughout. Clinicians felt increasing CTG use would enhance quality monitoring and decrease intervention rates, despite being aware of previous research findings, as only “the right” patients would have CS. In addition, they felt that more CTG machines, Dopplers, and training would be helpful.

Clinicians’ perspectives on risk

When there was a previous bad obstetric history or risk factors such as pre-eclampsia, some perceived waiting for normal birth as a risk to the mother and baby. “Don’t take a risk” do a caesarean section. CS is the default option in high-risk women in one centre in the pre-trial FGDs or private settings. The RAs describe a shift in practice for hypertensive patients, away from automatic CS, towards IOL and “trying for normal” as the RCT trial progressed.

CS rates

Clinicians perceived that CS rates were high, between 30-60%. In high-risk women, the CS rates were “of course” high due to the high rates of referrals, previous CS and free maternity services in the government hospital. In low-risk women, the CS rates were lower, but many felt they were very high. Perceptions did vary when comparing the local hospital CS rates to other local and national rates, particularly for low-risk primigravidas. In one site, clinicians expressed that vaginal birth was preferred and that “we give trial” (of normal labour/birth). On the other site, the group explained how although patients ask for CS

sometimes, maternal request CS is not practised, and CS is only done if there is a “clear cut” indication. However, when patients with bad obstetric history attend (including miscarriages, stillbirths and infertility), CS is usually done (even though these indications for CS are not universally recommended).

The potential impact of EFM on local CS rates

Clinicians knew that the research evidence says that increasing CTG use would increase CS rates through over-diagnosis of fetal distress, but they did not feel this was right or relevant for their setting. They felt it would reduce unnecessary CS by only intervening in the right patients, according to proper guidelines/definitions. Clinicians felt more variables of the FH are captured on the CTG than IA. Documentation and medico-legal concerns were important considerations, and CTG printouts could offer “proof” and justification for “waiting”.

The perceived potential impact of enhancing FM training and equipment

There was universal support for the FM project to train staff and bring more CTG machines to the labour ward. Staff felt it would improve patient care. Junior staff turnover is high every year, and these junior doctors would definitely benefit from training. There was no mention in this FGD of the benefits of training senior doctors specifically. However, the initial general question received an unequivocal positive response highlighting the benefit of training. Training staff in CTG was not perceived as difficult or “an issue”. CTG machines get broken and are not maintained, and previous purchasing requests for CTGs and centralised monitoring did not result in additional equipment.

The actual impact of enhancing FM training, equipment and MOLI study

Clinicians were aware of the additional CTG machines and Dopplers and perceived these as very helpful, especially for high-risk women. They changed clinical practice for the better, and clinicians felt there was “no disadvantage” to having additional equipment. Doctors had confidence in the research staff and high-quality monitoring. The doctors felt they could “wait for normal” for longer, and CS rates would therefore reduce. Clinicians used the CTG as an additional tool for their clinical assessment rather than the focus. Close fetal monitoring was just one aspect of the research associate’s role of “monitoring”. Researchers felt the CS rate in pre-eclamptic patients and referral rates in one site had reduced “drastically”. Disentangling the impact of the intervention's different elements and identifying the intervention's most important “ingredient” (training, additional equipment, research associates monitoring MOLI study patients) was difficult.

How can CS rates be reduced?

Different FGDs highlighted different issues, from antenatal care and education to workload and availability of senior staff and midwives in the labour ward, to fetal monitoring. FGD three highlighted that antenatal care, lifestyle advice, physiotherapy exercises and meditation were important during the antenatal period, promoting being calm in labour and different positions for birth, such as squatting. FGD four felt timely referrals and good counselling for women antenatally and during admission were important. Hence, patients knew when to come to the hospital and what to do when contractions started. They felt that both women and HCWs should know the warning signs. FGD 5 focused on the "multiple" "technical, logistical and administration" issues, highlighting workload being the main issue, especially as there are no midwives. In teaching hospitals, the senior doctors have multiple competing work such as teaching and exams. They felt that fetal monitoring was the most important aspect and that better monitoring, understanding and training of students and staff would help. FGD 6 felt more "facilities" were needed, such as "painless birth" and external cephalic version for breech babies (turning babies in utero, so the baby turns from the bottom first to headfirst).

3.10 Discussion

This study shows that for women, "hearing the beats" throughout labour was a positive experience that promoted happiness, reassurance and empowerment through knowledge at this worrying time. At the same time, clinicians felt fetal monitoring could not be performed as they knew it should be in this high-load setting. So, although women strongly preferred vaginal births, clinicians felt they could not "take a risk" and often opted for CS. Women clearly understood their indication for CS, despite Doctor's misconception that the women could not understand. The interactions and communication between women and clinicians played an important role in women's perceptions of their experiences.

This study has many strengths. Very few high-quality qualitative studies are available on clinicians' or birthing mothers' understanding, preferences, priorities and experiences for FM and MOB from around the world and none from India. The detailed data collection, review of the data, analysis and generation of themes was conducted by one lead researcher, with extensive input and regular research group meetings with academics and clinicians with varying backgrounds and expertise in qualitative research from UK, India and USA, promoting trustworthiness and rigour. A relatively large sample was used, according

to a sampling frame, from women and clinicians, allowing comparison and contrast between women's and clinicians' views and enhancing our understanding of this fundamental topic, both before and after birth. As unnecessary interventions rise globally, further studies are needed to understand this complex phenomenon in detail in order to design appropriate interventions to improve the outcomes and experiences of women globally.

The mixed research team had benefits, but also there were potential challenges in cultural understanding and translation issues. As this was a study alongside an RCT about IOL methods, all women had already planned vaginal birth when they entered the study and were at high risk. The local team felt, and the FGD data confirmed, that this reflected the typical hospital population, as maternal request CS was not an option and most women had risk factors. Women would also have experienced more fetal monitoring and one-to-one care than women not in the RCT, so the Hawthorne effect would have impacted women's experiences. (257) India is such a massive and diverse country that experiences in two government settings in one city will not reflect the experiences of women across the country. PPI involvement in protocol development and review was minimal. Transcripts and meaning were not cross-checked with participants due to logistical issues.

This study supports other studies globally that highlight that most women want vaginal birth. (76) It adds Indian data, which was previously lacking, highlighting that women want a vaginal birth, see this as natural and don't want the long-term implications of CS. In this study, requests for CS were related to experienced or witnessed pain and fear rather than concerns re future sexual function, perineal damage or control, as in other studies. (73) Fetal safety was the primary concern for both women and clinicians, as in other studies. This study adds significant understanding to concepts around women's knowledge around MOB in this setting. The literature base is weak, but there are widespread misconceptions that women in LMIC "don't know" and "can't understand". (80) This study demonstrates that women can understand their indication for CS and are experts in their own birth experience. They want and benefit from kind, simple explanations and value having this knowledge. Women were pleased to be part of this study and share their experiences, and they valued having their voices heard. The data from this study strongly suggests that future qualitative studies, even of this sensitive nature, would be welcomed by women in India, as having their voices heard was important to them.

The clinicians' data on mode of birth was in keeping with other studies in that they preferred vaginal birth but justified the risks of CS to promote fetal safety. Other studies suggest the fear of blame, which is echoed in this study, especially the voices of private practitioners through women's experiences. (47) Other studies highlighted that for CS rates to reduce, obstetricians must realise their role as decision-makers and the importance of underlying birth philosophy, context and negotiating the system. (85) So, the paradigm has now shifted; historically CS was the "risky" option, whereas now, to NOT do a CS is considered "riskier", and obstetricians fear "waiting for normal," where the quality of care cannot be guaranteed. Lack of adequate fetal monitoring was considered risky; therefore, CS was protective by averting these risks.

Despite fetal monitoring being so crucial, there is startlingly little contemporary research on this topic and little from LMIC. (120) FM was an overwhelmingly positive experience in this study, with only occasional reports of the "discomfort" highlighted in previous studies and no reports of anxiety related to machines beeping and malfunctioning. This study supports the finding of "reassurance" from FM. It adds that hearing the sound of FM is a particularly positive and empowering experience, far more than FM methods where women cannot "hear the beats" themselves. Hearing promotes "knowing" how the baby is, and "knowing" is important for women. This is very important that such a simple intervention had such a powerful positive impact on women. Whilst anxiety and fear were notable in the women's data, this was related to their overall situation (high-risk PET mothers with a high risk of complications and CS) rather than FM itself. The baby was the priority for women before, during and after birth. Communication with clinicians around FM was also important. Numerous conversations were related to FM throughout the dataset, supporting other studies' findings about FM as an important focus for dialogue. (126)

This study is one of the first to highlight the important relationship between intrapartum fetal monitoring and rising CS rates. Historically the narrative has always been that the technology of CTG raises additional concerns, which leads to increased numbers of CS. However, this data suggests that concerns about fetal outcomes generally give rise to increased CS rather than the technology of CTG itself. Despite knowing what the literature said about CTG, clinicians felt that the previously documented relationship was not relevant for their setting and that the potentially improved accuracy of CTG monitoring promoted waiting for normal birth and reduced the feeling of risk by providing reassurance regarding fetal health. However, high-quality fetal monitoring was hindered by a high workload,

multiple competing demands, and issues preserving delicate CTG equipment. Clinicians felt that more equipment and training would help.

Systematic reviews have recommended avoiding implementing electronic FM in LMIC due to the lack of evidence. (120) But as all international guidelines, except WHO, recommend electronic FM, it becomes inevitable that the additional technology of electronic FM is seen as part of the solution. There is minimal literature on the impact of electronic FM in a "too much too soon" setting, where fetal risk is not tolerated and medicolegal concerns are high. Previous scientific debates have focussed on CTG versus IA in low-risk births. However, the relevant questions in India are about intermittent/ continuous CTG versus IA (and varying protocols for this) in high-risk or unstratified-risk births. Is there a way of combining IA and CTG to find a middle ground, providing reassurance without alarm or unnecessary interventions? Significant research funding and focus are needed to develop new technologies for detecting fetal hypoxia in labour without increasing intervention. Improving fetal monitoring must be a research priority, especially in LMIC, where risks of operative birth are higher.

3.11 Conclusions

Women in this study wanted a vaginal birth, valued hearing their fetal heartbeat during labour, and being spoken to kindly by clinicians. These simple acts can promote a positive birth experience. Clinicians' views provided evidence of how suboptimal intrapartum fetal monitoring drives outcomes and impacts rising CS rates globally, as, without it, clinicians feel labour is unsafe for high-risk women.

Practice points

Hearing the sound of the fetal heart during labour contributes to a positive experience and empowerment through knowledge for high-risk women.

Simple comments about the baby being well after fetal monitoring have the power to make women feel good at a time when pain, fear and waiting predominate. Women value clinicians talking nicely.

Women generally prefer vaginal birth; therefore, clinicians should factor women's wishes into their decision-making during labour.

More detailed guidance and definitions on the diagnosis of fetal distress for intermittent auscultation are needed.

Understanding the background context of settings when planning interventions is critical.

When designing interventions to reduce unnecessary intervention rates, aspects such as providing high-quality intrapartum fetal monitoring for high-risk women, adequate analgesia for labour, privacy in maternity care and clinicians' perceptions of risk are important factors.

Chapter 4 – Results 2

Kirkpatrick's model 1-3. Reaction, learning, behaviour change and reflective diary

4.1 Overview

This second of four results chapters aims to evaluate the impact of the intrapartum fetal monitoring training package (thesis aim 2.1). It aims to understand if the training package was acceptable and feasible and increased knowledge using stages one to three of Kirkpatrick's four-stage training evaluation model (thesis aim 2.2 - reactions, knowledge gain and behaviour change). Data sources include the clinicians' attendance data, surveys, pre-/post knowledge tests and the reflective diary. The evolution of the intervention throughout the study and deviations from the planned intervention are also outlined.

4.2 Attendance

Throughout the two-month training period, 77 staff members engaged with the training, including 48 resident doctors, 24 senior doctors and five nurses. Thus, 85.7% of all 84 doctors within the department attended at least one training session/online learning. Of 16 potential training opportunities (15 face-to-face and one online), the mean number of training episodes that each doctor engaged with was 2.1 (SD 1.5) (standard deviation). Only 29.1% of doctors engaged in three or more training sessions.

Attendance varied according to training format, training location, and the cadre of staff. The number of attendees who signed the register per session ranged from 0-32 and was highest in the lecture hall, especially among seniors. Residents attended teaching more frequently than seniors; the mean attendance per training session was 2.7 for seniors (SD 4.5, IQR 0-4.5) and 7.5 for residents (SD 6.1, IQR 3.25-11). The research team was aware that more clinicians had attended the training, especially at some of the larger sessions, e.g. the keynote lecture, but had not signed into the register and therefore were not included. Senior doctors attended fewer small group sessions than residents and no labour ward sessions. Nurses only attended one session in the labour ward.

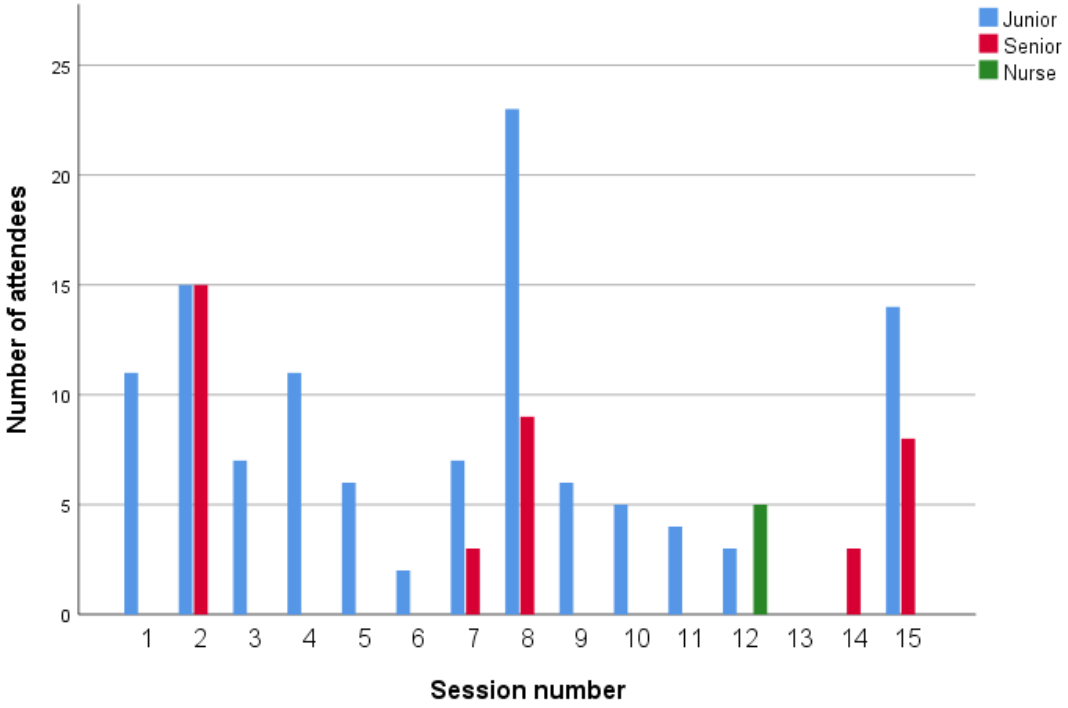

Figure 20 Attendance of staff at face-to-face training sessions

*This data was taken from the sign-in registers; in some sessions, more participants attended than signed in

** See appendix two for full details of individual training sessions

K2 online learning was only accessed by 16.4% of those given passwords (n=67, 30% seniors and 70% residents.) Eleven clinicians logged onto the system (46% seniors and 54% residents). All the logins were during the study training period of October and November (9/10/19 – 13/11/19). However, no clinicians completed one hour of training time or the required progress checkpoints or cases. In addition, there were no logins at the end of the intervention/post-intervention period.

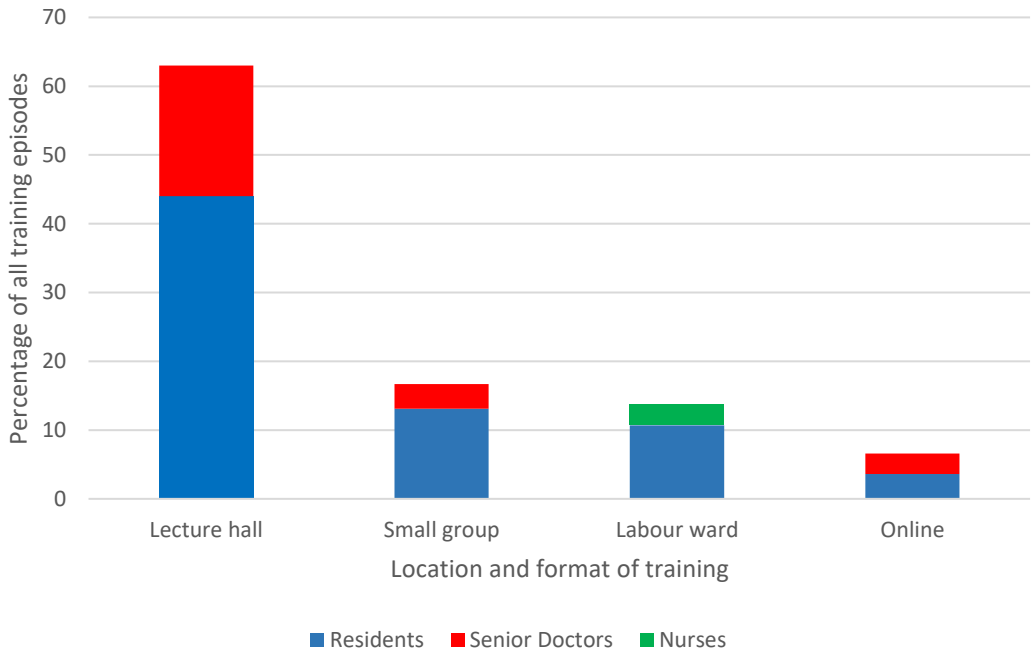

Figure 21 The location and format of all training episodes

* In this study, we defined a training episode as one training attendance by one clinician. Each person that engaged with online learning is classed as one training episode, as no online learning sessions exceeded one hour in duration.

4.3 Survey of clinicians before and during the training

Surveys were used before and during the training period to guide the training planning and implementation and evaluate the training. Data from the pre-training survey (n=24) was conducted to understand clinicians' prior experience with CTG training and their preferences for training formats. Paper surveys were completed by staff attending the department's introductory presentation about the study before the intervention period. 62.5% of clinicians surveyed reported no previous CTG training, and 33.3% reported some training (n=1 missing.) Of the staff that recalled previous CTG training, one recalled undergraduate teaching, three recalled informal on-the-job training, and four recalled training as a resident. Half of those surveyed highlighted that their preferred teaching format was hands-on labour ward teaching and online learning was the least preferred format (6.2%). When asked about preferred days/timings, three-quarters chose one to two-hour sessions around the usual postgraduate educational activity. In response, the training plan was delivered as suggested by clinicians, with a series of frequent, shorter sessions.

Midway through the training, a survey (n=10) of clinicians who attended a training session responded that the hands-on labour ward sessions were still the preferred teaching format (60%). However, the mid-intervention survey participants also more frequently selected multiple formats of CTG teaching, such as regular CTG meetings and one to two-hourly workshops.

Importance of fetal monitoring and potential impact of training

On a four-point Likert scale, participants (n=46) described intrapartum fetal monitoring skills as either “important” (49%) or “critical” (51%) in surveys throughout the study (pre, mid, and post). As the surveys were anonymised, the same participant may have responded more than once.

Before the keynote speech, the 40 participants answered four questions on a seven-point Likert score (responses were missing for three to six participants for each question). The mean scores demonstrated that clinicians felt that intrapartum fetal monitoring was very important to the successful performance of their roles, with a mean score of 6.3 (SD 0.9). However, their self-rated performance was much lower, with a mean of 4.7 (SD 1.2). In addition, those surveyed felt that training alone could improve performance, mean of 5.4 (SD 1.1) and that organisational change alone could improve performance, mean of 5.5 (SD 0.9).

4.4 Level 1 Kirkpatrick’s model - reaction

The reaction of clinicians to the overall training programme was very positive. When asked open questions such as “how do you feel about this training?” at the midpoint survey, 10/10 responses were positive, including comments such as "wonderful”, “awesome”, and “useful”. In the post-training survey (n=14), 78% very much enjoyed it, and 21.4% moderately enjoyed it. There were no negative responses when participants were asked about negative aspects or aspects that could be improved, in the post-training survey. Instead, the majority wrote “nil”/struck out the questions and a few added further positive comments. Participants’ favourite aspects included the “practical teaching” in the labour ward, the small group discussions and the detailed provision of “extensive and varied” “CTG graphs and cases”.

The keynote lecture specifically received more mixed feedback; the majority was positive, and participants particularly enjoyed the live polling via a link on phones used to assess pre/post knowledge. It received a mean score for content of 4.4 and 4.6 for the presenter on a seven-point Likert scale. Free text suggestions for improving the lecture included the wish for “more interaction”, “more CTGs”, “more clinical detail”, “practical teaching needed”, “more concise”, “refreshments served earlier”, and “lectures should not be more than 20 minutes followed by hands-on”.

4.5 Level 2 Kirkpatrick’s model - learning

Knowledge gain was assessed through tests and pre and post-tests throughout and after the intervention period. Competency tests are a core component of the online K2 package. However, they could not assess the knowledge gained in this study, as no participants undertook more than an hour of online training and therefore did not reach the tests. In the three tests conducted before and after a training session, post-test scores improved; the mean percentage difference was +10.8% in session one, +25.4% in session two and +6.4% after the keynote lecture (test number 5, in session number 8.) Only the differences in session two scores reached statistical significance (p = <0.001). Although test scores did improve, overall, they were low, and mean scores would fall below the expected standards (typically 85-90%) for settings requiring proof of competency.

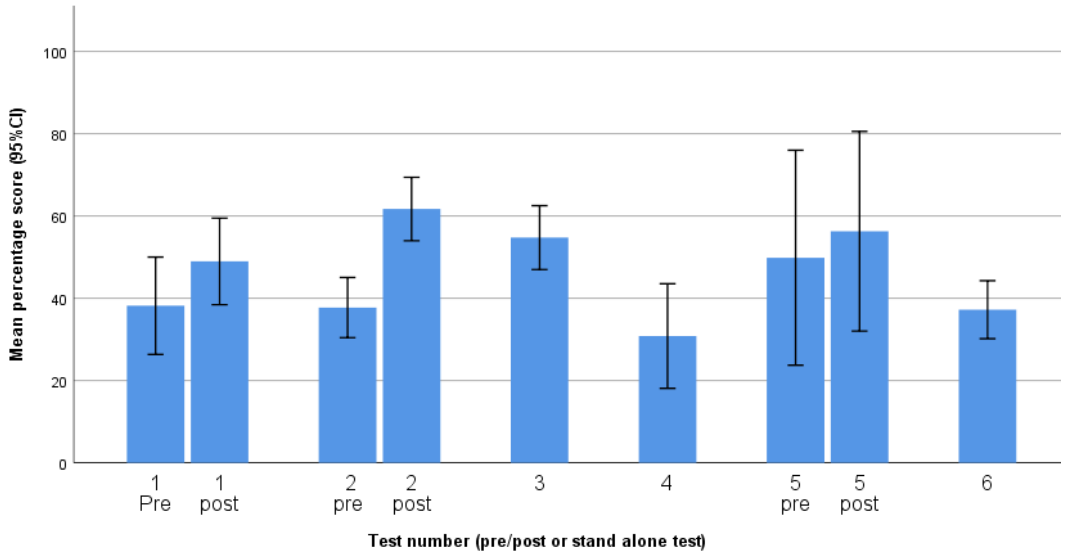

Figure 22 Mean test scores throughout the intervention

In the final post-intervention test (taken three weeks after the last training session, #6 in figure above), the mean score was 37.2% (SD 15.1). There were large individual variations in performance, ranging from 13% to 68.5%. Scores also varied for different aspects of the post-test. For example, short answer knowledge questions scored the highest (mean score of 46.7%). In contrast, the mean score for CTG case descriptions was 38.5%, but only 31.5% correctly planned the clinical management, and 19% correctly classified the CTG.

Table 8 Post-test scores (test number 6, session 15) for five clinical cases split according to CTG description, CTG classification and management plan

Test 6 case number	% correct description	% correct classification	% correct management	Total score/ case (%)
1	30	5	10	15
2	35	37.5	50	40.8
3	48	3	30	27
4	25	20	28	24.3
5	55	30	40	41.7
Mean overall score (%)	**38.5**	**19**	**31.5**	**29.8**

Where clinical CTG cases were used, there were marked differences in scores between the different CTG cases within the test. For example, in test number five, six different cases were used (see table below). For case two, almost all participants were correct in the pre and post-test. However, only ¼ were correct for case six, and scores decreased in the post-test. Mean scores also varied according to which case was used in the post-test (test six) and ranged between individual cases from 15% to 41.7%. It is also notable that there were 160 responses to the pre-keynote lecture test (15-35 responses/case) and 113 post-tests (16-22 responses/case). Although some participants had left, others simply did not answer as many post-test questions.

Table 9 Test scores pre and post-keynote lecture for each of the six cases (test number 5, session number 8)

Test 5 case no	Pre n=	% Correct pre	Post n=	% Correct post	% difference pre/post
1	21	14.3	16	37.5	23.2
2	15	93.3	19	94.7	1.4
3	28	71.4	22	72.7	1.3
4	28	60.7	21	76.2	15.5
5	35	20	19	31.6	11.6
6	33	39.4	16	25	-14.4

4.6 Level 3 Kirkpatrick's model – behavioural change

Opinion and practice change

Surveys with clinicians at the mid and endpoint highlighted that the training had changed their opinions and practice. In the post-training survey (n=14), 93.3% of participants had very much/somewhat changed their opinions, and 73.3% had very much/somewhat changed their clinical practice. All mid-training survey participants also felt this training impacted their clinical practice (n=10). Free text descriptions included "making me confident," "making us more accurate," "useful in categorising/triaging patients," "save so much of time", and "it will avoid unnecessary LSCS".

Focus groups

The FGDs were originally planned to occur a few months after the intervention period and have an important role in evaluating the training, especially for levels one and three. However, due to delays in starting the RCT and the global pandemic, the FGDs occurred nearly two years after the training intervention. Therefore, using them to evaluate the training as planned was not possible.

Examples of practice change

At the mid-point survey, 30% described an incident where this training changed clinicians' management of patients, including "more observing than intervening" and "monitored previous LSCS (caesarean section) for TOLAC (trial of labour after CS), successful VBAC (vaginal birth after CS)". In the post-survey, 80% could quantify the number of cases where the training had affected their clinical management.

- n=3 (20%) 1-5 cases
- n=7 (46%) 6-10 cases
- n=2 (13%) 11-30 cases

Examples of different clinical management included "more auscultation on labour wards", cases where instrumental delivery/LSCS were done and more instances where LSCS was avoided, e.g. fetal distress and meconium-stained liquor.

