AN INVESTIGATION INTO QUALITY OF CARE AT THE TIME OF BIRTH AT PUBLIC AND PRIVATE SECTOR MATERNITY FACILITIES IN UTTAR PRADESH, INDIA

GAURAV SHARMA

Thesis submitted in accordance with the requirements for the degree of Doctor of Philosophy of the University of London

JULY 2017

Department of Infectious Disease Epidemiology

Faculty of Epidemiology and Population Health

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Research group affiliation(s): Centre for Maternal, Reproductive and Child Health (MARCH)

Funding: MSD for Mothers

Declaration by candidate

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

Signed:  .....

Date: 7 December 2017

Abstract

Background: Ensuring high quality care during labour and childbirth is important to eliminate preventable maternal deaths, neonatal deaths and intrapartum stillbirths. My PhD investigates quality of care (QoC) during normal labour and childbirth, and examines whether QoC is influenced by management practices at 26 public and private sector maternity facilities in Uttar Pradesh, India.

Methods: First, I conducted clinical observations of labour and childbirth. I used descriptive statistics and multivariate analysis techniques to describe and compare differences in overall QoC, and quality for obstetric and neonatal care. Second, I used quantitative and qualitative methods to describe existing patterns of mistreatment encountered by women. Third, I described existing management practices using a separate survey dataset and linked both QoC and management datasets to examine the relationship between management practices and QoC.

Results: QoC was found to be poor at both public and private sector facilities. The private sector outperformed public sector facilities for overall essential care at birth, and for both obstetric and newborn care. All women encountered at least one indicator of mistreatment. There were no significant differences between qualified and unqualified personnel for QoC and mistreatment levels. Qualitative results suggest that informal payments are widespread, maternity care pathways are non-functional, and there are poor hygiene standards. Lastly, I found that maternity facilities scored poorly on management best practices. Overall, I found no association between total management scores and QoC.

Conclusions: The results of my PhD study indicate that in 2015, in maternity facilities of Uttar Pradesh, unqualified personnel provided the bulk of maternity care, adherence to evidence-based obstetric and neonatal care protocols was generally poor and all women encountered at least one practice of mistreatment. These results suggest the need to comprehensively measure and urgently improve QoC at the time of birth in Uttar Pradesh, India.

Acknowledgements

I am grateful for all the guidance and support that I have received and the people that I have met in this journey. For a passionate public health doctor from Nepal, it was a life-long dream to come to the LSHTM and learn advanced research skills.

This work would not have been possible without the mentorship of my excellent supervisors. I am deeply grateful to Professor Veronique Filippi, my primary supervisor, who always provided me with timely and insightful guidance, and treated me with immense kindness during the entire process. I am also indebted to Dr. Timothy Powell-Jackson, my co-supervisor, who provided superb mentorship and guidance throughout this process. I am grateful to Ms. Loveday Penn-Kekana for her advice on the qualitative aspects of my work and for many interesting discussions. Dr. John Bradley has been an integral member of my supervisory panel and provided timely guidance on quantitative aspects of my work.

I would also like to acknowledge many other inspiring academics within the maternal health group and the MARCH centre at the LSHTM, whose work has and will continue to inspire me. In particular, I have benefitted from many informal discussions with Professor Oona Campbell and I am grateful to her for generously giving me time and sharing her wisdom. I am also thankful for my friends, Schadrac Agbla and Anower Hossain for sharing this journey with me, their encouragement and for always helping me with any statistical problems that I encountered.

My PhD work has also been deeply informed by my past professional experiences, and I am grateful to my previous supervisors and mentors for their encouragement and ongoing support. My stay in Lucknow would have been miserable if it was not for Mr. Biren Thapar and I am grateful for his friendship and kindness.

This PhD thesis is dedicated to my parents and to my wife June. Thank you for allowing me to undertake this; and, for your unconditional love, support and sacrifices during this challenging process.

Table of Contents

List of Tables

Lists of figures

List of abbreviations

AMDD	Averting Maternal Death and Disability Program
AMTSL	Active Management of the third stage of labour
ANC	Antenatal care
ANM	Auxiliary Nurse midwife
ARR	Annual Rate of Reduction
ASHA	Accredited Social Health Activists
ASME	Advanced Statistical Methods in Epidemiology
BEmOC	Basic Emergency Obstetric Care
CEmOC	Comprehensive Emergency Obstetric Care
CHC	Community Health Centres
EmOC	Emergency Obstetric Care
EmONC	Emergency Obstetric and Newborn care
ENAP	Every Newborn Action Plan
EPMM	Ending preventable maternal mortality
IMPAC	Integrated Management of Pregnancy & Childbirth
FIGO	The International Federation of Gynaecology and Obstetrics
FRU	First Referral Units
JSY	Janani Suraksha Yojana
LMICs	Low and Middle-Income Countries
LSHTM	London School of Hygiene & Tropical Medicine
MARCH	Centre for Maternal, Adolescent, Reproductive and Child Health
MBA	Masters of Business Administration
MET	Maternal healthcare markets Evaluation Team
MCHIP	Maternal Child Health Integrated Program
MDG	Millennium Development Goals
MMR	Maternal Mortality Ratio
MNCH	Maternal, Newborn and Child health
MNH	Maternal and Newborn health

MOHFW	Ministry of Health and Family Welfare
MSD	Merck Sharp and Dohme Corp.
MICS	Multiple Indicator cluster survey
NICE	National Institute for Health and Clinical Excellence
NGOs	Non-Governmental Organizations
NRHM	National Rural Health Mission
NMR	Neonatal Mortality Rate
PHS	Public Healthcare Society
PhD	Doctor of Philosophy
PDSA	Plan Do Study Act
PCACL-R	Perceptions of Care Adjective Checklist
QoC	Quality of Care
QPP-I	Intrapartum-specific Quality from the Patients Perspective questionnaire
RMNH	Reproductive, Maternal and Newborn Health
RHFA	Rapid Health Facility Assessments
SARA	Service Availability and Readiness Assessment
SBA	Skilled Birth Attendant
SDGs	Sustainable Development Goals
SME	Statistical Methods in Epidemiology
SPA	Service Provision Assessment
SSQ	Six Simple Questions
UP	Uttar Pradesh
UK	United Kingdom of Great Britain and Northern Ireland
UHC	universal health coverage
USA	United Sates of America
USAID	United States Agency for International Development
UN	United Nations
WHO	World Health Organization

Chapter 1. Introduction

1.1. Motivation for the thesis

Although there has been considerable progress in maternal and newborn health over the past two decades, provision of high-quality care for women once they reach healthcare facilities has emerged as an important challenge.[1] Poor quality of care at the time of birth hampers health outcomes for women, children and communities; and research efforts should identify ways to improve the current state of affairs.

1.1.1: The high and inequitable burden of maternal and neonatal deaths

Maternal and newborn health are important issues for sustainable development. With an estimated annual 210 million pregnancies and 140 million live births globally, ensuring that every woman and every newborn across the globe has the right to high quality care is a formidable challenge.[2] The era of the Millennium Development Goals (MDGs) led to good progress and maternal deaths declined by nearly half (44%). However, this progress was inconsistent across many parts of the world, and many countries could not achieve the MDG 5a target of a 75% reduction in the maternal mortality ratio (MMR).[2]

In 2015, the MMR in high-income countries (12 per 100 000 live births) was found to be 46 times lower than the highest MMR in sub-Saharan Africa (546 per 100 000).[2] Similarly, the lifetime risk for maternal deaths in 2015 was more than 100 times higher in sub-Saharan Africa: one in 36 compared to one in 4900 in high-income countries.[2] During this time, inequalities also worsened. For example, in 1990 the pooled MMR for 10 countries with the highest levels of maternal mortality was 100 times greater than the pooled MMR for 10 countries with the lowest MMR levels. However, by 2013, this gap had doubled to 200 times greater. [2] These data suggest that improving maternal health is still an unfinished agenda.

1.1.2: Relevance of the research to ongoing global efforts

In 2016, world leaders welcomed the Sustainable Development Goals (SDGs), which unlike the MDGs, have a broader development focus.[3] Goal three of the SDGs is concerned with ensuring healthy lives for all, and has five health targets including a specific target for maternal mortality. [3] The targets for reducing preventable maternal mortality are that by 2030, all countries should reduce MMR by two thirds and no country should have an MMR

above 140.[4] The World Health Organization (WHO) and partners have called for intensified action, particularly in countries with MMR greater than 420 per 100,000 live births.[4] It is hoped that with collective efforts, the global target of MMR of less than 70 per 100,000 live births by 2030 can be achieved[4]. At the national level, two countries, Nigeria at 19% (58,000 deaths) and India at 15% (45,000 deaths) contributed up to one third of the global burden of maternal deaths in 2015.[5] Therefore, both these populous countries have to make rapid reductions in maternal mortality if the Global Strategy for Women's, Children's and Adolescents' Health's targets are to be met by 2030.[6]

The main strategy used to achieve maternal and newborn health targets during the MDGs was to expand coverage of simple and effective interventions proven to work against the main causes of deaths. Success was primarily measured through increased population coverage of indicators such as institutional births, deliveries by skilled attendants or antenatal care.[7] There was good progress between 1990 to 2013; the proportion of births occurring with skilled birth attendants (SBA) increased from 57% to 74%; the proportion of women receiving one or more antenatal care (ANC) visits increased from 65% to 83%; and four or more ANC visits rose from 37% to 64%.[8,9] However, increasing coverage alone without a specific focus on QoC may not be optimal for reasons outlined below.[7]

First, there is now increasing research evidence suggesting that, despite increased coverage of institutional births, associated declines in perinatal and neonatal mortality have been modest as shown by studies in India[10,11] and Rwanda.[12] In a recent cross-sectional study from Malawi, researchers also found that poor health facility quality was associated with higher risk of neonatal mortality.[13]

Second, global monitoring efforts are primarily designed to support global, regional and national comparisons of coverage indicators such as ANC visits, institutional births and SBA presence at delivery. These indicators track use of health care rather than content of care; therefore, a quality gap may arise despite the increased population coverage. [14] Furthermore, features beyond SBA and ANC coverage are likely to be important. For example, a high population density and long travel times may cause delays in access to emergency obstetric

care (EmOC), and women's underlying health conditions, nutritional status and other life circumstances also influence birth outcomes.[15]

Third, the main causes of maternal deaths in 2015 were found to have shifted away from the more preventable direct causes to indirect causes such as non-communicable diseases and other intractable direct causes such as ectopic pregnancies, embolism and gestational diabetes. [2] Therefore, there is growing recognition that improving maternal and newborn health outcomes in the SDG era will require an additional emphasis on quality of care once women reach health facilities.[7] I will elaborate on these issues further in the literature review section in chapter 2.

1.1.3: Importance of care at the time of birth

Despite the focus on promotion of institutional deliveries, the quality of routine care for normal labour and childbirth has not received enough research and programmatic attention.[15,16] The time around childbirth has always been the riskiest for women in many parts of the world.[16-18] Recent estimates suggest that closure of the quality gap through the provision of effective and woman-centred care for all women and newborn babies delivered in facilities could prevent an estimated 113,000 maternal deaths, 531,000 stillbirths, and 1·32 million neonatal deaths annually by 2020.[19]

Consensus exists on a minimum care package of interventions required during pregnancy, labour and childbirth[20]. High quality, routine care during labour and childbirth has the potential to prevent many maternal and neonatal deaths, either through the prevention of complications or by timely intervention prior to the development of complications.[21] For example, one of the elements of routine care includes the use of a partograph, which if used correctly, can alert us to the start of prolonged or obstructed labour. Similarly, the provision of active management of the third stage of labour (AMTSL) can reduce the risk of post-partum haemorrhage.

In addition to this package for routine care, some women and babies require higher-level care for complications. Facilities that provide such emergency obstetric and neonatal care are classified as Basic Emergency Obstetric Care (BEmOC) facilities or Comprehensive Emergency

Obstetric Care (CEmOC) facilities based on the provision of specified signal functions.[22] Signal functions includes clinical capabilities like providing injectable antibiotics, magnesium sulphate, oxytocics and procedures like assisted vaginal delivery, blood transfusion, caesarean operations and others. [22]

However, there are widespread examples in the literature which indicate that a high proportion of births occur in facilities that are not fully capable of providing the appropriate signal functions for obstetric care. [15, 23, 24 ,25] For example, providing assisted vaginal deliveries, injectable oxytocics or blood transfusion services are challenging in many resource-constrained settings.[16, 23]

Existing routine health information systems do not capture information on specific elements of care during normal labour and childbirth from women giving birth in LMIC hospitals. These individual level data on quality of routine care are essential for improvement purposes, but are only available through dedicated studies and hence, there is limited information on this topic. However, there are currently ongoing efforts at the global level to define metrics for quality of care at the time of birth[26] and on elements of skilled attendance at birth (SAB), which make this PhD relevant to these ongoing global efforts.

1.1.4: Evidence on QoC for maternity services in the private sector is limited

The private sector provides a range of health services including maternity care in LMIC settings and as I will show in the literature review section (chapter 2), evidence on quality of health services provided by the private sector is limited. The private sector can vary from small to large for-profit companies, or private practices formed by a group of health workers or clinics run by national and international non-governmental organizations and clinics run by individual health workers and pharmacies.[27]

There are arguments for and against the role of the private sector in providing essential health services. Proponents argue that the private sector is already an established provider of health services in many settings and can make significant contributions to expand efficient and high-quality health services to underserved populations.[28,29] Sceptics argue that since the private sector prioritises profits over public health impacts, they are unlikely to provide high quality services at low costs particularly in underserved populations.[30]

Despite these ideological arguments, the size and the market share of the private sector across LMIC settings appears to be increasing.[31,32] Although, the public sector still provides the majority of services globally, across the continuum of care, in terms of reproductive, maternal and newborn health, the private sector's contribution is substantial and estimates indicate that 19% of maternity care, 32% of antenatal care, and 22% of family planning services globally are provided in the private sector.[33]

The rapid growth of the private sector has drawn attention to many problems that it often shares with the public sector, which includes low standards of care, poor infrastructure, lack of qualified staff, inadequate or poor equipment and medical malpractice.[31] In addition, the ability to regulate the private sector has also not kept pace with its growth. Some challenges for regulation have included lack of government institutional capacity, the large size of the private sector, lack of resources and often-corrupt relationships between state and private sector actors. [31,34]

The heterogeneity and complexity of the private sector in LMICs such as India also means that high-quality research evidence on QoC in the private sector is limited. Many published studies have focussed on the increasing medicalisation of childbirth in the private sector, especially given high rates of caesarean sections among women seeking care in the private sector. [24,35-39] However, detailed evidence on quality of routine care for normal births in LMIC private sector facilities is limited. Therefore, further research to investigate the QoC for normal labour and childbirth in the private sector is important, especially in places like India, where estimates indicate that 22% of all deliveries occur in the private sector. [40]

1.1.5: Management practices at maternity facilities is an under-researched area

Strong management competencies are thought to be essential to ensure that health systems can respond to population needs.[41] While, these competencies are important in all settings, they seem particularly indispensable in LMIC settings, which are characterised by high burdens of maternal and neonatal mortality and hospitals here operate in an environment of resource-scarcity. [41] Further, since hospitals are the most expensive, resource-intensive and politically sensitive components of health systems, management practices at health facilities seem particularly important. In both public and private sector facilities, good management

practices seem essential to maintain effective hospital operations, hospital performance, hospital targets and to ensure good human-resource management. [42-45]

As I will explain in greater detail in the literature review section (chapter 2) empirical evidence on management practices at maternity facilities in LMIC settings is limited. Perhaps because management practices are hard to measure quantitatively and because methodological advances in measurement have been recent, most research on this topic originates from high-income settings.[42-45] Consequently, there is limited information on management practices and its relationship with QoC at maternity facilities in LMIC settings.

In high-income settings, large-scale data collection efforts such as the World Management survey (http://worldmanagementsurvey.org/), which collects data from over 2,000 hospitals in nine countries exist. These management data can often be linked to routinely collected clinical data available from electronic medical records of hospitals in high-income settings and the relationship between management and QoC examined. However, such data is generally not available in hospitals in LMIC settings.

Given that management practices have the potential to influence all elements of the maternity care pathway at facilities, the relationship between management and QoC needs detailed investigation. Examining whether management practices have the potential to drive gains in quality in LMIC settings is an innovative and interesting area of research with significant evidence gaps. In addition, given recent methodological advances, a comprehensive assessment tool,[42,43,46] is available that can be adapted and used to assess management practices at maternity facilities in India.

1.2. Purpose of the thesis

The central purpose of my thesis is to develop a detailed understanding of QoC during labour and childbirth at 26 public and private sector maternity facilities in Uttar Pradesh, India. Uttar Pradesh (UP) is a populous state with low rates of institutional deliveries and future progress in this Indian state has important implications for maternal and newborn survival in India.

To fulfil my research aim, I conducted clinical practice observations and assessed QoC provided during labour and childbirth for 275 mother-baby pairs at 26 maternity facilities. I assessed and described overall quality of care at the time of birth and specifically quality of obstetric and neonatal care at these maternity facilities. I also investigated whether QoC is associated with characteristics of the women, characteristics of health workers and characteristics of maternity facilities in three districts of Uttar Pradesh, India.

Thereafter, I identified practices that constitute mistreatment of women, assessed and described the nature, patterns and determinants of mistreatment encountered by women during labour and childbirth at these maternity facilities. I also investigated whether mistreatment is associated with socio-demographic characteristics of women, characteristics of health workers and characteristics of maternity facilities.

Another innovative component of my PhD is the investigation into management practices at maternity facilities, which I assessed through a separate survey with health facility managers in Uttar Pradesh. I described existing management practices at maternity facilities and examined whether there is a relationship between quality and management practices at maternity facilities

Investigating QoC for normal labour and childbirths comprehensively including any observed mistreatment is an important area for research particularly since there are many information gaps related to quality, especially in private sector. Moreover, investigating whether management practices have the potential to influence quality of care is an under-researched area. Generating evidence on these important questions could support quality improvement efforts in maternal and newborn health in low-resource settings.

1.3. Outline of thesis

This is a "research-paper-style" thesis with three prepared manuscripts presented as chapters. Chapter two presents a review of the literature relevant to the research questions addressed by my thesis. In this chapter, I provide an overview of why quality of care is important at maternity facilities; introduce concepts of essential care at the time of birth; maternity care pathways; skilled birth attendance and outline interventions that are recommended and not recommended for provision of care at the time of birth. I also discuss the concepts of respectful maternity care. Thereafter, I discuss concepts of quality of care, frameworks, definitions and measurement of QoC in maternal and newborn health using the framework of structure, process and outcomes. Thereafter, I outline the empirical evidence on deficiencies in QoC at the time of birth based on my review of the literature from India using the quality of care framework. Finally, in the last section of the literature review, I summarise the theoretical concepts and empirical evidence on management practices and quality of care.

In chapter 3, I describe the study setting, provide an overview of the health system, maternal and newborn health services provided at public sector facilities and discuss the evolution of quality in maternal health programmes in India. I then discuss my doctoral research within the larger evaluation of the *Matrika* project.