Ninety percent of attendees at the mid-survey n=10 thought that the training would be useful in future; one however highlighted, “no, we don’t have machine”.

Confidence

The proportion of surveyed doctors who described themselves as confident/very confident on a four-point Likert scale about intrapartum fetal monitoring was higher post-intervention (pre-20.8% vs post- 46.7%). The pre/post keynote lecture survey demonstrated the highest rates of confidence seen at any of the assessments, with 41.0% (n=40) rating themselves as confident or very confident before the lecture and 61.6% after (n=25). The proportion of seniors rating themselves as confident was higher (pre-56.3% vs post 63.3%), but residents’ confidence increased more (30.4% vs 53.8%) after the lecture.

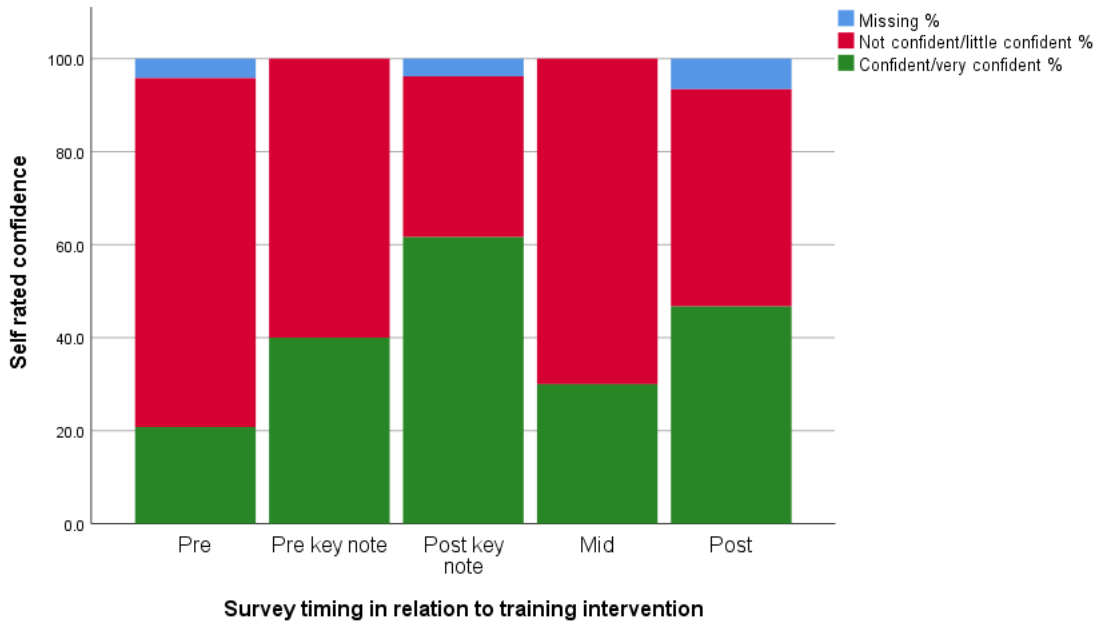

Figure 23 Clinicians self-rated confidence about intrapartum fetal monitoring before, during and after the intervention period

4.7 Post-training survey

In order to reduce sample selection bias, the post-training survey was conducted in the labour ward three weeks after the final training rather than after a training session. Therefore, the number of clinicians asked to respond and declined was not documented. The 15 respondents reported that they attended 56 training episodes: 21 lectures, 19 labour ward sessions, 13 small group sessions and three online learning. Thus, the number

of training sessions attended by survey respondents ranged between one to four attendances per clinician.

Participants were asked to indicate their preferred training format from the five used. There was a wide range of preferred options, with at least one participant selecting all options. The most popular format was small group teaching in the seminar room (50.0%), followed by lectures (37.5%), hands-on labour ward (35.7%), and small group work in the labour ward (28.6%). Online teaching was the least popular (14.3%).

Several participants highlighted the need for more training sessions, and others highlighted that more CTG machines were needed when asked about the project's next steps. One participant highlighted, “until the CTG machine is available, there is no use of applying knowledge, so make the CTG machine available”. Open questions about challenges attending teaching revealed that many clinicians surveyed encountered challenges attending teaching due to clinical duties (mid n= 7/10, post n= 8/15).

4.8 Evolution of intervention

Evolution of co-interventions (enabling activities) throughout the study

This study was conceptualised primarily around intrapartum fetal monitoring training. However, during the detailed planning process, it became clear that co-interventions, engagement and motivation of colleagues, relationship building and consensus-building were also essential components of the intervention. In addition, the link between policies, practices, and teaching content was imperative, as if they were not aligned, the training could cause harm through confusion.

It was necessary to encourage attendance; WhatsApp reminders, emails and posters were sent to encourage attendance. The Head of the Department regularly monitored attendance and enforced it with residents. Colleagues frequently reported wanting to attend the training but were too busy with clinical work or tired post-night duties. The issues of encouraging attendance at training, when the training is not mandatory, whilst managing multiple competing demands are universal. There were also complex psycho-social elements in encouraging attendance, particularly when training senior clinicians, which required careful thought and management (both inside and outside the classroom). As it was not a norm within the department for seniors to attend training, suggesting and

especially enforcing senior attendance was politically sensitive. It was met with ranging reactions, from keen to learn to total avoidance.

Evolution of training intervention throughout the study

Training experienced clinicians in IA felt slightly uncomfortable, as it is perceived as a basic skill that is likely never to have been explicitly taught. However, hearing the sounds aloud and seeing the variation in answers amongst the group was illuminating and made it clear this is a very important and poorly performed skill. Small amounts of IA were then included in several ongoing sessions to ensure more clinicians had been exposed to this aspect of the training.

Session three was planned as a second large group interactive lecture-style session to consolidate and expand on session two. However, it was clear that many residents had not retained basic concepts, and there were significant differences in the understanding of different group members. This could have occurred because of the different levels of experience within the group, differences in attendance between clinicians, and differences between clinicians in their natural ability to comprehend this difficult topic. Therefore, a small group with an interactive approach was implemented to permit frequent understanding checks and group discussions. Junior clinicians engaged more readily with the interactive case-based teaching and seemed to enjoy this teaching style, with positive body language, engagement and informal comments. In addition, this “practical” learning style was more aligned with the “hands-on learning” that clinicians had expressed they preferred. The next sessions were also taught through this small group case discussion, which made it easier for the facilitator to ensure all group members could understand. The small group work also facilitated peer-to-peer teaching informally, as part of the group, switching between Hindi/Marathi and English, which was necessary to aid the explanation of more difficult cases/concepts for some.

The keynote lecture in session eight, from a visiting Professor, was planned to encourage high attendance, particularly from seniors and overcome some of the potential barriers with hierarchy from the senior most clinicians between KL and the consultants (KL is a trainee). The HOD wrote a letter asking all Doctors to attend due to the external visiting speaker.

Sessions four to fourteen were held in the labour ward to enable different groups to attend, including the most junior residents and nurses. They typically would not be prioritised to leave the labour ward for teaching, and interprofessional learning had never been undertaken before. For the small group sessions, seniors and juniors did not attend together, reflecting the department's norms. For the penultimate session, middle-grade doctors were invited and reminded to attend via WhatsApp, as this group are the key decision makers on the LW. Fewer senior Doctors had attended the previous small group sessions.

Deviations from the planned intervention

- A variety of QI tools were not used as discussion aides, as the concepts of QI were new to clinicians in GMC, and the use of additional tools and techniques on top of the existing PDSA concepts and research protocols felt overpowering.
- Local guidelines were not adapted from international guidelines. Instead, local seniors chose to adopt an international guideline, with an edit to include the frequency of IA in this unit, at a consensus meeting. To have fully reworked a guideline did not feel appropriate or necessary. There were no other departmental policies, and a long document would unlikely have been used. There was no system for the application, audit or storage of guidelines.
- There were discussions with the Head of the Department about the training being mandatory. However, this was practically not possible as there was no precedent for mandatory training within the department.
- WHO “Service Availability and Readiness Assessment” survey outline (258) was not conducted, as a nuanced understanding of the department was already available within the local research team, and further research load was not appropriate or necessary at that time. (The same team started three studies within a few months.)
- Online lectures from physiological CTG.com were not shown, as the internet was not good enough in the teaching room, and there was no big screen. However, clinicians were made aware of these resources.
- It was hoped that some clinicians in Nagpur would deliver some of the sessions. However, this was not done as seniors did not typically deliver the training within the department. Instead, slide sets from the training sessions were used at a later date to deliver further training by the local FM project research lead.

- It was planned to deliver the session as a half-day/full-day session to ensure clinicians were exposed to the full curriculum. However, the pre-training survey highlighted that clinicians wanted the training to occur in hourly sessions, as per their current teaching format. To have created half-day/full-day sessions would have meant re-organising rotas and clinical staffing, which was not practical, and the training was run over a series of shorter one-hour/ninety-minute sessions.
- The frequent daily sessions meant that the content could not be delivered in one session, and staff could not receive all of the required content in one session. In addition, the same session could not be repeated, as some participants attended frequently and it was not known who could attend which sessions. Therefore, it was impossible to deliver all content to over 90% of the staff as planned.
- The training was intended to involve interprofessional learning. However, nurses only attended one session in the labour ward, as FM was not part of their usual role, and they could not be relieved from their ward duties.
- There were plans to purchase two further CTG machines to coincide with this study, with funding from the MOLI project. However, due to challenging and lengthy procurement processes, the machines arrived after this study closed.
- Throughout the intervention, at different sessions, it was necessary to target the invites and messaging to encourage different groups to attend and alternate the formats and locations of teaching to facilitate different groups' attendance.

4.9 Contextual elements

Writing a daily reflective diary during the intervention delivery and at key points during the intervention design period highlighted the fundamental importance of the teaching context, the co-interventions and personal interactions necessary to implement the teaching into clinical environments. Delivery of teaching sessions in the labour ward illuminated the complexity of putting learning into practice. It highlighted how seemingly simple barriers, such as plug sockets, could make change unfeasible. Also, how buy-in and alignment from all staff (especially seniors), policies and leadership are essential.

Several challenges were encountered throughout this study, many of which were typical challenges faced during training in LMIC. The labour ward was overwhelmingly busy, with many complex patients and busy and exhausted staff. The single CTG machine functioned well for most of the study, but there was no CTG paper to print off the CTGs (meaning

removing the CTG for group discussion and reflection was not possible.) There was only one functioning plug socket in the delivery area and no wheels on the CTG machine trolley, preventing movement of the machine and, therefore, implementing a two-stage assessment before operative intervention. CTG as planned would have required system change, not simply implementing individual knowledge gain. Keeping the bed next to the CTG machine free and moving patients into and out of this bed when they needed a CTG would have totally changed how the CTG machine was used and the flow of the labour ward. Plans were in place to purchase other machines, but this took months to achieve, despite active attempts to expedite this process. The precedence of the existing training norms, i.e. the daily post-graduate routine, governed the timing and format of teaching; longer sessions, e.g. half/all day or mandatory sessions, were not practised. This made delivery of the learning objectives to clinicians with different levels of experience, responsibility and previous training attendance, monitoring of attendance, and appropriately testing knowledge gain without compromising relationships and training time challenging. Ensuring senior doctors (the main clinical decision-makers) were motivated, engaged and trained was particularly challenging and required inputs from the HOD and visiting lecturers.

There were also factors related to the research itself. There were delays in starting the study due to complex MOLI study governance issues. The local MOLI Principal Investigator (SM) left the institution within two weeks of KL's arrival in Nagpur, which changed the dynamics of the research group and meant a new local project lead was required (MT). Finally, this teaching was conducted as part of a large, well-funded research study, making the results prone to the Hawthorne effect. (257) KL had responsibility for all of these studies, and this research was her primary focus, with no clinical responsibilities. KL was given privileged access, gained relationships and was a "disrupter" in the setting. The impact that another individual delivering the same teaching would have had is unknown, as the dynamics would have been different if KL was not a "foreigner" with clear research goals.

As far as the study team was aware, no other significant changes occurred in the department during the study period, affecting these outcomes. Although the labour ward rota pattern of one to three monthly changes and differing clinical practices of individual clinicians could account for some of the results, this could not be controlled. In addition, there was a two-week period when one of the main rooms in the NICU was closed. Hence,

the research associates followed the neonatal admissions to the paediatric admission wards and NICU.

4.10 Reflection on practice

The “four critical lenses” model (259) was used to consolidate reflections from the development and delivery of this training programme. This section summarises my personal reflections on the training and is built on the daily reflections and observations written in the diary.

Autobiographical lens

I have been passionate about clinical education for my entire career and have extensive experience organising and delivering training in the UK and low-income countries. Teaching CTG is one of the hardest things I have ever taught, and I often struggled with imposter syndrome throughout this research as an obstetric trainee and researcher. My impression is that even experienced teachers find CTG far harder to teach than most other subjects. This is because it is difficult, large, subjective and fundamentally about intrapartum care overall, rather than simply interpreting a graph. Attempts to protocolise this complexity commonly fall short.

This FM training programme did have some impact on individual clinicians and the whole department. I believe that most clinicians liked it, gained knowledge and some implemented practice change due to the training. Simply getting people really thinking deeply, talking about fetal monitoring and reflecting on their practice raised the issue in their minds and, therefore, impacted patient care. Numerous corridor conversations were about cord lactate readings, unnecessary CS and fetal monitoring. The fact that I was a “foreigner”, personable and had very different clinical and life experiences and research focus impacted how the training was received. However, clinicians face very many competing demands and work within highly complex and challenging systems. Therefore, learning and knowing something new is just one small aspect of what is needed to support clinicians to actually “do” something differently and “take a risk” to behave differently, especially long-term and against medical norms.

Learner's lens

The informal and formal feedback via surveys throughout the intervention was very positive. Learners, especially residents, visibly enjoyed the learning (seen both through engagement and body language). They seemed to find it unusual and fun to be taught by "a foreigner", especially with an interactive teaching style. In addition, residents valued being taught by a senior rather than the standard daily teaching delivered by fellow residents. On several occasions, I was told by the MOLI research assistants that I was perceived as "sincere" and really caring about my colleagues, the women, and their babies.

Many senior doctors undergo minimal CPD, and the perception is that seniors already "know" and are no longer viewed as "learners". This training was, therefore, more controversial for them. More than this specific training, this was primarily because of their role, social norms, and expected behaviours. I was not a very senior doctor, which must have been important for some of them, especially the more experienced clinicians.

Some learners moved from unconsciously incompetent or consciously incompetent into consciously competent. However, far more deliberate practice would be required for mastery of this complex skill for many attendees. Especially given the lack of equipment, so the teaching could not be fully implemented or practised. Classroom teaching alone would not be enough to fully implement it into routine work if others were not doing the same.

Colleagues lens

The learners were colleagues, which is often the case for training clinicians. This dynamic is a critical difference between the clinical education of practising clinicians and typical undergraduate medical education research. I feel the residents enjoyed my presence, partly because I was different and new. The seniors had mixed reactions. Many were very welcoming and keen to learn, but others hardly interacted with me or attended teaching sessions. Of course, it is risky to welcome a newcomer into a department, perhaps especially a female with alternative views and experiences. As I did not work clinically, and due to my white privilege and inability to conduct the planned focus groups, I am unlikely to understand the world from their lens.

Theoretical lens

On reflection, this training was built on previous experience and literature on CTG training rather than a deep understanding of educational theory. This criticism is common to other studies and is highlighted in the systematic review of CTG training. (53) Awareness of this lack of theory earlier in the research led to further deeper consideration of the role of theory later in the research and then the development of the theory of change in Chapter seven.

4.11 Discussion

Clinicians in this study felt that intrapartum fetal monitoring was very important for their practice. They enjoyed the training and gained confidence and some knowledge. Most felt the training had impacted their beliefs and practices, and many could quantify the number of clinical cases they managed differently after the training. This training was based on FIGO guidelines and delivered over 15 face-to-face sessions in different formats and access to K2 online learning. Co-interventions such as consensus building on departmental guidelines, meetings with different cadres of clinicians and building motivation and momentum for training attendance were vitally important steps. The training context strongly impacted whether clinicians could bring their new knowledge into practice and was impacted by various factors such as equipment, practicalities and logistics, seniors and leaders, and high patient volumes. Staff typically wanted to attend teaching but found it difficult due to multiple competing clinical demands, high workload and fatigue. Variations in the physical locations of the training made it more accessible for some groups.

There were many strengths of this project. The use of Kirkpatrick's model, supported by other methods, gave a holistic assessment of this programme, which enabled a richer understanding of its impact and barriers to change. Few studies have investigated fetal monitoring training to this level of detail, and none in low and middle-income countries, where the potential impact is far greater. A full research protocol outlined the rigorous pre-specification of outcomes and detailed thought that went into planning and evaluating this project. The detailed diary gave unexpected important insights into the role of the co-interventions and informal feedback. The research and clinical team have significant strengths, including local knowledge and experts in CTG, medical education and research. Materials, presentations and assessments had already been developed and used by leading

experts in the field. This adaption of existing materials, use of K2, and focus on clinical cases represents a real-world example of how CTG training is often structured.

There were also multiple limitations to the project. This was a single-centre study over a relatively short timeframe. Elements of the planned intervention were impossible to achieve, such as additional CTG machines in the labour ward, regular CTG meetings, training the trainers and hierarchy-free discussions. The FGDs planned for after the training were postponed so long that their role in evaluating the training was minimal due to the pandemic. The format of frequent, regular sessions made evaluation challenging due to time constraints and assessment burden. The questions in the survey and test were not validated, and the literature is unclear on how well self-perceived behaviour change reflects actual behaviour change. Finally, the project was led by an external visiting obstetrician, who was not staying in the department long term, making the sustainability of changes questionable.

Almost all doctors within the department attended at least one training session, but the mean attendance was only two sessions. Therefore, plans to deliver complex content over a series of regular shorter sessions were not feasible, as consistent and repeated attendance was too challenging to achieve. Varying the format and physical location of training may increase accessibility for some groups. Other studies of successful training have used mandatory one-day multidisciplinary training for all staff, away from clinical commitments, using mixed teaching methods and our results support that model. (173) (4) No studies have thus far evaluated the impact of “hands-on” on-the-job training or mentorship and supervision for FM training, which we believe warrants further study. Although staff had free access to high-quality internationally recognised online materials and certification for CTG training, it was used infrequently, and none completed the course. The online polling on phones received good feedback and was quick and easy; therefore, it may present a good option for informal testing of clinicians in shorter sessions.

How fetal monitoring is conducted varies worldwide, so the training must reflect the context appropriately. In most low-income countries, fetal distress is diagnosed with intermittent auscultation alone due to limited access to CTG. Intrapartum fetal monitoring training in these countries must therefore include IA too. Intelligent auscultation has been rolled out over the UK, and evaluation is ongoing. [Outcomes do appear to improve but have not been published yet.] The culture of each unit varies significantly. Therefore, local

teams are best placed to understand these issues and incorporate them into the training to meet the specific learning needs of clinicians in any given institution. The clinical environment must be conducive to change; through equipment, e.g. plugs, CTG machines and CTG paper in this study, to culture and hierarchy, finance and aligned policies. If training is to improve outcomes through changing clinical practice, the clinical environment and systems must work in partnership to facilitate these changes and "make it easy for clinicians to do the right thing".

4.12 Practice points

Intrapartum fetal monitoring is challenging and time-consuming to learn, teach and assess. It involves describing and classifying traces and planning management, clinical reasoning, situational analysis, communication, and leadership. For this reason, adding one session for one/two hours to annual mandatory training, as is conducted in some hospitals, is unlikely to be enough to impact patient outcomes significantly.

Co-interventions (enabling activities) and training must be embraced equally, as the training is just one element of a complex intervention. Like much clinical education research, it is impossible to understand the impact of the individual aspects of the intervention in isolation. Diary methods can be useful for noticing co-interventions and their impact.

Repeated attendance at regular sessions by doctors within working hours is challenging. Therefore, models that plan to deliver a curriculum over a series of sessions where clinicians attend ad hoc are likely only to provide a small portion of the required content to individuals.

Individual clinicians had different preferred teaching locations and formats; therefore, changing training locations and formats may make it more accessible and increase attendance.

Making high-quality resources available for free does not ensure their use.

Quantifiable numbers and descriptions of cases where clinical management has been changed due to the training are useful indicators to measure and link the impact of training on changing practice. In addition, self-perceived improvements in confidence and changed opinions and beliefs are relevant links. Practising clinicians will have beliefs that may need

to be deconstructed, reconstructed and rebuilt to incorporate the new ideas from the training.

Training clinicians must be viewed as a systems issue and one element of a change process. Training alone will not result in a change in practice unless complemented by leadership engagement, an appropriate working and educational culture, psychological safety to do something different, dedicated staff time for training, aligned policies that require practice to reflect the training and sufficient equipment.

4.13 Conclusion

This training was acceptable and feasible, increased knowledge and confidence and led to quantifiable practice changes for clinicians. However, intrapartum fetal monitoring training is a complex and complicated intervention that is time-consuming and challenging to teach and assess. Moreover, the training is only part of the complex intervention, and other co-interventions and systems thinking are essential. Leaders must consider barriers to knowledge use in practice, such as culture, policies, hierarchy and equipment, in order to overcome these barriers and achieve change.

Chapter 5 - Results - 3

Level 4 Kirkpatrick's model – Organisational performance, before and after study

5.1 Overview

This results chapter aims to evaluate thesis aim 2.3, to evaluate the impact of a fetal monitoring training and quality improvement package on short-term maternal and perinatal outcomes and operative birth rates, particularly for suspected fetal compromise (stage four of Kirkpatrick's model). A before-and-after design was used, and all outcomes were specified in the research protocol. Data are presented in this chapter for all deliveries in the two-month pre-intervention period (August and September 2019; women n= 2272, babies n= 2319) and two months post-intervention period (December 2019 and January 2020 (women n= 1881, babies n= 1920) and compared using percentage differences and corresponding confidence intervals. This includes live births and stillbirths where the fetus was alive or queried to be alive on admission.

5.2 Baseline characteristics of the population

The pre and post-intervention groups were broadly similar, albeit with some small differences between the two populations (see table below). There was no significant difference in the mean ages of the women (pre 25.7 vs post 25.5), mean gestational age of delivery (37.6 weeks) or the number of mothers with no documented risk factors (less than 10% in both groups). However, the mean parity was significantly higher, and the mean birth weight was significantly lower in the pre-intervention group. Notably, large numbers of babies in both groups were preterm (pre 23.5% vs post 21.9%) or low birth weight (pre 42.3% vs post 37.0%), reflecting the very high-risk nature of this population.

Table 10 Baseline characteristics of the population pre and post-intervention

	Pre	Post	
Population characteristics of mothers	**n=2272**	**n=1881**	**Mean difference (CI)**
Age – years			
Mean (SD)	25.7 (3.9)	25.5 (4.0)	-0.2 (-0.3, 0.5) [1]
Missing	27	5	
Parity			
Mean (SD)	0.63 (0.7)	0.55 (0.7)	0.08 (0.04, 0.13)*[2]
Nulliparous (%)	1058 (47.4)	1031 (55)	
Para 1 (%)	978 (43.8)	683 (36.5)	
Para 2-4 (%)	191 (8.6)	157 (8.4)	
Para 5+ (%)	4 (0.2)	2 (0.1)	
Missing (%)	41 (1.8)	8 (0.4)	
Population characteristics of babies	**n=2319**	**n=1920**	**Mean difference (CI) / P value**
Gestational age (completed weeks)			
Mean (SD)	37.6 (2.6)	37.6 *(2.4)*	0.20 (-0.2, 0.1) [1]
<28/40 (%)	17 (0.7)	9 (0.5)	
28 - 31 (%)	58 (2.5)	46 (2.4)	
32 - 36 (%)	471 (20.3)	364 (19.0)	
37 - 39 (%)	1324 (57.1)	1196 (62.3)	
40> (%)	413 (17.8)	297 (15.4)	
Missing	36 (1.6)	8 (0.4)	
Birth weight (g)			
Mean (SD)	2478.5 (531.3)	2555.3 (548.2)	p=<0.001*[3]
Under 2500g (%)	981 (42.3)	710 (37.0)	
Missing (%)	39 (1.7)	10 (0.5)	

(* represents a statistically significant result throughout the tables in this chapter)

(Test used throughout the chapter: Mann Whitney U[1], Kruskal Wallis[2], T test[3])

5.3 Intrapartum fetal monitoring documentation process measures

There were improvements in the decision to delivery time and fetal monitoring documentation during labour in the post-training group. The mean time between the last FHR recorded and delivery significantly reduced from 60 to 50 minutes (p=<0.001), where delivery was indicated for suspected fetal compromise. The mean number of times FHR was documented significantly increased from a median of five to 7.5 (p=<0.001). There was no difference in the number of risk factors for poor perinatal outcomes documented.

Table 11 Intrapartum fetal monitoring documentation parameters pre-and-post intervention

Intrapartum fetal monitoring documentation	**Pre**	**Post**	**P-value / CI**
Number of FHR readings taken in labour ward			
Median	5	7.5	p=<0.001*[1]
Range	0-335	0-172	
IQR	12 (2-14)	13 (3-19)	
Missing	123	62	
Decision to delivery interval for suspected fetal compromise (minutes)	n=337	n=324	
Median	60	50	p=<0.001*[2]
IQR	49	37	
Range	0-530	0-335	
Number of risk factors documented			
Mean	1.9 (1.2)	2.0 (1.3)	
Median	2	2	(-0.1, 0.04)[2]
IQR	2	2	
Range	0-7	0-7	

(Mann Whitney U[1], Kruskal Wallis[2])

5.4 Mode of birth and maternal outcomes

There was a non-statistically significant trend toward increased operative delivery rates overall, and operative birth indicated for suspected fetal compromise (SFC) 14.8% vs 16.7%. Although this was not statistically significant, caesarean section rates were high and increased from 42.5% pre- to 44.9% post-intervention. CS for suspected fetal compromise accounted for a very high proportion of all births, 14.6% vs 16.3%. Operative vaginal births (vacuum and forceps) were infrequent.

Table 12 Mode of birth and operative births where the indication was suspected fetal compromise pre-and-post intervention

Mode of birth	Pre	Post	% difference (CI)
CS (%)	966 (42.5)	844 (44.9)	+2.4 (-0.7, 5.4)
CS for SFC (%)	332 (14.6)	307 (16.3)	+1.7 (-0.5, 3.9)
Operative vaginal (%)	8 (0.4)	12 (0.6)	+0.2 (-0.1, 0.7)
Operative vaginal for SFC (%)	5 (0.2)	8 (0.4)	+0.2 (-0.1, 0.6)
All operative birth for SFC (%)	337 (14.8)	315 (16.7)	+1.9 (-0.3, 4.2)

There were 12 maternal deaths in the pre-intervention group and two in the post-intervention group. There were more maternal deaths in the pre-intervention group; however, reviewing the causes of death (see chapter six), the difference was not related to fetal monitoring. In addition, the maternal length of stay was the same across the pre- and post-groups.

Table 13 Maternal total length of stay and maternal deaths pre-and-post intervention

Maternal outcomes	Pre	Post	% difference (CI) / P value
Maternal deaths (n,%)	12 (0.5)	2 (0.1)	-0.4 (-0.8, -0.1)*
Length of stay	n=2214	n=1870	
Median, IQR	5.0 (2.0-7.0)	4.0 (2.0-7.0)	p= 0.4 [1]
Mode	2.0	2.0	
Mean (SD)	5.9 (6.1)	5.8 (6.0)	
Range	96 (0-96)	105 (0-105)	
Missing	58	11	

(Mann Whitney U[1])

5.5 Perinatal mortality

There was a non-statistically significant trend toward reduced perinatal mortality, 4.6% vs 3.7%. This trend was seen in facility stillbirths (where the fetus was confirmed alive/ unclear if the fetus was alive on admission), in facility neonatal deaths and neonatal deaths where hypoxic-ischaemic encephalopathy (HIE) or asphyxia was recorded on the death certificate. However, asphyxia/HIE was an infrequent cause of neonatal death (see chapter six).

Table 14 Perinatal mortality pre-and-post intervention

Perinatal mortality	Pre	Post	% difference (CI)
In-facility FSB (%)	25 (1.1)	14 (0.7)	-0.4 (-0.9, 0.2)
Neonatal death (%)	81 (3.5)	56 (2.9)	-0.6 (-1.7, 0.5)
Perinatal death (%)	106 (4.6)	70 (3.7)	-0.9 (-2.1, 0.3)
Neonatal death from HIE/asphyxia (%)	16 (0.7)	7 (0.4)	-0.3 (-0.8, 0.1)

5.6 Neonatal outcomes

Some important neonatal outcomes improved in the post-intervention group. For example, overall neonatal intensive care unit (NICU) admission rates significantly reduced, 16.7% vs 10.2%, as did NICU admissions for asphyxia, 1.2% vs 0.6%. However, the median length of stay for those babies admitted to NICU increased significantly from 3.0 to 4.0 days, suggesting that the reduction in admissions came in those that would have been admitted briefly.

The number of babies that required neonatal resuscitation (ventilation/intubation) at birth did not change. The number of babies with APGAR scores of seven or below at five minutes increased by 0.5% vs 1.1%. However, APGAR scores were poorly documented in the notes, and "BCIAB" (baby cried immediately after birth) was frequently recorded instead. Therefore, we evaluated the total number of APGAR scores documented at five minutes and found this also increased significantly, 35.2% vs 41.3%. Cord lactate samples were taken from more babies in the pre-intervention group (75) than in the post-intervention group (18). There were no significant differences in the numbers of babies with raised cord lactate post-training.

Table 15 Neonatal outcomes pre-and-post intervention

Neonatal outcomes	Pre	Post	% difference (CI) / p-value
NICU admission (%)	382 (16.7)	194 (10.2)	-6.5 (-8.5, -4.4) *
NICU admission with a final diagnosis of asphyxia (%)	27 (1.2)	11 (0.6)	-0.6 (-1.2, -0.04) *
Length of NICU stay (days)	N=381	N=193	
Median	3	4	p=0.024* [1]
IQR	5 (1-6)	8 (1-9)	
Range	0-50	0-48	
Neonatal resuscitation (%)	15 (0.7)	18 (0.9)	+0.3 (-0.3, 0.8)
APGAR score at 5 minutes			
Number recorded (%)	808 (35.2)	787 (41.3)	+6.1 (3.1, 9.0) *

</= 7 (%)	11 (0.5)	21 (1.1)	+0.6 (0.1, 1.2) *
Cord lactate			
Number of results recorded (%)	75 (3.3)	18 (0.9)	
Lactate result >4.8mmol/l (%)	48/75 (64)	9/18 (50)	-14 (-39.5, 11.5)

(Mann Whitney U[1])

5.7 Discussion

In this study, some improvements were seen in the speed of delivery when fetal compromise was suspected and the quality of fetal monitoring following the intervention period. There was a significant decrease in the decision to delivery interval when fetal compromise was suspected and a significant increase in the number of fetal heart rates recorded during labour. There was also a non-statistically significant reduction in perinatal mortality for stillbirths and neonatal deaths, including deaths from HIE and asphyxia. Significantly fewer babies were admitted to NICU, and more babies had recorded APGAR scores. The reductions in time to delivery once fetal compromise was suspected, could have led to these improvements, as the hypoxic insult was shorter. However, there was also a non-statistically significant trend toward increased maternal intervention rates.

The strengths of this study include the large prospective dataset with a large number of variables and patients. This detailed dataset includes risk factors, a variety of outcome measures, and fetal monitoring process indicators. It provides a quantitative link between the fetal monitoring process and outcomes. Fewer measures and less detail would have risked a flawed interpretation of the results. An example of this is the maternal deaths, where there were differences in the pre-and-post groups, but these were not direct deaths and were unrelated to the intervention. The outcome measures were carefully planned according to a research protocol. The detailed prospective data collection contrasts with many published studies evaluating training. In the recently published systematic review on CTG training (172), only three of the eight studies that studied outcomes after FM training were rated as having a low risk of bias. Understanding the impact of training on outcomes is even more important in LMIC settings where morbidity and mortality are higher.

This study has some limitations; it was undertaken in just one hospital over a relatively short timeframe. In addition, the pre-post design is flawed methodologically: a time-series

study and a higher number of sites would have been better. However, the budget and logistics were not available for this. There were fewer daily deliveries during the post-intervention period, and the individual clinical practice of obstetricians rotating through the labour ward varies. One room in the NICU was closed for two weeks during the post-intervention period, requiring babies to be managed in three clinical areas rather than one. Although the research staff carefully ensured rigorous data collection, this period may have altered clinical practice and made data harder to collate. As far as the study team is aware, no other changes occurred during the study period that could have impacted outcomes.

Perinatal death rates, especially intrapartum stillbirths, are highest in LMICs. Therefore, there is a greater potential for improving mortality rates in LMIC through quality intrapartum fetal monitoring. In this study, intrapartum stillbirths, neonatal deaths overall and neonatal deaths due to HIE all showed decreases, although not statistically significant. Most previous studies were conducted in HIC, where intrapartum stillbirth is rare, and therefore stillbirths were excluded. (172) In this study, only 15% of neonatal deaths pre-intervention and 10% post-intervention had HIE recorded on the death certificate, suggesting the role of intrapartum hypoxia in death rates was lower than typically reported in LMICs. Term, normal birth weight stillbirths were infrequent. Other studies highlight that focusing on CTG misinterpretation as a key cause of harm may overestimate the role of hypoxic brain injuries. For example, hypoxic injury during labour only constitutes 10% of all cerebral palsy cases. (260) The causes of perinatal morbidity and mortality in this cohort will be reviewed in detail in chapter six.

Although there was no statistically significant increase in operative births in this study, the rises in operative births or increased CS rates have also been seen in other studies where fetal monitoring education packages were introduced. (172) The causes of rising CS rates globally extend beyond medical factors; political, financial, societal influences, fear of blame and litigation, and risk perception all contribute. (43) Training HCP is just a small aspect of these broader issues.

Rising operative birth rates have been attributed to electronic fetal monitoring for decades; therefore, many would disagree with the initial hypothesis that training could reduce CS rates. This premise was built on local experts' opinions with a detailed understanding of their context. Many other LMICs, such as Rwanda, are also looking into following in the footsteps of HIC and increasing electronic fetal monitoring training and use. Increased

vigilance of the fetus can mean increased intervention for the mother. It is not just the implementation of the CTG technology; even the training could increase maternal intervention rates. However, crude metrics do not reflect the complex picture of the appropriate use of CS and the interpretation of CTG. Improved quality of intrapartum fetal monitoring will involve less CS for some women and more for others; therefore, measuring a change in percentage does not reflect the whole picture.

Patterns in neonatal outcomes vary across studies, and some typically reported parameters, such as rates of therapeutic cooling and cord pH levels, are not routine practices in this setting. Attempts were made to take cord lactate, a more affordable technology for babies delivered urgently for suspected fetal compromise. Although the initial use of the lactate monitor was promising, the logistics of machine use posed challenges, and therefore few cord lactate samples were taken in the post-intervention group. In this study, NICU admissions and NICU admission for possible asphyxia were reduced significantly, suggesting improved outcomes after the training. Other studies showed increases (173) or did not report NICU admissions. In addition, the number of cases of poor APGAR scores increased, whereas, in other studies, rates decreased (173)(150) or stayed the same. (175) The training did include several discussions on the APGAR score and prompted conversations between the senior obstetric and neonatal team on this poor APGAR documentation. So, this could reflect improved documentation of APGAR scores, as APGAR recording was generally poor and increased significantly in the post-intervention group.

On the other hand, it could reflect more babies being born in poor condition or undergoing resuscitation in the labour ward due to increased awareness of babies with poor APGAR scores and, therefore, earlier intervention by the obstetric team. However, if these babies born in poor condition did not result in NICU admission, they are unlikely to signify babies who have undergone a significant hypoxic insult. The number of babies resuscitated with ventilation or intubation was low.

As the decision to delivery interval decreased and the numbers of fetal heart recordings improved, patient outcomes followed similar trends, and many clinicians could quantify the number of cases managed differently (chapter 4). Some of these outcomes could be attributable to the training and QI intervention. However, due to the nature of a pre-and-

post study, it is not possible to prove a causal relationship. It is impossible to know the extent to which each element of the (co-)intervention made a difference.

5.8 Conclusions

In this study, training staff in intrapartum fetal monitoring improved fetal monitoring process indicators and some perinatal outcomes, although maternal interventions did increase non-significantly. Further research is needed about the role of training staff in LMIC regarding intrapartum fetal monitoring and the impact of training on outcomes and intervention rates in varying LMIC contexts.

Chapter 6 – Results 4

Prospective cohort study – Maternal and perinatal risk factors and outcomes

6.1 Overview

This chapter describes the prospective cohort study data of 6511 consecutive deliveries over the six-month study. It aims to explore the maternal characteristics and risk factors, indications for operative birth, maternal and perinatal outcomes and fetal monitoring practices in a government tertiary referral hospital in Nagpur, India (thesis aim three).

6.2 Screening

During the study, 6989 cases were screened; 307 cases were removed. These cases were duplications or incorrectly created case report forms (CRFs) (n=292), stillbirths under 499g (n=8) or livebirths in the Accident and Emergency Department (n=7). A further 171 stillbirths were excluded from the main analyses, as the study focus was intrapartum fetal monitoring; 102 were macerated stillbirths, and 69 were fresh stillbirths. Of the excluded FSBs, 55 were confirmed as already dead upon admission to the hospital, eight were early fetal deaths with birth weights 500-999g (therefore did not meet the international stillbirth definition), and six had an unknown birth weight and gestational age, and consequently were unclassifiable. Overall, 6511 babies and 6379 women were included in the full analysis. This included 6453 live births and 58 stillbirths.

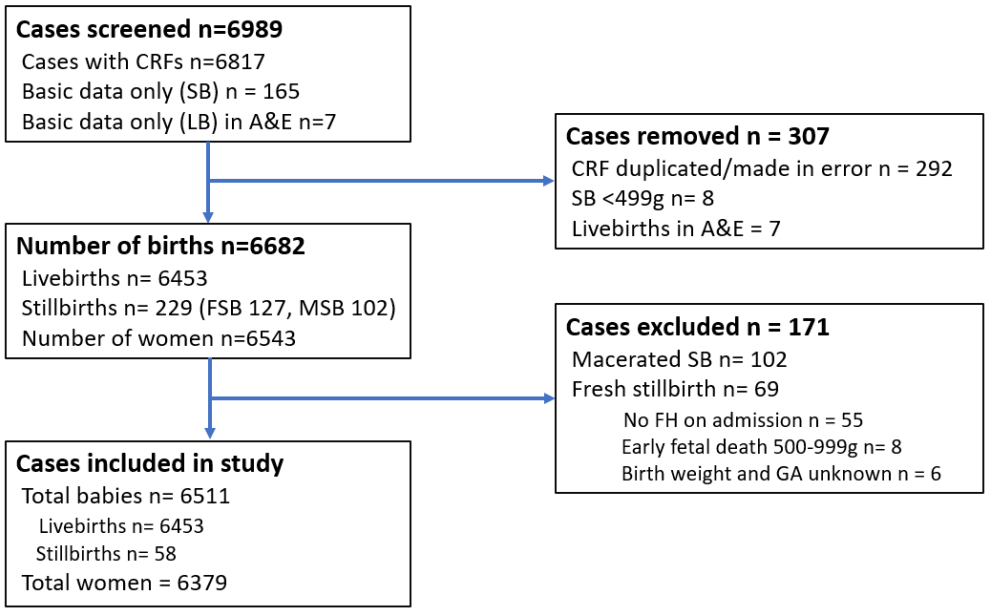

Figure 24 STROBE diagram

6.3 Maternal basic demographics

The mean age of women was 25.7 (SD 4.0), ranging from 14 to 50 years. There were small numbers of women at the extremes of maternal age; only nine women were under 17 years old, and nine were over 40 years. The mean parity was low (0.6, SD 0.7), and just over half of the women were nulliparous. There were very small numbers of grand multiparas (0.1%). Almost all patients were booked (seen at least once in an antenatal clinic), and nearly 40% were referred from another unit.

Table 16 Basic maternal characteristics

Age - years	**n (%)**
<20	143 (2.3)
20-24	2582 (40.8)
25-29	2520 (39.8)
30-34	885 (14.0)
35<	195 (3.1)
Missing	54
Parity	
Nulliparous (%)	3230 (51.3)
Para 1 (%)	2544 (40.4)
Para 2 (%)	466 (7.5)
Para 3 (%)	45 (0.7)
Para 3< (%)	14 (0.1)
Missing	80
Booking status	
Booked	6312 (99.5)
Unbooked	30 (0.5)
Missing	37
Referral status	
Referred	2473 (39.2)
Not referred	3839 (60.8)
Missing	67

6.4 Maternal risk factors

This was a very high-risk population, with over one quarter having at least one medical condition (25.5%). Nearly half were induced or augmented (46.2%). One-fifth had a previous CS (20.9%), were preterm (22.6%) or had hypertensive disorders (20.8%). Few women (less than 1/10) could be classified as low risk on hospital admission, and even fewer postnatally.

Table 17 Maternal risk factors

Pre-existing risk factors	**n (%)**
Medical condition*	1627 (25.5)
- haematology	745 (11.6)
- cardiac	114 (1.8)
- diabetes	64 (1.0)
- hypothyroidism	539 (8.4)
- renal disease	12 (0.2)
- respiratory disease	35 (0.5)
- other	255 (8.7)
Previous CS	1334 (20.9)
Infertility	298 (4.7)
Previous IUD	52 (0.8)
Previous "bad obstetric history"/abortions	108 (1.7)
Antenatal complications/reason for admission to hospital	
Preterm	1444 (22.6)
Hypertensive disorder	1326 (20.8)
Prelabour ROM	1189 (18.7)
USS abnormality	797 (12.5)
Post-term (or 41/40 GA)	290 (4.5)
Antepartum haemorrhage	183 (2.9)
Multiple pregnancies	141 (2.2)
Acute infection/sepsis	103 (1.6)
Reduced fetal movements	35 (0.5)
Intrapartum complications	
IOL/augmentation of labour	2949 (46.2)
Meconium	591 (9.3)
Cephalopelvic disproportion	373 (5.8)
Malpresentation	224 (3.4)
Prolonged labour	83 (1.3)
Abnormal lie	59 (0.9)
Hyperstimulation	11 (0.2)
Cord accident	12 (0.2)

* some women had more than one medical condition

6.5 Intrapartum fetal monitoring

The fetal heart was documented as present on admission for 95.9% of cases. However, the numerical fetal heart rate was only documented in 60.2% of cases, and "*FH+*" was a frequently used term instead of a numeric rate. The mean fetal heart rate on admission was 140.3 (SD 10.2), and the median, mode and range were all 140. The range was from 60-200 beats/minute. The last fetal heart rate before birth was recorded as a numeric rate (rather than FH+) in a slightly higher number of cases (61.8%). The mean rate was slightly lower, 135.6 (SD 18.6), and the median and mode were also 140, with a range of 50-200 beats/minute.

The total number of fetal heart rates documented in the notes during labour ward admission was known for 95.4% of babies. The median number of fetal heart recordings was six, mode one and range 0-420. CTG was used in 525 cases during the labour ward admission (8%). Cord lactate was performed on 128/983 (13.0%) cases of operative birth for suspected fetal compromise. 60.9% of the lactate results were raised at 4.9 or more.

6.6 Mode of birth and indications for operative birth

Overall, 57.5% of women gave birth vaginally; 56.4% had a cephalic vaginal delivery, 0.5% had vaginal breech, and 0.6% had an operative vaginal birth. 42.5% of women delivered by caesarean section.

Table 18 Mode of birth

Mode of birth	n (%)
Vaginal delivery	
Cephalic vaginal delivery	3598 (56.4)
Breech vaginal delivery	31 (0.5)
Forceps	27 (0.4)
Vacuum	10 (0.2)
Caesarean section	2713 (42.5)
Missing	0

Of the 2750 operative births (43.1%), 4049 indications were recorded on the operative delivery notes (11 women had no indication recorded (0.2%)). Fetal concerns were the most commonly recorded indication for operative birth (n=1493, 23.4%); 14.2% for

suspected fetal compromise on fetal monitoring in labour, 7% for meconium passage and a further 2.3% for fetal concerns diagnosed with ultrasound. Previous caesarean section was the second most common indication (n=1141, 17.8%), including 12.1% where previous CS was noted and a further 5.7% where both previous CS and scar tenderness were reported. The third and fourth most common indications were cephalopelvic disproportion (5.5%) and maternal medical conditions (3.5%). Other less frequent indications were breech presentation (2.9%), antepartum haemorrhage (APH) (1.8%), failure to progress in labour (1.7%), pre-labour rupture of membranes (1.6%), multiple pregnancies (1.1%), abnormal lie (0.9%), cord accident (0.2%) and other (2.8%).

Table 19 Indications for operative birth

Indication for operative birth	n (% of all births)
Suspected fetal compromise on FM	905 (14.2)
Previous CS	775 (12.1)
Meconium	444 (7.0)
Previous CS and scar tenderness	366 (5.7)
Cephalopelvic disproportion	353 (5.5)
Medical condition	223 (3.5)
Breech	184 (2.9)
Fetal condition other (USS diagnosis)	144 (2.3)
Antepartum haemorrhage	118 (1.8)
Pre-labour rupture of membranes	102 (1.6)
Multiple	69 (1.1)
Failure to progress, 1st stage	65 (1.0)
Abnormal lie (transverse/oblique)	59 (0.9)
Failure to progress, 2nd stage	42 (0.7)
Cord accident	12 (0.2)
Other	177 (2.8)
None documented	11 (0.2)

*Total is over 100% as many women had more than one indication.

6.7 Operative birth for suspected fetal compromise

Of the 2750 operative births, 983 (35.7% of operative births and 15.4% of total births) were conducted for suspected fetal compromise (women with suspected fetal compromise, meconium or both). This does not include indications related to USS diagnoses. Of these

983 operative deliveries for suspected fetal compromise, the majority were CS (n=957, 97.4%), with 19 forceps (1.9%) and seven by vacuum (0.7%).

The majority of decisions for operative birth for suspected fetal compromise were based on intermittent auscultation (88.5%), either alone (45.9%) or in conjunction with meconium-stained liquor (37.1%). Meconium staining alone was used to diagnose suspected fetal compromise for 8.4% of births. Meconium was highlighted as a sign of suspected fetal compromise in nearly half of births for suspected fetal compromise, n=457 (46.5%). CTG was used only for 6.2% of decisions for operative birth and CTG alone in only 1.4% of cases.

Table 20 Methods used to diagnose suspected fetal compromise

Intermittent auscultation	**n (% of operative birth for SFC cases)**
IA alone	451 (45.9)
IA and meconium	365 (37.1)
IA and CTG	37 (3.8)
IA and APH	8 (0.8)
IA, meconium and CTG	8 (0.8)
IA and cord accident	1 (0.1)
Total IA	**870 (88.5)**
Other methods to diagnose SFC	
Meconium alone	82 (8.4)
CTG alone	14 (1.4)
APH alone	5 (0.5)
Cord accident	3 (0.3)
Meconium and APH	2 (0.2)
CTG and meconium	2 (0.2)
Unclear documentation	5 (0.5)
Total other	**113 (11.5)**

6.8 Ten groups classification for caesarean section

Group five, the previous CS group, was the biggest overall contributor to the CS rate (group 5, 13.7% of all births). The second is the term cephalic, nulliparous women, who were either induced or had a pre-labour CS (group 2, 12.0%). Preterm, cephalic, singletons were the third most common group (group 10, 7.9%). All of the other groups were between 0-

2%. Finally, 23 cases were unclassifiable, as although the mode of birth was known, parity and gestational age were unknown.

In the patient files and clinically, there was often no clear discrepancy between those patients who were induced or those who were augmented with a spontaneous onset of labour. 46.2% of all women were induced/augmented; 21.7% received misoprostol, 20% received oxytocin, 18.7% had an artificial rupture of membranes, and 11.5% had a Foley catheter IOL. As 1396 women had either an ARM or oxytocin (without misoprostol or Foley IOL), it is likely that some women in group two were actually augmented in spontaneous labour and should be in group one. Still, it is not possible to quantify how many.

Table 21 Ten group classification for caesarean section

TGCS Group	No CS / no vaginal birth	Size of group %	C/S rate in group %	Contribution of group %
1. Nulliparous single ceph, term spont lab	102/563	8.8	18.2	1.6
2. Nulliparous single ceph, term, IOL or pre-lab CS	763/1868	29.3	40.8	12
3. Multiparous (excl prev CS) single ceph, term, spont lab	24/562	8.8	4.2	0.4
4. Multiparous (excl prev CS) single ceph, term, IOL or pre-lab CS	122/792	12.4	15.4	1.9
5. Previous CS single ceph, term	874/962	15.1	90.9	13.7
6. All nulliparous breeches	91/109	1.7	83.5	1.4
7. All multiparous breeches (incl prev CS)	72/84	1.3	85.7	1.1
8. All multiple pregnancies (incl prev CS)	83/141	2.2	58.9	1.3
9. All abnormal lies (incl prev CS)	55/55	0.9	100	0.9
10. All single ceph preterm (incl prev CS)	508/1220	19.1	41.6	7.9
Unclassifiable	19/23	0.4	82.6	0.3
Total	**2713/6379**	**100**	**n/a**	**42.5**

6.9 Maternal mortality and maternal outcomes

Nineteen maternal deaths were captured in this data set during the study period. Further deaths did occur during the study period in the department but were not captured in this data set, as the baby was not delivered before the death, the fetus was stillborn and already dead upon admission, or the mother delivered elsewhere. Just over half of the deaths were direct (n=10). Of these direct deaths, six died from hypertensive disorders, and three died from haemorrhage and one from sepsis. Of the nine indirect deaths, five had fulminant hepatitis, two had sickle cell disease and severe anaemia, one had cardiac disease and one had status epilepticus.

Table 22 Direct and indirect causes of maternal mortality

Direct	**n**
Hypertensive disorders	6
Haemorrhage	3
Sepsis	1
Indirect	
Hepatitis	5
SCD, severe anaemia	2
Cardiac	1
Status epilepticus	1

Maternal length of stay (n=6273) varied from 0-152 days, the median length of stay was five days, and the mode was two days.

6.10 Neonatal condition and resuscitation at birth

The most frequent documentation in the patient files about neonatal condition immediately after birth was whether the baby cried immediately after birth “BCIAB” or not. For 95.1% of babies, “BCIAB” was documented in the patient file. 3.5% “did not cry immediately”, 0.9% FSB and 0.5% unknown.

Of the 226 live births that “did not cry immediately”, further information was documented on 68% (155/226) cases. Intervention to help babies breathe was documented in 78 cases (including suction and stimulation), and only 44 cases were ventilated (0.7%), and 15 (0.2%) were intubated in the labour ward.

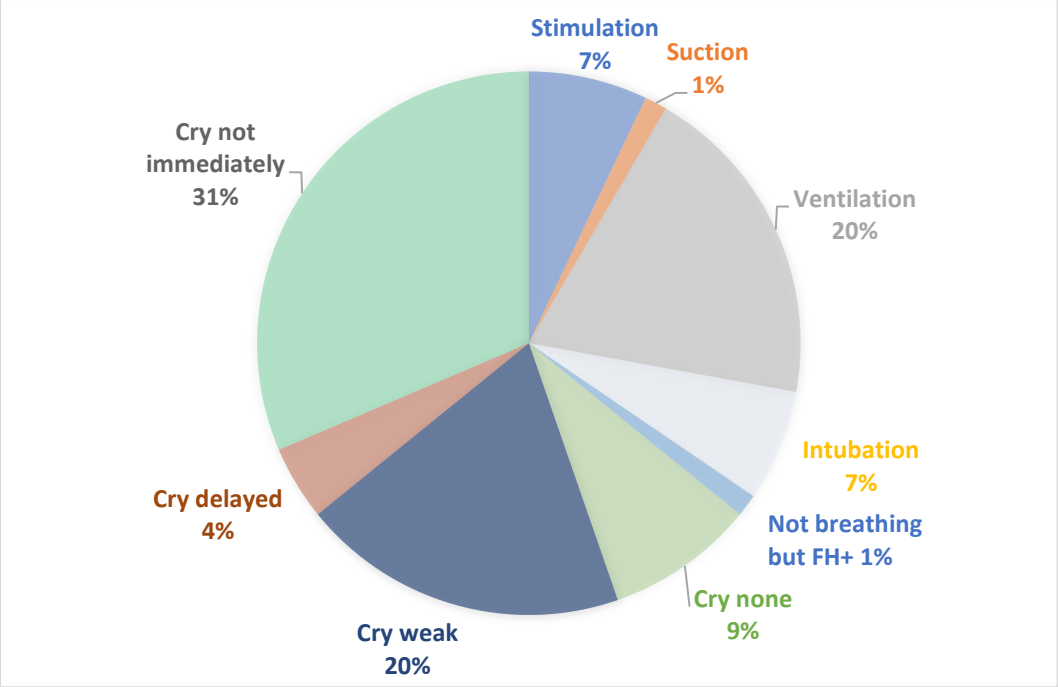

Figure 25 Documentation of neonatal condition and interventions at the time of birth for live births who "did not cry immediately"

APGAR scores were only recorded on live births at one minute in 37.6% of babies and 37.4% at five minutes. At one minute, 140 babies had an APGAR recorded as seven or less (5.8% with one-minute APGAR recorded, 2.2% of live births). At five minutes, 34 babies had an APGAR recorded as seven or less (1.4% with five-minute APGAR recorded, 0.5% of live births). No stillbirths had APGAR scores recorded.