In chapter 4, I outline my role in conducting this doctoral research, funding and overall timeline for this research. In chapter 5, I present a conceptual framework for my PhD, and discuss the aim, objectives and design of the studies described in this PhD. Thereafter, I provide an overview of the methods used in the different research studies presented in this thesis. However, detailed methods for each study are also presented in individual results chapters (chapters 6-8).

Chapter six presents the first research paper entitled "Quality of essential care at the time of birth: Findings from clinical observations of spontaneous labour and childbirth at 26 public and private sector facilities in Uttar Pradesh, India." Addressing objective one, this paper describes the overall quality of care, and quality for obstetric and neonatal care during normal labour and childbirth at 26 maternity facilities in Uttar Pradesh. This manuscript has been

peer-reviewed and a slightly shortened and edited version was published by the Bulletin of the WHO in a special series on quality of care (published in June 2017). [47]

Chapter seven presents the second research paper entitled "An investigation into mistreatment of women during labour and childbirth in maternity care facilities in Uttar Pradesh, India: a mixed methods study". Addressing objective two, this paper investigates and describe the nature and patterns of mistreatment observed during labour and childbirth at maternity facilities. I aim to submit this manuscript to Reproductive Health.

Chapter eight presents the third research paper entitled "Management is not associated with quality of care during labour and childbirth: evidence from cross-sectional study of maternity facilities in Uttar Pradesh, India". Addressing objective three, this paper describes management practices at maternity facilities in Uttar Pradesh, India and demonstrates that overall management practices are not associated with QoC during labour and childbirth in maternity facilities in Uttar Pradesh. I aim to submit this manuscript to Health Affairs or a similar journal.

Chapter nine synthesizes the main findings from these papers, discusses my reflections on the different studies described in this thesis, and the strengths and limitations of individual studies. I then discuss the implications of my PhD findings for research, programmes and policy, and provide recommendations. In Chapter 10, I present the conclusions of my PhD.

Chapter 2: Literature review

2.1: Introduction

This chapter aims to improve our understanding of the literature on quality of care at the time of birth and management practices at hospitals. I conducted a comprehensive review of the literature on quality of care during labour and childbirth and management practices at hospitals with a focus on LMIC settings. As my research objectives covered a broad range of topics and I was interested in research from a range of disciplines such as economics, hospital management, and health care administration, it was not possible undertake a systematic literature review. However, I have tried to ensure that my literature review is comprehensive and covers all key aspects of management practices at health facilities and quality of care for maternal and newborn health.

To examine the literature on QoC at the time of birth at maternity facilities in LMICs, I searched published papers and the latest WHO, United Nations (UN) resources and other reports examining QoC in health services and specifically QoC in maternal and newborn health in LMIC settings. Searches were carried out in Medline and google scholar by combining the relevant free-text and Medical Subject Headings (MeSH) for terms, such as 'quality of care,' with those for the field of interest ('maternal health,' 'safe motherhood,' or 'obstetrics;' 'newborn' or 'neonatal;' or 'childbirth' or 'intrapartum' or 'intra-partum' or 'hospital' 'health facility' 'maternity facility'; 'postpartum' or 'post-partum'; 'puerperal' or 'puerperium' or 'pregnancy' or 'delivery'). In Medline, I applied search limits and restricted results to studies from LMIC settings, involving human subjects, articles in English, published during 1980 to 2016. Additional articles and reports were identified through web searches of organisations working in maternal and neonatal health, conferences or meeting reports, and from experts in the field. Additional references were also identified from the reference lists of peer-reviewed journal articles and published reports.

For the study on management practices at hospitals, the search strategy involved three key free-text search terms: management, quality of care and hospital setting. Searches were conducted using these free-text search terms in Medline and google scholar. In addition to these key terms, Medical Subject Headings (MeSH) terms were used in Medline, which were

'exploded' to include all MeSH subheadings. Limits were applied to restrict articles published in English, involving human subjects, between 1980 and 2016. In addition, I also conducted extensive web searches to identify reports produced by management consulting firms, working papers in economics, hospital management produced leading experts in the field of management and economics. Additional references were also extracted from the reference lists of relevant published manuscripts, monographs and reports.

In the subsequent sections of chapter 2, I will present the key findings from my literature review.

2.2: The importance of quality at maternity facility in LMIC settings

Despite the impressive improvements in maternal and child health during the era of the Millennium Development Goals, approximately 5.6 million women and babies died in 2015 during pregnancy, labour, childbirth and the neonatal period.[5, 48,49] In order to achieve the new mortality targets set out in the Sustainable Development Goals, there needs to be a renewed emphasis in research, programmes and policies that aim to reduce preventable maternal deaths, neonatal deaths and stillbirths.[50]

For maternal mortality, as indicated in the introduction, the global target for 2030 is an MMR of less than 70/100,000 live births with different sub-targets for specific contexts.[4] Countries, depending on their baseline levels in 2015, should either reduce their MMR by at least two-thirds of their baseline, not have an MMR greater than 140/100,000 live births by 2030, or achieve reductions in inequalities in MMR at a subnational level. These sub-targets require an annual rate of reduction (ARR) of mortality greater than 5.5% in the countries with the highest MMRs (MMR >420/ 100,000). [4,50]

For neonatal deaths, the Every Newborn Action Plan set an absolute target of 12 or fewer neonatal deaths per 1000 live births in every country by 2030. An ARR of 4.3% will be needed to achieve the global NMR target, but this varies considerably between countries, with 29 countries needing to at least double their ARR.[18,51] For stillbirths, the ENAP set an absolute target of 12 or fewer stillbirths per 1000 total births in all countries by 2030. To achieve this, a global ARR of 4.2% is needed and 56 countries will need to double their ARR.[52]

Researchers have also demonstrated that it is essential to go beyond ensuring increased coverage and utilisation of services to reduce maternal and neonatal deaths. [53] As noted in the introduction, studies from India, Malawi and Rwanda have shown that greater access to institutional deliveries was not associated with reductions in neonatal mortality; a finding they attribute to poor quality of care at health facilities. [10,12,13] In a multi-country study, higher than expected maternal mortality was also found in hospitals in high-mortality, LMIC countries, despite the availability of essential medicines. This suggest gaps in clinical management or treatment delays for hospitalised women who had life-threatening obstetric complications (maternal near-miss).[53]

Recent global trends have been encouraging as up to 74% of deliveries are now conducted by skilled birth attendants and up to 63% of deliveries occur in institutions.[8] With this increase in institutional births, higher proportions of avoidable maternal and perinatal mortality and morbidity have also moved into health facilities.[53] In addition, a rising proportion of maternal deaths are now due to indirect causes (27.5%), while the majority of maternal deaths (over 70%) still occur because of complications that require facility-based care, such as post-partum haemorrhage, hypertensive disorders, sepsis and complications related to abortions.[54]

Similarly, up to 85% of neonatal deaths are due to complications of preterm birth, birth asphyxia, intrapartum-related neonatal deaths and severe neonatal infections that require facility-based care. [55] In 2015, estimates also indicated that over half of the stillbirths that occur, do so after the start of labour at maternity facilities. [56]

Poor QoC at the time of birth also causes significant physical and psychological morbidities for women with negative consequences for the health and survival of infants and affects the future financial security of families.[57,58] Therefore, improving the quality of facility-based care at the time of birth offers tremendous opportunities to reduce maternal and perinatal deaths.[23]

2.3: Quality of essential care at the time of birth

2.3.1: Background

Although expanding coverage rather than quality has been the focus of maternal health programmes historically in LMIC settings, experts have argued that efforts to improve QoC at

institutions have lagged behind efforts to increase demand for institutional maternity services. [7,15,59]

Many facilities in high-burden LMIC settings are ill-equipped to provide emergency obstetric care particularly lower levels facilities.[15] A comprehensive assessment of 86 health facilities in seven districts in Ghana found that the quality of routine and emergency obstetric and newborn care was generally poor and there was a large quality gap at facilities.[60] Similarly, a cross-sectional study from Nigeria found that only 40% of primary health care facilities could provide emergency obstetric care and that most EmOC signal functions were not provided regularly.[61]

In India, cross-sectional research evidence from multiple states has found that most maternity facilities have poor EmOC capability and are not able to provide all the basic signal functions.[62-64] The knowledge, skills and competence of SBAs providing maternity services in institutions was also found to be deficient in a study from Madhya Pradesh state in India. [65] In addition, researchers have also highlighted systemic problems such as bed shortages, inadequate supplies, shortages of skilled staff, which is not conducive to the provision of high-quality and respectful care at the time of birth. [65-67] Moreover, many facilities in LMICs often lack basic requirements such as regular electricity and clean water supply. [15,61,68]

Although, skilled birth attendants working within an enabling environment has been promoted as an essential strategy to provide high-quality intrapartum care[69], many women delivering at facilities in LMIC report doing so without skilled birth attendants. In Senegal, data from 2009–14 indicates that 28% of births in lower-level facilities and 8% in hospitals occurred without skilled birth attendants.[15] In India, studies in Rajasthan have found that unqualified providers are frequently involved in maternity care provision in institutions, including in up to half of all observed cases with significant deficiencies in QoC at the time of birth.[70,71]

Other studies have also found that skilled birth attendants often do not have the required skills[72] and that numbers of SBAs deployed are frequently not enough which further exacerbates poor facility EmOC capability.[73] In a study at nine sub-Saharan African countries, researchers found that skilled birth attendants lacked adequate knowledge and skills since their training curricula did not include trainings on manual removal of the placenta. [74] Some

governments also designate cadres as skilled birth attendants, despite them lacking requisite midwifery competencies. [75,76]

Available research evidence from facilities in LMICs highlights many deficiencies in essential care at the time of birth, such as non- adherence to recommended protocols for care, [71,77,78] mistreatment of women[79-81] and early discharge from facilities without adequate postpartum monitoring.[82] The 2016 Lancet maternal health series articulated these deficiencies in care as "Too Little Too Late" which refers to absent, delayed or inadequate care and as "Too Much Too Soon", referring to over-medicalization that results in overtreatment.[83]

The reasons behind poor quality of care at facilities are multi-faceted and could arise due to many different reasons such as: lack of material resources, limited knowledge and skills, inappropriate applications of technology[84], inability of organizations to change[85] , failure to align health worker's incentives and quality improvement efforts to improved health outcomes. [86] Given the multi-faceted nature of quality as highlighted above, ensuring QoC at the time of birth has proved to be challenging.

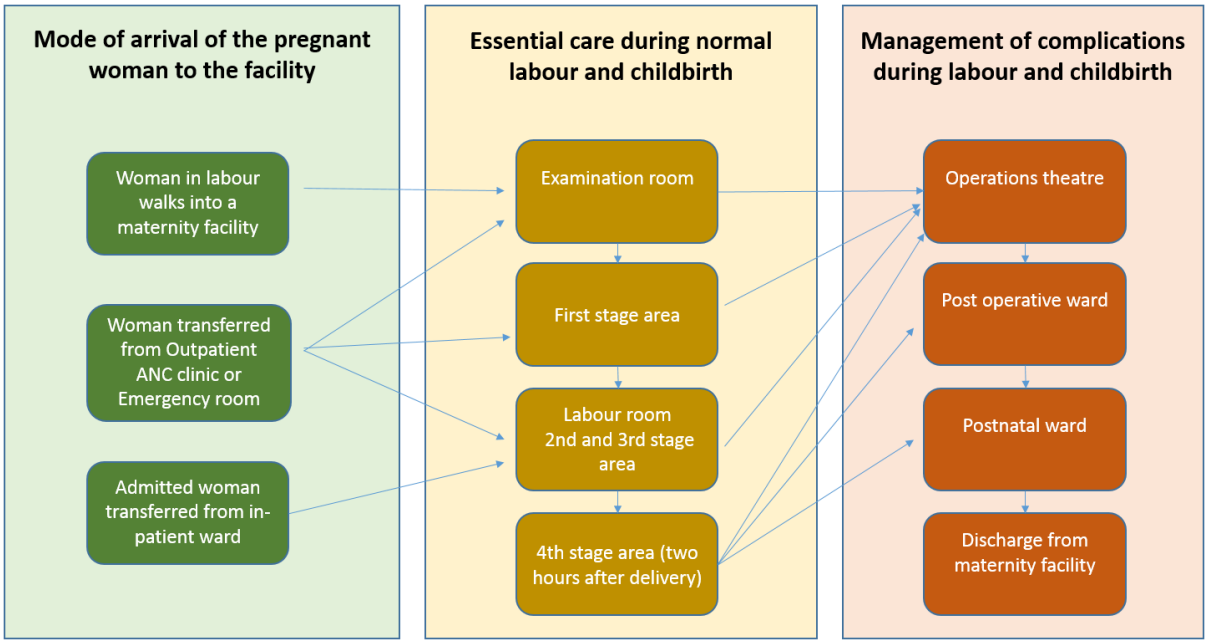
The bulk of the available research evidence on quality of essential care at the time of birth - mostly from public sector LMIC facilities - highlights the need to carefully examine existing deficiencies in QoC at the time of birth and work towards improving QoC in institutions. Research evidence shows that it is possible to improve QoC but in order to do so it is essential to define, measure and then develop appropriate strategies for quality improvement. [87,88] In the next section, I will elaborate on conceptualising and defining high-quality maternity care at facilities.

2.3.2: Conceptualising and defining high quality maternity care pathways at facilities

There is consensus that in order to reduce avoidable maternal and neonatal mortality, every pregnant woman and newborn baby will need skilled care at the time of birth with evidence-based clinical and non-clinical interventions delivered in a compassionate and enabling environment which ensures that respect, dignity and equity of care are maintained.[89] In figure 1, I have conceptualised a maternity care pathway that outlines the different ways in which a pregnant woman could arrive at a hospital, either at the onset of labour or fully in labour; her care pathway within the hospital until her discharge from the hospital after

childbirth. This is, in some ways, is similar to what others have referred to as the “gate- to-gate” approach.[90]

Figure 1: Schematic diagram of maternity care pathways for delivery



A pregnant woman may directly come to the hospital once labour begins or may be transferred to the examination or labour rooms from another place within the hospital such as the outpatient clinic or the emergency room. Upon arrival, the first step will be determined by whether the labour has actually started. An obstetric examination to assess change in uterine contractions and uterine cervix (effacement and dilation) will help to establish the stage of labour. Depending upon the stage of labour, she may be transferred to different areas of the hospital as outline in the figure 1.

To implement this maternity care pathway, it is essential that other fundamental requirements for provision of high-quality services are available. For example, teams of skilled and auxiliary health workers should be available at the hospital round-the clock. Staff should adhere to relevant clinical protocols for obstetric and newborn care. Infection prevention and control measures should be implemented rigorously. Equipment must be accessible and functional, and subject to checks during every duty shift. Drugs and consumables should be available round-the-clock. Daily rounds should be conducted by managers to identify gaps and bottlenecks, and these must be corrected on an urgent basis. The time taken from arrival of woman at the hospital to the actual receipt of services should be minimised to tackle the

third delay.[91] Specialist back-up within the hospital or referral to another higher level facility, if needed, should also be a part of the maternity care pathway.[15]

It is theoretically possible that provision of such a maternity care pathway along with other essential requirements (staff, equipment, drugs, electricity, water and others) and efficient transfer of women in case of complications, could lead to provision of high-quality maternity care at hospitals.

2.3.3: Skilled birth attendance

As noted earlier, an important strategy employed to prevent maternal and neonatal mortality, has been to ensure that skilled birth attendants (SBA), working in enabling environments, are able to attend every childbirth.[69] SBAs are defined as "an accredited health professional such as a midwife, doctor or nurse who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period, and in identification, management and referral of complications in women and newborns." [69]

Although SBAs are well defined, the enabling environment is less well-defined but considered to include the availability of equipment, drugs and a functional referral pathway.[92] Several studies have shown a correlation between an increased proportion of births attended by SBA and a reduced maternal mortality ratio.[93-96] Modelling suggests that a critical threshold of 40% of population coverage of births attended by a SBA is essential for any reductions in maternal mortality and stillbirths.[97]

The core competencies identified for SBAs include the ability to communicate in a caring and respectful manner and provide holistic "women-centred" care, with the appropriate knowledge and skills to provide evidence-based obstetric and neonatal care in a timely manner. [80,81,98] Unfortunately, research evidence indicates that, women in many settings do not receive appropriate interpersonal care and that SBAs may often have limited skills and confidence. [72,74,99-101] Researchers have also reported that some countries may also designate cadres as skilled attendants, despite them lacking the requisite midwifery skills.[75,76]

The indicator- the percentage of births delivered by skilled attendant, assesses progress towards "skilled attendance at birth". This indicator was used for the Millennium Development Goal (MDG) reports[9] and the Countdown to 2015 report.[102] This indicator has

also been proposed as a core coverage monitoring indicator by the Ending Preventable Maternal Mortality (EPMM) initiative[4], the Every Newborn Action Plan (ENAP)[103] and the SDGs[6]. Reporting of this indicator at the population level relies heavily on national household surveys such as the Multiple Indicator Cluster Surveys (MICS)[104] or the Demographic and Health Surveys (DHS).[105] In reality, most population-based surveys only measure births attended by skilled attendants rather than the quality of care they provide or the environment in which these SBAs work. These questions on quality and the enabling environment are much harder to answer through population-based surveys and also vary depending on the national context.

Further, there are many issues with the SBA indicator at the country level since there is lack of clarity in terms of which cadre is considered a skilled birth attendant in a particular country. For example, many countries do not have a formal midwifery cadre instead they have other multipurpose workers such as auxiliary nurse midwives that do not undergo specialised midwifery training. There is also a problem in terms of standardization of names and responsibilities of different cadres, and task- shifting to less trained providers which complicates measurement efforts.[74] As a result, researchers have found that in many countries there are large gaps between the defined standards and competencies of SBA and their ability to manage normal labour and childbirth and other obstetric and neonatal complications.[100]

Availability of adequate numbers of SBAs at the national and subnational levels is also important. The 2014 update of the Global Health Workforce statistics indicates that amongst 132 countries for which data was available, 64 countries did not meet the minimum critical threshold of 23 midwives, nurses, and doctors per 10,000 population needed to implement primary health programmes including maternity care services.[106] In addition, shortages of specialists such as obstetricians, anaesthetists and neonatal nurses is also frequent in LMIC settings. [16,107]

Even when SBAs are available, they maybe poorly distributed within urban and rural areas or within the public and private sectors. [15,107,108] This is particularly challenging in remote and rural areas where reasons such as poor infrastructure, limited career opportunities, family reasons like schooling for children and others, becomes a challenge for SBA recruitment and deployment.[107,109] As a result of these factors, women may not be able to receive timely care

and end up either delivering alone or without appropriately qualified or skilled attendants, despite going to institutions for maternity care services.[15]

2.3.4: Interventions recommended for care at the time of birth

In their vision for quality of care, the WHO and other international development partners envision a future where "Every mother and newborn receives quality care throughout pregnancy, labour, childbirth and postnatal period".[4,89,110] Recent increases in institutional births across the world, offer a unique opportunity to realise this vision. However, to achieve this vision, health workers must apply evidence-based interventions consistently while providing care. Adherence to best-practice guidelines for essential care at the time of birth, together with effective implementation strategies,[111,112] have the potential to support health workers in making correct decisions at the right time and use effective interventions while providing care.[83]

A recent systematic review[83] published as a part of the Lancet 2016 maternal health series reviewed all available clinical practice guidelines for the provision of routine intrapartum care and postnatal care and provided up-to date guidance on recommended interventions identified using a rigorous review methodology.[83] Researchers retained 51 guidelines out of 163 guidelines reviewed, fifteen of them focussed specifically on intrapartum care and nineteen covered postnatal care. Most of the retained guidelines were issued by the WHO, the International Federation of Gynaecology and Obstetrics (FIGO), and the national obstetrics and gynaecology societies of the USA, Canada, UK, and Germany and the remaining were from Non-Governmental Organizations (NGOs) in low-income settings. Unfortunately, most of the governmental guidelines from low-income countries did not meet their strict criteria (researchers used the AGREE –II instrument and only retained guidelines that received a score of 6 or more).[83] Table 1 below summarises the interventions recommended for use during intrapartum and postpartum periods.