6.11 NICU admission

Of the 6453 live births, 884 were admitted to NICU (13.7%). The most common reason for admission to NICU was low birth weight (LBW) (31.5%), then prematurity (26.3%), and for observation (9.4%). Admission for intrapartum fetal hypoxia-related diagnoses was less than 5%; only 3.4% were admitted for birth asphyxia or 1.2% for meconium aspiration syndrome.

Table 23 NICU admission diagnosis

NICU admission diagnosis	n (% of NICU admis)
Low birth weight	455 (31.5)
Preterm	380 (26.3)
For observation	136 (9.4)
Hyperbilirubinaemia	99 (6.9)
Septicaemia	91 (6.3)
Congenital anomaly	65 (4.5)
Birth asphyxia	49 (3.4)
Respiratory distress	46 (3.2)
Weight loss	28 (1.9)
Meconium aspiration syndrome	18 (1.2)
Convulsions	11 (0.8)
Birth trauma	8 (0.6)
Other	57 (4.0)
Total	**n=1443**

NICU length of stay (n=879) ranged from 0 – 56 days. The median length of stay was three days and 0 days was the mode (18.5% of admissions.)

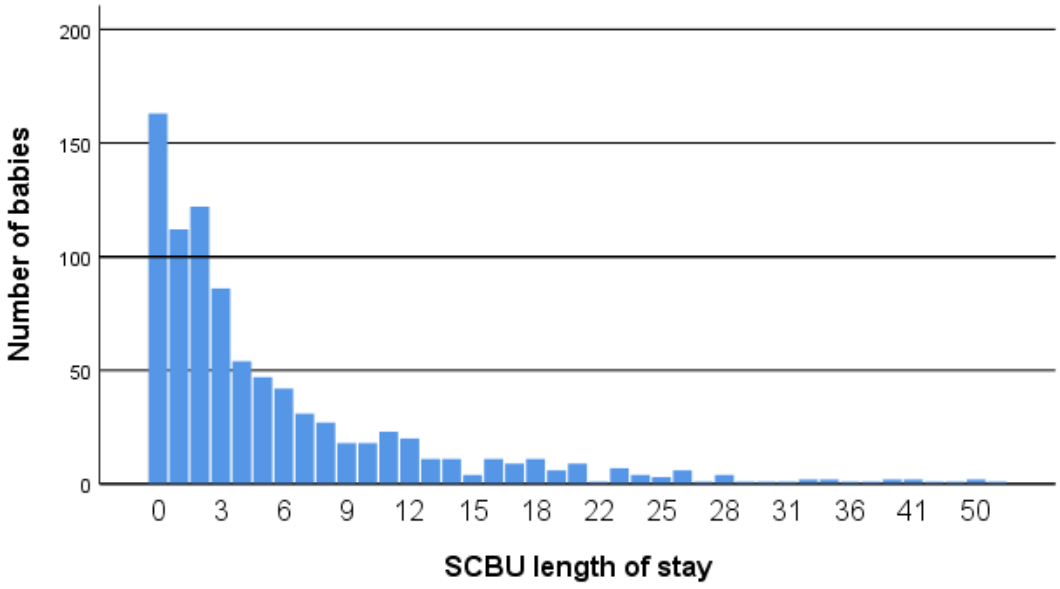

Figure 26 NICU length of stay (days)

6.12 Perinatal mortality

Full data from 6511 babies were included in this study: 6453 live births and 58 stillbirths. Throughout the six-month study period, a total of 229 stillbirths occurred, and the timing of these deaths is included in this section for completeness and not referred to elsewhere. The deaths were excluded from the full analyses if they were macerated, no fetal heart was heard on admission or did not meet the international definition of stillbirth. Using the Indian definition of over 500g, the total perinatal mortality rate was 68.7/1000 (459/6682).

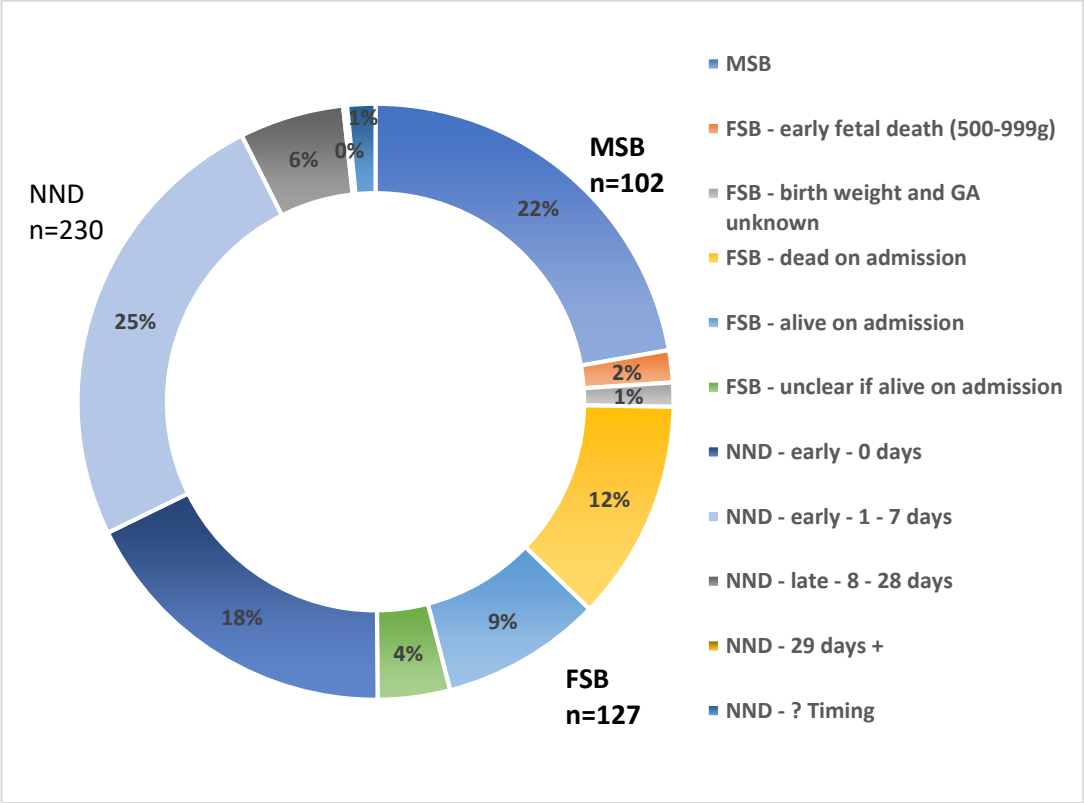

Figure 27 Timing of all perinatal deaths over 500g

6.13 Stillbirths

During this six-month study, the stillbirth rate was 34.3/1000 (229/6682), however as many of the MSB were not weighed and did not have the gestational age recorded (and the Indian definition of stillbirth is 500g), this estimate is likely to be higher than if international definitions were used. The possible/confirmed intrapartum fresh stillbirth rate, according to the international definition of late fetal death (over 28/40 gestation or 1000g if GA unknown), was 8.9/1000 (58/6551). Some of these FSB were likely to be already dead upon

admission to the hospital, but they were classified in this group where this was unclear, or the file was not found.

The mean gestational age of the in-facility stillbirths was 33.3 weeks (SD 3.8* The majority were preterm (86.5%) and low birth weight (89.7%.) Of the live births, the mean gestational age was 37.6 weeks (SD 2.5), 23.1% were preterm, and 40.0% were low birth weight. Three of the six FSBs weighing over 2.5kg were confirmed alive on hospital admission, and three were unclear. One was preterm, and one gestational age was unknown. Two were delivered by CS, and the others vaginal birth; none were indicated for suspected fetal compromise. Of the nine FSBs known to be term, all were booked, 2/3 were referred, 1/3 had a birth weight above 2.5kg, and only one was delivered by CS for suspected fetal compromise.

Table 24 Comparison of in-facility fresh stillbirth and livebirth birth weight and gestational age

Gestational age (completed weeks)	**Livebirths n(%)**	**In facility FSB n(%)**
≤28 (%)	38 (0.6)	3 (5.8)
28 - 31 (%)	159 (2.5)	13 (25.0)
32 - 36 (%)	1281 (20.0)	27 (51.9)
37 - 39 (%)	3789 (59.4)	5 (9.6)
40≥(%)	1118 (17.5)	4 (7.7)
Missing	68	6
Birth weight (grams)		
≤999 (ELBW)	68 (1.1)	5 (8.6)
1000-1499 (VLBW)	204 (3.2)	26 (44.9)
1500-2499 (LBW)	2319 (36.4)	21 (36.2)
2500-3999	3770 (59.2)	6 (10.3)
4000 ≥	6 (0.1)	0
Missing	86	0
Total	**6453**	**58**

For 40/58 possible in-facility stillbirths, the fetus was confirmed alive on admission to the hospital. The file was not found for the other 18 stillbirths, or it was unclear in the file if the fetus was alive on admission. For these 40 FSB (all late fetal deaths over 28/40 or 1000g), the mean gestational age was 33.5 (SD 3.9), and 80% were preterm. The mean birth weight

was 1517.7g (SD 560.9), and 92.5 % had low birth weight. 67.5% mothers were primigravidas. Only 22.5% were delivered by CS (there were no operative vaginal births). Suspected fetal compromise was suspected in 5/40 babies, and all were delivered by CS. A brief summary of these five confirmed in-facility stillbirths with suspected fetal compromise is included.

Table 25 Clinical details of in-facility stillbirths where fetal compromise was suspected

Mat age	Birth wt (g)	GA	Age	Parity	Referred?	Risk factors	No FH	CTG used?	Last FHR
24	1400	30	24	1	Yes	APH, PROM, breech	1	No	120
28	1200	32	28	0	Yes	APH, unfavourable cervix	?	No	FH+
21	1500	34	21	0	No	DM, hypothyroidism, breech	3	No	"60 per minute with difficulty"
22	2000	36	22	0	No	Multiple, oligohydramnios, infertility	6	No	"First twin NLS, second FD"
22	2085	37	22	0	No	Cord accident, sepsis	58	Yes	80

*Abbreviations used – Age (maternal age), B wt (birth weight), GA (gestational age), No FH (number of fetal heart recordings taken during labour ward admission), last FHR (last recorded fetal heart recording before birth), FH+ (fetal heart present), NLS (no live sounds), FD (fetal distress)

6.14 Neonatal deaths

This cohort had 230 in-facility neonatal deaths, and the neonatal in-facility death rate was 36.6/1000. In addition, there were two further babies, where it was unclear whether the baby was alive at discharge. Of the NND, where the birthweight was known (n=215), the majority had low birth weights under 2500g (n=192; 89.3%). Where the gestational age was known (n=221), nearly ¾ were preterm (n=161; 72.9%).

For over ¾ of babies, more than one cause of death was recorded on the death certificate/neonatal death record book, and 441 causes were recorded for the 230 deaths. However, the cause of death was not recorded/known for only four babies. The NNDs were classified into the ICD-PM classification. (261) Low birth weight and prematurity (N9) were

the highest cause of mortality (34.9%), then respiratory and cardiovascular (N7) (23.8%), and then infection (N6) (18.4%).

In the ICD-PM classification, deaths due to hypoxic insult are grouped into different codes (N4 and N5). Asphyxia was listed as a cause of death in 20 babies (N4) and HIE in 12 babies (N5). A total of 25 babies died due to asphyxia/HIE; of these, 52.2% were preterm (GA known n=24), and 80% were below 2500g (birth weight known n=21). A further two babies died of meconium aspiration (N7).

Table 26 Number of causes of neonatal deaths recorded/neonatal death

Number of causes/NND	n (%)
0	4 (1.7)
1	58 (25.2)
2	127 (55.2)
3	39 (17.0)
4	2 (0.9)
	230

Table 27 Causes of neonatal death using the ICD-PM Code

ICD-PM Code	Cause of NND	n (%)
N1	Congenital abnormalities	39 (8.8)
N2	Growth disorders	0 (0.0)
N3	Birth trauma	0 (0.0)
N4	Intrapartum complications	20 (4.5)
N5	Convulsions and cerebral status disorders	12 (2.7)
N6	Infection	81 (18.4)
N7	Respiratory and cardiovascular	105 (23.8)
N8	Other neonatal conditions	17 (3.9)
N9	Low birth weight and prematurity	154 (34.9)
N10	Miscellaneous	9 (2.0)
N11	Unspecified cause	4 (0.9)
		441

6.15 Post hoc sample size calculations

Post hoc sample size calculations were used to understand if the original sample size used for this study was correct and if the before and after the study was appropriately powered. Post-hoc power calculations using the actual study data where 14.7% of births were operative births for suspected fetal compromise revealed a study of 3809 patients both before and after the training (7618 total) would be required to detect a 15% reduction in CS rates, using a conventional 0.05 (5%) level of statistical significance, with 80% power. (262)

Seven thousand six hundred eighteen patients would be required to have an 80% chance of detecting, as significant at the 5% level, a decrease in the primary outcome measure from 14.7% in the control group to 12.5% in the experimental group. Conversely, eight thousand six hundred twenty-six patients would be required to have an 80% chance of detecting, at the significance level of 5%, an increase in the primary outcome from 14.7% in the control group to 16.9% in the experimental group.

6.16 Discussion

Detailed analysis of this cohort revealed that operative birth rates were high (43.1%) and that fetal concerns were the most common indication for operative birth. This was a very high-risk population, with high numbers of medical conditions, previous CS, prematurity, low birth weight babies, induction/augmentation of labour and nulliparous women. Most patients were monitored with intermittent auscultation, and CTG was used infrequently. Factors such as meconium were often used alone to diagnose fetal distress, and IA was the key tool used to diagnose “fetal distress”. Hypoxia-related morbidity and mortality were relatively low, especially in term or normally grown babies, despite high perinatal mortality and NICU admission rates.

This is a high-quality data set, collected prospectively by four trained research associates in this large cohort of over 6500 deliveries over six months on all consecutive deliveries. Important data points and missing data were cross-checked from different sources, leading to a low rate of missing data. Such detailed information is challenging to collect in LMIC environments where challenges with basic amenities such as electricity, internet and heat often pose challenges to the research team. However, this level of detail and data quality for risk factors, outcomes and fetal monitoring allows a holistic quantitative assessment of

the research questions, which was not available before this study. It also ensures the focus on fetal monitoring and intervention rates are appropriately set in the context of the complex risk factors within this cohort.

There are limitations to this work. Data points on several important factors for perinatal mortality risk were not collected, e.g. gender of baby, socio-economic status, ethnic origin, education level, BMI and smoking status. In addition, NICU data were collected on admission, not discharge, and data on maternal complications was not collected. There were higher rates of missing data in the first few weeks of the study. It was not anticipated that four RAs would be needed to collect this data adequately and follow up on all missing data, despite piloting. It may have been useful for further comparisons to collect full data on all patients, especially all stillbirths. Finally, in the notes, it was often impossible to define the start of active labour and the timing of stillbirth, even with senior obstetric input. The typical documentation did not reflect whether the labour had started spontaneously and was augmented or induced; clinically, there was often no clear discrepancy between them. Therefore, a pragmatic decision was made to count the number of FH recorded whilst the patient was in the labour ward. For most, this would have represented the intrapartum period, as patients typically present early in labour. However, some sicker patients, who were managed in the labour ward due to their medical condition, appear to have a large number of FH recorded due to their length of stay on the labour ward whilst not in labour. For the TGCS, some patients were incorrectly distributed between groups one and two or three and four.

The overall CS rate was above the national rate (42.5% vs 17.7%) (27), but it is a high-risk population in a tertiary referral hospital. There were some differences in rates of CS among the groups, as per the WHO survey and multi-country survey; for example, higher rates of CS in group five (previous CS) and higher preterm CS (group ten). (65) Stillbirth rates were in line with national averages (34.3/1000 vs 33/1000), and the neonatal mortality rate was higher than national reports (36.6/1000 vs 20.35/1000). (27) This study adds to the literature demonstrating suspected fetal compromise as the most common indication for operative birth in this setting and that issues around intrapartum fetal monitoring are key drivers for high CS rates. It also brings together data about intrapartum fetal monitoring, indications for operative birth and perinatal outcomes, which few studies offer. Nearly a quarter of all births were operative births, indicated for fetal concerns. Even meconium passage alone was a common indication for operative birth. Coupled with low hypoxia-

related NICU admission rates and deaths, this “too much, too soon” scenario of over-intervention is observed.

Detailed analysis of this dataset has added value to the complex issues of causality in perinatal mortality in this setting. Without significant detail and many relevant variables, future studies and quality improvement projects could miss outcomes of importance in that particular study setting and target future interventions inappropriately. In this study, intrapartum stillbirth was lower than anticipated from the literature from LMICs. There are several reasons for this; this hospital was very busy but well organised and the standard decision to delivery times were short, with high CS and IOL rates. As outlined in Chapter 3, decisions for CS were made earlier, to avoid potential risks to mother and fetus, as soon as any concerns were noted. Due to the focus of this study on intrapartum fetal monitoring, great care was taken by the research team to understand whether the fetus was alive or not on admission to the hospital. In many other studies, this key data point is not meticulously evaluated and if a SB is fresh, it is counted as an intrapartum SB. Using all FSBs as a proxy marker for intrapartum care was inappropriate for this setting, as women have short transfer to hospital times due to the good transport links and urban setting and early presentation in labour, with low levels of obstructed labour, coupled with high CS and IOL rates.

Whether a fresh stillbirth occurs before admission to a health care facility or during admission in LMIC is a critical data point that is very challenging to collect. This is because if the fetus is already dead upon arrival at the hospital, antenatal and public health interventions are needed to avert these deaths. Improving intrapartum fetal monitoring is only relevant if the fetus is alive on admission. Post hoc sample size analysis using the actual data highlights that very large sample sizes are needed to evaluate this intervention. However, context and setting are hugely variable, even within tiny geographical areas. Researchers must be mindful of this when designing future studies and even quantitative studies to be flexible to maximise relevant data capture to incorporate local documentation disparities. Clinical trial governance procedures must be updated to permit this flexibility in global health studies, especially where detailed piloting is unfeasible for financial and practical reasons and routine data collection is often inadequate.

6.17 Conclusion

Suspected fetal compromise is a key driver of high operative birth rates in this setting. Intrapartum stillbirth and perinatal morbidity and mortality due to hypoxia-related insult were not common. On the contrary, prematurity, low birth weight and hypertensive disorders are very prevalent, suggesting that perinatal morbidity and mortality are largely a public health problem rather than one of poor-quality intrapartum care and further research and interventions in these areas are important. Comprehensive data collection and a detailed understanding of every facility's morbidity, mortality, and outcome data are imperative to ensure that improvement interventions are locally relevant.

Chapter 7 – Improving outcomes through intrapartum fetal monitoring training: a theory of change (TOC)

7.1 Overview

This chapter aims to describe our understanding of the relevant "building blocks" of FM training interventions and potential "pathways of change" through FM training, as a complex intervention. We have created a Theory of Change (TOC), which could be adaptable to any local context, to consolidate and share the understanding gained during this PhD and update the traditional over simplistic narrative of how training clinicians leads to improved outcomes.

The research group retrospectively devised this TOC, building data, literature, theory, scholarship, experiences and expert opinion into our original QI hypothesis. A TOC provides a framework to outline "how and why an initiative may work" (263) using standard terms such as inputs, activities, outputs, and outcomes. We aimed to outline how fetal monitoring training could lead to improved outcomes, explain some of the complexity that can impact this, and provide a basis for future research, training planning, and evaluation, which could be adapted to the local context as required. To our knowledge, we are the first research team to create a TOC for fetal monitoring training and bring much-needed pragmatic theory to this important intervention.

7.2 Theory of change background

Evaluation of complex interventions

Over the last twenty years, there have been monumental shifts in our understanding of how complex interventions are designed and evaluated, leading to the Medical Research Council updating its guidance in 2021. (57) (264) In the 1970s, the pioneer Archie Cochrane outlined three core concepts about testing healthcare interventions that are still relevant today: can it work in ideal circumstances? (efficacy), does it work in practice/usual circumstances? (effectiveness), and is it worth it? (efficiency). (265) (266) As traditionally, almost all clinical trials are effectiveness studies, in order to comprehensively evaluate complex interventions, we must also shift our thinking and methods to enable a thorough understanding of this complexity. (267)

The MRC highlights two key questions that we must consider about complex evaluations. Firstly, "practical effectiveness", i.e., whether the intervention works in routine clinical practice and then the spectrum of effects, how effects vary amongst recipients/location/time and the causes for these differences. The second key question is how the intervention works, what are the "active ingredients", and how do these "ingredients" make this effect happen? (264) The MRC highlights the numerous challenges involved with designing, evaluating and implementing complex interventions. This includes difficulty with standardising design and provision, the critical role of context and how to understand and describe this, the feasibility of applying rigorous and reproducible research designs within health system change and the convoluted and dynamic causal pathways between intervention and outcome. (264) strong theoretical understanding of how interventions cause change and the underlying causal mechanisms will lead to a better understanding of the issues so that "weak links in the causal chain" can be noted and improved upon. This theory-driven, enhanced understanding should lead to better design and implementation of interventions that are more likely to change behaviour and improve outcomes.

Theory-driven understanding of complex evaluations

The essence of a theory-driven approach to evaluation is that understanding the theory underpinning a programme is essential to understanding if and how it works. Theory-driven approaches have been recognised for nearly a century, with multiple scholars, including Kirkpatrick contributing to the organic development of these concepts. De Silva et al. (268) argue that the MRC document does not include enough detail about theory-driven approaches, although its importance is recognised. They suggest supplementing the core process of complex evaluation with a TOC, as demonstrated in the figure below, to make “effective, sustainable and scalable” interventions. (268) They implore other academics to use TOCs and evaluate their impact in order to hone the method. TOCs have been used in designing and evaluating multiple programmes as a framework for evaluation and learning and increasingly by international donors, e.g. Gates Foundation. However, there are still few research papers within global maternal health (269) and none on CTG training (172) using TOCs.

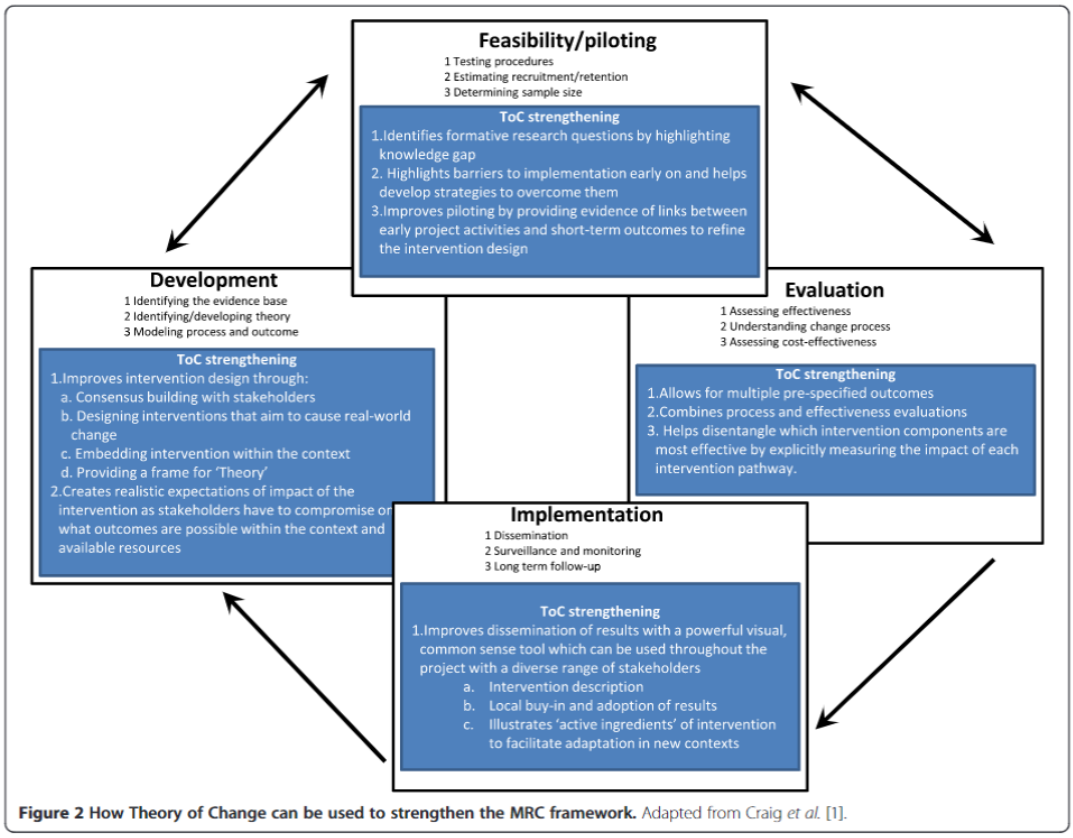

Figure 28 How a theory of change can be used to strengthen the MRC framework. Source article (268)

What a TOC is, and what it is not

A TOC is "a theory of how and why an initiative works". (270) It is not an educational, psychological or sociological theory. Instead, it is a pragmatic framework to outline how an intervention impacts change and aims to unpack the "black box" of a complex intervention.

A TOC is typically developed with stakeholders to increase engagement and collaboration. Empirical testing can be undertaken for each proposed step on the pathway to impact. It can be modified throughout the process through ongoing reflection and is presented as a graphical representation. The image can be used to demonstrate the relevant inputs etc., the proposed causal pathways and constraints. A good TOC should be "plausible, doable and testable"(270); drawing on various sources and consideration of context is key.

Firstly, the desired long-term goals are outlined, and then the team work backwards to outline and map all of the necessary outcomes (conditions/requirements) and how these outcomes relate to each other. Assumptions must be identified and outlined, as they impact on the other elements and may be unique to each context. This framework or "pathway of change" can then be used to identify the best intervention/activity that can be

used to achieve the long-term goal and indicators to measure their performance. This can then be written into a narrative. (271) (272)

A TOC differs from a logic model, as it is not so linear, and attempts are made to outline linkages and measure achievements. Logical frameworks are structured and include resources, inputs, indicators, outputs, outcomes, assumptions, impacts and milestones. (273) However, they do not show linkages between activities and outcomes nor combine causal pathways to demonstrate how they achieve impact. A TOC has a more flexible format, allowing several causal pathways, loops of feedback and levels of intervention. Due to their organic development, there is no standard definition of TOC. (263)

7.3 Rationale for devising a theory of change for fetal monitoring training

During the work underpinning this PhD, especially towards the end of the process, it was obvious that significant, ongoing challenges hampered the ability of this research to change practice. From discussing the work with colleagues, experts and researchers and reading the relevant literature, it became clear that underpinning beliefs about how training could result in behaviour change were often misplaced. The dominant understanding of how training, as an intervention, by most clinicians and policymakers (even clinical educators) is over-simplistic and linear (see diagram below). The commonly understood perception amongst clinicians, managers and policy makers is that training is delivered, clinicians attend and learn, they improve and therefore outcomes improve. The pathways between "how" training leads to improvements (and particularly clinician behaviour change) and therefore outcomes improve are seldom considered or articulated. As if clinician's behaviours do not change, in response to training, outcomes will not change. A key attribute of effective training is whether it inspires changes in knowledge, skills, attitudes and then behaviour. Ultimately, all training for practising clinicians aims to create positive behaviour change and for clinicians to implement this new/modified knowledge, skills and attitudes. If knowledge is not used, it quickly becomes irrelevant.

Figure 29 Dominant narrative about how training clinicians improves outcomes

FM training is a complex and complicated intervention that aims to effect behavioural change in a challenging clinical environment. It became apparent throughout this PhD (qMOLI, FM study and diary) that the influence of systems and external factors on the individual learner is far greater than the role of individuals themselves. Individual knowledge or competence is only one small aspect of the "black box" of intrapartum fetal monitoring. What clinicians “do” is far more important than what they “know”.

Importantly, all previous studies of such training do not mention theory or use frameworks of "how" training might improve outcomes. The systematic review was unable to answer key questions for training planners (172) about the “active ingredients” of FM training. Therefore, for this research to be meaningful to clinicians and implementers, we needed to be able to better articulate and communicate our understanding of this intervention, so future interventions and evaluations can be built with this rich understanding as a foundation.

This chapter uses a TOC as a tool to articulate our understanding of FM training, as an intervention, aiming to try to unpick the “black box” of the intervention including the relevant “magic ingredients.” We have used the standard terms and approaches of a TOC to make this research more generalisable for future implementers and researchers. This TOC is based on work in this PhD, extrapolating from the studies in India, but aiming to discuss FM training as a generic intervention.

7.4 Methods

This aspect of the research was informed by a realist approach. Realist methodology focuses on understanding healthcare change processes and aims to understand why

complex interventions work, how, for whom, in what context and to what extent. (274) Taking this into account, our original project quality improvement hypothesis was retrospectively built into a broader concept grounded in our data, literature and scholarship to develop a TOC model using a standard format. We aimed to share our updated understanding, focusing on how FM training could impact change. This identified key inputs and activities necessary to achieve the outcomes and outputs. The TOC was devised by the research group and an expert in realist evaluation.

We originally planned a quality improvement project that utilised training to change practice to improve outcomes. We hypothesised that creating local guidelines and training staff in intrapartum FM would improve staff knowledge and confidence, improve FM quality and documentation, and therefore, improve perinatal and maternal outcomes. We designed a data gathering process through a multi-methods FM training evaluation in a government hospital in India; surveys, pre/post knowledge tests, prospective maternal and perinatal outcomes data, interviews with women, focus groups with staff and a reflective diary. Memo writing during the qualitative study and reflections on conversations and observation of training noted in the diary were particularly pertinent.

All potentially relevant concepts, ideas, theories, and activities were noted down over several months. All the papers included in the FM training systematic review were re-read with the lens of building a TOC and understanding ”building blocks” and “magic ingredients” for FM training. These concepts were summarised and categorised; many fell together as broader concepts. Then, these were integrated into a TOC model using a standard format (275) (276) over multiple meetings and iterations. This version of the TOC was discussed over multiple meetings and email conversations with CTG training implementers, experts and academics to verify it and highlight omissions. Further edits were then incorporated to reflect the experts’ shared understanding of the complexities of FM training.

7.5 Key terms and definitions

(adapted from the Centre for TOC glossary of terms) (276)

Theory of change is described as “all building blocks required to bring about a given long-term goal. This set of connected building blocks — interchangeably referred to as outcomes, results, accomplishments, or preconditions — is depicted on a map known as

a pathway of change/change framework, which is a graphic representation of the change process".

Assumptions are necessary conditions or resources for the success of a program that already exists and do not need to be brought about. Assumptions are critical for programme success; if they are wrong, they can fundamentally change if and how a programme works. Like a pre-condition, they are necessary, but unlike a pre-condition, they are already in place.

Inputs typically relate to resources or investments required to ensure project activities occur.

Interventions/activities are the things programs or stakeholders will undertake to bring about outcomes. A combination of the activities together is the intervention.

Outputs describe actions/items that contribute to achieving the outcome, either directly or indirectly.

Outcomes are states or conditions that do not currently exist and are necessary for the initiative to work. When TOC are typically being developed, the long-term outcomes are considered first, and then the teamwork backwards to fill in the steps necessary to reach the goal. The long-term outcomes of a programme are the overall goals for the programme, and all other outcomes are building blocks, or pre-conditions, which are necessary steps for long-term outcomes.

Impacts are the longer-term and broader effects of a programme.

Preconditions are precursors, or conditions that are required, before the next outcome in the process.

Indicators are measurable and visible evidence of meeting a goal. They can be quantitative or qualitative and should have four components;
population, target, threshold and timeline.

7.6 Assumptions

As the context and culture of labour wards globally are so diverse, variations are difficult to account for and describe. This means that some assumptions listed here may not manifest in all settings but are rather inputs that need to be brought about. This is especially true when resources are limited and staff are burnt out. Local educational and clinical context is key to all aspects of this TOC.

Assumptions outlined in this TOC are:

- Staff want to learn
- Staff and their institution are willing to change
- Training leads to behaviour change
- FM is the issue and the priority
- FM changes can improve outcomes for both mother and baby
- Well-trained staff deliver better care
- Staff are part of well-functioning multi-disciplinary teams

Staff wanting to learn and staff and their institution being willing to change comes from the improvement culture literature (outlined in section 1.7.6) (208) and motivation underpins several medical education models (outlined in section 1.6.4). (159) The literature supporting training leading to behaviour change is outlined in section 1.7.3. (145) The literature supporting FM being the issue and priority and how FM should improve outcomes is outlined in section 1.8.1. The literature supporting the importance of well-trained staff and well-functioning teams is outlined in section 1.8.2. Reflections in the diary during the FM study, qMOLI data and observing UK best practices contributed to the building of these assumptions.

7.7 Inputs

We have outlined six necessary inputs for fetal monitoring training: motivation, leadership, data, funding, planning and perseverance.

Motivation

For training to create a change in clinical practice, institutions and clinicians must want to improve and change enough to prioritise time and energy over other clinical commitments,

training needs, quality improvement initiatives, and many other competing demands. Motivation is at the base of several medical education models, a fundamental basis underpinning all other aspects and representing a desire to learn and improve, as outlined in section 1.6.4. (159) Motivation is far more complex for practising clinicians than undergraduate learners and is based on individual and collective working cultures, perspectives, experiences, priorities, rewards, time, energy, and capacity. Healthcare professionals may not recognise themselves as learners, may be burnt out, unable to assimilate new learning into practice, and may not wish to risk trying something new. In addition, local and national trends in serious adverse events and governance may generate training needs and motivation within departments. Both collective and individual drive to learn and improve is needed. Creating motivation for colleagues to attend the FM training, through co-interventions was essential to encourage attendance during the FM study.

Leadership

Effective leadership is an essential driver of any change process, particularly in complex systems, as outlined in section 1.7.6. (208) Leadership roles are critical; for motivation, steering the direction of activities, liaison and engaging with all relevant stakeholders, staff, funders, managers and senior clinicians, organisation and delivery of activities, and ensuring alignment with other projects and senior oversight. Leadership was present throughout the FM study from KL, MT and the local research team, with critical and regular input from HOD.

Leaders are necessary at all system levels, and current literature highlights that leadership is the responsibility of all HCP. (277) In contexts with shared midwifery and obstetric care, front-line clinical leaders from both backgrounds, in both formal and informal roles, are required. Named leaders have a role in providing professional experience, providing expertise and advice for colleagues, and ensuring the training happens. All leaders can act as experts, advocates, engagers, trainers and motivators. More senior leaders (at a departmental, hospital, regional and national level) must also drive this to ensure the programme has system-wide support, priority and scrutiny and adequate focus and funding amongst other projects.

Data

Globally, healthcare is consistently underfunded and overstretched, necessitating the prioritisation of interventions that are likely to make the most impact. Focusing activity on areas where realistic improvements in outcomes can be made is paramount. Lack of data collection and monitoring is known to be one of the common difficulties faced when trying to improve programmes. (212) For example, intrapartum fetal monitoring primarily aims to identify the fetus at risk of hypoxic injury and rescue it; however, it is now clearly documented that less than 10% of cerebral palsy cases are caused by this mechanism and therefore poor outcomes due to hypoxic insult are thankfully rare in many settings. (90) Other issues, such as prematurity or infection, maybe more frequent causes of avoidable poor outcomes in a specific context (90) and as demonstrated in the FM cohort data. Therefore, each institution needs ready access to and a good understanding of its outcome data. Data from local, regional and national levels are relevant for benchmarking and understanding which outcomes could be feasibly improved, therefore planning interventions and using limited resources accordingly.

Funding

Funding, directly or in the form of staff time, is needed to ensure regular attendance of all staff, time for trainers and leaders, focus from managers, and access to the materials needed to apply the training in practice. Training is unlikely to create widespread change without this additional financial support and risks becoming another tick-box exercise and incurring fruitless costs. Section 1.7.3 costs and resource implications of training outlines the existing literature on the cost of training. (187) (188) Labour wards are persistently understaffed due to workload, sickness and burnout, and the clinical need will always be prioritised over educational needs. Additionally, staff may be expected to undertake training in their own time, without payment (overtly and covertly). These concepts subliminally suggest that training is not an essential component of work, undermining its value and relying on individual motivations rather than core expectations for it to be achieved.

Planning and strategy

Due to the challenges and complexity of training maternity care workers, a strategic perspective is required for training planning. The plans and overall strategy must recognise, understand and value all of the programmes that demand the attention of decision-makers and maternity care workers. Other organisations and bodies may need to be involved, such as commissioners and regulatory or funding bodies. In other industries, e.g. airlines, it is widely understood that the planning of high-quality training is essential and can be time-consuming, (282) due to the multiple steps that are required. (144) (278) Time and capacity need to be built into job plans, and adequate staff time must be costed into funding plans and bids for attendance and delivery.

For the FM study, a lack of understanding of the context and educational environment made detailed planning challenging and a more flexible approach was needed. A detailed understanding of the context and specific educational context, to allow appropriate planning would facilitate more effective training that can address specific local needs.

Perseverance

Passion and perseverance are necessary inputs for trainers, leaders, managers and all maternity care workers. The qMOLI and FM study diary data highlighted how although clinicians knew FM was important, it was “practically not possible” and therefore changes in FM require significant perseverance. Unfortunately, it is common for quality improvement projects to be initiated without a data-driven understanding of the problems and then quickly lose momentum, as improvements in outcomes are not realised. (181) Achieving change is incredibly hard; sustaining it is even harder. Motivation and perseverance are highlighted as different inputs to demonstrate the difference between the desire to improve and the continued struggle to actually improve and then maintain this. The Oxford dictionary defines motivation as “the feeling of wanting to do something, especially something that involves hard work and effort.” (279) In comparison, perseverance is “the quality of continuing to try to achieve a particular aim despite difficulties.” (280) The inclusion of perseverance was derived from discussions at the national FM meeting, by one of the UK’s lead Consultants and is supported by the literature outlined above.

7.8 Activities

The eleven activities that we outlined for FM training are training needs analysis, training the trainers (expert trainers), developing materials, formal training, informal training, application and repetition, aligning guidelines and policies, monitoring and audit, feedback and reflection, coaching and mentoring and other QI activities.

Training needs analysis

Undertaking a training needs analysis is an important preliminary step before developing any educational programme (144) (185) and was used in the FM study. There are particular challenges with learning needs in intrapartum fetal monitoring in every specific unit (as outlined in section 1.7.3 who should be trained and curriculum/course content). Different cadres of staff work in the intrapartum care areas, frequently or infrequently, and are involved in it either directly or indirectly. Yet they have different learning needs and roles. Those directly involved include obstetricians/medical officers and hospital midwives/nurses/students. Other staff, such as maternity assistants, auxiliary nurses, and theatre and anaesthetic staff, are part of the team directly involved in the timely actions when a fetal heart is abnormal but do not make decisions about FM. Some cadres of staff, such as ward or community staff, also work on the labour ward when it is busy or there are staffing issues, but not every day.

Training the trainers (expert trainers)

CTG trainers need to feel confident and knowledgeable in fetal monitoring and teaching. If they are responsible for planning and implementing the overall project, they ideally should understand quality improvement to ensure systems thinking and coherence across the QI initiative elements. CTG classes are likely to cause debate and controversy, which must be well managed to ensure the attendees do not get side tracked from achieving the session's learning objectives and avoid blame. It is well documented that teachers' skills and attributes impact the uptake of their messages. (162)

The reflective diary noted the challenges that FM training leads face, due to this particularly challenging topic to teach.

Developing training materials

Written/online materials are required for the delivery and assessment of training that is suitable for different styles of learning. For training delivery, access to pre-reading/online learning before the face-to-face session and to supplement the training session for those who want to read more is ideal. Presentations, access to various cases, and different CTG images are essential. Making the materials implementable and aligned with the local policies is imperative to avoid confusion. In addition, they must address the softer skills such as human factors, communication and situational awareness, and the core skills of interpretation and management planning. This is based on expert opinion and literature outlined in section 1.7.3.

Formal training

Formal training sessions typically occur in training rooms away from the labour ward, in the format of lectures, workshops, case discussions and questions and answers or as online learning. This is often supplemented through regular weekly departmental meetings on or near the clinical areas. Although these may be poorly attended, and engagement may vary. These formal sessions ensure all staff have received the core training and covered specific topics. However, the evidence does not highlight a specific optimal format, duration or curriculum. Nor does such sessional delivery ensure staff have absorbed learning or are convinced by it. This is based on expert opinion and literature outlined in section 1.7.3.

Informal training

"On the job" preceptorship is a huge part of CTG training, bringing together all relevant clinical and non-technical aspects. Without frequent and repeated informal teaching encounters, which accelerate learning and reinforce new practices, classroom-based learning will not be incorporated into standard clinical norms and, therefore, quickly forgotten. Therefore, the role of informal training is far more than named FM leaders and more focused on adopting a generic learning and education culture, where all clinical interactions are transformed into learning opportunities. This encourages openness, reflection and non-threatening conversations instead of conflict, where inevitable disagreements occur. This is based on expert opinion and literature outlined in sections 1.7.2 and 1.7.3. The CTG training published literature does not describe the informal

training aspect of FM training well, hence section 1.7.2 was written to describe the six key occurrences when FM training happens.

Application of knowledge and repetition

Changing behaviour involves repeated use of new knowledge (159) until familiarity increases so much that this new behaviour becomes the clinician's new "mindline" and responses change. The "forgetting curve" highlights just how quickly new information is forgotten if not used and if the exposure to information is not repeated. (281) Clinicians will not feel they truly "know" something until it has been incorporated into their clinical mind lines and is "done" frequently.

Aligning guidelines and policies

CTG training must be seen as one aspect of active guideline implementation, and therefore training must be aligned with local guidelines for learning to be put into practice. The entire team in a unit needs a shared understanding and language to discuss CTG concerns and a common understanding of expected actions when CTG abnormalities arise. If local policymakers underscore an acknowledged multi-disciplinary approach and roles and responsibilities, it could facilitate timely clinical decisions. However, if only some staff had been trained or others followed different guidelines, confusion, potential conflict, and costly time delays could occur. CTG training delegates repeatedly mentioned these issues around confusion between guidelines and teaching. This is derived from the quality improvement literature outlined in section 1.7.6 (208) and reflection on the ongoing debates in UK FM network meetings about the most appropriate guidelines for UK use.

Monitoring and audit

Local governance processes and ongoing monitoring of attendance, assessments, use of CTG, current departmental issues and maternal and perinatal outcomes are important. Considerable time and resources are allocated to these programmes of work. Therefore, they must create a confident and knowledgeable workforce to deliver high-quality maternity care and be cost-effective. Ideally, the monitoring should be planned before the programme is rolled out, and costs must be understood. The literature to support monitoring and audit is outlined in section 1.7.5. (133) (204)

Feedback and reflection

Both formal and informal feedback on the training throughout should be used to strengthen the programme, improve areas where confusion remains and ensure the whole team is engaged. Whether attendees feel that the training has met their learning needs and if they feel confident and competent is relevant to and influences CTG usage and outcomes. As educators and clinicians, we are encouraged to reflect on our work to highlight areas that are already good and can be improved. In addition, self-identification of one's own learning needs can be a powerful motivator. Feedback and reflection are well recognised in the medical education literature, as outlined in section 1.6.4. (159) (161) (163)

Coaching and mentoring

Both formal and informal, in-practice supervision and mentoring are key to training and supporting happy and competent clinicians (section 1.7.3). (184) This is especially important for staff who fail the routine assessment, new staff, junior staff and staff working in an unfamiliar environment. This role is especially vital when concerns have arisen through the governance, risk processes, or complaints/serious adverse incidents. Additional training is required to ensure these roles are conducted well, learning is supported, and time is allowed for these important tasks. Typically, more formal roles such as FM leads and educational supervisors support these tasks.

Other quality improvement activities

Any training which aims to achieve practice change must be embedded within a wider QI project to ensure local barriers to change can be overcome, which may be beyond the scope of training alone, such as equipment/staffing/external processes. This was exemplified in the FM and qMOLI study with clinicians highlighting issues with inadequate staffing, access to machines, plugs, printers and training. In many healthcare facilities, especially in LMIC, technologies and equipment may be needed to implement change. The QI literature is outlined in section 1.7.6. (208)

7.9 Outputs

The output was defined as maternity care workers (MCW) who practice FM with knowledge (a proxy marker is the proportion trained and competent). This output section is derived from expert opinion and literature on FM and curriculum development outlined in this thesis. (184) (185) (186) (217) (252) (253)This includes MCW, who can competently:

Risk assess

Throughout labour, HCP must be able to comprehend the often-evolving clinical picture and assess risk appropriately throughout. Therefore, CTG parameters must be considered within the background of risk factors for each woman and baby.

Understand "how is this baby?"

Fetal monitoring in labour is just one aspect of a complex clinical picture of the mother, the baby, the labour progress and various risk factors. So, understanding all of these factors together as a complex picture, rather than simply focusing on the CTG graph, is imperative. Therefore, MCW must think carefully about how this baby is coping, with this situation, at this time.

Recognise and interpret abnormalities

The correct interpretation of CTG includes knowledge of clinical practice guidelines and CTG parameters, interpretation of those parameters to this CTG in this clinical scenario and dynamic risk assessment for each review.

Take appropriate and timely actions

Once an abnormality has been correctly identified, the correct actions must be taken, in an appropriate timeframe, according to the situation’s urgency. The correct actions include avoiding perinatal harm and avoiding unnecessary interventions that can cause maternal harm. The right action, at the right time, for the right woman is needed.

Communicate and escalate concerns

Communication is key. Informing the right team members in a clear and concise format, which relays the severity and urgency of the concern calmly and respectfully. To ensure situational awareness and ensure the right actions are taken in the right timeframes.

Respond to concerns appropriately

Human factors are fundamental to maternity safety, especially intrapartum fetal monitoring, as there is much subjectivity. Collectively, all team members must act in the patient's best interests. To do this, colleagues must feel respected and heard, and concerns must be acted upon appropriately.

7.10 Outcomes

The programme's long-term outcomes or overall goals are to deliver valued and valuable, high-quality intrapartum fetal monitoring. The short/medium-term outcomes are outlined below. They were derived from opinions and discussions within the research team to outline the various steps in outcomes. Then once outlined, they were discussed and verified with experts in the field, over a series of meetings and email discussions.

Short term outcomes

The short-term outcomes needed are:

- Shared understanding of local issues, supported by data
- Understanding of training inputs needed to achieve outcomes
- Leaders convinced and supportive
- MCWs are trained
- MCWs are competent and empowered

Medium-term outcomes

Medium-term outcomes occur when new practices become routine elements of care. This means that the training is implemented and embedded into practice. Abnormal fetal monitoring indicators consistently result in timely and appropriate actions. Local barriers

and challenges will consistently arise and cause struggles, but these are overcome by multi-disciplinary team (MDT) consensus.

- Improve the quality of FM (implementing and embedding training into practice)
- More timely, appropriate actions to abnormal FM
- Local barriers and challenges identified and overcome by MDT

Long term outcomes

The overall aims of fetal monitoring training derive from shared team goals to improve perinatal outcomes, reduce unnecessary interventions, reduce obstetric litigation claims, and maintain an ethos of education and quality improvement. Ultimately CTG training aims to reduce perinatal morbidity (APGAR scores at five minutes below seven, need for neonatal resuscitation, NICU admissions, HIE cases) and perinatal mortality (intrapartum stillbirth and neonatal deaths from hypoxic injury), reduce caesarean and instrumental births (appropriate CTG classification without intervening unnecessarily) and therefore reduce obstetric litigation claims. Multifaced interventions are needed to improve outcomes. Training is just one of these. Intrapartum fetal monitoring training alone is just one of these core training topics. An institution and departmental-wide ethos of education and quality improvement can ultimately achieve these goals with appropriate inputs and activities.

These long-term outcomes are likely to be above the accountability ceiling that intrapartum fetal monitoring training could achieve alone, particularly in reducing obstetric litigation. However, as they are the overall aim of the training and as part of a wider system focused on quality improvement and education programmes, intrapartum fetal monitoring training is still a crucial component of improving outcomes.

7.11 Impacts

For fetal monitoring training, the longer-term and broader effects of an effective programme are outlined below. They were derived from opinions and discussions within the research team. Then once outlined, they were discussed and verified with experts in the field, over a series of meetings and email discussions.

- Change is data and experientially driven
- Leaders listen, support and enable change

- Staff competent and skilled
- Enhanced clinical and educational environment
- Improved patient care, experiences, and outcomes

7.12 Pre-conditions/critical success factors

We have outlined the factors the research group believe to be pre-conditions for a valued and valuable fetal monitoring training programme. In different iterations of this TOC, the group had also outlined both pre-conditions and critical success factors, which were almost identical. Although critical success factors are not typical TOC terminology, we felt the term was compelling and aligned with the pre-conditions and was therefore included.

- Local strategic priority with support
- Ring-fenced funding/time for leaders/trainers
- Ring fenced time for all staff to attend
- Clinical environment that enables change
- Skilled and motivating trainers and leaders
- Resources to implement changes
- Component of wider QI initiative

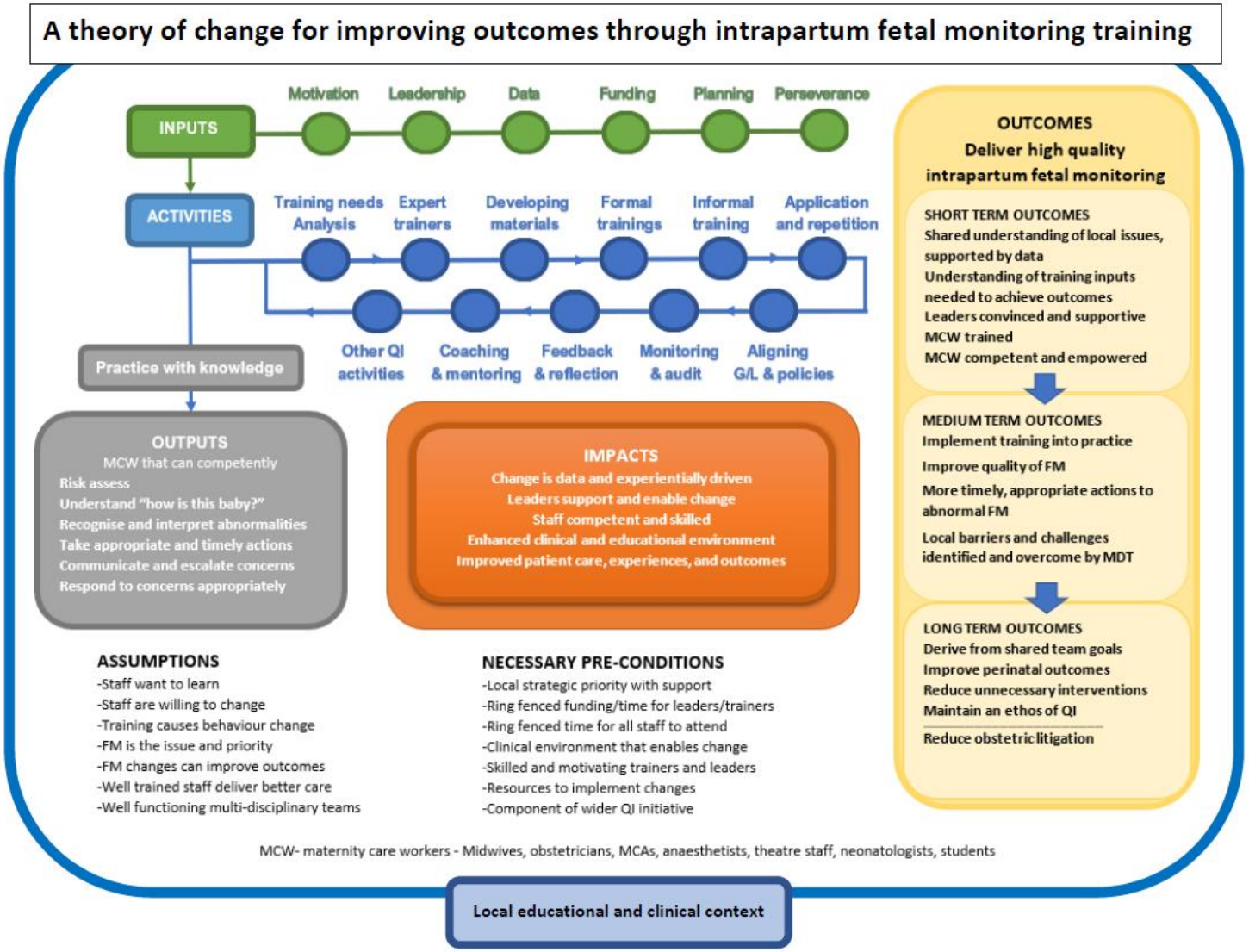

Figure 30 A proposed theory of change of how intrapartum fetal monitoring training could improve outcomes

7.13 Discussion

This TOC demonstrates that fetal monitoring training is a complex and complicated intervention and outlines the "building blocks" of how fetal monitoring training could lead to improved outcomes. A TOC's well-recognised structure is used to summarise all relevant inputs, activities, outputs, outcomes, impacts, assumptions and pre-conditions that could be considered when designing and implementing future training programs. Using a broad lens and pragmatic theory-driven approach, the role of systems factors has become evident. This TOC represents a more comprehensive and real-world conceptualisation of how training clinicians works and moves the thinking on from the outdated, simplistic, linear model.