Table 1: Interventions recommended for use during intrapartum and postpartum period

Recommended interventions for the intrapartum period
1. Respectful care, communication and birth companions
• Offer women the possibility of being cared for by a midwife; provide one-to-one continuous supportive care • Allow and encourage women to have a birth companion of their choice • Treat every woman with respect, provide her with all information about what she might expect, ask her about her expectations, and involve her in the decisions about her care
2. Assessments and monitoring of labour progress, and maternal and foetal health
• Perform vaginal examination every 4 hours • Routinely assess the frequency of uterine contractions every 30 min • Routinely assess maternal pulse every hour, maternal blood pressure and temperature every 4 h, and frequently assess passing of urine • Consider the psychological and emotional needs of the woman • Offer intermittent auscultation of the foetal heart rate to women in established first stage of labour in all birth settings (recommendations include frequency, timing, and recording) • Consider using a partograph; use a 4-hour action line to monitor the progress of labour during second stage • Document the presence or absence of substantial meconium-stained fluid when membranes rupture (waters break)
3. Pain relief
• Assess the labouring woman's pain level and her desire for non-pharmacological and pharmacological approaches to pain relief • Encourage women to adopt any upright position they find comfortable throughout labour • Advise women that breathing exercises, immersion in water, and massage might reduce pain during first stage of labour, and that breathing exercises and massage might reduce pain during second stage of labour • Ensure the availability of opioids (e.g., pethidine, diamorphine) in all birth settings; inform women about their side-effects; if opioids are used for pain relief, provide anti-emetics in case of nausea or vomiting • Ensure the availability of nitrous oxide (1:1 mixture with oxygen) for pain relief in all birth settings; inform women about its side-effects • In obstetric units, ensure the availability of regional analgesia; inform women about risks and benefits and potential implications of epidural analgesia during labour; provide regional analgesia for women who request it (including recommendations for drugs, dosing, maintenance, co-interventions, and precautions); ensure intravenous access before initiation of analgesia
4. Care during first-stage and second-stage labour
• Routine hygiene measures taken by staff caring for women in labour, including standard hand hygiene and single-use sterile gloves are recommended to reduce cross-contamination between women, babies, and health-care professionals • Allow and encourage women to drink water, juice or isotonic drinks, and eat light meals or snacks during labour • Encourage and help women to move and adopt any position they find most comfortable throughout labour and childbirth, except supine or semi-supine • Inform women that in the second stage they should be guided by their own urge to push
5. Care during third-stage and fourth-stage labour
• Inform women that active management of third stage prevents post-partum haemorrhage

• Oxytocin (10 IU, intravenously or intramuscular) is the recommended drug for prevention of post-partum haemorrhage • Ergometrine or 600 µg of oral misoprostol can be used as an alternative if oxytocin is not available • Delayed cord clamping (done 1–3 min after birth) is recommended for all births while initiating essential newborn care • Early cord clamping (<1 min after birth) is not recommended unless the neonate is asphyxiated and needs to be moved immediately for resuscitation • Controlled cord traction and palpation should be used after cord clamping in settings with skilled birth attendants. • Encourage women to have skin-to-skin contact with their babies as soon as possible after birth • Avoid mother–baby separation before the first hour following birth, unless at the mother's request; delay postnatal routine procedures (e.g. weighing, bathing, and measuring); monitor the neonate's condition during skin-to-skin contact. • Encourage and support breastfeeding initiation within first hour.
Recommended interventions for the Postnatal period
6. Woman-centred respectful maternity care
• Provide individualised, culturally and contextually appropriate care, responsive to changing needs, and based on individual care plan
7. During postnatal facility stay
• Following an uncomplicated vaginal delivery, women are advised to stay at least 24 h in the facility • Evaluate post-partum bleeding, maternal blood pressure, and document urine void • Evaluate perineal healing and look for signs of infection to identify and treat puerperal infection or sepsis (refer when necessary) • Provide pain relief • Ask women about headache, assess bowel movements, and promote early mobilisation to prevent thrombosis • Facilitate rooming-in (mother and baby should stay in the same room 24 h a day) and promote parent participation in educational activities related to newborn babies' health • Anti-D immunoglobulin should be offered within 72 h to every non-sensitised Rh-D-negative woman following miscarriage or birth of a positive baby • Evaluate rubella immunisation and offer immunisation
8. At discharge from health facility
• At time of discharge from health facility, provide information about danger signs for the mother and baby, and counsel women on adequate nutrition, hygiene, handwashing, and safe sex • Provide iron and folic acid supplements for 3 months • Promote excusive breastfeeding from birth until 6 months of age; observe breastfeeding technique before hospital discharge • In malaria endemic areas, advise mother to sleep together with the baby under insecticide-impregnated bed nets.
9. Organisation and content of postnatal care after discharge
• Recommend two to three post-partum visits after facility discharge • At each post-partum visit, provide information about danger signs for the mother and baby, and counsel women on adequate nutrition, hygiene, handwashing, and safe sex • Ask about dyspareunia and resumption of sexual intercourse, and recommend pelvic floor exercises • Assess mental health and wellbeing or post-partum depression using screening questions

• Explore social support and assess for signs of domestic abuse • Promote excusive breastfeeding from birth until 6 months of age; mothers should be counselled and provided with support for exclusive breastfeeding at each postnatal contact • In malaria endemic areas, advise mother to continue to sleep together with the baby under insecticide-impregnated bed nets
Source: Miller at.al (2016)[83]

2.3.5: Interventions not recommended for use during the time of birth

Having identified interventions recommended for the provision of routine intrapartum and postpartum care, Table 2 below outlines the interventions that do not have recommendations for use, but still continue to be used frequently during provision of intrapartum and postpartum care, particularly in LMIC settings.[83,113-116] Lack of up-to-date knowledge, attrition of skills, low levels of motivation, restrictive institutional policies and health system bottlenecks can perpetuate the use of these interventions that are not recommended for providing care during labour and childbirth. [16,117-120] As shown in Table 2, many of these interventions such as routine use of enemas, prophylactic insertion of intravenous fluids, administration of oxytocics before delivery, routine episiotomy and others, do not have evidence of effectiveness.[114] Adoption of these ineffective practices into routine care is harmful especially in LMIC settings with weak health systems, where service quality is not routinely monitored and where women may not regularly come to facilities.

Table 2: Interventions for intrapartum and postpartum care that do not have recommendations for use

1. **During labour and the intrapartum period**
• Do not carry out a speculum examination if membranes have certainly ruptured. • Do not perform cardiotocography on admission for low-risk women in suspected or established labour in any birth setting as part of the initial assessment. • Do not perform routine fetal pulse oximetry. • Do not make any decision about a woman's care in labour on the basis of cardiotocography findings alone. • Restriction of food and fluids during labour. • Routine intravenous infusion in labour. • Repeated or frequent vaginal examinations, especially by more than one caregiver <u>For pain relief:</u> • Do not offer transcutaneous electrical nerve stimulation to women in established labour • Do not offer lidocaine spray to reduce pain in the second stage of labour • Do not offer or advise aromatherapy, yoga, acupressure, acupuncture, or hypnosis, or water papules for pain relief • Do not offer either H2-receptor antagonists or antacids routinely to low-risk women
2. Recommended against interventions for care during first and second stage of labour.

• Do not offer or advise clinical intervention if labour is progressing normally and the woman and baby are well (including amniotomy and oxytocin augmentation, even in women with epidural analgesia). • Discourage the woman from lying supine or semi-supine in the second stage of labour. • Do not perform routine perineal shaving or enemas. • Do not perform perineal massage in the second stage of labour. • Do not carry out a routine episiotomy during spontaneous vaginal birth. • Do not perform Kristeller maneuver. • Administration of oxytocin at any time before delivery in such a way that the effect cannot be controlled. • Sustained, directed bearing down efforts during the second stage of labour. • Massaging and stretching the perineum during the second stage of labour. • Do not perform fundal pressure during labour. • As a routine, do not move laboring woman to a different room at onset of second stage. • Do not encourage woman to push when full dilation or nearly full dilation of cervix has been diagnosed, before woman feels urge to bear down
3. **Recommended against interventions for care during the postnatal period**
• Palpation or measurement of uterus in absence of abnormal bleeding is not recommended. • Do not perform manual exploration of the uterus after delivery. • Do not perform lavage of the uterus after delivery. • Do not use antibiotics routinely in low-risk women with a vaginal delivery for endometritis prophylaxis • Aspirin for thromboprophylaxis is not recommended. • Vitamin A supplementation for the prevention of maternal and infant morbidity and mortality is not recommended
Sources: WHO 1999[114], Eason et al. 2000[115], Nielson 1998[121]; Ludka and Roberts 1993[116], Miller et al. 2016.[83]

2.3.6: The importance of respectful maternity care during labour and childbirth

In recent years, researchers and organizations such as FIGO, WHO and others have highlighted the importance of providing high quality care during labour and childbirth by using evidence-based interventions and delivering them in a humane and dignified manner with respect for women's human rights.[80,81,122,123] The Lancet 2014 midwifery series also identified that women value relevant, timely information and support, so that they are able to maintain dignity and control during the birthing process. [124]

There is often a complex interplay of factors such as those at the individual level (socio-economic status, educational levels, caste), institutional levels (policies on companionship, clinical guidelines, lack of resources for example: inadequate privacy screens) and at the health worker level (deficiencies in knowledge, skills and increased workloads) that may result in mistreatment of women at maternity facilities. [79,80] A recent WHO statement (2014) on preventing and eliminating disrespect and abuse highlighted the urgency of addressing this

issue and recommended that there needs to be a greater research and action in order to improve respectful care during labour and childbirth.[123]

This growing importance of ensuring respectful maternity care has evolved from research evidence that has previously conceptualised this issue as disrespect and abuse[125], obstetric violence[126] and dehumanised care.[127] There is now increasing research evidence indicating that that this phenomenon occurs in both high[80,128-131] and low income settings[132-134], indicating that this is a universal issue, and not just limited to resource-constrained settings.

Women's experiences of maternity care are negatively influenced by factors such as unhygienic conditions at facilities, any disrespect and abuse they encounter, limited information or explanations provided prior to conducting invasive procedures, discrimination and inequitable care provision.[81,135] Low cost of treatment, convenience, kindness, interpersonal qualities of the health worker, attention and time received, technical capability, communication and integrity are all valued qualities by women when it comes to choosing health workers.[136-140]

In a landscape analysis from 2010, Bowser and Hill described seven categories of disrespectful and abusive care during childbirth: physical abuse, non-consented clinical care, non-confidential care, non-dignified care, discrimination, abandonment, and detention in health facilities. [125] Since then, researchers have advanced this concept and proposed a definition to articulate the criteria for determining when an interaction with a health worker or circumstances at maternity facilities that should be considered abusive and disrespectful.[81,99]

Freedman *et al.* (2014) proposed that a comprehensive definition of mistreatment needs to capture the health, human rights and socio-cultural dimensions of mistreatment; while measurement efforts need to capture where, how and why mistreatment occurs.[81] Further, measurement efforts should also be able to capture whether mistreatment was intentional or not, and the role of local societal norms (for example, women's status, patient-provider dynamics) that influences women's perceptions of mistreatment in different contexts.[81] Given this background, Freedman *et al.* (2014) defined disrespect and abuse during childbirth as "interactions or facility conditions that local consensus deem to be humiliating or undignified, and those interactions or conditions that are experienced as or intended to be humiliating or undignified." [99]

In 2015, the WHO conducted a systematic review and tried to establish the evidence-base for mistreatment globally.[80] The authors reviewed 65 studies (53 qualitative and 12 quantitative) from 34 countries and found that most studies used different operational definitions and measurement approaches.[80] Amongst the quantitative studies, only three studies reported a prevalence of mistreatment at maternity facilities, which varied from 15 to 98%.[80] This review also proposed a typology of items considered mistreatment and identified the following: physical, verbal or sexual abuse, stigma and discrimination, failure to meet professional standards of care, poor rapport between women and providers and health system conditions and constraints.[80]

However, mistreatment and poor quality of clinical care are closely interlinked.[83] As the 2016 Lancet maternal health series noted, there are two extremes of maternal health care provision in a growing number of LMICs.[83] The first extreme is associated with over-treatment or the routine over-medicalisation of normal labour and births, which they referred as "Too Much Too Soon". The second extreme is under-treatment or underuse of evidence-based practices signified by the terminology "Too Little, Too Late" which is the underlying cause of high maternal mortality and considerable morbidity.[83] Both over-medicalisation such as increased use of unnecessary procedures like episiotomies without indications or under-treatment such as absent hygienic standards at maternity facilities are also against the rights of child bearing women.[141]

Therefore, mistreatment of women during labour and childbirth can occur because of inappropriate care practices, which may include those related to disrespect and abuse (intentional harm or degradation), over-treatment, or under-treatment. Regardless of the terminology used, mistreatment of women falls under poor quality of care. As women who are mistreated are less likely to come back to facilities for future pregnancies,[142] this is an important issue that needs to be addressed urgently.

In the next section, I will present findings from my literature review on quality of care in health systems and quality as it relates to maternal and newborn health. Thereafter, I will outline approaches to measure various elements of QoC in maternal and newborn health. QoC for health systems includes broader issues than QoC in health facilities and they both require different interventions for improvement. However, since both of these issues are closely interlinked, it is useful to understand the meaning of these concepts and understand the ways

that they overlap or interact. In the subsequent section, I will then summarise findings from my literature review on the empirical evidence on QoC during labour and childbirth in India using the quality of care framework.

2.4: Frameworks of quality in health and definitions

Over the past two decades, numerous frameworks on quality have been conceptualised based on differing notions of quality. Since quality is multi-dimensional, it is widely accepted that there is no single concept or framework of quality of care.

Previous frameworks of quality of care for health services have included the perspective model[143] focussed on client and provider's perceptions of quality, the characteristic model[144] which focussed on specific care elements (safety, efficacy, timeliness, patient centeredness etc.) and the systems models[145] which considered quality as a by-product of good structures and processes resulting to good outcomes.

2.4.1: Definitions of quality of care in health services

Historically, many definitions have existed for QoC in health services. Earlier definitions seem to have favoured biomedical outcomes alone. For example, Donabedian (1980) defined quality as "the application of medical science and technology in a manner that maximises its benefit to health without correspondingly increasing the risk. The degree of quality is, therefore, the extent to which the care provided is expected to achieve the most favourable balance of risks and benefits."[146]

In 1988, Roemer and Montoya-Aguilar made a distinction between assessment of quality and assurance of quality based on pre-defined set of standards.[147] They wrote, "Quality of health care consists of the proper performance (according to standards) of interventions that are known to be safe, that are affordable to the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition."[147]

Another definition which stressed on decreasing the gap between desired and actual health outcomes was the Institute of Medicine definition (1990) which defined quality of care as, "the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge." [148]

Other definitions have been more comprehensive. Wilson and Goldsmith (1998) described QoC as "the sum of four components: technical quality, resource consumption, patient satisfaction and values". [149] Perhaps, the simplest and most well-accepted definition of quality is Godlee's (2009), who defined quality as "clinical effectiveness, safety, and good experience for the patient." [150]

2.4.2: Elements of quality of care in health services

Elements of quality of care in health services are generally assessed using Donabedian's classic framework of structure, process and outcomes.[146,151] As explained by Peabody et al. (2006) in describing elements of quality for health systems, "structure refers to physical infrastructure, supplies, commodities, resources, financing of health services and others." [86] Process refer to "health worker and client interactions which occur during consultations, examination or procedures." [86] Outcomes refer to indicators "that measure health status, mortality and disability adjusted life years of the population".[86]

More recently, the Institute of Medicine's report "Crossing the Quality chasm: a new health system for the 21st century" broadened the concept of quality by expanding on contextual elements of quality to illustrate how improved processes can actually lead to improved quality[152]. According to their framework, quality of health care means provision of services that are:

1. Effective: delivering health care that is adherent to an evidence-base and results in improved health outcomes for individuals and communities, based on need;
2. Efficient: delivering health care in a manner which maximizes resource use and avoids waste, delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
3. Acceptable/patient-centred: delivering health care which considers the preferences and aspirations of individual service users and the cultures of their communities;
4. Equitable: delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status and
5. Safe: Delivering health care, which minimizes risks and harm to service users.