This TOC is grounded in data and reflections gathered throughout this PhD literature review, including CTG, medical education theory and realist evaluation, as well as lived experiences. It was crafted by experts immersed in this field, with feedback from relevant stakeholders. To our knowledge, we are the first group to outline a TOC for FM training or bring pragmatic theory to this potentially life-saving intervention. The Kelly systematic review clearly stipulated this need for theory. (172) We hope that future training planners can update this TOC to their context and devise locally relevant log frames with metrics to supplement their TOC to plan, implement and evaluate future training programmes. We anticipate these programmes are more likely to improve maternal and perinatal outcomes as the mechanisms for change are explicitly outlined and planning adapted accordingly.

A TOC should typically be devised at the beginning of a project, through a series of stakeholder meetings for consensus building, with built-in metrics for evaluation. Our research group devised this TOC retrospectively by expanding on our original QI hypothesis. Despite our cognisance of this and aiming to be reflexive, this TOC is inherently biased and reflects primarily our research groups' beliefs and perceptions. Retrospective drafting meant our study evaluation was not built around the TOC and, therefore, has not been tested. However, the retrospective nature gave some freedom as researchers, rather than implementers, to focus on the underlying mechanisms and wider influences. This meant the elements could be outlined without the constraints of needing to evaluate and measure them, which could often render evaluations unfeasible due to their breadth or subjectivity. Therefore, our gaze could focus on and capture our perception of the realities of clinical education rather than simply the readily measurable attributes, which clearly do

not tell the whole story. However, making many of these concepts measurable and designing comprehensive and meaningful evaluations pose ongoing challenges.

This TOC has been a useful tool for integrating these research findings and conveying our key findings to audiences of differing backgrounds. Other key researchers in global health involved in complex evaluation have also found this retrospective approach useful, although there are pitfalls. (268) Clinical education research and interventions are almost ubiquitously complex and complicated; therefore, the research approaches must address this complexity if they are to add value. Standard quality improvement approaches do not recognise the complexities of clinical education training, specifically contextual nuances and personal interpretations of the content. The concept that staff attending training change their practice and that outcomes improve accordingly is over-simplistic. Each factor highlighted must be considered by policymakers, managers, leaders, training planners and maternity care workers.

Based on our experiences of devising this TOC retrospectively and building on the Aspen Institute's work, we agree with their views that future projects could use a TOC at the beginning of future projects to "sharpen" the planning and implementation, aid measurement and data collection and reduce issues around causal attribution of impact. (270) The pathway to achieving high-quality fetal monitoring training that improves outcomes is unclear, and different stakeholders have varying and sometimes opposing views on what a successful intervention looks like. Using a TOC model could encourage stakeholders to focus and agree on the key long-term goals, how and why these changes should happen, map out the steps to achieve these goals, identify measurable success indicators and create appropriate actions. Considering these links may help infer causality if improvements are seen in outcomes. As a result, attention could become focused on goals (both process and outcomes) rather than what happens now, and individuals' assumptions would become clearer.

We have outlined critical success factors which we believe are necessary for fetal monitoring training to impact change. This list spans far beyond what simply organising and delivering a high-quality training session involves. It particularly highlights the need for systems thinking and local strategic priority, which is essential to ensure ring-fenced funding and time for trainers and all staff to engage in training (without compromising clinical care). In addition, a culture that supports change, prioritises education and

evaluates impact, enough resources to implement change and hard work, perseverance and ongoing reflection by all members of the maternity care workforce.

7.14 Conclusion

Fetal monitoring training is a complex intervention that aims to effect behavioural change in a challenging and dynamic clinical environment. For clinical education programmes to make a valuable and sustainable difference in practice, stakeholders must accept that achieving regular change in behaviour is very challenging. Outlining a theory of change provides a potentially useful process which could enhance the potential for impact from clinical education interventions through identifying pathways to change and addressing barriers within the educational delivery plan.

Chapter 8 - Discussion, conclusion and future research

8.1 Introduction

This multi-methods thesis aimed to evaluate the impact of applying an intrapartum fetal monitoring training and quality improvement package, in the context of staff and patient perspectives on intrapartum fetal monitoring and mode of birth, in a Government Hospital in India. The research objectives have been achieved and exceeded through developing a theory of change; to re-conceptualise the complex intervention of FM training. This chapter aims to summarise the research findings, discuss the implications of the research findings and outline future research questions.

8.2 Summary and key findings

8.2.1 qMOLI study: summary and key findings

The first results chapter (chapter three) presents the findings of the FM and MOB aspects of the qMOLI study to set the context of staff and patient perspectives on intrapartum fetal monitoring in this setting. It aimed to explore high-risk patients' perceptions, understanding, preferences, priorities and experiences regarding intrapartum fetal monitoring and mode of birth prior to induction of labour and in the first few days after birth. Then to explore clinicians' perspectives on intrapartum fetal monitoring, training on intrapartum fetal monitoring and mode of birth. A pragmatic approach, using a framework analysis and thematic analysis was used.

This study consisted of 53 semi-structured interviews with high-risk women before and after birth in two urban government hospitals in central India and eight focus groups with clinicians and research staff. Six themes were developed, as shown in bold below. Firstly, women strongly preferred vaginal birth, viewing it as **"trouble for two hours [rather than] trouble for two months"** (or even "a lifetime"). Secondly, women gained **knowledge through experience** (both their own and others') and understood their indication for caesarean through these experiences. This runs contrary to clinicians' views that most women do not understand. Thirdly, for women, **fetal monitoring was part of a positive birthing experience [and women] "felt good by hearing the beats**". Women preferred methods where the sound was audible. It made women "feel happy", reduced fear, empowered them with knowledge and promoted bonding. Fourth, **interactions with women, relatives and clinicians** could make women "feel good" by simply "explaining

nicely". Fifth, clinicians knew about fetal monitoring guidelines and felt fetal monitoring was "essential", but that **fetal monitoring as per guidelines was "practically not possible**". Finally, **FM, MOB and risk were linked**. "Trying for normal" birth, in high-risk women, without adequate fetal monitoring was considered "too risky" by clinicians. "Sometimes, we do not wait. We can't put the baby and mother at risk… and we go for CS."

Women in this study wanted a vaginal birth and a healthy baby. They valued hearing their fetal heartbeat during labour and being spoken to kindly by clinicians. These simple acts can promote a positive birth experience. Clinicians' views provided evidence of how suboptimal intrapartum fetal monitoring drives outcomes and impacts rising CS rates globally, as, without it, clinicians feel labour is unsafe for high-risk women.

8.2.2 Fetal monitoring training evaluation: summary and key findings

The second and third results chapters (chapters four and five) present the results of the fetal monitoring study. This study aimed to evaluate the impact of applying a quality improvement package for intrapartum fetal monitoring, including training and guideline development. Kirkpatrick's four-stage training evaluation model was used to understand if the training package was acceptable, feasible and increased knowledge (stages one to three of Kirkpatrick's model). In addition, to evaluate the impact of the training on short-term maternal and perinatal outcomes, especially in-hospital perinatal morbidity and mortality rates and operative birth rates, particularly for suspected fetal compromise (stage four of Kirkpatrick's model). A multi-methods evaluation was conducted using a fixed, parallel, convergent design. Quality improvement methodology was used to design the intervention.

The research team hypothesised that creating local guidelines and training all staff in a government hospital in central India about intrapartum fetal monitoring would:

- Improve the quality of fetal monitoring during labour, which would, in turn, improve perinatal and maternal outcomes.
- Improve the antepartum diagnosis of "fetal distress" and therefore reduce the caesarean section rates for "fetal distress" (especially when meconium is noted, and the fetal heart is normal).

After ethical approval, prospective data were collected on consecutive births after delivery and before discharge between 1st August 2019 and 1st February 2020. Discharge and NICU

data were collected for a further six weeks and data collection closed on 13th March 2020. Clinicians' reactions to the training (level one) and behaviour change (level three) were measured with surveys and knowledge gain (level two) using pre/post-tests. A detailed reflective diary was kept throughout. Two months of data before (August/September 2019) and after (December 2019/January 2020) the intervention was analysed using a pre-post design (level four). Stillbirths at <28 weeks gestation, stillbirths confirmed dead on admission, or births <1000g (or gestation and birth weight unknown) were excluded from the full analyses.

Training on FIGO intrapartum fetal monitoring guidelines, intermittent/"intelligent" fetal heart rate (FHR) auscultation with cardiotocograph to confirm abnormalities, and related aspects of intrapartum care were undertaken through 15 face-to-face sessions and a K2 online learning package during the two intervention months of October/November 2019. Throughout the study, it was clear that the interactions between the training and co-interventions and people, policies and systems were critical.

Clinicians enjoyed the training, gained knowledge and confidence, and believed the training had changed their clinical practice. They were able to quantify and describe the number of cases managed differently. Of the 84 clinicians studied, 77 (86%) engaged with at least one session. The pre-and post-intervention groups included 2272 women (2319 babies) and 1881 women (1920 babies), respectively. Mean FHR documentation occurrences per labour increased significantly from 5 to 7.5 (p=<0.001); the mean time between the last FHR recorded and delivery fell significantly from 60 to 50 minutes (p=<0.001). There were non-significant trends toward increased operative delivery rates overall (CS rates 42.5% vs 44.9%), operative birth indicated for suspected fetal compromise (14.8% vs 16.7%) and reduced perinatal mortality (4.6% vs 3.7%). NICU admission rates fell significantly (16.7% vs 10.2%: % change -6.5; 95% CI -8.5, -4.4), as did NICU admissions for asphyxia (1.2% vs 0.6%: -0.6; 95% CI -1.2, -0.04). The median length of stay for babies admitted to NICU increased significantly from 3.0 to 4.0 days (p=0.024).

In this study, clinicians enjoyed the intrapartum fetal monitoring training; it increased knowledge and confidence, and clinicians could quantify and describe their practice change. Some fetal monitoring process measures and perinatal outcomes improved, but there was a non-statistically significant trend towards increased operative birth.

8.2.3 Fetal monitoring prospective cohort study: summary and key findings

The fourth results chapter (chapter six) analyses maternal and perinatal risk factors, outcomes, indications for operative birth, and fetal monitoring practices in a government tertiary referral hospital in Nagpur, India. This chapter aimed to understand the burden of hypoxic insult during birth and, therefore, whether the training programme, as an intervention, could ever have the desired impact on outcomes. In this analysis, 6989 cases were screened. Full analysable data was available on 6511 babies and 6379 women, including 6453 live births and 58 fresh stillbirths.

The mean age of women was 25.7 years (SD 4.0), the mean parity was 0.6 (SD 0.7), and 39.2% were referred from another healthcare facility. This was a very high-risk population: 25.5% had medical conditions, 46.2% were induced/augmented, 20.9% had a previous caesarean, 22.6% were preterm, and 20.8% had hypertensive disorders. For mode of birth, 56.4% of women had a cephalic vaginal birth, 0.5% had a breech vaginal birth, 0.6% had an operative vaginal birth, and 42.5% had a caesarean. Fetal indications were the most common indication for operative birth (983, or 15.4% of total births). Most decisions for operative birth for suspected fetal compromise were based on intermittent auscultation (88.5%), either alone (45.9%) or with meconium-stained liquor (37.1%). CTG was only used for 6.2% of decisions for operative birth.

For the neonates, NICU admissions were common (n=884, 13.7%). The most common reason for admission was low birth weight (31.5%) and prematurity (26.3%). Only 3.4% were admitted for birth asphyxia and 1.2% for meconium aspiration syndrome. The total perinatal mortality rate, using the Indian definition, was 68.7/1000 (459/6682). There were 229 stillbirths recorded during the study period (34.3/1000). Of these stillbirths, 58 were possible/confirmed in-facility intrapartum fresh stillbirths (8.9/1000 WHO definition), and most of these babies were preterm or LBW. Of the 230 in-facility neonatal deaths (36.6/1000), low birth weight and prematurity were the leading causes of mortality (34.9%). Twenty-five babies died due to asphyxia/HIE; of these, 52.2% were preterm (n=24), and 80% were below 2500g (n=21).

Caesarean and perinatal mortality rates were high, and fetal concerns were the most common indications for operative birth in this very high-risk population. However, there were comparatively low intrapartum fetal hypoxia-related morbidity and mortality rates, especially in term or normally grown babies. This was despite high perinatal mortality and

NICU admission rates (primarily related to prematurity and LBW). Although a good working knowledge of fetal monitoring is essential for obstetricians' core skills, focusing on fetal monitoring training alone could not achieve the desired outcomes to reduce perinatal mortality and operative birth rates, as hypoxic injury is not the most prevalent cause of mortality.

8.2.4 Theory of change: summary and key findings

Later in the PhD, it was clear that the complexity of fetal monitoring training as an intervention was typically vastly underestimated. The fundamental concept that staff who attend training will also change behaviour is over-simplistic. Chapter seven aimed to outline the inputs, activities, outputs, outcomes, and assumptions relevant to FM training and create an evidence-based theory of change adaptable to any local context. The original project quality improvement hypothesis was retrospectively modified by incorporating data, literature and scholarship to develop a TOC model using a standard format in consultation with experts. This identified key inputs and activities necessary to achieve the outcomes and outputs. A realist approach informed this research.

Local educational and clinical context is key. Critical inputs were motivation, leadership, data, funding, planning and perseverance. Necessary activities were training needs analysis, training the trainers, aligning guidelines/policies, developing materials, formal training, informal training, practical application and repetition, reflection/audit, mentoring/coaching and other quality improvement activities. The output was defined as maternity care workers (MCW) who practice FM with knowledge (proxy - proportion trained and competent). Short-term outcomes were MCW that can competently risk assess, understand "how is this baby?", recognise and interpret abnormalities, take appropriate and timely actions, communicate and escalate concerns, and respond to concerns appropriately. Medium-term outcomes occur when new practices become routine elements of care, abnormal FM indicators result in timely and appropriate actions, and local barriers and challenges are overcome by MDT consensus. Long-term outcomes derive from shared team goals to improve perinatal outcomes, reduce unnecessary interventions, reduce obstetric litigation claims, and maintain an improvement ethos.

FM training is a complex intervention that aims to effect behavioural change in a challenging clinical environment. The conceptualisation of fetal monitoring training as an intervention to change clinicians' behaviour and improve maternal and perinatal outcomes

must be embedded. For clinical education programmes to make a valuable and sustainable difference in practice, stakeholders must accept that achieving regular change in behaviour is complex. Multiple barriers to change must first be identified and addressed within the educational delivery plan to enable the use and implementation of new knowledge. Clinical education interventions need to be focused on what clinicians do, rather than what they know. Detailed consideration and mapping of the pathways between intervention and intended outcomes, such as a TOC, can guide planning and implementation and could lead to more impactful interventions.

8.3 Strengths of the thesis

There are significant strengths to this PhD. First, the use of multiple methods led to an in-depth assessment of the study phenomenon focused on the research question whilst maintaining a broad lens on fetal monitoring, which is embedded in the context of intrapartum care, birth and society. The qualitative study was conducted rigorously and transparently by a team of experts from around the world. There are very few qualitative studies from India, and capacity building in qualitative research skills, through training and supervision, was built into the work. Gender inequity is so strong in India that simply hearing women's voices and sharing them demonstrates a deep respect for their views. Understanding women's views and priorities around birth also provides policymakers with much-needed data to support the respectful care agenda.

As India has the highest number of stillbirths of any country on earth, it is right that studies aiming to reduce stillbirths are conducted here, where the prevalence is high and studies could have a greater measurable impact. However, simply applying research findings from high-income to lower-income settings could be harmful, and consideration of the context and setting is paramount. In previous studies, appreciation of the importance of context in research is often lacking. For example, no previously published FM training studies have included all four levels of Kirkpatrick's model. The reflective diary illustrated how FM training is typically understood as an intervention and lays the foundations for conceptualising and outlining links between training, outcomes and challenges. The cohort study data was of high quality, collected prospectively from various sources by a team of research associates. Such detailed datasets prospectively collected from LMIC on over 6500 women and babies are uncommon.

8.4 Limitations of thesis

Both studies were sub-studies of the funded MOLI RCT, so delays due to governance issues and the COVID-19 pandemic hugely impacted the timescales. This included a significantly diminished role of the FGDs in the evaluation of the training and delays in cleaning the FM dataset. It also meant providing study oversight online rather than on the ground. The qMOLI study was designed primarily to evaluate labour induction, as per the RCT. Fetal monitoring and mode of birth were just a subset of this vast dataset and one objective of four from the protocol. Therefore, fetal monitoring was not the focus of the wider research team, which primarily aimed to evaluate the induction process. However, as this was the focus of this doctoral study, enough input on fetal monitoring issues was maintained throughout. KL led the study team throughout and supervised the IOL qMOLI data analysis after completing the FM/MOB analysis.

The mixed clinical, research, geographical and cultural backgrounds of the research team had some benefits. However, there were also risks of losing data quality during translation and misunderstanding due to a lack of cultural competence. In addition, this research was influenced by KL's "foreigner" or "outsider" status and the Hawthorne effect of several research studies in the same department. However, the assessment of this impact was not comprehensive. Furthermore, foreign researchers leading research programmes overseas is an ethical minefield, and whilst the research team aimed to be cognisant of these issues and have vast experience of working in LMICs, there are inevitable power and cultural differences and imbalances.

Throughout this PhD, the use of theory was pragmatic, with aspects of different theories influencing different aspects of the work rather than one coherent approach with true theoretical underpinning. Increased initial planning could have prevented this responsive approach and benefitted the overall coherence of the research.

Finally, the FM study was only based in one hospital and then for a short duration. This, combined with the relatively weak pre/post methodology, means that the results must be interpreted cautiously, especially regarding their generalisability to other settings or countries. It also means that the sustainability of change has not been assessed long term.

8.5 Comparison with previous literature

This thesis supports the existing literature that most women and clinicians prefer normal birth. (81) It adds to the "too much too soon" literature, by highlighting that for high-risk women in this setting, without adequate monitoring, NOT doing a CS is considered "risky", and clinicians fear "waiting for normal". FM was a more positive experience than in previous studies, (126) with only occasional reports of "discomfort" and no anxiety, as highlighted in previous studies. This study supports the finding of "reassurance" from FM from other studies (131) and adds that "hearing the beats" is a particularly positive aspect. Previous studies raise questions about the role of FM in empowering women. (126) This study demonstrates that "hearing" and "knowing" the baby is well is empowering at this time of pain, anxiety and fear. More staff, training and electronic fetal monitoring are all seen as part of the solution. Still, many obstetricians do not necessarily understand their role as the "gatekeepers" of CS rates.

As with other studies, the FM study used diverse, multi-faceted training methods, but the impacts of the different teaching methods (other than participants' preferences and reactions) were not assessed. (172) Like other studies, clinicians enjoyed the training. (172) Detailed quantitative and qualitative measures were presented in this thesis in light of the very low certainty of the evidence of previous assessments of participant reactions. This study did show some knowledge gain in some pre-post-tests, which is aligned with the existing literature. (172) However, due to logistical challenges and the study methodology, the impact of knowledge gain assessment is weaker in this study than in some of the previous literature; inter-observer agreement and simulated scenarios were not assessed. The previous behaviour change assessment in the literature was "mixed and inconclusive", with different and non-validated outcomes. The multi-methods assessment behaviour changes in this thesis gave both quantitative and qualitative descriptions of clinicians' self-described behaviour change. They linked them to the training, promoting rigour and triangulation of findings. Previous studies have shown contrasting impacts on MOB, with some showing no difference in CS rates and some increases (172); this study found no statistically significant difference but trends towards increasing operative birth. Like other studies, no difference in perinatal mortality was found. (172) The neonatal morbidity results were more challenging to interpret, with reductions in NICU admissions and yet increased numbers of babies with low APGAR scores. Previous studies show conflicting

results, with no differences or improvements in APGAR scores. (172) High-quality HIE data was not available in this study.

This thesis supports the conclusions of other systematic reviews and wider thinking on the role of training in improving HCW performance; combined approaches that include training with other multi-faceted strategies are crucial. (179) “The key to improving healthcare quality is a multilevel, systems-oriented approach that monitors, adapts, and innovates, plus a generous dose of persistence and patience.” (283)

8.6 Thesis contribution

This thesis adds to the very minimal literature on Indian women’s preferences for mode of birth and experiences of childbirth. Indian and international policymakers and clinicians must take steps to mitigate the rising CS rates, as this is not the safest mode of birth for women and not what women want. It also adds new evidence demonstrating that sub-optimal fetal monitoring drives rising CS rates, as clinicians feel that labour is unsafe without it. The dominant narrative is that obstetricians in India primarily do CS for convenience and ease. However, this data clearly demonstrates the realities and perceived risks of providing safe labour care for so many high-risk women at once. In many circumstances, clinicians perceive that CS is safer for the fetus and is one way to ensure a good outcome.

It appears to be a commonly held belief for clinicians that women in Indian Government hospitals “do not know”. However, this study highlights the contradiction between clinicians’ views on women’s understanding and what women do actually understand. Clinicians must be aware of this and adjust their perceptions and counselling accordingly to ensure that respectful maternity care is delivered and that women can make autonomous decisions around childbirth.

The importance of women “hearing the beats” and its role in empowering women with knowledge and contributing to a positive birth experience was significant, especially in LMIC settings and high-risk patients. This study reinforces what is already well documented: how clinicians communicate is critical, and simply “talking nicely” is not just a common courtesy but has an important positive impact on patients’ experience.

In this study, failing to deliver high-quality fetal monitoring in labour was much more about system factors, such as high workload and multiple competing demands, than inadequate knowledge of fetal monitoring. However, the challenges of delivering the training were also system factors. Therefore, solutions to improve fetal monitoring must be driven by systems thinking.

Before any quality improvement project, a detailed understanding of the current data and maternal and perinatal outcomes is essential to understand the nature of the problem and exactly what an intervention could achieve. Clinicians' perceptions of problems do not necessarily reflect the data-driven "truth" of problems. Fetal concerns during labour were the highest indication for CS, but hypoxic morbidity and mortality were uncommon. A huge amount of funding and research focus needs to go into developing better tools for detecting fetal hypoxia in labour, as current methods are inadequate.

Fetal monitoring training is a complex intervention that must be embedded within a wider QI approach to effect change. FM training must be seen as an intervention to create behaviour change rather than a tick-box exercise. Training is well-liked by clinicians and can improve knowledge and change behaviours. If planners, policymakers, and trainees view and plan the training in this way, the knowledge gained is likely to be more implementable and therefore, practice and outcomes are more likely to improve.

8.7 What does good CTG training look like?

There is increasing literature about the importance of describing "what good looks like", an approach to behavioural change known as "positive deviance". (283) Therefore, based on the literature, educational theory, talking to experts and undertaking this research, I aim to outline my perspectives on the important elements of a CTG training programme that aims to implement change and outline what good CTG training looks like.

CTG training must be viewed as a complex intervention, where education is one workstream within the active implementation of a guideline. This means that the policies and training are aligned, and the training is just one aspect of system change that supports the other's changes and is pushed by leaders and the departmental strategic plan. Funding, leadership and prioritisation of education are critical to achieving this. For example, ensuring the funding is available to provide staff time and capacity to lead the training and

quality improvement processes. All maternity care workers must be expected to attend without compromising staffing in clinical areas and working additional hours.

Universal education for the whole maternity workforce is needed as it is necessary to train a critical mass of staff. This includes mandatory attendance from all obstetricians and midwives of all grades who work on the labour ward (including consultants, registrars, and residents), even if the labour ward responsibilities are infrequent. This training should be essential for new starters at induction and also recommended for midwifery students. In addition, mandatory attendance, testing and accreditation could support motivation, especially among senior doctors.

The training should take place within hospitals, but without clinical interruptions, with appropriate breaks and refreshments. It should be led by passionate, enthusiastic and knowledgeable clinicians who colleagues respect. Training formats should be mixed, including an online pre-learning component (due to the sheer volume of necessary knowledge with a test) and face-to-face mixed format sessions, including interactive lectures/workshops /small group discussions/cases/simulations, with a focus on human factors and communication, and clear management and timely management plans. Ensuring the learning is readily implementable is essential. As is ensuring a positive working and educational departmental culture, where clinicians feel safe to incorporate their new knowledge into their day-to-day practice and have the appropriate support for this. Barriers must be outlined, in order to be overcome.

8.8 Implications and recommendations for practice, research and policy

The next section of this thesis outlines the implications for different stakeholders impacted by this research. The three key areas of impact are clinical practice, research and policy, and within each of these areas, there are important stakeholder groups outlined below. Key stakeholders for clinical practice are women who receive care, clinicians, and those responsible for delivering FM training. For research, stakeholders are researchers and funders. For policy, key stakeholders are local and national/international policymakers. The recommendations outlined are addressed to the stakeholders directly.

8.8.1 Implications and recommendations for practice

Implications and recommendations for women

This research shows that clinicians want what is best for women and their babies; they recommend CS birth when they feel it is less risky for the baby and mother than vaginal birth. This is often a complex decision-making process in which multiple factors are relevant. Doctors are likely to face many competing demands, which they are trying to prioritise. In addition, they may not know how much you, the mother, already understand about your birth.

- If you are unsure why the doctor recommends something, please ask them.

Implications and recommendations for clinicians

The interactions between clinicians and women are critical, and both want healthy mothers and babies and vaginal births where appropriate. How clinicians and women perceive interventions during birth, however, are different. For example, whilst vaginal examinations are routine for doctors, they are significant and often traumatic interventions for women. Witnessing others in the labour ward is deeply upsetting for women, making them scared about birth and even request CS. On the other hand, hearing the fetal heartbeat during birth is a strongly positive experience for women, which provides reassurance and a sense of knowledge and empowerment through knowing the baby is well. Having a caesarean birth is not what most women want, and requests for CS during labour are typically related to pain or fear rather than true CS preferences. Most women want normal birth and often fear that they could suffer for months or even a lifetime after CS. Women in Indian government hospitals know and understand more than clinicians realise about their birth. They can understand key information when it is explained kindly and appropriately. The following simple actions are suggested:

- Talk nicely to patients. This costs nothing and makes a huge difference to women's experience and clinical outcomes.
- Know that women are experts in their own birth experience.
- If possible, use fetal monitoring methods where the sound is audible to the mother, and tell your patients the fetal heart is normal when it is.
- Make careful decisions about recommending CS and understand your important role as a gatekeeper of CS rates.

- Pay close attention during training sessions and actively use and implement new knowledge. If you do not use new knowledge, it will not benefit patients, and the learning will quickly be forgotten.
- Gain a data-driven understanding of any problem before you start a quality improvement project.

Implications and recommendations for local fetal monitoring training leads and planners

Intrapartum fetal monitoring training must be viewed as a complex intervention aiming to create behaviour change in a highly challenging clinical environment. Bringing in co-interventions and understanding the interaction between leadership, policies, finances, and time is essential. The curriculum and learning objectives must be based on existing literature, educational theory, expert opinion, and local training needs assessment. Training needs analysis is essential to understand clinicians' existing knowledge and specific concerns within each maternity unit. Training must be aligned with national and local policies and guidelines. All staff working in maternity units must be trained, including new staff. Staff need to receive updates on the training regularly. No literature gives clear evidence on recommended frequencies, although annually seems pragmatic. Mandatory attendance and testing support motivation for many, especially senior Doctors. In short:

- Understand that FM training is a complex intervention; all co-interventions and barriers to change must be considered and overcome if new knowledge is to be implemented.
- The critical inputs for FM training to implement change are motivation, leadership, data, funding, planning and perseverance.
- Plan training to create behaviour change rather than simply knowledge gain. Map out and then plan how knowledge can be implemented.
- Ensure training is part of an aligned wider quality improvement initiative which supports the implementation of new knowledge
- Learning must be supported in the clinical environment with a supportive learning and working culture where everyone strives to improve and change and achieve the best outcomes for patients.

8.8.2 Implications and recommendations for research

Implications and recommendations for researchers

Multi methods research is particularly suited to clinical education research, as most education programmes for practising clinicians are complex interventions designed for complex systems. Multi methods research enables the collection and analysis of both qualitative and quantitative data, provides a credible, intuitive, real-life understanding of the issues, ensures problems are viewed from multiple angles and ensures limitations of the different research methods are overcome. For this research, Kirkpatrick's model provided a useful foundation for research. However, additional tools and methods were necessary. For example, writing a reflective diary throughout the research process, especially for clinical education research, can highlight important but subtle features and enable deep and reflective insight into the research. In addition, measuring variables that linked potential outcome change to the intervention are critical; for example, linking process measures of fetal heart recording to clinicians' perspectives on how many cases were managed differently.

In fetal monitoring training research, it is important to embrace, acknowledge and incorporate complexity. Attempting to ignore the complex world in which clinical education features means the research is unlikely to incorporate the "real world" and will not be useful in practice. One framework for doing this is a theory of change. This is a useful tool to consider and plan complex interventions such as fetal monitoring training, where the links between training and outcomes are convoluted and unclear. In summary:

- Consider using mixed/multi-methods research for clinical education research.
- Consider using additional research tools such as a diary or theory of change to incorporate and document the complexities of clinical education research.
- Asking clinicians to quantify and give anonymised examples of how training has changed their practice was useful in linking training to patient outcomes.

Implications and recommendations for research funders

Fetal monitoring during labour should be a priority for future research. Errors in fetal monitoring lead to huge perinatal morbidity and mortality globally, and fetal concerns lead to over-intervention in birth. Over-intervention in birth increases complications such as

PPH, surgical complications, sepsis, uterine rupture, morbidly adherent placenta and maternal death. As such, improved fetal monitoring holds one of the keys to unlocking improved maternal health worldwide. Our current tools are inadequate and not evidence-based. Large amounts of funding and research are required to overcome this, as study designs are likely to be mixed, with very large sample sizes.

Funders should value the benefits of mixed/multi-methods research and understand what good looks like. In order for research to address real-world problems, methods must be able to manage that complexity. RCTs are not the gold standard for all FM studies, as the settings and context are so varied and critical. The value of mixed/multi-methods research must be understood. In short:

- Create significant funding to overcome the current challenges in diagnosing fetal hypoxia during labour, recognising its centrality to improving maternal health.
- Recognise the value of different and appropriate research methods; to ensure the right methods are used for the right questions and the methods used can deal with the complexities involved with FM studies.

8.8.3 Implications and recommendations for policy

Although staff training is an important aspect of improving the quality of care, it should not be considered in isolation. Training packages must be designed so that new knowledge is implementable, and the systems, policies and procedures are aligned to facilitate the implementation of new knowledge. In addition, the critical success factors must be in place if training is to improve outcomes; local strategic priority and support, ring-fenced funding/time for leaders/trainers and all staff to attend, a clinical and educational environment that enables change, skilled and motivating trainers and leaders, resources to implement changes and a component of wider QI initiative.

Soaring CS rates are the next massive public health issue, and activities at the national/international policy level have an important role in maintaining an appropriate CS rate. Vaginal birth and CS should command equal financial compensation; there should be no financial gain for clinicians for CS over vaginal birth. The legislative governance structures have implications for obstetric practice. They must be fair and just to ensure obstetricians and families have faith in the processes and do not fear the risks of vaginal

birth. Healthcare models which promote continuity of carer and one-to-one care throughout labour with midwives are proven to improve outcomes for mothers and babies.

- Understand the complexity of the systems involved in delivering high-quality intrapartum care (including fetal monitoring) and design interventions with systems thinking in mind.
- High-level policies, the law and financing and staffing issues contribute to rising CS rates; addressing these issues must be prioritised.

8.9 Future research studies

India is a diverse country with diverse geographies, populations and challenges. Therefore, to truly understand women's and clinicians' perspectives of MOB and FM in India, further similar studies are required in different geographical areas, in different types of healthcare facilities (including private and public) and with women from differing socio-cultural backgrounds. It remains a notable gap that whilst there are multiple qualitative studies on this topic from other LMICs, such as Iran (284) and China (285), there are still, to our knowledge, no previous studies from India.

As the context of FM training is variable, important and difficult to describe and measure, data and reflections during this thesis suggest that the overall clinical and educational environment are more important than the focus on just CTG training alone. Therefore, a large appreciative inquiry study could shed more light on the important "active ingredients" that create behaviour change and improve outcomes. For a UK context, this study could consist of two cohorts; one of the "best" units and one of the "most improved" units could be studied in detail. Definitions of which units to be included would have to be carefully considered but would include maternal and perinatal outcomes, maternity experience surveys, adverse outcomes, staff surveys and trainee evaluations. Then mixed methods approaches could be used to describe their "intervention package" and the "active ingredients" of this, using qualitative research methods and the TIDieR checklist. This could be used to describe "what good looks like" or positive deviance. The "improver" units would be studied with even greater depth, focusing on the pathways to change, aiming to describe the active ingredients to change and the reproducible steps other units could follow.

All of the literature suggests that electronic FM does not improve outcomes. Yet, despite this lack of evidence, its use is engrained in clinical practice and clinical practice guidelines and is currently impossible to de-implement. Several randomised controlled trials are needed, for example, to compare intermittent auscultation alone and intermittent auscultation with intermittent CTG to confirm abnormalities in higher-risk women. As CTG is so engrained, reproducing previous studies would not be acceptable to clinicians and women in high-risk groups. However, many of the groups which are now defined as high risk which were not previously categorised in this way, such as post-dates IOL, large for gestational age and induction for maternal request (i.e. where there are no signs of maternal or fetal compromise). Studies on these women could offer important findings. In LMICs, RCTs of differing IA schedules, e.g. doppler every 15/30/60 minutes, would be enlightening. High-quality intrapartum FM is highly time-consuming, and current regimes are not feasible in much of India; therefore, high-quality RCT evidence is needed to outline this essential aspect of care.

The pathways between training, behaviour change and improvements in outcomes are poorly defined. Further qualitative explorations of these pathways are needed, including interviews, focus groups and ethnographies to understand what good clinical education looks like within obstetrics and gynaecology, define good training and disseminate these findings in ways that are actionable for clinicians and trainers.

The theory of change defined in this thesis has not been used in practice. Future FM training studies **c**ould ideally use this TOC as a basis for discussions for their intervention development at the beginning of training development. The QI journey and pathways to change should be carefully documented in future studies to outline how FM training can result in behaviour change and improve outcomes.

8.10 Conclusion

Although having a healthy newborn baby is central to the needs of both mothers and clinicians, ensuring this in a resource-poor environment is challenging. Inadequate FM in Indian government hospitals is typically due to system factors and multiple competing demands on clinicians. In turn, sub-optimal intrapartum FM is a driver of high operative birth rates, as, without good fetal monitoring, clinicians feel that labour and vaginal birth are risky. Clinicians believe that additional FM training and equipment could improve outcomes. For women, having a healthy baby, vaginal birth, kind communication with staff

and reassurance of fetal health during labour through hearing the fetal heart sounds were important and promoted a positive birth experience.

When an FM training intervention using mixed formats was applied in an Indian government tertiary referral hospital, clinicians enjoyed the training. There was some evidence of knowledge and confidence gain, and clinicians could describe and quantify their change in practice. There were some increases in fetal monitoring process indicators, such as the number of FHR recordings, and some improvements in perinatal outcomes, such as NICU admission for asphyxia and overall NICU admission rates. There were non-statistically significant trends towards increased operative birth and reduced perinatal mortality.

The dominant narrative of how HCP training can improve outcomes (training delivered, clinicians learn, clinicians improve, outcomes improve, and fewer babies are harmed) is over simplistic and outdated. Intrapartum FM training is a complex intervention that aims to effect behavioural change in a challenging and dynamic clinical environment. It is time-consuming and challenging to teach and assess. Moreover, the training is only part of the necessary intervention, and other co-interventions, context and systems thinking are essential. For clinical education programmes to make a valuable and sustainable difference in practice, stakeholders must accept that achieving regular change in behaviour is very challenging and that training alone is insufficient to improve outcomes. The training must be embedded in a wider QI intervention and educational delivery plan, where barriers to knowledge use in practice and change are identified and addressed.

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Appendix 1. Themes, sub-themes and key quotes from Chapter three

Theme 1. Women's views about mode of birth: "trouble for two hours, or trouble for two months"

Theme	Subtheme	Illustrative quotes
1. Women's views about mode of birth (MOB): "trouble for two hours, or trouble for two months"	*Feelings (priorities/importance) about birth*	*"Means, how will the delivery happen? This was the fear in my mind. I was very much afraid of how the delivery will happen. What will happen?... I didn't know. I didn't have that much knowledge."* *Postnatal woman (P24)*
	Experiences of birth	*"It was good…Now, feeling better. Now, feeling very nice as the baby is delivered. By seeing the baby, we remain happy. Means that whatever worry was there, we forgot all and paid attention to our baby…We keep aside our pain and pay attention to the baby nicely."* *Postnatal woman (P24)*
	MOB preferences: Trouble for two hours or two months	*"Because everyone says the pain of normal delivery remains till the baby comes, and after Caesar operation, it remains 'til two months. Means I wanted it for a short time only and didn't want long-term pain. Therefore, I was thinking of normal."* *Antenatal woman (P46)*
	MOB expectations	*"Nothing. It should be normal. That's it. All should go well. Baby should remain well, and me too. That's only my expectation…* *I feel when it will come out (how long will it take?)."* *Antenatal woman (P29)*

Theme 2. Women's knowledge and understanding; knowledge through experience

Theme	Subtheme	Illustrative quotes
Women's knowledge and understanding; knowledge through experience	*Women's knowledge of methods and reasons for FM*	"*Don't know any other methods; no one told me. Only that method I have seen"* *Postnatal woman (P7)* *"We are the ones who will take care (of baby). In future, we have to take care. I think it's necessary to be aware of everything."* *Postnatal woman (P42)*
	Women's knowledge about birth	*"No. Don't have any knowledge about it. No one told us any details. Only told that I had a normal delivery. Told that only (all that is said is I had NVD). And it's said that if pain increases, the baby will soon deliver because of the pain. Then, we have to apply the force (push), so it happens early. Therefore, I liked that.* *No one asks such things. Till now, whoever asked said only that it's normal."(Only share it was NVD, no details shared.)* *Postnatal woman (P45)*
	Women's knowledge about indications for CS	*"There is no progress," "BP is raised," "baby passed stool in abdomen", and "pain didn't come."* *Postnatal women (P1B, 2, 5, 24)*
	Others on the labour ward	*"I had seen. So, therefore I was more afraid. RA- Okay. What did you see?* *Seen all (Smiled). RA- Like?* *That whatever happened was a normal delivery; it's from below. I have seen all that. Because of that, I was more scared."*

		Antenatal woman (P26)
	Previous delivery experience (multip)	*" It was good. RA- What happened then?* *Means that suddenly the pain started and then delivered soon. RA- Did the pain last too long? P- Yes."* *Antenatal woman (P28)*
	Clinicians' perspectives on women's knowledge	*"The counselling part is very much neglected in our setup. Usually, the patient is ill-informed. Because they don't understand,* *mostly the kind of class we get here, they usually don't understand these things."* *FGD 1, P3*

Theme 3. Fetal monitoring was part of a positive birthing experience: felt good by hearing the beats (it felt good to hear the beats)

Theme	Subtheme	Illustrative quotes
Fetal monitoring was part of a positive birthing experience: felt good by	*Women's experiences of FM (perceptions of what was done)*	*"Many times. They listened every one hour. RA- By all of the three (methods)?* *Not by all three. By NST (CTG), they only did it 1-2 times. NST was done two times, and that machine was applied to me and continued all day when I was in pain. And they used to be checked by Doppler every one hour. RA- Okay.* *And this stethoscope, when doctors came, they used to check with this. RA- Okay. So, who checked the baby's heartbeats by this (stethoscope)?* *Only doctors checked."*

hearing the beats **(it felt good to hear the beats)**		*Postnatal woman (P51)*
	Mentions of FM independent of the interview guide	*"Checked me up lots of times. Checked the BP, checked baby's heartbeats. The whole night they cared a lot."* *Postnatal woman (P24)*
	"Hearing the beats"	*"Good means...I felt in this that my baby is good. Means can hear the heartbeats na. Ghur...ghur...ghur...ghur.. (sound of Doppler) RA- Hmm-hmm.* *My baby is good. Means I felt very good. RA- Felt good? Sound was coming."* *Postnatal woman (P12)* *"We can also hear so that we can also understand how our baby's heart beats. Is it going normal or higher? If other people don't tell us, then we keep thinking, what's going on? People don't want to tell so she (patient) might not get afraid."* *Postnatal woman (P39)*
	How could FM have been better?	*"There is nothing that I do not like, I swear."* *Postnatal woman (P5)*
	Feelings and importance	*"I can hear my own baby's heartbeat; it was a very big thing for me. And, I was waiting when it (baby) will come (laughed innocently in anticipation)."* *Postnatal woman (P7)* *"We have a heartbeat, like this inside us there is a life/soul, he also has the heartbeat. It's also going. So, that will be important."*

		Antenatal woman (P43)
	Fetal monitoring methods preferences	*"Because of that means baby's beats, the sound was coming. And that putting in the ears (stethoscope) that we couldn't understand. That Madam could understand."* *Postnatal woman (P10)* *"But, when checked by stethoscope na that time they pressed a little bit, so that time little bit trouble was there."* *Antenatal woman (P21)* *"Baby's heartbeats can be heard in it. Get to know that baby is well."* *Antenatal woman (P29)*
	Clinicians' perceptions of women's views and experiences of FM	*"Sir, they get satisfied when we make them listen to their baby's heartbeat and when they are told that now everything is normal. They also feel security that now we have also checked up. Our baby is also safe, in so much pain."* *FGD 4, P1*

Theme 4. Interactions with women, relatives and clinicians

Theme	Subtheme	Illustrative quotes
Interactions with women,	*Interactions about FM*	*"Means, someone was saying it's good. Someone was telling about the speed (too fast), and someone was saying that it's normal…Therefore, they [Drs] were afraid. They were telling me about my baby, and I was asking them. Then, they were telling me that baby's heartbeats are good. This much percent is better; that much percent is better. They were telling me like this. Then, I was feeling better. I was feeling that no, this is important."*

relatives and clinicians		*Postnatal woman (P42)*
	Interactions about birth	*"My treatment was going on in private. RA- Okay.* *They told me caesar. RA- For what?* *Said that BP is more. RA- Okay.* *Hmm(yes). They people said that we can't take risk of normal. Said that your vein may burst. I was like scared. Then, I thought that instead of investing that much money. Instead of investing Rs.18,000/- there, I will do my delivery in government…..* *That it should not happen, means said that during labour pains of normal, it may happen. Doctors said. It was in my mind."* *Postnatal woman (P12)*
	CS requests in labour	*"At the last, I myself told them that I don't want [normal] then what they people could do. I insisted, said that I would not bear the pain.. like this.* *RA- Pain? Would not bear the pain like this. RA- Okay. Hmm.* *So, I myself said to do my caesar. RA- Okay. You said yourself?"* *Postnatal woman (P18)*
	Family and relatives	*"So, my husband was not ready to sign [CS consent]. He was very much scared. He was saying that I'll not sign. Then, my family pressurised said that you have to sign; otherwise, they will not do delivery. And otherwise, anything will happen, you do or not. Then, he signed. So, all prayed in the way of GOD IS ONE (parmatma ek). They didn't tell me all because I might have raised BP."* *Postnatal woman (P19)*

	Clinician's perspectives on interactions with patients	*"Their importance is that the baby should come out safely, do whatever you want. They also willing to endure the pain. But baby should deliver well. First, they take guarantee of it."* *FGD 4, P8*

Theme 5. Fetal monitoring as per guidelines was "practically not possible"

Theme	Subtheme	Illustrative quotes
Fetal monitoring as per guidelines was "practically not possible."	*Fetal monitoring guidelines, practices and norms*	*"P2 [interrupts] - It's rarely possible. I disagree. It is practically not possible in active labour every 15 minutes…* *P6,7 - High-risk patients in active labour are monitored half-hourly. But it should be done.* *P5 - Maximum frequency is hourly, depending on the severity of the patient and risk.* *P2 - It's definitely not half-hourly, depending on the severity of the patient. Definitely not half-hourly."* *FGD 1, P2,5,6,7*
	Hospital system barriers to quality FM	*"Twenty-five patients are there at one time, some are delivering functionally (NVD) and then we are attending to the deliveries, new patients are coming, some patients are getting shifted (to the theatre), so much things to do."* *FGD 2, P8* *"Amount of caseload over here is so high that apparently whatever existing infrastructure we have and doctors especially we have, they are very skilled. So has to be, there is a big need of upgrading and enhancing the infrastructure, manpower, equipment, everything."* *FGD 5, P3*

	Clinicians' previous experiences with FM	*"We are more tolerant; even if the FHS [fetal heart sounds] is 100 or 110, we do not have to panic. Suppose some foreign person is there; he saw that it is hundred he will panic and call the senior and all that and create Hungama (chaos.)."* *FGD 1, P2*

Theme 6. Relationship between intrapartum fetal monitoring, mode of birth and risk

Theme	Subtheme	Illustrative quotes
Relationship between intrapartum fetal monitoring, mode of birth and risk	*Clinicians' perspectives on risk*	*"P6 - In starting, when we went there, they were not inducing the PIH patients. They didn't do the induction there.* *M - Used to prefer the caesarean section? [asked as a question]* *P6 - Direct shift to OT (theatre). But, ever since we started, since then counselling, in each shift, we also had to explain the protocol to the doctors. Now, the condition is such that they give at least five pills."* *FGD 8, P6*
	CS rates	*"M - What's the general caesarean rates in the hospital? Do you think it's (interrupted)…?"* *P8 - It is very high, 40 to 60%.* *P7 - Maybe 30 to 40%, and the reason behind this is that this is the referral institute. All high-risk patients are referred here, and they come here for caesarean section because the indication is like that. So, most of the time, cases preeclampsia, eclampsia patients, LSCS, previous LSCS, placenta praevia. These patients are only referred here. So, the indication itself is a caesarean section for these patients.*

		P8 - But, in low-risk patients also, we have a high rate of caesarean section. And I personally think that we don't have, compared to the rest of Nagpur, rest of Maharashtra, normal delivery is quite good. We are not that bad comparatively. *P7 - Even with this, the rate is going to be high because of this problem. Because of the referrals that we get, it's going to be high."* *FGD 5, P7,8,9*
	The potential impact of EFM on local CS rates	*"M - My next question is, there is always a concern with CTG that it leads to overdiagnosis intervention rates, CS rates"* *P7 - echoed by 2-3 other participants: All the studies show that it leads to overdiagnosis, but in our setting, we feel it will decrease the rates of CS [echoed by few]* *P10 - Sometimes, we do not wait. We can't put the baby and mother at risk, we can't see the monitor, and we go for CS* *P11 - CS rate is very much high in a low-risk population. It is already high in high risk. Of course, we go for C section. It will help reduce the CS rate in the low-risk population* *P9 - Second medical-legal, so we can wait and show them the CTG report that's why we were waiting, so it will help in documentation [echoed by few]."* *FGD 1, P7, 10, 11,9* *"M - Do most of you agree that having additional CTG machines will help in better fetal monitoring?* *P2 - When we practise auscultation, an occasional drop-in FHR we perceive as fetal distress if there is a CTG, we can correlate that with contraction. If it is post contraction, it carries more significance rather than variable deceleration, so in that way, maybe CS rates can be decreased if CTG is there rather than doing only auscultatory monitoring*

		M - Anyone else, do you agree or disagree with that? *P9 - Many variables are seen on a CTG, the accelerations are seen, the variability is seen and by auscultating, you only get the drop.* *M - There is a concern that when you have CTG machines and regularly monitor fetal heart rate, the rates of CS goes up. Do you all agree or not?* *P9 - [If you have a CTG], only the right patients will go to CS; unnecessary CS will be avoided. Fetal distress also, there is a proper definition it should last for more than.....according to that if we will go then the rate will decrease comparatively."* *FGD 2, P2,9*
	The perceived potential impact of enhancing FM training and equipment	*"M - Under this project, there is also a plan to bring CTG machines to labour wards and train staff and residents on fetal monitoring. Do you think it is necessary?* *[Almost all the participants unequivocally replied yes to it, saying that there is no doubt in it.]* *M - Do you agree that monitoring is beneficial for patients? Routine regular monitoring only shows that the field is the high load setting, so how do you feel that an additional CTG in your ward and training for fetal monitoring is it going to be beneficial for you and patients?* *[Most participants replied with a "yes, definitely".]* *M - Do you think it is going to affect patient care in future, having an additional CTG and training? [2-3 participants replied, Yes, yes, of course. New residents come; they are not aware. So training is going to definitely help them.]* *M - What is the role of CTG machines in labour ward? Will it help?* *P1 - Definitely help, yes [Most of them agreed and said yes]* *M - And will it be easy to train the staff?* *P3 - Yes, the staff, once trained, we can start CTG; not an issue"*

		FGD 2, all
	The actual impact of enhancing FM training, equipment and MOLI study	*"M - Now, as much closer monitoring was done with CTG machines, it's generally felt that caesarean rates go up because you know about every movement that this is raised. So let's take her, shift to the OT (theatre) table. Otherwise, you wait for some time. Later it also comes down. And do you agree that there is a concern that the closer the monitoring is, the more likely there are chances of raised CS rates?* *P3 - Along with this fetal heart rate, we also see for vaginal examination is there light meconium, thick meconium. So, keep trying even for labour also.* *P6 - Extended CTG really helps. If we feel there is one abnormality, usually prolonged time, we repeat CTG after 20 minutes to see. So, I don't think we have increased the rates along with CTG. But, because of repeated CTGs that we do, just in case, if we find one abnormality, we do not shift a patient with one abnormality, usually repeat after 20 minutes. And then go ahead, and if still find there is distress or there is an abnormality, then we go ahead in such cases.* *P3 - And also clinical assessment, it also matters.* *P1 - Sir, if the patient is non-high risk and if we see FHS are changing, then we will wait. We will wait to give her left lateral position; we will monitor her. If a similar scenario happens if the patient is on PIH, we will suspect abruption or any other thing like that can happen.* *P6 - So, clinical assessment along with CTG is usually what we do."* *FGD 7,P1,3,6*
	How can CS rates be reduced?	*"P3 - It's multiple issues. Multi-problem thing.* *P8 - The main thing is that the workload. I think everything can be explained on the basis of workload which we have over here. Otherwise, the things are better than any other institute, I think.* *P2 - And missing those midwives. We don't have midwives. We are all doctors here. They are doing caesarean, everything, right from preparation of the patient's everything. Everything is done by the doctors. Many times, nurses are not there. Once the baby is out, they vanish. Right from assisting episiotomy, they don't know anything. That problem is also there…*

		M - Anything that can be done to reduce the rates of caesarean section? *P7 - The most important is fetal monitoring.* *P8 - Better monitoring.* *P7 - If you can monitor the fetal heart sounds, sincerely and [interrupted]* *P8 - Better understanding and better training of the like students and the staff will help in reducing the caesarean sections."* *FGD 5, P2,3,7,8*

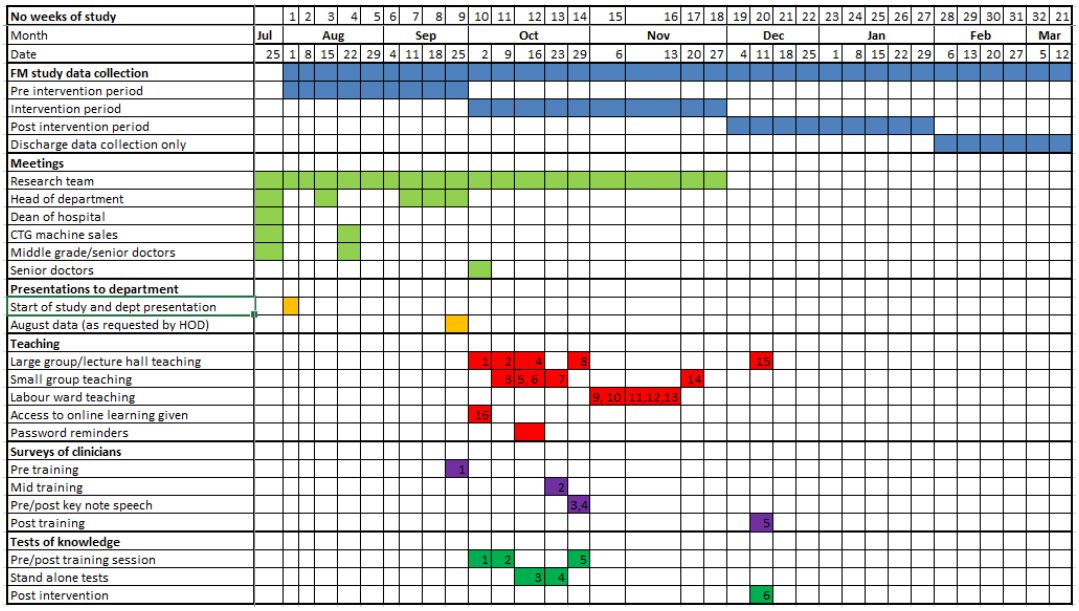
Appendix 2 – Fetal monitoring training intervention details

2.1 Fetal monitoring training intervention details

No	Date	Location	Format	Attendance	Title	Further information/assessment of learning
na	1.8.20	Lecture hall	Presentation	24	Introduction to FM study	A shorter presentation to explain the FM study and MOLI study ***Pre-training survey – 1*** The team discussed pre-training testing, but local concerns were raised about testing discouraging attendance and de-motivating colleagues
na	26.09.20	Lecture hall	Presentation	25 (not rec)	FM study august data	A short presentation to department to share some brief findings of August cohort study data
na	2.11.20	Lecture hall	Presentation	? 35 (not rec)	FM study august data	Presentation to department to share August cohort study data
1	4.10.20	Lecture hall	Lecture interactive case discussion	11	Intelligent auscultation	PowerPoint on IA and intelligent auscultation, interactive cases focused on risk assessment, describing and classifying FH sound and managements plans (KL) *Test 1 – Pre/post session. Basic knowledge of parameters and actions for IA (5) and 5 cases with IA audible sounds 5x (FHR, impression, plan)*
2	11.10.20	Lecture hall	Lecture	30	CTG outline and physiology	PowerPoint on risk assessments, acid-base balance, physiology, detailed description of CTG parameters and FIGO guidelines (KL) *Test 2 – Pre/post session. 17 questions testing basic understanding, terms, normal ranges and management plans*
3	15.10.20	Seminar room	Small group	7	CTG outline	PowerPoint with a recap of session 2, an overview of CTG focusing on baseline rate and variability. Initially planned large group session, but few attendees and informal questions at the beginning of the session highlighted the need to review CTG overview in a different format. The small group worked well as it was much easier to gauge the understanding (KL)
4	16.10.20	Lecture hall	Lecture interactive case discussion	11	Decelerations	Recap previous learning and detailed discussions of different types of decelerations, their significance, linking to physiology, management plans and cases with decelerations (KL) *Test 3 – Analysed as stand-alone. Five questions describing, drawing, naming decelerations and management plans*
5	17.10.20	Seminar room	Small group	6	CTG cases	Abnormal CTG cases – description, classification and management plan. Residents were discussing and teaching each other primarily (KL)
6	22.10.20	Seminar room	Small group	2	CTG cases	Abnormal CTG cases – description, classification and management plan (KL)
7	23.10.20	Seminar room	Small group	10	CTG cases	Abnormal CTG cases – description, classification and management plan (KL) *Test 4 – Analysed as stand-alone. 13 pattern recognition questions (13 marks) and 8 cases (3 marks, CTG description, classification and clinical management)* ***Mid-training survey – 2***

No	Date	Location	Format	Attendance	Title	Further information/assessment of learning
8	2.1120	Lecture hall	Lecture (keynote)	32	Monitoring fetal wellbeing in labour	Overview of CTG, risk assessments, FIGO and local guidelines, examples of CTGs (AW) Test 5 – Pre/post. 6 CTG cases, classified using online polling via phones pre/post lecture **Pre/post keynote survey – 3 / 4**
9	9.11.20	Labour ward	Labour ward	6	CTG cases	Partograph and IA, breech head entrapment (KL)
10	11.11.20	Labour ward	Labour ward	5	CTG cases	Partograph and IA (KL)
11	13.11.20	Labour ward	Labour ward	4	CTG cases	Partograph, IA, abnormal IA management, instrumental delivery (KL)
12	14.1120	Labour ward	Labour ward	8	CTG cases	Abnormal CTG cases – description, classification and management (KL)
13	15.1120	Labour ward	Labour ward	0	CTG cases	Labour ward busy, unable to undertake planned teaching session (KL)
14	22.11.20	Seminar room	Small group	3	CTG cases	CTG cases and management. Only senior doctors were invited (KL)
15	16.12.20	Lecture hall testing and survey on LW	Large group	22	CTG cases	CTG cases, description and management (KL) *Test 6 – Standalone. Basic knowledge of parameters and actions (12). Then 5 cases (3 marks, CTG description, classification, clinical management)* ***Post training survey – 5***
16	All	Online	Online	11	K2 online learning	Full online interactive learning package used in many UK hospitals *Assessment built into e-learning, with interactive cases of CTGs, at set stages throughout the package*

2.2 Fetal monitoring study Gantt chart



2.3 TIDieR checklist for fetal monitoring study intervention description (286)

1. **Provide the name or a phrase that describes the intervention**

An intrapartum fetal monitoring training (CTG and IA) and quality improvement programme.