2.5: Frameworks and definitions of QoC specific to maternal and newborn health

Similar to frameworks on quality of health services, there have also been many frameworks to assess quality in maternal and newborn health. [153,154] Some of these includes frameworks that have assessed QoC from clients perspectives,[138] rights–based approaches,[155] provider needs[156] and models to overcome delays.[157]

Perhaps, the most widely used framework was developed by Hulton *et al.*[153] (2000) who adapted the IOM definition of quality while incorporating the concepts of effective and timely access and of reproductive rights.[153] They define quality of maternal health as "the degree to which maternal health services for individuals and populations increase the likelihood of timely and appropriate treatment for the purpose of achieving desired outcomes that are both consistent with current professional knowledge and uphold basic reproductive rights."[153]

More recently, in 2015, the WHO published its vision for QoC for maternal and newborn health[89]. The WHO vision was informed by Hulton's framework[153] and the IOM definition, and defines QoC as 'the extent to which health services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care needs to be safe, effective, timely, efficient, equitable, and people-centred.' [89]

Similar to the Hulton framework[153], the WHO framework for QoC in maternal and newborn health (Figure 2) also conceptualises quality as both provision of evidence-based care and positive experiences for women seeking care.[89] Satisfaction of women with maternity care is closely linked to women's experiences of care in the QoC framework and is associated with all elements of structure, process and outcomes. For example, a lack of adequate supplies or skilled personal leads to poor satisfaction amongst women. Similarly process of care elements such as good interpersonal behaviours, emotional support, and treatment with respect and dignity are essential to ensure satisfaction with maternity care. [89,158] Outcome indicators for quality include those related to women's satisfaction and labour and childbirth outcomes.[89]

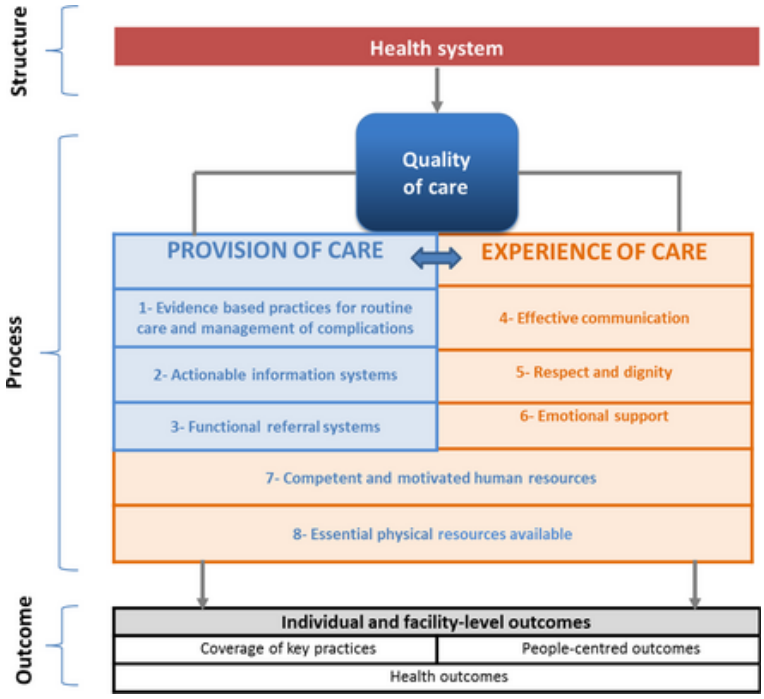
However, there is a complex relationship between satisfaction and QoC.[159] It is possible that care received by patients is of high technical quality but inadequate in terms of patient's satisfaction. In addition, women's satisfaction is also associated, at least, in part, with labour and childbirth outcomes. Research suggests that women who are dissatisfied with maternity

services also tend to have poor pregnancy outcomes such as poor postnatal psychological outcomes, a preference for caesarean sections, negative feelings towards the neonate and problems with breastfeeding.[160-162]

The WHO framework recognises that quality is a normative concept, therefore, standards for care are needed for assessment and improvement purposes.[89] WHO guidelines for both routine and emergency obstetric and newborn care are well-defined. [163] The WHO framework also recognises the importance of robust information systems to capture data on QoC, and the need for effective referral systems in case of emergencies.[89]

The QoC framework is linked to the six WHO health system building blocks[164] of 1) service delivery; 2) health workforce; 3) information systems; 4) medical products, vaccines and technologies; 5) health financing and; 6) leadership/governance. It thereby creates linkages so that analytical work and improvement projects to improve QoC can be taken using a health systems approach. Finally, the framework recognises that health systems are platforms that enable access to high QoC and allows processes to occur, along two important and inter-linked dimensions of service provision and experience of care leading to improved individual and facility-level outcomes.[89]

Figure 2: WHO Quality of Care Framework for maternal and newborn health



2.6: Measurement of QoC for maternal and newborn health in LMIC settings.

Given the recent emphasis on emphasis on accountability in MNH, [165] national governments and development partners need to generate or have access to high-quality, representative data on QoC to inform their policy and programme decisions. [166] However, measurement of QoC is often difficult given the wide-ranging issues that quality encompasses and weaknesses in information systems in many LMIC settings.

Donabedian's approach to measuring quality by assessing elements of structure, process and outcomes is also widely used for measuring QoC in maternal and newborn health.[167] These elements are described in the sections below with a specific focus on measurement of quality of MNH services.

2.6.1: Measuring structure elements of quality of care

Data on structural elements of quality are perhaps the easiest to obtain. Routine monitoring data is collected by national health systems or monitoring systems of implementing agencies and are often an obvious source of information on structural elements of QoC. For example, facility inventories of drugs and supplies are often available through logistics management information systems. Service utilisation data on indicators such as number of institutional births, deliveries by skilled birth attendants and others is available through the national health information systems.

Potential advantages of routine data for structural measures include their availability at a relatively low-cost, on a continuous basis, data are often disaggregated up to the facility or district level. In addition, routine data provide more detailed information on service availability and utilisation compared to household surveys.[166] However, there are also limitations with using routine data, for example: many elements of MNH care are not collected through routine systems, denominators are limited to those in contact with the health system, data may also be of poor quality, incomplete or updated infrequently.[166]

Given these issues, data on structural elements of QoC tends to be collected through special surveys or censuses. Readiness which often refers to the availability of necessary drugs, commodities and trained health workers, is often used as a proxy for structural quality. Some large-scale facility-based surveys regularly measure structural elements. Some of these include: the World Health Organization's Service Availability and Readiness Assessment

(SARA)[168], the DHS Program's Service Provision Assessment (SPA) surveys,[169] and the MEASURE Evaluation's Rapid Health Facility Assessments (RHFA).[170] These surveys capture information on training, supervision, availability of services, tools and guidelines, infrastructure conditions, availability and storage conditions of medications, supplies and equipment. [60,171] However, none of these methods assess competency of health workers.[166]

Specific to MNH, materials such as EmOC needs assessment toolkit[22], United States Agency for International Development's (USAID)- Maternal and Child Health Integrated Project's (MCHIP) QoC surveys [172] have separate modules on facility inventory assessment that capture information on infrastructure, availability and conditions of commodities, supplies, and equipment required for provision of maternity services.

However, structural improvements by themselves may not improve health outcomes. [151] Therefore, in maternal and newborn health, measurement of inputs alone, such as readiness, either of facilities (through measurement of signal functions) or of the provider (through measurement of knowledge and skills) does not provide a comprehensive picture and therefore, measurement of process of care is important.

2.6.2: Measuring process elements of quality of care

Theoretically, processes of care can be measured during every health care encounter. However, in some cases, the private nature of health worker-client interaction, absence of appropriate measurement scales or instruments limits measurement efforts. [173] Over the past decade, there have been many methodological advances in measurement of processes of care for MNH. There is also robust research evidence, which suggests that measuring processes of care, as a part of quality improvement efforts can lead to improved health outcomes.[88,111,174] This makes process measurement a preferred approach to assess QoC for maternal and newborn health.

Below I discuss nine approaches to measure processes of care for maternal and newborn health such as standardized patients, clinical vignettes, review of medical records, audits, simulations or clinical skills and drills, direct clinical observations, video filming and satisfaction surveys. All methods have their own advantages and disadvantages.[86,175]

Standardized patients are a popular method to assess processes of care and have been employed by a number of studies in Asia and Africa to measure QoC for childhood illnesses

such as diarrhoea, acute respiratory infections,[176] and sexually transmitted infections[177]. Standardized patients are trained actors, often from local communities, who make unannounced visits to a hospital and present symptoms of a simulated condition.[178] These patients complete an assessment checklist on providers clinical actions after the visit.[175] Since this methodology employs cases that are standardised and predetermined, it allows for quality comparisons across different types of providers and contexts. [179]

Some proponents of standardized patients argue that that since health workers do not know the true identity of standardized patients, their behaviours approximates that of "real-patients" and hence, health workers are less prone to Hawthorne effect.[180] Hawthorne effect is a phenomenon whereby health workers become aware that they are being observed, and thereafter, exert additional effort which is a change in their actual behaviour.[181] However, predicting health worker's behaviours in real life is complex. For example, health workers may provide better care to someone they know personally or provide discriminatory care to other patients. Moreover, these simulated patients are not suitable for assessing QoC for invasive procedures or conditions like childbirth that cannot be simulated by actors.

Clinical vignettes were developed for measuring quality within a group of providers[86,179,182] and they have been used to study QoC for a range of conditions, including for measuring EmOC capability[65] and intrapartum decision-making of midwives.[183] Vignettes can be administered either on paper, by computer, or over the Internet.[86] When clinical vignettes are used to assess many providers, each provider is given the same case or the same set of cases.[86] Health workers follow that particular written clinical-case, respond to questions that replicate certain components of a patient's visit, for example- history-taking, examination, ordering of investigations or prescribing a treatment plan.[86] The questions are open-ended and include interactive responses that simulate a patient's visit and evaluate the health workers knowledge. Health workers' performance is assessed against a criteria for managing the particular condition.[184]

Vignettes have several advantages, such as allowing comparison between health workers, and comparison before and after implementation of a new policy.[86] They are also cheap, easy to administer and easy to analyse which makes them useful.[86] However, researchers have argued that health worker's behaviours during an actual consultation is not accurately captured by vignettes, and that knowledge does not always translate into actual clinical

practice.[185] Therefore, although vignettes are a useful quality assessment tool, they are often incomplete when used in isolation, and should be used with other methods such as direct observations of clinical practice. [185 186]

Record reviews are one of the most frequently used methods to evaluate clinical quality such as for emergency caesarean sections.[187] Their main advantages are that medical records are available after every health care encounter and they are easily obtained. However, often when medical records are handwritten, they may not be legible or may have been written for other purposes like obtaining payments, or medico-legal reasons rather than to document details of procedures.[86] Their utility is perhaps greater in high-income settings where electronic medical records are routinely used. In contrast, such systems do not exist in most low-resource settings and there is often inconsistency[1] and poor clinical documentation for indicators of interest such as partograph use, timing of oxytocin, or blood transfusion and others.

Audits such as near-miss audits, maternal and perinatal death reviews have also been used extensively to identify and address deficiencies in processes of MNH care.[90,188-193] Audits have been defined as: 'the systematic and critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.[194 193] Audits often combine information from different sources, which makes them superior to other methods such as record reviews. However, it is important to ensure that the purpose of conducting the audit as a learning exercise aimed to improve clinical practices is communicated effectively for them to be accepted at hospitals.[193]

A variety of studies have used audits to measure and improve quality in MNH and evidence indicates that under certain contextual conditions audits can be feasible, effective and acceptable. [90,192,193 195] However, like record reviews, audits are retrospective and require a trained health worker to undertake detailed abstraction of records from different sources which make it a time consuming endeavour.[175]

Clinical skills and drills approaches like the obstetric emergency skills and drills methods have been used extensively to maintain health workers' competence in managing obstetric emergencies that health workers may not always encounter such as eclampsia or post-partum

haemorrhage.[196,197] In these skills and drills approaches, participants are given clinical scenarios, and are instructed to demonstrate clinical skills on mannequins or other simulators. Simulation-based-training is considered to be a proactive approach to reduce errors and risk in obstetrics and aims to provide participants a range of transferrable skills to improve their actual clinical performance. [196] However, these methods have mostly been used for educational purposes rather than for measuring quality, [198] and simulators can also be a costly investment, particularly for use in LMIC settings.

Clinical practice observations are direct observations of care processes as they happen and are an established method for evaluation of QoC.[1,86] They generally utilise external observers and are separate to ongoing supervision and mentorship during regular clinical practice which may involve observations. From an ethics standpoint, it is essential that both health workers and patients are informed prior to the start of clinical observations. This may often introduce a bias referred to as Hawthorne effect.[181] Clinical practice observations and standardized patients are thought to be gold-standard methods to assess QoC [1,86,179] but they are not suitable for outcomes that are infrequent or conditions that cannot be simulated by actors, for example: neonatal resuscitation or maternal complications of pregnancy. They are also resource-intensive and therefore may not be suitable for frequent or routine monitoring of quality.

Clinical practice observations have been utilised by various studies to examine quality of obstetric and neonatal care in many LMIC settings. [70,71,78,199-201] The Averting Maternal Death and Disability (AMDD) programme of the Columbia University, which initiated the needs assessment of emergency obstetric and newborn care[22], USAID/ MCHIP QoC surveys[172], Helping Babies Breathe programme for neonatal resuscitation[202] and assessment tools from the Gaala study[203] have specific sections on measuring processes of care during routine labour and childbirth. They also have specific sections on intrapartum and immediate post-partum care including aspects of woman-centered respectful maternity care. These instruments been used in multiple countries and are based on globally recognised best practices such as the WHO's care in normal birth and Integrated Management of Pregnancy & Childbirth manuals.[114,204]

Some exciting recent advances in measuring QoC have included the use of video-filming[205] which is suitable for rarer outcomes, events that unfold over a shorter period of time or

involve a series of steps such as neonatal resuscitation or observation of oxytocin use. However, the costs of closed-circuit cameras, ethical and sensitive issues around the use of video filming, consent procedures, data anonymization and data management needs careful considered prior to using such video filming methods in LMIC settings.

Clients' experiences including satisfaction with care is generally assessed using cross-sectional surveys. Donabedian (1980) defined user satisfaction as "patient's judgment on the quality and goodness of care"[146]. Linder-Pelz and Struening (1985) have argued that satisfaction comprises of "multiple evaluations of distinct aspects of healthcare which are determined (in some way) by the individual's perceptions, attitudes and comparison processes."[206] As highlighted by these definitions, the concept of satisfaction is multidimensional[207] and any evaluation of satisfaction is likely to be influenced by individual women's personal preferences, their expectations, the cultural and social context and actual care received by them.[208]

Although satisfaction is considered to be important for future utilization and choice of health facility,[209] further research is needed to fully understand the mechanism through which women perceive satisfaction with maternity services.[210-212] Surveys to measure satisfaction have been criticised for limitations such as measurement errors and inability to assess changes over time. For example, surveys may often use a single item to assess satisfaction with care ignoring the multi-dimensional nature of satisfaction. [208,210,213] Research indicates multiple determinants that influence women's satisfaction such as staff-woman interaction, information exchange, involvement in decision making, control during the birthing process, pain relief, and birth environment.[214-216,210,217] Detailed information on these determinants is not always collected in satisfaction surveys.

Some researchers have also argued that surveys on satisfaction with maternity care are not grounded in concepts and theory.[218,207] Others have also noted that high levels of satisfaction are frequently reported in surveys which questions the reliability and validity of existing measurement tools. Often data from satisfaction surveys shows a lack of variability which questions the ability of surveys to discriminate.[211] Lastly, measures of satisfaction reported in research studies often do not always differentiate between the actual experience of labour and childbirth (such as pain or mistreatment) and the overall experience of care during the hospital stay. [208,219,220]

A recent systematic review that aimed to identify existing instruments to measure satisfaction with labour and childbirth found that there were only a small number of validated instruments.[208] Based on a detailed review of the literature, researchers identified all available multi-item scales of satisfaction of care during labour and childbirth and assessed whether psychometric information (such as information on questionnaire construction, reliability and validity) was available. Based on their findings, researchers recommended that for a detailed investigation of satisfaction with maternity care, the Intrapartum- specific Quality from the Patients Perspective questionnaire (QPP-I) was the most appropriate. [218] Other shorter instruments found to have good reliability and validity were reported to be the Six Simple Questions (SSQ)[161] and the Perceptions of Care Adjective Checklist (PCACL-R).[221,222] However, research evidence examining the extent to which these instruments have been used in LMIC settings is hard to obtain.

Although, measuring satisfaction with maternity services has been discussed under measuring processes of care, I will not measure women's satisfaction with maternity care as a part of my PhD.

2.6.3: Measuring health outcome measures of quality of care

Outcome measures are indicators of the health status of the group of patients using facilities and of broader populations, however, measuring health outcomes alone, is not necessarily ideal for measuring quality of care for three reasons.

First, a patient may receive poor quality care but may recover completely or may receive high quality care but still may not recover. Second, adverse health outcomes such as maternal deaths and/or maternal complications tend to be rare. [86] Third, in health facilities, case fatality and complication rates are influenced by the case mix of patients using facilities which complicates analysis and interpretation efforts.

At the population level and with the aim of assessing health system quality, there are five opportunities to collect data on outcomes such as maternal mortality. These include data from death registration systems, routine data from health facilities, censuses (once every ten years), specialised surveys and surveillance efforts.[223] Other composite methods such as Reproductive Age Mortality Studies (RAMOS) also exist, which draw upon a combination of

these methods. [73] Essentially, in these studies researchers aim to identify all deaths of reproductive age woman and then ascertain cases of maternal deaths and identify the circumstances behind these maternal death.[95,223] However, it is generally accepted that in LMIC countries lacking complete vital registration, no approach is guaranteed to give precise population-based estimates, in particular as maternal death is statistically a relatively rare event.

Some common problems associated with reporting of maternal mortality are misclassification and underreporting of maternal deaths. Misclassification may occur in cases where deaths are associated with induced abortion (especially where it is illegal); early pregnancy deaths (resulting from ectopic or molar pregnancy), where the pregnancy may have been unknown to the woman or her family; indirect maternal causes (malaria, anaemia, tuberculosis, hepatitis, or cardiovascular disease). It may also happen if deaths occur sometime after the end of childbirth, especially in cases where the death occurs in a non-obstetric hospital wards, for example, in an intensive care or other specialized units.[224] Underreporting of maternal deaths in LMIC settings is also thought to occur because of limited incentives to report vital events, differential under-reporting of deaths by sex and inaccurate classification of maternal deaths as highlighted earlier.[223]

Measuring maternal health outcomes with certainty at the population level, therefore can require research studies conducted on a very large scale, which makes them an expensive endeavour.

However, depending on the research question, studies frequently measure outcomes to assess the effectiveness of clinical interventions or programmatic approaches in improving maternal health at the health facility level. For example, a recent large-scale trial known as the WOMAN trial enrolled over 20,000 women across 21 countries, examined the effect of Tranexamic acid on risk of mortality from post-partum haemorrhage (outcome) and found that Tranexamic acid reduced death due to bleeding in women with post-partum haemorrhage with no adverse effects.[225] Similarly, Dumont et al. (2013) conducted a pragmatic cluster randomised trial and investigated the impact of a multi-faceted intervention (trainings, audit cycles, maternal death reviews, refresher trainings, certification and others) on reducing hospital-based maternal death (outcome measure) in 46 hospitals in Senegal and Mali. [226] Their results showed that that this multi-faceted intervention was

successful in reducing maternal deaths (odds ratio [OR] 0.85; 95% CI 0·73 to 0·98, p= 0.029) in primary referral hospitals. [226]

However, it is important to note that while measuring outcomes at the health facility level such as maternal deaths or complications, researchers have to be careful in interpreting their findings because of issues such as misclassification and underreporting (described earlier), but also larger health system factors that influence maternal and perinatal outcomes in facilities.

2.6.4: Summary of measuring quality of care in maternal and newborn health

Measurement of structure alone, such as readiness, either of facilities (through measurement of signal functions) or of the provider (through measurement of knowledge and skills) does not provide a comprehensive picture. Similarly, a focus on clinical outcomes alone is not enough, as most pregnancies are uneventful, complications may occur, and negative outcomes may also occur in the presence of good clinical care. Therefore, measurement of QoC in obstetrics needs to focus on the processes of care and should include both technical quality as well as experiences of care that women receive while seeking institutional maternity care.

2.7: Empirical evidence on deficiencies in QoC during labour and childbirth in India

This section will present the findings of my literature review on QoC during labour and childbirth at maternity facilities including relevant literature on health systems issues in India. I have used the framework of structure, process and outcomes to summarise the findings of my literature review related to QoC during labour and childbirth in India. Additional details on the Indian health system are provided in the study setting section.

2.7.1: For structural elements of QoC in India

This section will discuss deficiencies in structural elements of quality, both at the level of health systems and at health facilities since they are both integral to the provision of high-quality maternity care at facilities.

Although there seems to be a shortage of clinical workforce across every Indian state, this situation is particularly acute in states with poorest health indicators such as Uttar Pradesh, which also has the lowest density of health workers.[227,228] Data from the Indian National Sample Survey (2011-2012) estimated that the density of doctors, nurses and midwives of 6.4

per 10,000 population was significantly below the WHO benchmark of 22.8 workers per 10,000 population.[227]

Overall, the Indian public health system is known to suffers from staff shortages, imbalances, mal-distribution, poor work environments, low personnel productivity, numerous vacant posts, high staff turnover, loss of qualified personnel to private sector, and migration of workers to urban areas[229], which make human resources shortages a significant concern. The distribution of qualified health workers in the country also seems to be skewed in favour of urban areas; 77.4% of the qualified workforce lives in urban areas, whereas 31% of the Indian population is urban.[227] Moreover, there are many challenges to recruiting and retaining qualified staff in the public sector especially in rural areas. [228]

India's health workforce also includes doctors trained in Indian systems of medicine such as Ayurveda, Yoga, Unani, Sidha and Homeopathy which are collectively known as AYUSH providers and they offer health care through both public and private sector facilities. [230]

Apart from AYUSH personnel, there are also a large number of informal medical practitioners commonly referred as registered medical practitioners (RMPs). These RMPs are often the first point of contact, particularly for the rural population and the urban poor. Although they practice allopathic medicine, RMP's often do not have the required formal qualifications or license to do so.[230] Detailed information on RMP's qualifications and skills are hard to obtain, however, one study estimated that an average 25% of RMP's classified as allopathic doctors reported no medical training (42% in rural and 15% in urban settings). [231] Another study in Udaipur district, in the state of Rajasthan found that 41% of private practitioners who called themselves doctors had no medical degree, 18% had no medical training at all and 17% had not even graduated from high school. [232]

These unregistered private "doctors" are considered to provide a substantial proportion of maternal and newborn care, although as mentioned earlier, disaggregated data on their share of the market is hard to obtain. However, available research suggests that these informal providers often have strong professional networks with qualified private sector doctors (or the private practices of public sector doctors), pathology laboratories, and private for-profit hospitals and they make referrals to these places in return for commissions on procedures, diagnostics, medicines and consultations. [233]

Furthermore, India also has other practitioners of traditional medicine such as herbalists and faith healers, traditional birth attendants (dais), and others who are also involved in care provision. As a result, available research evidence suggests that there is a high reliance on unqualified personnel, particularly in rural areas.[230]

Specific to maternity care, there is no formal midwifery cadre in India. [234] A needs assessment report by Johns Hopkins Program for International Education in Gynaecology and Obstetrics (Jhpiego) India in 2015 estimated that there was a deficit of over two million nurses, with over 18% posts of staff nurses and auxiliary nurse midwives at primary and community health centres reported to be vacant.[235] Jhpiego (2015) also reports that the training curricula of nurses in India did not meet the internationally defined competencies for SBA.[235] In addition, 61% nursing institutions were reported as unsuitable for conducting competency-based trainings. [234]

Researchers have also reported that in some states of India there is a lack of nationally agreed minimum standards for drugs, supplies and equipment that results in procurement of resources of variable quality. [16] In addition, poor hospital infrastructure and strict institutional policies (for example, not allowing nurses to give injectable/s or not allowing birth companions in labour rooms) also hamper the provision of high quality care at the time of birth.

The health facility environment in India also appears to have many structural constraints. For example, a facility survey from Uttar Pradesh (2009) reported that clean water was only available in 57% and essential drugs and supplies were only available in 29% of primary health centres and regular electricity supply is a major challenge[236]. A gap analysis of first referral units (FRU) in Uttar Pradesh conducted by the UP government and partners (November 2013) found that one fifth of higher level facilities such as district hospitals and medical colleges do not have adequate space allotted for labour rooms.[237] This study reported that compared to higher-level facilities, greater proportions of lower level facilities performed poorly for many structural indicators. For example, just 35% of Community Health Centres (CHC) had appropriate handwashing areas with elbow-operated taps, 16% had functional and clean toilets attached to the labour room, 31% had the adequate availability of essential equipment and supplies and 31% of CHCs had sufficient number of beds.[237] These data indicate indicates significant structural deficiencies at maternity facilities in Uttar Pradesh.

Other cross-sectional evidence from Indian studies such as in Madhya Pradesh, which has similar indicators to Uttar Pradesh, has found that 86% of deliveries occur in public sector facilities that are unable to provide the recommended BEmOC signal functions. [62] In this study, researchers reported that amongst 29 facilities that could perform caesarean operations, none could perform all the BEmOC functions.[62] Capacity to provide signal functions such as parenteral anticonvulsants, manual exploration of the uterus, removal of retained products of conception and assisted vaginal deliveries were particularly problematic.[62] In addition, researchers reported that CEmOC services were more likely to be available in a greater proportion of private-sector facilities compared to public sector facilities, just one in six public-sector facilities could provide all CEmOC services.[62]

Other structural constraints documented in Indian maternity facilities have included limited triaging mechanisms, limited availability of round-the clock services, weak referral and transportation services, limited onsite blood transfusion and anaesthesia services; all of which indicate that there are significant structural challenges for the provision of high-quality care at the time of birth in India. [16,238-240]

2.7.2: For process elements of QoC in India

Most of the available research evidence on process measures of QoC during normal labour and childbirth in India emerges from cross-sectional studies in the public sector. Information on QoC from the private sector is scarce. Available research evidence indicates poor quality of maternity care as shown by high rates of labour augmentation, routine conduct of episiotomies, non-adherence to active management of third stage of labour, limited use of partograph or foetal heart rate monitoring, early discharge from the hospital, limited preparedness for neonatal resuscitation, poor initiation of breastfeeding, and inadequate thermal care of neonates. [241-244]

Evidence from a quantitative study in 2007 in Rajasthan found that up to 85% of all deliveries were augmented, 67% of women were subjected to strong fundal pressure and more than half of postpartum women were discharged before 24 hours (national guidelines recommend 48 hours).[243] Similarly, another observational study found that foetal heart rate monitoring was not performed regularly, preparedness for neonatal resuscitation was minimal, episiotomy; perineal-shaving and enema were common.[244] The authors also report that the presence of SBAs during childbirth at facilities did not guarantee the receipt of skilled care by

the mother and her newborn, and that unqualified attendants are frequently involved in maternity care provision in facilities.[244]

Some researchers have argued that limited knowledge of maternity care personnel is behind the poor QoC at facilities in India. [65] For example, an Indian study utilising clinical vignettes, found that as little as 20 percent of nurses working as SBAs appeared competent in managing eclampsia and haemorrhage, and only 10% seemed competent in performing a correct initial assessment of women with pregnancy complications. [65] Two cross-sectional studies have also reported that ANMs, nurses and medical officers (doctors) did not have the required skills and were not confident in providing basic EmOC services including stabilisation prior to referral. [245,246]

Researchers have also found overuse of prophylactic antibiotics during labour in India irrespective of the type of delivery. [247] This overuse of antibiotics without proper indications is thought to be due to health workers' beliefs regarding poor hygiene and infection control standards at maternity facilities and their own assumptions of poor personal hygiene of women that come for deliveries.[247]

Stanton *et al.* (2014) conducted an observational study in two Indian states, and found widespread non-adherence to existing protocols on uterotonic drug use at public sector facilities. [242] They found that that labour augmentation rates ranged from 78.6% (Karnataka) and 99.1% (Uttar Pradesh), correct use of oxytocics for postpartum haemorrhage varied from 6%–8.8% in Uttar Pradesh and 41.2%–76.4% in Karnataka. Active management of the third stage of labour was found to be performed correctly in less than 10% of deliveries in both districts and that storage of uterotonics at room temperature was common.[242]

Other qualitative research evidence from India[66,239] has described situations where labouring women were mistreated (shouted at or slapped), cases where women were not given adequate information about the procedures being done, births occurring in hospitals without a health professional in attendance, and cases where post-partum women were not monitored or supported after childbirth. [66,239]

Evidence from various Indian states has also revealed poor routines in care, such as inappropriate monitoring during labour and childbirth, use of harmful and unnecessary practices, limited preparedness and widespread staff shortages at health facilities. [66,67,70,71,78]

There is also some research information on who uses private sector facilities. Cross-sectional research evidence indicates that socio-demographic factors are a key determinant for choosing private sector for maternity care.[40] The effect of education seems to be important, with one study finding a positive effect in India.[248] Other factors such as ethnicity and caste/tribe status were found to be negatively associated with the use of private facilities in India. [248] Cognition which means provider–client information exchange was identified as the most important determinant for service-utilisation in south Asia.[239] Women who attended a greater number of ANC visits were more likely to use the private sector during childbirth. [248] However, there is also contradictory evidence on whether obstetric complications could prompt women to seek care in a private sector. [40,249] A higher socio-economic status and urban residence was associated with greater use of private sector facilities for maternity care in India. [248]

Most published studies from India (and specifically from Uttar Pradesh) have not comprehensively measured QoC during labour and childbirth, most have employed qualitative methodologies, were conducted in the public sector, examined home-based childbirth practices[70] or focus on specific issues such as PPH management[77], labour augmentation with oxytocin, [250,251] neonatal cord care, breastfeeding or thermal care.[252] As a result, there is limited descriptive information from robust studies that comprehensively measure QoC during labour and childbirth. This is especially true for the private sector in India which provides approximately a quarter of maternity care services in India.[253, 254] However, available evidence from the private sector does indicate that there is increasing medicalisation of childbirth driven primarily by caesareans in private sector hospitals in south Asia including in India. [25,39]

2.7.3: Health outcome measures of quality of care at the time of birth in India

Given the increasing global attention towards improving maternal and newborn health (MNH) in India and effective advocacy by grassroots organizations, there appears to be lot of momentum around improving MNH in India. The Government of India, through the National Rural Health Mission's efforts and the Janani Suraksha Yojana programme has been successful in increasing institutional births from 41% in 2004 to 73% in 2012.[255]

However, there is limited availability of information on facility-based outcome measures such as hospital mortality rates, obstetric case-fatality rates, near-miss events or never-events in Uttar Pradesh. This information could not be obtained from existing routine data sources at health facilities and these are scarce in the peer-reviewed literature.

Available population-based outcome measures illustrate the high burden of maternal, neonatal and perinatal mortality in India. The MDG 5a target for India was to reduce the MMR to 109 maternal deaths per 100,000 live births by 2015.[256] However, despite impressive progress, with declines in MMR from 437 to 178 per 100,000 live births (a 59% decline) between 1990 and 2012, India could not achieve the MDG5a targets. Furthermore, national estimates hide striking disparities between Indian states. For example, the MMR in Assam was found to be 328 per 100, 000 compared to Uttar Pradesh, where the MMR was 240, considerably higher than states like Kerala where the MMR was just 66 per 100, 000 live births.[253] Available research evidence also indicates that the major causes of maternal deaths in India were due to direct obstetric causes such as - haemorrhage (38%), sepsis (11%), unsafe abortion (8%), hypertensive disorders (5%) and obstructed labour (5%)[257], although data on causes of death after 2003 is not available.

For neonatal mortality, in 2013, India had the highest burden globally with 0.75 million neonatal deaths. [258] Currently, the NMR stands at 28 per 1000 live births.[259] The annual burden of neonatal deaths reduced from 1.35 million in 1990 to 0.75 million in 2013[258] with rapid acceleration of NMR declines (33%) between 2000- 2013 compared to 17% declines between 1990 and 2000. [260] In India, the main direct causes of neonatal death in 2015 were prematurity (43.8%), birth asphyxia/trauma (18.9%) and sepsis (13.6%)[261] which suggests that care at the time of birth is an significant concern.

For stillbirths, in 2015, India had the highest rates in the world with approximately 592,100 stillbirths, contributing up to 22.6% of the global burden.[52] A hospital-based study has found that pregnancy-induced hypertension, eclampsia, abruptio-placenta, birth asphyxia, and pre-term labour are the underlying causes contributing to stillbirths in India.[262] Researchers suggest that poor quality of antenatal and intrapartum care are the leading causes for most preventable stillbirths in India.[262,263]

2.7.4: Summary of the literature review on QoC in India.

The previous section discussed the findings of my literature review and established a case for investigating the QoC at the time of birth in India.

In summary, the findings of my literature review highlighted that the bulk of the available evidence on quality of essential care during labour and childbirth in India emerges from the public sector. Most identified studies did not examine care at the time of birth in a comprehensive manner. The literature review on structural aspects of QoC identified deficiencies related to inadequate human resources, limited functioning of EmOC facilities and inadequate provision of recommended signal functions. I also found problems related to limited supplies of essential drugs and commodities, gaps in knowledge of health workers and wider infrastructural constraints.

The literature review on process aspects of QoC identified deficiencies related to non-adherence to evidence-based protocols for maternal and neonatal care and mistreatment of women at maternity facilities in India. In particular, research evidence on quality of maternity care provided in the private sector and research studies that have comprehensively addressed care at the time of birth were found to be limited.

Outcome deficiencies identified were related to a lack of information from health facilities on outcome indicators of QoC such as information on obstetric case fatality rates, near-misses or never- events. Overall, population based outcome measures show high rates of maternal mortality, neonatal mortality and stillbirths in India. All of these findings suggest that QoC at the time of birth is an extremely important concern for India.

2.8: Management practices at maternity facilities

2.8.1: Theoretical concepts on management practices

Management capacity has often been identified as a critical bottleneck for poor health indicators in LMICs[264] but their potential in improving QoC at hospitals has not been extensively studied. The World Health Organization (2005) defines good management as "providing direction to, and gaining commitment from partners and staff, facilitating change and achieving better health services through efficient, creative and responsible deployment of people and other resources." [264]

In hospitals, management competencies are needed to identify and prioritise problems, develop appropriate plans, effectively utilise available resources and track progress towards achievement of institutional goals.[264] Theoretically, it seems likely that if resources are available, a manager who understands the requirements necessary to provide high-quality maternity care pathways (figure 1) will put in place appropriate systems and procedures to support high-quality clinical care and respectful maternity services at institutions.

It appears that most of the theoretical concepts around management come from the business sector, which has been progressive to test innovative management strategies and quantify the impact of management practices in monetary terms rather than gains in quality. The notion that health services will be more effective if staff with managerial competencies are employed at a senior level is well established, and appears to have been influenced by many factors. [265] First, it is thought that effective cost-containment at hospitals will not be achieved without drawing health workers into a framework of accountability. Second, there is a belief that modern management practices such as those employed in the business sector could be applied to hospitals to increase their productivity. Third, funders (whether public or private) require accountability for the large sums of money they invest into health institutions. Fourth, the processes and transactions created by hospitals such as contracting, costing and billing are thought to better dealt by professionally trained managers and fifth, there is a belief that good management practices could lead to better returns on investment through financial earnings and cost savings.[265]

However, in hospitals unlike other organizations, managers need to understand not just the operational, human, institutional and structural factors but also issues around clinical care provision, patient safety and medical errors. [266, 267] These factors make the role of a hospital manager particularly challenging. Moreover, at public-sector hospitals in LMIC settings, there are more fundamental barriers to providing high QoC that are often beyond the control of individual managers. Some of these include limited availability of essential drugs, commodities, irregular electricity supply, infrastructural deficiencies and lack of skilled human resources as described in previous sections.[16]

Based on my review of the literature on management, quality of care and hospital setting, management practices at hospitals have been conceptualised as operations management,

performance management, target management and people management.[42-45] These practices are illustrated in figure 3 and further details are outlined below.

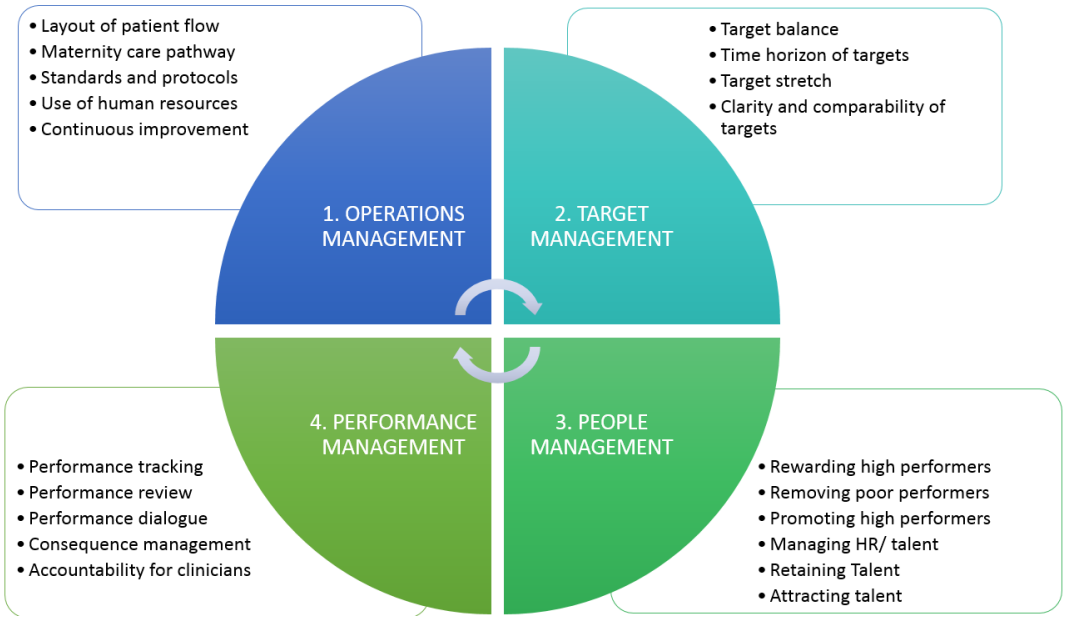
1. Operations management: Operations management refers to the design, management, and improvement of systems that affect a hospital's performance. A review of operations management literature identifies the following best practice categories: "lean systems" to eliminate waste and non-value-added activities, planning and control systems and quality management systems. [268-273] Good hospital operations are supported if health workers adhere to clinical guidelines and care pathways[274] that facilitate efficient patient-flow through the hospital[275] and by improving quality of clinical documentation. [276] Bloom *et al*. and Dorgan *et al*. have also proposed that efficient layout of patient flow, focus on continuous improvement and optimal utilization of resources are also operational best practices. [277,43] In the Indian context, although government guidelines on operational standards exist, there is limited research examining whether these operational standards are followed.[278,279]

2. Targets management: Performance targets are tools designed to improve accountability, transparency and performance of health facilities.[280,281] Effective target management refers to setting realistic, well-defined, time-bound and specific targets for maternity care services at facilities.[282] Bloom *et al.* and Dorgan *et al.* suggest that best practices in target management requires targets to include operational and financial dimensions and have short and long-term timeframes. [43,277] The introduction of targets and performance contracts is thought to encourage better hospital performance[283] and that incentives tend to be more effective when linked to institutional targets. [284]

3. People management: Human resources at maternity facilities are comprised of teams of medical, paramedical and auxiliary staff responsible for various individual functions with an aim to provide high-quality continuity of care to pregnant woman from the time of admission to discharge from the facility.[16] To a large extent hospital performance, depends on the knowledge, skills and motivations of individuals responsible for providing services. [285] A study of 61 hospitals in England found a positive association between good human resource practices (specifically, performance appraisal) and patient mortality.[286] Evidence from high-income countries suggests that incentives and team-based working increases job satisfaction[287], employee motivation, retention[288] and causes less stress[289].