2. **Describe any rationale, theory, or goal of the elements essential to the intervention**

We hypothesised that creating local guidelines and training all staff in intrapartum fetal monitoring would:

1. Improve staff knowledge and confidence in intrapartum fetal monitoring using IA and intermittent CTG.
2. Improve the quality and documentation of fetal monitoring during labour, which will, in turn, improve perinatal and maternal outcomes.

Improve the accuracy of the antepartum diagnosis of "fetal distress" and therefore reduce the number of unnecessary Caesarean sections conducted for false positive diagnoses of "fetal distress" (especially when meconium is noted and the fetal heart is normal.)

3. **Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in the training of intervention providers. Provide information on where the materials can be accessed (such as the online appendix and URL)**

Free access to the K2 e-learning package, used commonly in the UK to train staff.

Handout of CTG guideline summary (based on FIGO guideline). (see Appendix)

Emails of PowerPoint handouts when requested.

Training PowerPoint slides and pre-post tests were adapted from existing training material from renowned CTG and IA training experts.

At the beginning of data collection, two handheld lactate monitors were introduced in labour wards/theatres to enable cord lactate samples to be taken when a baby was delivered for suspected fetal compromise.

4. **Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities (see Appendix 2)**

Laying the foundations for the intervention

Several meetings with senior staff and departmental presentations about the project were held to engage and enthuse colleagues.

A local fetal monitoring research group was created, and the Head of the Department (HOD) was invited to attend these meetings.

The research group fed back to the HOD regularly (weekly/fortnightly) throughout the project.

Training needs assessment and local preferences on training format

An informal brief local training needs evaluation was undertaken, and the final document was circulated and discussed within the local FM research group.

Following this, a pre-intervention survey was undertaken to understand clinicians' preferences regarding the training format and previous CTG training and experience.

The HOD facilitated a meeting of all key senior staff stakeholders to review available international guidelines and discuss with KL which would be best applied. It was decided to use FIGO guidelines, as they do not recommend FBS, are simpler to understand and disseminate and the senior clinicians felt it was more suited to this context. There was also discussion and consensus-building around the recommended frequency of IA for high-risk and low-risk mothers.

Co-interventions (enabling/supporting activities)

Meetings included formal (twelve) and numerous informal meetings, including with the Head of the Department, local and international research groups, senior doctors, junior doctors and some nurses.

The one-page summary of FIGO parameters was printed and shared widely.

Mobile phone messages (via the WhatsApp social media platform) reminded clinicians about teaching sessions and online learning access. The HOD also personally reminded colleagues to attend, especially for the key note and larger group sessions.

A WhatsApp group was set up amongst middle-grade doctors to facilitate sharing the lactate machine and learning.

An open-door policy and trainers' contact details were shared, enabling conversations in and out of classroom questions and discussions and numerous "corridor conversations".

The intrapartum fetal monitoring training programme

The training took place through a series of fifteen face-to-face teaching sessions in October and November 2019. These included five lectures (one of which was delivered by a keynote speaker), five small group tutorials and five clinical teaching sessions in the labour ward. Mixed formats were used in the classroom, including lectures, workshops, case-based discussions, peer-to-peer teaching, quizzes, and informal role-play in the communication of abnormal CTGs. Practical hands-on skills, communication skills, case-based discussions were used in the labour ward. Free access to K2 online CTG e-learning was available throughout the intervention period.

The training intervention was based on fetal monitoring as an integral part of labour ward management. The curriculum included fetal physiology, normal and abnormal intrapartum fetal monitoring parameters as per FIGO guidelines, key definitions and terms, description of CTGs, classification, management of various cases and CTGs, communication of abnormal findings and teaching colleagues.

The first session was about intelligent auscultation, a form of intermittent auscultation. The IA training session was based entirely on existing slides and tests.

The next sessions were large group sessions focused on CTG in the lecture hall, in an interactive lecture-based format containing the basics of fetal physiology, CTG interpretation and parameters for CTG.

The fourth session was planned again as an interactive lecture, focusing on different parameters and types of hypoxia and decelerations to ensure all parameters were fully understood.

The fifth/sixth/seventh sessions were interactive case-based discussions around different CTG traces, focused on applying knowledge to cases, and more aligned with CTG meetings in the UK.

Session eight was a keynote lecture from a visiting Professor from the UK (AW).

Sessions nine to fourteen were case-based discussions and more practical sessions about fetal monitoring in the context of real clinical cases in the labour ward. They included communication, escalation, and partograms.

The final session was a large group session in the lecture hall, summarising the learning, focusing on cases, and conducting the post-test.

Online learning with K2, commonly used for CTG training in the UK, was made available for free. Email links to the learning and reminders, plus WhatsApp reminders, were used. K2 online learning consists of presentations, interactive cases and competency tests and typically takes six to eight hours to complete.

5. **Who provided?**

Much of the training was provided by a UK-trained obstetrician and gynaecologist trainee with experience in working in low-resource settings and training health care professionals. In addition, a UK-based consultant and professor of International Maternal Health delivered the keynote speech.

It was aimed at training local "train-the-trainers", but this was not feasible

6. **Describe the modes of delivery (such as face-to-face or by some other mechanism, such as the internet or telephone) of the intervention and whether it was provided individually or in a group**

Face-to-face teaching with interactive lectures, a keynote lecture from a visiting Professor, interactive discussions, small group discussions around cases, small group teaching, small group teaching in the labour ward, practical teaching in the labour ward and online learning via K2. See Appendix Two for the full details.

7. **Where?**

This project was based in Government Medical College (GMC), Nagpur, a busy Government hospital in Maharashtra, central India, with an estimated 1000-1300 deliveries/month. The obstetrics and gynaecology department are based in the main Government teaching hospital.

Lectures were in the lecture hall, small group sessions were either conducted in a separate training room/at the front of the lecture theatre/in the research office, and labour ward sessions were conducted in the labour ward. Fans were necessary due to the heat.

8. **Describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedule, and their duration, intensity, or dose**

Over the two-month "intervention period" in October/November 2019, 15 training sessions were held in varying formats at the usual time of day for postgraduate education (2 pm.) Sessions lasted between 60-90 minutes (see Appendix Two for full details.)

9. **If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how**

This QI project was reviewed regularly at team meetings. Feedback from surveys and staff (particularly the HOD, seniors and juniors) was incorporated into future session planning. Logistics and local circumstances played a large role in the organisation of this training. They shifted the format from a half/full day session to a series of frequent shorter sessions that fit with the department's training norms. The formats were quickly changed from larger interactive lectures to more small group discussions and case-based teaching, with frequent knowledge checks to ensure understanding due to the complex subject, English accent of trainers and different cadres of staff. The last sessions were conducted in the labour ward, as junior Doctors preferred this and allowed attendance from the most junior residents and nurses.

10. **If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)**

The detail of the intervention was flexible due to the initial lack of understanding of the setting of the project lead. Training needs analysis and curriculum outline highlighted which areas needed to be covered. Liaison between staff in the department was critical.

11. **Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them**

Intervention adherence and fidelity were not assessed. Planning meetings and training needs analysis were held on arrival in Nagpur. The process was diarised to support accurate reporting and reflections on the process.

Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned NA

2.4 FIGO Guideline Summary – Teaching handout (87) (110)

1. Intermittent auscultation

Features to evaluate		What to register
FHR	Duration: for at least 60 seconds; for 3 contractions if the FHR is not always in the normal range (110-160 bpm).	Baseline (as a single counted number in bpm), presence or absence of accelerations and decelerations.
	Timing: during and at least 30 seconds after a contraction.	
	Interval: Every 15 minutes in the active phase of the 1st stage of labor. Every 5 minutes in the 2nd stage of labor.	
Uterine contractions	Before and during FHR auscultation, in order to detect at least two contractions.	Frequency in 10 minutes
Fetal movements	At the same time as evaluation of uterine contractions.	Presence or absence
Maternal heart rate	At the time of FHR auscultation.	Single counted number in bpm

Note for GMC Consensus

1st stage – FH every 15 minutes for high-risk patients

1st stage – FH every 30 minutes for low-risk patients

2nd stage –FH every 5 minutes

2. If intermittent auscultation is abnormal

Baseline	Below 110 bpm or above 160 bpm
Decelerations	Presence of repetitive or prolonged (>3 minutes) decelerations
Contractions	More than 5 contractions in a 10 minute period

Table 4. Abnormal findings on IA.

A FHR value under 110 bpm lasting more than 3 minutes, when the rate has previously been normal, is very suggestive of a prolonged deceleration or of fetal bradycardia, and constitutes an indication for immediate continuous CTG. A FHR value exceeding 160 bpm during three contractions is very suggestive of fetal tachycardia, and constitutes an indication for continuous CTG.

3. CTG

	Normal CTG[a]	Suspicious CTG	Pathological CTG
Baseline[b]	110-160 bpm	Lacking at least one of normal characteristics, but with no pathological features	<100 bpm
Variability[c,d,j]	5-25 bpm		Reduced/increased variability[c,d]; sinusoidal pattern[j]
Decelerations[e,f,g,h,i]	No repetitive* decelerations		Repetitive* late or prolonged decelerations for >30 min (or >20 min if reduced variability); one deceleration >5 min
Interpretation	No hypoxia/acidosis	Low probability of hypoxia/acidosis	High probability of hypoxia/acidosis

*) Decelerations are repetitive if they occur at >50% of uterine contractions.

2.5 qMOLI study interview and focus group guides from protocol

Interview Guide 1: Women, pre IOL

The interviewer will ensure that the participant has consented and is willing to continue. The patient and researchers will move to a private room on the ward. The interviewer will thank the participant for agreeing to be interviewed and will attempt to make them feel as relaxed as possible.

To achieve the study objectives following the semi-structured schedule will be followed. The discussion will be participant-led with prompting questions from the interviewers.

Potential prompts are written in brackets, in italics, which can be used if the patient is not forthcoming with their responses. These do not have to be used, but could help the participant share more information if they are shy.

Setting of ground rules

Explain:

- The study and why it is being done
- Tape recording and transcription
- Study numbers/confidentiality
- Use of interpreter, if necessary
- That the participant can stop at any time
- That the participant can refuse to answer questions
- Explain opportunity to ask questions at any time
- Encourage participant be talkative and share their views as much as possible

Check consent form is signed, and the patient is happy to proceed

Check both tapes and start recording

Interview guide

Open by stating that we are trying to find out about how women feel about induction of labour, any previous experiences of it and what they know about it. So, we understand that your doctor has recommended induction of labour for you and you are already recruited to the MOLI trial.

- Can you tell me what induction of labour is and what you understand about it? *(Having medications to start labour, what does it mean? Have you heard of it before? What did your doctor say about it to you?)*
- Please can you describe to me the process of labour induction?

  (What will they do to help start your labour? Will they give you drugs? Which ones? Any other methods?)

- Can you explain why are you having an induction of labour?

  (Having medications to start labour, do you have a medical condition? What is it? What did the doctor say?)

- How do you feel about it?

  (In your own words tell me what you think about being induced/having medicine to start labour)

- Can you explain what things are important to you about this process?

  Different things are important to different people and we would like to know what you think, it could be anything from timings, to safety, to place of birth, to the care you receive, to your family's thoughts, just what you think)

- Of these things (mentioned in last question), what is the most important thing?
  (The one thing that is the most important thing to you, it could be anything. If you had to choose one aspect, which would it be)

- Is there anything that you feel particularly positive/happy about this process?

  (Things you were glad about or liked)

- Is there anything that makes you feel particularly concerned/worried about this process?

  (Things that you didn't like or made you sad/unhappy/sad about or things that could be better)

- What do your family members/husband/think about this process?

  (Is anyone in the hospital with you now? What do they think/feel about you being induced?)

- Have you ever been induced before/any of your relative/friends been induced before?

  (Had the drugs to start labour off, your friends? mother? sisters?)

- What was your experience/their experiences like? Can you describe them?

  (How did they find it? We're they happy or sad about it? What do you remember them telling you about it)

- What do you think being induced will be like for you?

  What do you expect will happen? How do you think you will feel?

- Can you tell me what you know about how your baby will be monitored (looked after) during labour?

  Will they listen to the babies heart beat during labour? How will they do this? Why do they do this? Is it important?

- Can you tell me about the different types of fetal heart monitoring?

  (e.g. intermittent auscultation with Pinnard/Doppler or CTG intermittent/continuous)

- What is important to you about monitoring the baby's heart beat during labour?

  (How often, how long, straps around your tummy, who does it, why they are doing it, if its normal etc)

- Do you have any preferences about how your baby is monitored? Why?

  Do any of these methods seem better than others? Or worse? Why? Do any methods appeal to you? Do any methods concern you? Why?

- In some places around the world staff and women worry that listening to the babies heart beat all of the time in labour, using electronic monitoring, could mean extra false alarms and this means increases in interventions such as caesarean sections, unnecessary tests, or forceps deliveries, which are not needed. How do you feel about this?

  Does that worry you? Is it important to you?

- If you could choose, how would you like to give birth? *(CS, forceps, normal)* And why?
- As part of the study paperwork you completed the Mother Generated Birth Satisfaction Index, (show the CRF) how did you feel about this process?

  Was it clear? Was it confusing? Was it too long? Or too short? Was it hard to think of the answers?

- Do you feel that what was written on the form reflects your current thoughts about birth?

  Do the answers on the form reflect your honest thoughts and priorities?

- Is there anything you want to add or tell me about that hasn't been discussed?

After completion of the interview/discussion, ask the participant if they have any questions, thank them for their time and stop the recording.

Interview Guide 2: Women, postnatal

The interviewer will ensure that the participant has consented and is willing to continue. The mother and child must also be settled and feeling well enough for the interview. The patient and researchers will move to a private room on the ward. The interviewer will thank the participant for agreeing to be interviewed, congratulate her on the birth of her child and will attempt to make them feel as relaxed as possible.

To achieve the study objectives following the semi-structured schedule will be followed. The discussion will be participant-led with prompting questions from the interviewers.

Potential prompts are written in brackets, in italics, which can be used if the patient is not forthcoming with their responses. These do not have to be used, but could help the participant share more information if they are shy.

Setting of ground rules

Explain:

- The study and why it is being done
- Tape recording and transcription
- Study numbers/confidentiality
- Use of interpreter
- That the participant can stop at any time
- That the participant can refuse to answer questions
- Explain opportunity to ask questions at any time
- Encourage participant be talkative and share their views as much as possible

Check consent form is signed, and the patient is happy to proceed

Check both tapes and start recording

Interview guide

Open by stating that we want to explore women's understanding of and feelings towards induction of labour.

We understand that you were a participant in the MOLI trial and your labour was induced.

- Please can you tell me about the induction process and labour and how it was for you? What happened?

  (Can you remember when you were first given medicines to start labour, how did you feel, what happened next, then what happened…)

- Do you know which induction method you had?

  (Breaking waters, tablet/tablet or tablet/hormone drip)

- How do you feel about the induction in general?

  (In your own words tell me what you think about being induced/having medicine to start labour, did you like/dislike the idea)

- Was the process acceptable for you overall?

  (All in all, did the induction and labour go ok? When you look back on it, how did it go)

- Is there anything that you feel particularly positive/happy about this process?

  (Things you were glad about or liked)

- Is there anything that makes you feel particularly concerned/worried about this process?

  (Things that you didn't like or made you sad/unhappy/sad about or things that could be better)

- How did going through the induction process compare to what you thought it would be like before the induction?

  (Was having the medicines like how you imagined it to be? Was it better or worse? Or had you not really thought about it? Which aspects were different)

- Before you had your baby, what were the most important things to you about the process?

  (Tell me all of the things that were important to you before you had your baby, of these which was the most important or the thing you cared about the most?)

- What is the most important thing to you now, about this induction process, now that you have gone through it and you have had your baby?

  (Tell me all of the things that are important to you now, of these which is the most important or the thing you care about the most?)

- Is what is important to you now after the birthing process, the same as what was important to you before you had your baby? How has your view changed?

  (Tell me all of the things that are important to you, are these the same now that you have had your baby?)

- Was there anything especially good about the induction method that you had?

  (Things you were glad about or liked about the tablets/drip)

- Was there anything bad/that you did not like about the induction method that you had?

  (*Things that you didn't like or made you sad/unhappy/sad about or things that could be better about the tablets/drip)*

- Would you use this method (tablets/drip) again if you had the choice? Why?

  (If you had to be induced again, would you choose to have the tablets or the drip when you have your next baby, what did you like/not like about it?)

- Would you recommend this method to a friend/family member? Why?

  (If you were advising your friend or family member, which medicine would to suggest? tablets/drip?, what did you like/not like about it?)

- If you could choose to have the drip or the tablets throughout labour, which would you prefer? Why?

  (Tablets/drip, what did you like/not like about it?)

- Which way was your baby born? (caesarean/forceps/normal)
- How do you feel about this?

  (Happy, sad, indifferent)

- Which way do you think is the best way for a baby to be delivered? (caesarean/forceps/normal) Why?

  (If you could choose which way to deliver a baby, which way is the best?)

- Can you describe to me how your baby monitored during the labour? *(Describe hand held device IA and CTG machines)*
- How often was it done?

  (Regularly, every hour, never, all of the time, 2x in labour 20x in labour)

- How did you feel about this fetal monitoring?

  (Happy, sad, indifferent, did you notice it?)

- Do you know of any other ways of monitoring the baby in labour?

  (Describe hand held device and CTG machines)

- Was there anything good about it?

  (Monitoring the babies heart beat)

- Was there anything that could have been better about it or you didn't like?

  (*Things that you didn't like or made you sad/unhappy/sad about or things that could be better about the tablets/drip)*

- What fetal monitoring would you ideally like if you could choose?

  (Describe hand held device and CTG machines)

- As part of the study paperwork you completed the Mother Generated Birth Satisfaction Index, (show the CRF) how did you feel about this process?

  Was it clear? Was it confusing? Was it too long? Or too short? Was it hard to think of the answers?

- Do you feel that what was written on the form reflects your current thoughts about birth?

  Do the answers on the form reflect your honest thoughts and priorities?

- Is there anything you want to add or tell me about that hasn't been discussed?

After completion of the interview/discussion, ask the participant if they have any questions, thank them for their time and stop the recording.

MOLI Interview Guide 3: MOLI Interview Guide: Staff focus groups – before start of trial

The researcher will ensure that the participants are happy to join the focus group and understand that this is voluntary. The interviewer will thank the participants for agreeing to join the focus group and attempt to make them feel as relaxed as possible. It is important to emphasise that any information disclosed is confidential, unless there is any potential patient harm from anything disclosed and that openness and sharing of views is essential, in order to maximise the information gathering potential of the focus group.

Setting of ground rules

Explain:

- The study and why it is being done
- Tape recording and transcription
- Study numbers/confidentiality
- That the participants can stop/leave at any time
- That the participants can refuse to answer questions
- Explain opportunity to ask questions at any time

Check consent forms are signed

Check both tapes and start recording

Interview guide

This aim of this focus group is to gather information from the staff involved in screening, recruiting, randomising and consenting for the MOLI trial in order to gather as much information as possible surrounding the trial and the different regimes. We would like to hear your honest views, so that we can understand the results of the trial better.

Research generally (ice breaker)

Tell me about your experiences of taking part in the trial MOLI Trial so far

Do you feel it will be acceptable to patients?

Do you have concerns/worries about the trial/these protocols?

Can you forsee any potential barriers to recruitment?

Can anyone suggest any potential solutions for any problems?

Can you highlight any areas for improvement?

Tell me about your previous experiences of induction of labour

Any positive?

Any negatives?

How do patients find induction of labour?

What is the hardest part of induction for women?

In this trial there are two treatments, one is a misoprostol/oxytocin regime

Do you have any experience of using this regime?

What were your previous experiences of using the miso/oxytocin regime?

Any positive?

Any negatives?

How do patients find it?

The other treatment in this trial is misoprostol/misoprostol regime, using misoprostol from the start of induction to birth

Do you have any previous experiences of using the miso/miso regime?

Do you have concerns/worries about using it?

How do you think it will work logistically?

As part of the MOLI trial, we plan to have more CTG machines available on labour ward and to do some training about fetal monitoring in labour

What do you currently use for fetal monitoring in your hospital?

How well does this work?

Are there any good things about it?

Any bad things about it?

How do you feel about having CTGs on labour ward?

Do you feel it will change patient care?

How?

Are there any good things about it?

Any bad things about it?

Internationally there is concern that introducing CTG could increase the intervention rate e.g. increase the caesarean rate. How do you feel about this?

Is there anything you want to add or tell me about that hasn't been discussed?

After completion of the focus group, ask the participants if they have any questions, thank them for their time and switch off the recording.

Interview Guide 4: Staff focus groups during trial

The researcher will ensure that the participants are happy to join the focus group and understand that this is voluntary. The interviewer will thank the participants for agreeing to join the focus group and attempt to make them feel as relaxed as possible. It is important to emphasise that any information disclosed is confidential, unless there is any potential patient harm from anything disclosed and that openness and sharing of views is essential, in order to maximise the information gathering potential of the focus group.

Setting of ground rules

Explain:

- The study and why it is being done
- Tape recording and transcription
- Study numbers/confidentiality
- That the participants can stop/leave at any time
- That the participants can refuse to answer questions
- Explain opportunity to ask questions at any time

Check consent forms are signed

Check both tapes and start recording

Interview guide

This aim of this focus group is to gather information from the staff involved in screening, recruiting, randomising and consenting for the MOLI trail in order to gather as much information as possible surrounding the trial and the different regimes. We would like to hear your honest views, so that we can understand the results of the trial better.

MOLI Trial

How do you feel the trial has gone so far?

Has anything gone particularly well/you liked?

Do you have concerns/worries about the trial?

Is there anything that could have been done better?

Tell me about your previous experiences of induction of labour

Any positive?

Any negatives?

How do patients find induction of labour?

What is the hardest part of induction for women?

In this trial there are two treatments, one is a misoprostol/oxytocin regime

What are your experiences of using the miso/oxytocin regime?

Any positive aspects/benefits for patients or staff?

Any negative aspects for patients or staff?

Do you think it works well?

How do patients find it?

Suggestions for improvements?

The other treatment in this trial is misoprostol/misoprostol regime, using misoprostol from the start of induction to birth

What were your experiences of using the miso/miso regime?

Any positive aspects/ benefits for patients or staff?

Any negative aspects for patients or staff??

How do patients find it?

Barriers for implementation if found to be better?

Suggestions for improvements?

If you/your relative/friend had to be induced, which regime would you prefer and why?

As part of the MOLI trial, we plan to have more CTG machines available on labour ward and to do some training about fetal monitoring in labour

Tell me about the different types of fetal monitoring available on labour ward currently

Which fetal monitoring do you prefer and why?

How well does this work?

Have you noticed that there are now more CTG machine on labour ward?

How do you feel about having more CTG machines on labour ward?

Do you feel it has changed patient care at all?

How?

Has it had any good changes/impacts?

Has it had any bad changes/impacts?

Internationally there is concern that introducing CTG could increase the intervention rate e.g. increase the caesarean rate. How do you feel about this?

How do you feel about the Mother Generated Birth Satisfaction Index used?

Is there anything you want to add or tell us about that hasn't been discussed?

After completion of the focus group, ask the participants if they have any questions, thank them for their time and switch off the recording.