Systems of training, supervision and career development are also thought to improve retention of health workers. [290,291] Bloom *et al.*[277] and Dorgan *et al*[43] suggest that good practices for people management include a structured approach to recruit, retain and manage health workers. They also suggest that effective incentive systems are linked to performance appraisals and should balance both financial and non-financial incentives. Merit-based promotions rather than by tenure or seniority are also considered best practices. [277] However, in LMIC settings, human resource systems are not as developed, and people management is often challenging. For example, in the public sector, decision-making on recruitment, positing and transfers is usually centralized and adequate supervision is an on-going challenge. [292]

Figure 3: Dimensions of management practices at maternity facilities



4. Performance management: Performance management allows managers to identify deficiencies in service provision[293] and if done effectively, is thought to improve care-processes and clinical outcomes.[294,295,296]Researchers have argued that multiple performance indicators are required to measure hospital performance accurately. [297-299] According to Scott *et al.*, an effective performance monitoring system is based on evidence-based clinical decision-making (through guidelines, protocols and pathways); it incorporates systems for process evaluation (audits, feedback, clinical indicators and process measures); and supports in defining, implementing and monitoring appropriate

indicators to measure quality improvement. [274] There is robust evidence from a Cochrane systematic review that supports the effectiveness of audits and feedback in improving professional practice and health outcomes. [195]

2.8.2: Empirical evidence on hospital management practices and quality

Although it is generally accepted that management practices influence quality of care at hospitals, empirical evidence examining this relationship is limited.[300] Perhaps, because management is hard to measure using quantitative methods and methodological advances in measurement have been recent, there is limited evidence to support these claims, particularly as there is a dearth of studies from LMIC settings.

The bulk of the peer-reviewed literature consists of non-empirical articles such as case studies, opinion-pieces, editorials but these often lack empirical data examining the relationship between management and quality of care.[301,302 303] Many researchers have noted this as an important evidence gap. [300,304-306] The only systematic review which examined the role of hospital managers in quality and patient safety found limited and inconsistent evidence on this relationship.[300] The modest evidence that exists does suggest that managers' time spent, engagement and work specifically on quality assurance influences indicators of clinical quality and patient-safety positively. [300] Managerial activities thought to improve quality include activities such as establishing goals and strategies to improve QoC, setting the quality agenda, promoting a quality improvement culture and procurement of institutional resources to ensure quality of care. [300]

The past decade has seen a rise in the innovative measurement efforts that have tried to quantify the relationship between management and QoC outcomes. Most of this research stems from the field of health economics and are primarily from studies in high-income countries. [42,46,300] Notable amongst these, is the pioneering work by Bloom *et al.* (2010) who initially studied management practices across manufacturing firms in numerous countries. [307] This work has since been replicated in the health sector and the tools developed by Bloom *et al.* (2010) have now been used for measuring management practices in diverse health system contexts such as in high-income (Australia, Canada, France, Germany, Sweden, UK, USA), upper-middle income (Brazil) and lower-middle income countries (India).[43,282,308,309]

These research efforts have employed a telephone-based interview methodology and assessed management practices under four key dimensions described earlier: measures of hospital operations, measures of hospital performance, measures of targets management at hospitals and measures of people management at hospitals.[44,310,311]

These measurement efforts have uncovered some interesting results. For example, in a cross-sectional study at cardiac units in USA, management practices were significantly associated with mortality as well as process of care measures.[312] In another study at substance abuse clinics in the USA, researchers have found a strong association between management practices and client days to treatment and increased revenue generated at these clinics. [313] Similarly, in UK hospitals, management practices were found to be strongly associated with both health outcomes (improved survival rates after acute myocardial infarction) and financial indicators. [310]

Other studies that conducted secondary analysis of data conducted as a part of the World Management Survey efforts (http://worldmanagementsurvey.org/), which collects data from over 2,000 hospitals in nine countries have found that hospitals with more effective management practices provide higher quality care.[46,42,311] One of these studies which restricted analysis to data from hospitals in the USA and England found that when hospital boards paid more attention to clinical quality, managers were more likely to pay attention to clinical quality and that hospital boards which used clinical quality measures more effectively had higher scores on target management and operations management.[46]

Bloom *et. al 's* tool has also been used in India, where it was administered to managers of 3,892 private sector hospitals as a part of a descriptive study. [44] In India, the researchers found that the average total management scores in Indian hospitals were poorer compared to hospitals in other high income countries but this study did not examine the relationship between management scores obtained by hospitals and QoC outcomes. [44]

However, it is important to note that the majority of research studies examining the relationship between management practices and QoC were done in high-income countries, mostly in the private sector and none of them specifically focused on examining the relationship between management practices and quality of maternity care provision.

Therefore, examining whether there is a relationship between management practices and QoC offered during labour and childbirth in maternity facilities is a key evidence gap.

Given the wide application of the Bloom *et al.*'s study instrument, the standard research methodology used across multiple countries which supports comparability and the limited time-frame of a PhD, this tool appears promising for adaptation and use at maternity facilities in Uttar Pradesh, India.

Chapter 3: Research setting and the context for the doctoral research

3.1 Study setting

Uttar Pradesh (UP) is India's most populous state with approximately 200 million people (about 17% of the population of India) living across its 18 divisions and 75 districts.[314] The population is predominantly rural (77%). Eight cities in Uttar Pradesh contain more than 1 million people (Kanpur, Lucknow, Ghaziabad, Agra, Varanasi, Meerut, Allahabad and Bareilly). Seventy-five percent of the population lives in rural areas and about 33% lives below the poverty line. The per-capita income of UP was US$522 compared to India's average of about US$1,097 in 2010-11. [314] UP has consistently been ranked within the bottom third amongst all Indian states on the Human Poverty Index since 1981, and has poor human development indicators compared to other Indian states.[314] The overall literacy rate is 70%, with 60% female literacy compared to a national average of 74% and 65%, respectively. [315]

The religious and caste characteristics of Uttar Pradesh show the strong presence of both Hindu and Muslim populations, and of Scheduled Caste groups (marginalised groups).[3] Approximately 80% of the population of Uttar Pradesh is Hindu, with the remaining 20% being Muslim. It is estimated that about 21% of the population belong to so called Scheduled Caste communities.[253,316]

In 2010-2011, Uttar Pradesh's maternal mortality ratio (359 per 100,000 live births) was the second highest in the country.[317] Neonatal mortality (45 per 1,000 live births) and infant mortality rates (63 per 1000 live births) are the highest in the country.[318] The total fertility rate of 3.8 is the highest in India, although contraceptive coverage is increasing.[319] Anaemia (85% in children and 51% in women) and malnutrition are significant concerns with a high percentage of children underweight (42%), wasted (20%) and stunted (52%). [320]

My doctoral study was conducted in three districts of Uttar Pradesh: Kanpur Nagar, Kanpur Dehat and Kannauj. With Kanpur as its capital, Kanpur Nagar district is the most populated of the study districts with 4.6 million people. Kanpur Dehat and Kannauj districts are almost exclusively rural with 90% and 83% of the population residing in rural areas and a population of 1.8 million and 1.7 million respectively. The proportion of Muslim population is lower in Kanpur Dehat (10%) than in Kannauj (17%) and Kanpur Nagar (16%). Kanpur Dehat has the

highest proportion of Scheduled Caste communities (26%) while Kannuj has 19% and Kanpur Nagar has 18%. [253]

Despite government schemes to improve rates of institutional births, 54 % of deliveries occur at home in Uttar Pradesh (57 % in Kannauj, 40 % in Kanpur Nagar and 52 % in Kanpur Dehat). Of the home deliveries, 11 %, 53 % and 29 % were conducted by skilled health personnel in Kannauj, Kanpur Nagar and Kanpur Dehat, respectively. [253]

Table 3 highlights important Reproductive, Maternal and Newborn Health (RMNH) indicators in Kannauj, Kanpur Nagar and Kanpur Dehat as compared to the UP-state average. Kanpur Nagar is predominantly urban, with higher literacy and lower mortality rates than the state average. By contrast, Kannauj and Kanpur Dehat are more rural with lower levels of literacy and higher mortality rates closer to the state average. Specifically, Kannauj district fares the worst across most of these RMNH indicators compared to the other two study districts. [315]

Table 3: Demographic and health indicators in Uttar Pradesh and study districts

Indicator	Uttar Pradesh	Kannauj	Kanpur Nagar	Kanpur Dehat
Population (in millions)	199.8	1.7	4.6	1.8
Rural population (%)	78	83	34	90
Literacy (%)	57	61	71	65
Fertility (lifetime)	3.3	3.7	2.6	3.2
Maternal mortality ratio (per 100,000)	345	267	267	267
Under five mortality (per 1,000)	94	99	52	97
Infant mortality rate (per 1,000)	71	78	36	65
Neonatal mortality rate (per 1,000)	50	55	24	43
Current use of modern FP methods among currently married (women (%)	31.8	23.2	39.7	38.6
Unmet need for family planning among currently married women (%)	29.7	43.2	23.7	25.0
ANC 3+ visit (%)	29.6	14.5	51.0	32.3
Institutional birth rate (%)	45.6	42.4	59.7	47.7
Delivery at home conducted by SBA (%)	21.8	11.2	53.2	28.6
Mother received post-natal check-up within 48 hours (%)	68.4	48.8	66.5	72.7
Newborn was checked within 24 hours of birth (%)	68.2	49.9	71.7	74.4

Newborn breastfed within one hour of birth (%)	32.9	27.0	41.0	47.0

Sources: Census 2011[315] and Annual Health Survey 2011[316]

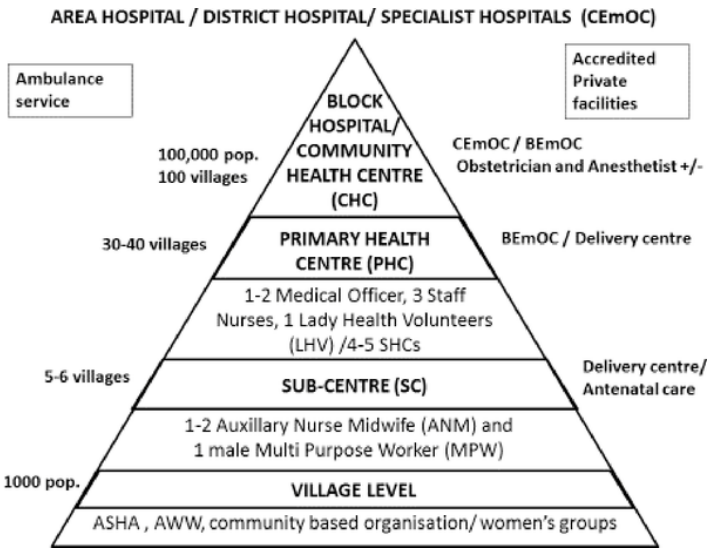
Note: The MMR estimates are grouped by states due to sample size limitations and the three districts have the same MMR grouping.

3.2: Health care system in India

The health system in India is mixed and consists of the public sector, the private-for-profit and the private not-for-profit sector. The public health system is three-tiered including primary, secondary and tertiary level facilities (Figure 4)[321]. The private-for-profit sector is heterogeneous and varies in size and capacity, depending on context of the district whereas the private not-for profit sector is relatively small.

In the public sector, the sub-centre is the primary unit in rural areas and often the first point of contact where women go to receive antenatal care services. In some instances, maternity services are also available at sub-centres, if auxiliary nurse midwife (ANM), female health worker (cadre) or staff nurses are available. At the next level are primary health centres, which although, envisioned as round-the-clock BEmOC sites, may not always provide maternity services. Community health centres (CHCs) are sites where obstetricians and paediatricians are available and they may function at the BEmOC or CEmOC level. First referral units (FRUs) are upgraded CHCs, sub-district hospitals, district hospitals and specialist hospitals that should, in principal, provide CEmOC care.[322]

Figure 4: Schematic representation of the public health system in India



Source: https://doi.org/10.1371/journal.pone.0159793

In urban areas, there are dispensaries, urban health centres and urban health posts, which provide antenatal care and referral services. Some urban health centres have been upgraded to provide maternity services. At the next level are maternity hospitals and other secondary and tertiary level hospitals that provide both BEmOC and CEmOC services.[323] There are medical colleges in most districts that provide specialised tertiary care services including CEmOC services.

Health workers in the public sector are paid a regular monthly salary depending on their grade and level of expertise. These salaries tend to be lower than earnings in the private sector and hence these jobs are not as lucrative. In recent times, there have many innovative schemes to attract health workers to the public sector such as additional monetary incentives if they work in rural areas, educational incentives, promotion and career enhancement opportunities and innovative public- private partnership schemes. However, the distinction between private and public sector providers is not straightforward as health care workers in public sectors may also have their own private practices where they work after their regular-working hours in the public sector.

Qualified health workers providing maternity care services at institutions include doctors, nurses, auxiliary nurse midwives who receive 5 years, 3 years and 2 years of pre-service training respectively. These qualified health workers are regulated, and legally allowed to provide institutional services. However, in India, as described previously, available evidence indicates that the distribution of qualified health workers is inequitable: 77.4% of the qualified health workforce lives in urban areas, although, just 31% of the Indian population is urban.[227] Also, research evidence suggests that there is a high reliance on unqualified personnel in rural areas including at hospitals.[70,230] In addition, there is no separate midwifery cadre in India and it is thought that a serious human resource shortages exist throughout the health system.[228]

In the private sector, there is extreme heterogeneity of facilities in India. An estimated 75% of private health facilities are micro-enterprises and the rest are medium to large medical establishments.[324] In my study, private sector maternity facilities were either private-for

profit or NGO owned facilities with basic emergency obstetric care (or higher) capability. The majority of private sector hospitals and beds are located in urban areas and are operated by qualified and registered private sector doctors or nurses.[325] Generally, larger private sector facilities tend to be registered with public authorities and therefore, in theory have some level of regulation and monitoring. Depending on the type of facility, health workers in the private sector earn a fixed monthly salary or receive fee-for-services.

3.3: Maternal and newborn health services provided at public sector facilities

Under the umbrella of the National Rural Health Mission, Indian public health standards have been defined that prescribe uniform standards for MNH services above the PHC level. These standards are shown in Table 4. They emphasize SBA, EmONC capability and efficient referral capacity at facilities. [326] Private sector facilities are also encouraged to provide similar standards of MNH services but detailed information on adherence to these standards by private sector is not available.

Table 4: Maternal and newborn care standards at Indian public sector facilities.

Level 2: Institutional (Basic Level)	**Level 3 Institutional (Comprehensive Level)**
PHC-Basic Obstetric and Neonatal Care (round-the clock services at PHCs, CHCs other than FRUs)	*FRU-Comprehensive Obstetric and Neonatal Care (DH, SDH, RH, CEmOC, selected CHCs)*
Standards for intrapartum care	
All in Level 1 (delivery by SBA or home delivery or at CHCs, PHCs not functioning round-the clock plus: *Availability of following services round the clock* • Episiotomy and suturing cervical tear • Assisted vaginal deliveries like outlet forceps, vacuum • Stabilisation of patients with obstetric emergencies, e.g. eclampsia, PPH, sepsis, shock • Referral linkages with higher facilities Essential newborn care as in Level 1 plus • Antenatal Corticosteroids to the mother in case of pre-term babies to prevent Respiratory Distress Syndrome • Immediate care of LBW newborns (>1800 grams)	All in Level 2 plus availability of following services round the clock: • Management of obstructed labour • Surgical interventions like Caesarean section • Comprehensive management of all obstetric emergencies, e.g. Eclampsia, Sepsis, PPH, retained placenta, shock. • In-house blood bank/blood storage centre • Referral linkages with higher facilities including medical colleges Essential newborn care as in Level 2 plus • Care of LBW newborns <1800 gm.
Postnatal and Newborn Care	
All in Level 1 plus • 48 hours stay post-delivery and all postnatal services for zero and third day to mother and baby. • Timely referral of women with postnatal complications.	All in Level 2 plus • Clinical management of all maternal emergencies such as PPH, Puerperal Sepsis, Eclampsia, Breast Abscess, post-surgical complication, shock and any other postnatal complications such as RH incompatibility etc. • Newborn Care as in Level 2 plus in district hospitals through Sick Newborn Care Unit

• Stabilisation of mother with postnatal emergencies, e.g. PPH, sepsis, shock, retained placenta • Referral linkages with higher facilities Newborn Care as in Level 1 plus: • Stabilisation of complications and referral • Care of LBW newborns >1800 gm. • Referral services for newborns that are <1800 gm. and other newborn complications • Management of sepsis	• Management of complications • Care of LBW newborns <1800 grams. • Establish referral linkages with higher facilities

3.4: Maternal health programmes and policies

Maternal and newborn health in India falls under the remit of the Ministry of Health and Family Welfare (MoHFW). Since India obtained its independence in 1947, there have been significant shifts with regards to programmes and policies on reproductive and maternal health. The evolution of quality in maternal health and major programmatic efforts for maternal newborn health are highlighted in Table 5.[327] Although, previous policy and programme efforts were focussed on expanding coverage, since 2000, there appears to have been a considerable emphasis on QoC for MNH.

As mentioned earlier, despite impressive progress, with declines in MMR from 437 to 178 per 100,000 live births (a 59% decline) between 1990-91 and 2010-12, India could not achieve MDG5a targets.[256] Since 2000, the Government adopted three major policies- the National Population Policy (2000)[328], the National Policy for Empowerment of Women (2001)[329] and the National Health Policy (2002)[330], all of which have a specific focus on quality in MNH.

Table 5: Summary of the evolution of quality in maternal health

Time periods	Key events
1947-60	• Focus on expansion of services in underserved areas • Limited health sector funding • Launch of vertical disease eradication programmes with first five-year plan • Maternal and child health priority area with expanded programming in first five-year plan • No evidence of effort on quality assurance - focus restricted to equity and human resources
1960-80	• Adoption of target-based family planning approach; pressure for meeting targets damages community maternal and child health services • Forced sterilizations during Emergency (1975-77) lead to neglect of maternal healthcare services • Quality concerns restricted to equity and quality of human resources

	• Alma Ata declaration (1978) renews focus on primary health and inspires concern for quality in health care
1980-90	• Vertical programmes on immunization and maternal health launched • Quality scope limited to equity, human and physical resources and effectiveness; no action strategies
1990-2000	• Structural Adjustment Programme leads to rise in private sector health investment in India • Reproductive and Child Health programme introduces integrated maternal and child health, family planning and reproductive health services • Efforts to ensure essential obstetric care and EmOC through strengthening health facilities and transport facilities, improving first referral units and blood transfusion services • Quality concerns voiced increasingly but no action strategies formulated

2000-present	• National Population Policy (2000) outlines Reproductive and Child Health strategy and sets specific maternal and infant mortality reduction goals
	• Quality focus in tenth and eleventh plans with strategies for quality assurance and appraisal
	• National Rural Health Mission launched, leading to expanded funding and decentralized programme implementation
	  ○ Emphasis on facility births
	  ○ Focus on skilled birth attendance (SBA)
	  ○ Infrastructure strengthening for basic and comprehensive EmOC through reforms under the NRHM
	  ○ Capacity building for SBA- training of nurse-midwives for SBA, task shifting – general physicians trained for anaesthesia for EmOC and for Caesarean section
	  ○ Raising demand for facility births- the JSY cash transfer program offering incentives to women and to ASHAs
	• Quality focus and action strategies in both programmes along with regular monitoring and feedback mechanisms
	• Quality initiatives include Indian Public Health Standards for quality assurance in primary care; Quality Assurance Committees at district/State level and assistance to states by National Accreditation Board for Hospitals and Healthcare Providers (NABH) for quality certification

Source:	**Srivastava *et al.* (2013), Chaturvedi *et al.* (2015)**

In 2006, the MoHFW initiated a conditional cash transfer programme known as the Janani Suraksha Yojana (JSY) that pays a cash incentive to women attending institutions for birth. The JSY has been a leading programme of the National Rural Health Mission (NRHM) of the Government of India.[331] The monetary incentives for women differs based on the context of individual states. In low performing states, the JSY program provides a cash incentive of INR 1400 and INR 1000 (equivalent £12-17) to women giving birth in a public or accredited private health facility. In high-performing states, the cash incentive is about half of that amount and

is restricted to women living below the poverty line and those from marginalised communities.[332]

The NRHM has also appointed community health workers known as Accredited Social Health Activists (ASHAs) in every Indian village.[333] Motivating pregnant women, accompanying them to institutions for childbirth and arranging suitable transportation to hospitals falls under the responsibilities of the ASHAs, who receive INR 600 (equivalent £7) for these tasks.

In the initial years, JSY benefits were restricted to women above 19 years of age and to women with parity of up to two, but due to opposition from advocacy groups, these restrictions were later removed. There were also other conditions that women had to fulfill such as completing all antenatal care visits which was later removed since it was not feasible to monitor this. A mandatary 48-hour postpartum stay at hospitals was also a condition for obtaining payments but this has also not proved practical since many women prefer to be discharged early[332] and vacating beds for other clients is an important priority especially in high-volume facilities. The JSY is one of the largest conditional cash transfer programmes in the world, with an estimated 80 million beneficiaries. Despite contributing to remarkable increases in institutional births, results from many evaluations have not found associated declines in mortality. [10,11,64]

3.5: Context of the PhD research within the Matrika project

My PhD research benefitted from funding by MSD for Mothers obtained by LSHTM academics leading the external evaluation of Matrika project funded by MSD for mothers and implemented by two NGOs – Pathfinder International (lead) and World Health Partners (partner) in Uttar Pradesh.

The aim of the Matrika project was to increase access to, and use of, basic emergency obstetric care and family planning services. It operated in Kanpur Nagar, Kannauj and Kanpur Dehat districts of Uttar Pradesh. The project worked towards three objectives between March 2013 to May 2016; (1) Establish a social franchise network of private providers and functional referral centres offering affordable antenatal care, emergency obstetric care, and family planning services; (2) Strengthen capacity of and linkages between rural private and public sector health providers to offer high quality services; and (3) Improve community awareness, demand and linkages with maternal health services among rural populations.

The overall impact evaluation of Matrika used quantitative and qualitative research methods to assess the impact of the project on a wide range of study outcomes, covering healthcare utilisation, quality of care, patient experience, healthy behaviours, health status and financial strain. The findings from the impact evaluation showed that the multi-faceted project did not have a measurable impact on the vast majority of outcomes, with the exception of a small effect on recommended delivery care practices. Notably, Matrika was found to have no effect on antenatal care (ANC) utilisation, ANC content of care, or ANC knowledge and preparedness.

The Matrika evaluation was led by Dr. Timothy Powell-Jackson, Ms. Loveday Penn Kekana and Dr. Andreia Santos at LSHTM and was done in collaboration with an Indian research agency called Sambodhi Research and Communications (Kultar Singh, Paresh Kumar and Dr. Kaveri Halder) based in New Delhi, India. My PhD research work was done alongside the overall impact evaluation and contributed some important information to the impact evaluation. Apart from receiving regular guidance from my co-supervisor Dr. Timothy Powell- Jackson, and guidance from Ms. Loveday Penn-Kekana on the analysis of qualitative data, none of the other academics involved with the larger Matrika impact evaluation provided substantial inputs on my PhD. I conceived and executed all aspects of the three separate research studies described in chapters six, seven and eight of this thesis.

Chapter 4: Role of the candidate, funding and research timeline

4.1: The role of the candidate

I am a medical doctor from Nepal and graduated from the Kathmandu University in 2004. I then received further training in public health from the University of Aberdeen graduating in 2007. After that, I went back to Nepal and worked in a variety of positions with non-governmental organizations, bilateral donors and UN agencies in Nepal and other countries in south Asia and south-east Asia. The focus of my professional career has been towards improving maternal and newborn health in resource-constrained settings.

In September 2013, I joined the LSHTM and developed my PhD research idea on QoC during labour and childbirth, after discussion with several academics at the LSHTM, my future career interests and the scope to conduct this work within the Matrika evaluation. Prior to finalisation of the protocol, I undertook a preparatory field-visit, designed all the data collection tools, finalised the research methodology and submitted an ethics application for the study. I wrote my doctoral research protocol that was approved by LSHTM examiners as a part of my upgrading document.

I lived in Lucknow, Uttar Pradesh, India for approximately seven months leading all research activities related to the PhD. During that time, I initiated contact with government officials from National Rural Health Mission and obtained the necessary permissions prior to approaching hospitals. I coordinated and managed relationships with local partners at Sambodhi, Pathfinder and World Health Partners. I finalised all the study instruments and provided oversight to the: I) translation of the tools into Hindi; ii) pretesting of the tools; and iii) development of the data collection mechanisms.

I conducted a pilot study to finalise the overall logistics for the study. I carried out sampling as described in the protocol and made site selection visits to most hospitals in the three study districts. I provided managerial and technical oversight to the primary data collection efforts and kept all partners informed of the progress. I developed a training manual using clinical training skills methodology and conducted the trainings myself to ensure that field-researchers were trained to competency over a 5-day training period. I ensured that the data were checked regularly for quality and consistency during the entire data collection phase. I travelled to all the twenty-six hospitals numerous times during data collection and managed

all logistical and administrative issues. I was responsible for deploying 14-field researchers and three field- supervisors during this time.

For the management survey, I adapted a pre-existing tool so that it was relevant to the context of Uttar Pradesh and led a three-day orientation programme to field-researchers on management. I piloted the management survey instrument at one hospital over a day, made required changes to the tool after piloting and then finalised the survey instrument. I conducted all the interviews with managers at thirty-three hospitals myself, prepared the transcripts, entered the data, ensured data quality and consistency.

During my time in Uttar Pradesh, I also provided regular updates to my supervisors and incorporated their feedback into the on-going work. I was responsible for all the data cleaning, data analysis and interpretation of all the work in this thesis. I wrote the first two drafts of all the three papers that have been included as results chapters and I have been managing the process of collaborating with all my co-authors and supervisors.

I was hired as a research assistant by MET for doing this work in Uttar Pradesh and paid a monthly salary for the duration of the fieldwork. In addition, the QoC tools that I developed were used for subsequent studies in Uganda and in Rajasthan, where I conducted the trainings. As a part of my contract with MET, I also submitted a preliminary report on QoC and management practices at maternity facilities in Uttar Pradesh to MSD for mothers. Although, my research provided important information to the larger Matrika evaluation, I was not involved in other aspects of the larger impact evaluation study.

4.2: Funding

Funding for this research was obtained from Merck Sharp & Dohme Corp. (“MSD”), a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, through its MSD for Mothers programme. Funding was used for general financial support, salaries, travel and overhead costs and all data collection activities. Non-financial support was received from Sambodhi Research and Communications, New Delhi, India who provided two-research assistants’ pro-bono that were involved in the management survey. MSD had a role in the design, collection, analysis and interpretation of data, in writing of the thesis or the manuscripts contained in this thesis or in the decision to submit the manuscripts for publication.

4.3: Research timeline

This section provides a timeline of activities involved in conducting my PhD research, which started when I enrolled into LSHTM in late September 2013. As mentioned earlier, over the course of my PhD work, I spent approximately seven months in Uttar Pradesh. Further details on the timeline of the PhD are presented in table 6 below.

Table 6: Timeline for the PhD

Year	Month	Activities
2013- 2014	September 2013- Dec 2014	• Preparatory reading and formative research • Finalised research topic • Concept note finalisation • Exploratory visit to India • Took relevant modules: Extended epidemiology, Statistical Methods in Epidemiology, Advanced Statistical Methods in Epidemiology, Data management • Research instrument development • Submitted for local ethics • Upgrading document finalised and upgrading seminar
2015	Jan – April 2015	• Preparatory work for fieldwork begins. • Translation of data collection tools into Hindi and back-translation • Conducted further pretesting and formative research to finalize tools. • Submitted to LSHTM ethics • Resubmission to ethics
	May – July 2015	• Travelled for fieldwork to Uttar Pradesh. • Meeting with local partners at Pathfinder and WHP • Meeting with MoH and hospital authorities • Conducted pretesting of the tools and training manual • Conducted a pilot study for QoC assessments: 3 days at public sector and 4 days at private sector using 2 observers for private sector and 4 for public facility • Amendments of tools based on results of the pilot study • Pilot tested the data entry software in CS- pro • Regular communication with supervisors. • Data collection begins with clinical observations and QoC study ends.
2015	Aug- Oct 2015	• Site Selection for the management survey • Training to field researchers • Pilot study at one public sector hospital x 1 day • Amendment of the data collection instrument • Data collection and data entry begins.
	Oct- Dec 2015	• Data cleaning and preliminary analysis

		• Submitted report to MSD for mothers
2016	Jan- Dec 2016	• Data analysis and writing up • Finalized paper 1 • Finalised paper 3
2017	Jan- July 2017	• Data analysis and writing up • Resubmission of paper 1- accepted at BWHO • Learnt qualitative analysis using NVIVO • Finalized paper 2- submitted at RH journal • Finalised first draft of paper 3 • Finalised thesis and submitted

Chapter 5: Conceptual framework, aims, objectives and study design

This chapter provides an overview of the conceptual framework, aims, objectives and the study design of my PhD study. The first section outlines the conceptual framework of my PhD and the aim and objectives. I then discuss the study design with sections on the development of the data collection instruments, sample size calculations, sampling strategy, study participants, data analysis, ethical issues, and data management.

5.1: Conceptual framework for my PhD

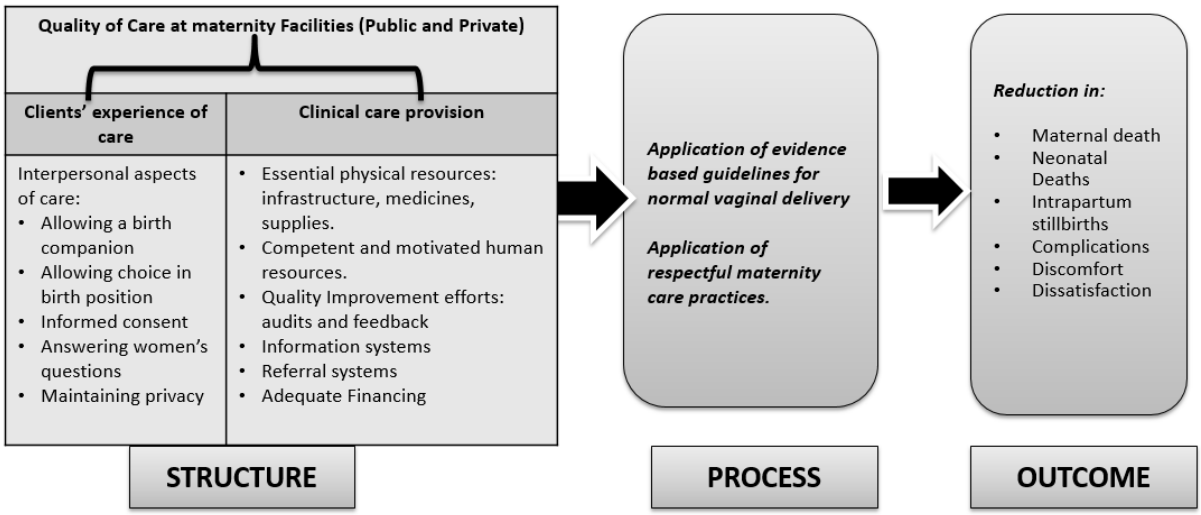
A conceptual framework is the composition of various concepts developed from the theoretical underpinnings to guide and better explain the proposed research work. The conceptual framework for my PhD (Figure 5) was developed to assess QoC for normal labour and childbirth at public and private sector maternity facilities (BEmOC or higher) in UP, India and combines the Donabedian QoC causal chain model (structure, process and outcome)[145] with the Hulton[239] and WHO framework[89].

At the level of maternity facility, QoC comprises of clients experiences of care and clinical care provision[239]. Experiences of care depend upon interpersonal aspects of care received during the labour and birthing process such as ensuring privacy, allowing a birth companion, freedom to choose birthing position, right to information, respect for choice and preferences, freedom from discrimination and others.[334] Clinical care provision or adherence to evidence-based practices depends upon numerous factors such as organizational factors, financing, infrastructure, health workforce, existing quality improvement mechanisms such audits and feedback mechanisms.[174] This corresponds to *structure* in Donabedian's framework; i.e. the context in which care is provided.[145]

The second box in the framework relates to my operational definition of QoC which is the application of evidence-based guidelines and respectful maternity care practices by maternity care personnel. This corresponds to the *process* element in Donabedian's framework.[145] Finally, the last box corresponds to *outcomes* such as improvements in clinical outcomes[335] (reduction of maternal, neonatal deaths, disability and complications) and positive client experiences. [157] Although, a comprehensive conceptual framework has been presented, my

doctoral research focuses on assessment of selected structure and process measures. Outcome measurement was beyond the scope of this PhD study.

Figure 5: Conceptual framework for my PhD



5.2: Aims of the doctoral research

Ultimately, my doctoral research aims to provide policymakers, public health managers, academics and clinicians with novel information about QoC during normal labour and childbirth in Uttar Pradesh. I will also examine whether management practices influence QoC at 26 public and private sector maternity facilities in U.P, India.

5.3: Specific Objectives

1. To describe QoC for normal labour and childbirth at 26 maternity facilities and to examine whether QoC is associated with characteristics of the women, characteristics of health workers and characteristics of maternity facilities in three districts of Uttar Pradesh, India.
2. To investigate and describe patterns of mistreatment encountered by women during labour and childbirth at 26 public and private sector maternity facilities and examine whether mistreatment is associated with socio-demographic characteristics of women, characteristics of health workers and characteristics of maternity facilities.
3. To assess and describe existing management practices at 33 maternity facilities and examine whether there is a relationship between QoC and management practices at 26 maternity facilities where clinical observations had taken place.

In addition to advancing the evidence-base on these topics, I hope that the data collection instruments developed in this study will be useful for measuring and improving QoC in labour and childbirth in high-burden settings of south Asia and sub-Saharan Africa.

5.4: Study design

This thesis uses cross-sectional datasets from two separate research studies. Over a seven-month period, I led two primary data collection efforts in three districts of Uttar Pradesh, India. To address objective one and two, I conducted clinical practice observations of 275 mother-newborn pairs at 26 public and private sector maternity facilities utilising a structured tool designed to assess QoC during normal labour and childbirth including aspects of mistreatment of women at maternity facilities.

To address objective three, I conducted a separate cross-sectional survey by interviewing hospital managers at 33 maternity facilities by using a previously tested survey instrument that was adapted to the context of rural Uttar Pradesh. These 33 maternity facilities also included the 26 facilities where clinical observations had taken place.

5.5: Data collection instruments

5.5.1: Quality of care assessments

For developing the clinical practice observation tools, I reviewed available guidance on best practices in management of normal labour and childbirth. These included the WHO guidelines for care during normal labour and childbirth,[204,336] NICE guidelines for intrapartum care, [5] AMDD EmONC needs assessment tools[22] and research instruments from the Gaala study[337]. I also conducted exploratory visits to the study sites in order to understand the socio-cultural factors, maternity-facility context, health worker characteristics, facility caseloads and existing maternity care pathways at health facilities. After reviewing the available literature, and learning from the field visits, I developed an early version of the study instruments that underwent peer-reviews by Indian and LSHTM researchers.

I also pre-tested these tools with field-researchers in Lucknow, UP and made relevant changes after pre-testing. A pilot study was also conducted to test the feasibility of methods and data collection procedures over 3 days in a sample of public sector facilities and 4 days in a sample of private sector facilities prior to finalizing the clinical practice observation tools.

Overall, the QoC assessment tool has three sections. The first section is a screening questionnaire that captured medical and obstetric history from client case records to ensure participants fulfil case definitions for normal labour and childbirth. Normal labour and childbirth was defined as labours that are spontaneous in onset, low-risk at the start of labour with a singleton pregnancy, in a vertex presentation, with a gestational age between 37 to 42 completed weeks of pregnancy. The second section captured information on demographic, socio-economic and educational status which was adapted from the National Family Health Survey questionnaire (2014-2015).[338] The third section included modules that captured provision of technical interventions and respectful maternity care provision from the time of admission of women up to one-hour post-partum. This section was developed based on review of WHO Integrated Management of Pregnancy and Childbirth (IMPAC) guidelines and NICE guidelines for care during normal labour and childbirth.[204,339] The entire QoC assessment tool is available from appendix 1.

5.5.2: Survey on management practices at maternity facilities

I adapted and used a management survey tool that has previously been used for measuring management practices in diverse hospital settings including in India[282,308,309] and tailored it to be applicable to the context of health facilities in rural Uttar Pradesh. Essentially, this interview-based tool assessed management practices at hospitals through four key management domains as described previously. Questions were structured but open-ended.

A scoring grid (between 1 to 5) was used by interviewers to give scores for responses to all questions depending on how closely answers matched descriptors for each question. The entire management assessment instrument is available from appendix 2. Briefly, operations management and performance management sections of the tool assessed how well modern management techniques were applied at maternity facilities, whether systems for continuous improvement existed; and whether facility performance was regularly tracked with useful indicators. Target management section assessed whether appropriate targets had been set, whether they pushed maternity facilities to improve their performance, and whether they were communicated, effectively throughout the hospital. People management section assessed whether there was an emphasis on good human resource practices.[42,277,307,310]

5.6: Sample size calculations

5.6.1: For clinical practice observations

The primary focus on my study is to examine the quality of normal labour and childbirth, which is the commonest event at any maternity facility. Clinical observations, therefore, were the most appropriate method to assess processes of care. Sample size calculations were done in the context of a defined evaluation with earmarked funds for data collection. Sample size estimation was dictated by logistical feasibility of obtaining necessary cases for clinical observations and response rates at individual public and private sector facilities. Obtaining good response rates and adequate number of 'normal vaginal birth' cases was found to be particularly challenging in the private sector. To ensure that I followed a scientific approach for estimating the required number of clinical observations at maternity facilities, I conducted power calculations for important indicators of interest such as Active Management of Third Stage of Labour (AMTSL), partograph and oxytocin use.

For calculating the required numbers of observations, I used the methodology of cluster-randomised trials, with clusters divided into 1) Public sector facilities and 2) Private sector facilities. The total number of clusters required, denoted by c, is calculated using the following equation[340] which is multiplied by the constant (4/3) to account for the approximately 3:1 ratio of public (n=18) and private facilities (n=7).[341]

$$c = 1 + (z_{\alpha/2} + z_{\beta})^2 \frac{\pi_0(1-\pi_0)/m + \pi_1(1-\pi_1)/m + k^2(\pi_0^2 + \pi_1^2)}{(\pi_0 - \pi_1)^2} \times 2 \times \frac{4}{3} \ldots\ldots (1)$$

Where, $z_{\alpha/2}$ is the level of significance and z_{β} is power, π_1 and π_0 are the proportions of use of evidence based practices at facilities in both sectors, m is the number of clinical practice observations at each health facility and k is the coefficient of variation, a measure of variation between heath facilities.

For Active Management of Third stage of labour: The recent *Stanton et.al* study found that AMTSL was practiced in 10% of all births in public sector facilities in similar neighbouring districts of UP.[242] The above formula shows that, assuming a coefficient of variation of 0.25, then if 10 observations each are conducted at 18 public sector facilities and 7 private sector

facilities, the study will have 80% power to detect difference between 10% use of AMTSL in public sector facilities and 28% use of AMTSL in private sector facilities.

Partograph use: A recent cross-sectional study done in 44 public sector facilities in a similar neighbouring state of India found that partograph was used in 11% of all births.[243] Using the above formula, assuming a coefficient of variation of 0.25, then if 10 observations each are conducted at 18 public sector facilities and 7 private sector facilities, the study will have 80% power to detect difference between 11% partograph use in public sector facilities and 30% partograph use in private sector facilities.

Use of oxytocics: *Iyengar et.al's* study in a neighbouring state of Uttar Pradesh found that oxytocin was given in 57% of all childbirths[243]. Using the above formula and assuming a coefficient of variation of 0.25, then if 10 observations each are conducted at 18 public sector facilities and 7 private sector facilities, the study will have 80% power to detect a difference between the use of oxytocin in 57% of public sector facilities and 88% oxytocin use after the birth of the baby in private sector facilities.

5.6.2: The assessment of management practices

The assessment of management practices at maternity facilities was purposive. Separate sample size calculations were not done for the management survey. Instead, I interviewed managers at all the facilities where clinical practice observations had taken place.

5.7: Sampling strategy

5.7.1: Clinical practice observations

I used a multistage sampling method. The initial sampling frame included 59 facilities in Uttar Pradesh that provided maternity services: all 29 of the larger public facilities listed by the Indian Department of Health i.e. facilities that reported at least 200 deliveries per month[342] and in theory were round-the clock BEmOC sites. In addition, I also identified 30 private facilities that, in theory, provided continuous maternity care. The private facilities were identified by key informants from Sambodhi Research and Communications (Lucknow, India), an organization that has worked in health research in the study districts for several years.[47]

In the second stage of sampling, I attempted to select six public facilities per district. This included a random selection of four community health centers, one medical college and one district hospital per district. Since Kanpur Dehat did not have a medical college, I had to select

an additional district hospital. We invited the 18 selected public facilities and all 30 private facilities to participate in our study; however, 13 facilities – all private – refused to participate. Among the nine private facilities that agreed to participate, no deliveries occurred while observers were present. The observational data that I analyzed therefore came from 18 public and eight private facilities. Further details on the sampling strategy and the study flow diagram are provided in chapter 6 and figure 6 and published elsewhere[47].

5.7.2: Management survey

A purposive sampling technique was utilized and all maternity facilities where clinical observations had taken place were selected for the management survey. All selected facilities had complex organizational structures, defined as facilities with separate administrative, information, therapeutic, diagnostic and support services and greater than five postnatal care beds. I received a better response rate and was able to interview managers at 33 facilities whereas clinical observations could only be obtained in 26 maternity facilities. The sampling strategy for the management survey is illustrated in Figure 10 in chapter 8.

5.8: Data collection

5.8.1: Clinical practice observations

At health facilities, female observers with nursing or midwifery backgrounds visited admissions, emergency, labour room and postnatal wards to identify pregnant women in latent phase of labour (regular uterine contractions with cervical dilatation less than 4cm), who are likely to undergo normal vaginal deliveries. They provided information sheets and consent forms to these women and obtained an informed consent following ethical consent procedures. After obtaining informed consent, they collected background information on women's medical and obstetric history from their case records to ensure that she was eligible for participation in the study. They prospectively observed care provided to these pregnant women during the entire duration of labour and childbirth up to one hour postpartum, using a structured, paper- based, clinical observation tool without interfering in any aspects of clinical care provision. Accompanying family members or companions were also approached, consent taken and detailed information on demographic, socio-economic and educational characteristic of women was collected from them, to minimise distress to the labouring woman.

5.8.2: Assessment of management practices

I established telephone contact with facility managers early on and set up appointments to ensure a high response rate. The management survey was conducted as a follow- up activity to the QoC assessments. Interviews were presented as confidential conversations about management experiences and challenges and did not cover sensitive issues, for example financial earnings of the hospital. The participants were not aware that they were being rated for their responses to the management questionnaire. All the interviews were double-scored; while I conducted all the interviews, another researcher also scored them independently.

5.9: Study participants

Clinical practice observations of labour and childbirth: Study participants included pregnant women with spontaneous, uncomplicated labour operationally defined as women with low-risk, gestational age between 37 and 42 (+0) weeks with singleton pregnancy with vertex presentation admitted to facilities who consented to participate in the study and their newborns.

Assessment of management practices at maternity facilities: Study participants for the management survey included administrators or clinical leaders at 33 maternity facilities (10 private and 23 public sector).

5.10: Data analysis

In this section, I have summarised the data analysis plan for my doctoral study. However, the individual results chapters (chapters 6 to 8) describe the methods and the analysis plan for each objective in greater detail.

The data obtained from clinical practice observations (for objective 1 and 2) and the management survey (objective 3) were coded either as binary, continuous or categorical variables. Both QoC and management datasets were double entered. Frequencies were calculated for all variables, and outliers or errors in the dataset were identified. In cases there were inconsistencies, I went back to the paper–based questionnaires and verified the entered data. After crosschecking for data accuracy and completeness, I conducted appropriate statistical tests to answer the study objectives using STATA 14 (Stata Corp. LP, College Station, United States of America).

For objective 1:

For every clinical observation, I assessed 42 clinical items related to QoC during labour and childbirth. Each item was coded as 1 if completed, and 0 otherwise. I finalised a comprehensive framework to assess QoC during labour and childbirth, by mapping these 42 clinical items into 17 overall essential care practices. Nine of these clinical practices were related to obstetric care and eight clinical practices were related to neonatal care. Some practices were based on a single item (e.g., early initiation of breastfeeding). Other practices were based on multiple items (e.g. Active Management of Third Stage of Labour). Further details on the development of the QoC indices using during analysis are provided in chapter six.

I applied principal component analysis to data on ownership of a common set of assets, and thereby, generated quintiles of wealth status for individual women.[343] I also applied weights using data on facility caseload of normal deliveries, the idea being to correct underrepresentation of facilities with fewer cases.

Descriptive analyses was conducted at the level of individual women using Svy command in STATA to account for clustering of patients within facilities. Prevalence, proportions, frequencies, and means were calculated for covariates disaggregated by public or private sector. Summary scores for obstetric care (nine practices), newborn care (eight practices) and an overall essential care at birth index (17 practices) were calculated as the percentage of practices completed per woman (i.e. the number of practices done divided by the number of practices measured within the QoC domain).

For investigating whether QoC was associated with characteristics of the women, health workers and health facilities, I used a two-level linear mixed effects model with a random effect at the facility level to account for clustering.[344] The exposure variable was public or private sector and the explanatory variables were women's characteristics (parity, age, referral status, caste, wealth, time and day of admission), health worker characteristics (delivery by qualified personnel, duty hours) and facility characteristics (volume). I also added a dummy variable for each observer in the regression model to mitigate biases across observers.

For objective 2:

I analysed quantitative data on 15 potentially harmful interventions obtained from quantitative checklist used during clinical observations of 275 normal labour and childbirth in maternity facilities. I also used qualitative data obtained from open-ended observers' comments recorded at the end of every clinical observation.

For the quantitative analysis, each item of mistreatment was coded as 1 if observed, and 0 otherwise. An aggregate score for mistreatment was calculated for every woman, which ranged from 0-15. Descriptive analyses were carried out at the level of individual women to describe patterns of mistreatment that occurs at maternity facilities. I then conducted a bivariate analysis to examine the relationship between indicators of mistreatment and socio-demographic characteristics of women. Means, proportions and a summary total mistreatment score were calculated for all covariates. Chi square tests were used to assess whether there was a significant difference amongst the use of practices considered mistreatment and the relevant co-variates. Since, this paper was conceptualised as a descriptive paper written to document and explain the context and reasons for mistreatment, I did not conduct any advanced regression analysis. Instead, I used qualitative insights obtained from observer's comments to further explain quantitative data on mistreatment.

For analysing the qualitative data obtained from observers' comments, I used a thematic approach to data analysis using Nvivo 11 software (QSR International). Comments that summarised similar findings across observations were used as examples to describe different themes of mistreatment.

For objective 3:

Two separate analyses were done to address objective three. First, to analyse the determinants of management practices at 33 maternity facilities, I calculated total scores for overall management, operations management, performance management, target management and people management at maternity facilities. I then categorised the sampled maternity facilities based on their management scores and conducted a descriptive analysis of the determinants of management practices at maternity facilities.

Second, to investigate the relationship between management and QoC, I merged the QoC and management datasets, which meant that data were analysed at the level of 275 individual

women. I then calculated Z scores for overall management and specific management dimensions to standardize these management scores. As with the earlier analysis, I applied sampling weights so that equal weights were given for observations at each facility, thereby, correcting for underrepresentation of facilities with fewer cases. The relationship between QoC (outcome) and total management and specific management Z scores (explanatory variables) were then analysed using multilevel, mixed-effects linear regression models. The models included robust standard errors, accounted for clustering at the level of facilities and used sampling weights. I also included a dummy variable for observer ratings and controlled for random effects at the level of individual facilities and health workers.

5.11: Research ethics

Ethical approval for the study was obtained from the Public Healthcare Society (PHS) Ethics Review Board in India and the London School of Hygiene & Tropical Medicine in the UK (LSHTM Ethics Ref: 8858) which included specific details on the QoC assessments and the final study instruments. The study protocol also received clearance from the National Health Mission in Uttar Pradesh.

The focus of this PhD research was on the observations of labour and childbirth at maternity facilities. It did not involve clinical interventions or other controversial issues such as collection of biological samples or conduct of clinical examinations. All the investigators, field researchers and staff from the local research partner were external and did not have a role in project implementation or provision of services at maternity facilities. All the observers employed for clinical practice observations were females. Efforts were taken to ensure that respect, dignity, privacy and cultural sensitivity were maintained as much as possible.

The observers were provided a five-day training including four hours specifically devoted to research ethics and informed consent as a part of their training. Unless, there were life-threatening emergencies, the observers were instructed not to directly intervene in cases where they observed medical mistreatment or in instances where substandard care was being delivered. In the training manuals, I had also designed various case- studies outlining different scenarios that observers could come across and the suggested process of dealing with such instances. The observers were instructed to report such instances to me at the end of every

day and I discussed these issues with field supervisors and informed the facility in-charges, as appropriate.

Informed written consent was taken prior to the start of data collection from all health workers, all the labouring women and managers of health facilities that participated in the study. An information sheet with details on the objectives of the research, confidentiality of data collected, the voluntary nature of participation, the possibility of refusal to participate at any time without providing a specific reason, and my contact details were provided to all the participants prior to the start of data collection. All participants in the study provided a written informed consent. The copies of the ethical approval letters and samples of the consent and information form are provided in appendix 3 and 4.

5.12: Data management

Data confidentiality was maintained through secure storage of paper-based questionnaires, anonymization of data once entered and secure storage with password protection. All efforts were made to ensure that the risk of confidentiality breaches was minimum. Data collected from QoC assessment and management survey were only linked at the time of analysis by me. Data were not shared with anyone apart from my supervisors. All completed questionnaires have been stored in a locked cupboard and will be destroyed after my Phd is completed.

Chapter 6: Quality of essential care at the time of birth: Findings from clinical observations of spontaneous labour and childbirth at 26 public and private sector facilities in Uttar Pradesh, India.

Preface

This chapter presents the first of three research papers, which form the results section in my PhD thesis. The objective of this paper was to describe variations in QoC at the time of birth in public and private sector maternity facilities and examine whether quality is associated with characteristics of women, health workers or facilities. This paper utilised primary data collected from clinical observations of 275 mother-baby pairs at 26 hospitals which were then weighted to obtain population-based estimates for the study districts. I also developed innovative frameworks for the measurement of QoC at the time of birth, by developing the overall essential QoC index, an index for quality of obstetric care and an index for quality of neonatal care. I conducted a descriptive analysis using the Svy command to incorporate weights and account for clustering at the facility level and used a multi-level mixed effects linear regression technique using the mixed command in Stata to investigate the association of QoC with characteristics of women, health workers and health facilities. Mixed effects regressions are a robust method that offers a practical way to analyse clustered data such as data from different hospitals and these techniques account for random effects and fixed effects in the linear regression model.

This is the pre-copy edited, final author approved version of the article submitted after peer review to the publishers. Since the published version of the article was copy-edited further for language and style and could not accommodate many of the interesting figures and important discussion points, in chapter 6, I have submitted the final author-approved version. A shorter copy-edited version of this paper was published by the Bulletin of the World Health Organization in a special theme issue on measuring quality of care (published June 2017). It is available online at http://www.who.int/bulletin/volumes/95/6/16-179291.pdf. The published version of the final manuscript is also available from appendix 5.

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Gaurav Sharma
Principal Supervisor	Véronique Filippi
Thesis Title	An investigation into quality of care at the time of birth at public and private sector maternity facilities in Uttar Pradesh, India

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

SECTION B – Paper already published

Where was the work published?	Bulletin of the WHO		
When was the work published?	June 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	No		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	The Bulletin of the World Health Organization
Please list the paper's authors in the intended authorship order:	Gaurav Sharma, Timothy Powell-Jackson, Kaveri Haldar, John Bradley, Véronique Filippi
Stage of publication	**In press**

SECTION D – Multi-authored work

6.1: Introduction

The quality of care (QoC) offered at maternity facilities affects pregnant women, physically and emotionally, but also impacts the survival and long-term health of mothers and newborns.[16,21] An increased focus on care during childbirth has multiple returns on investment through the reduction of maternal and neonatal deaths, prevention of stillbirths and future disability.[16,18]

Many countries have adopted policies to encourage births in health facilities and globally 72% of all deliveries, including 69% of deliveries in South Asia are now at institutions.[345] Failures in processes of care result in bad obstetric and neonatal outcomes[346,347] and poor quality is associated with low demand for maternal health services.[348,349] In addition, as childbirth is a normal physiological process, some care provided can be ineffective or even harmful.[114]

Despite substantial efforts to promote evidence-based obstetrics, the uptake of recommended interventions into clinical practice has been limited worldwide.[119,120,337] Clinical practices are influenced by multiple factors such as health-worker characteristics, patient characteristics, task-complexity, the institutional environment, and the socio-cultural environment,[350,351] making practices difficult to change.

India is the second highest contributor to maternal deaths globally (45 000 deaths in 2015)[352] and achieving the "Survive" targets for mothers and newborns as a part of the global strategy for women's, children's and adolescents' health (2016-2030)[6] is dependent upon future progress in India. Maternity services in India are available in both public and private sectors, from an enormous range of health providers. Maternity care in the public sector is provided through a network of level 1, 2 and 3 facilities, which in principle provide routine care, Basic Emergency Obstetric Care and Comprehensive Emergency Obstetric Care respectively.[353] The private sector is heterogeneous and ranges from small maternity homes to large (100 or more beds) multispecialty tertiary hospitals and medical colleges.

Increasingly, the private-sector has emerged as an important provider of maternity services. A recent analysis of Demographic and Health Surveys for 57 countries (2000–2013) found that the private-sector share among appropriate deliveries was 9–56% across world regions and it

is often less equitable than the public sector.[33] India has a mixed health system with a dominant private sector and extreme heterogeneity of facilities. An estimated 75% of private health facilities are micro-enterprises and the rest are medium to large medical establishments.[324] Recent estimates indicate that up to 22% of all deliveries in India occur in the private sector.[40] Women with previously negative pregnancy outcomes tend to choose private sector.[40] Higher socio-economic status and accessibility are associated with increased private sector use.[40] Scheduled caste and tribe status are negatively associated with use of private facilities.[248] The private sector is more expensive than the public sector and there is a perception that they provide better amenities and a higher standard of care.[248]

Although, there is considerable literature on the quality of emergency obstetric care,[354,355] there is limited descriptive information on QoC for uncomplicated spontaneous vaginal births in India, particularly, from private sector facilities. Most of the available evidence is from the public sector and from qualitative studies. These studies have found poor QoC with high rates of labour augmentation, routine episiotomies, no choice of position, non-adherence to protocols, limited monitoring, early discharge from the hospital and poor neonatal care.[71,77,78] It is well-established that the private sector is a driver of caesarean section rates in most world-regions.[36,39,356,357]In addition, a 2011 study using multivariate analysis of over 11 000 delivery records in Thailand found that women who delivered in the private sector were 9.4 times more likely to have had a caesarean than those who delivered in a public sector.[358] Using primary data obtained from clinical observations, we sought to describe QoC for labour and childbirth in public and private facilities and examine whether quality is associated with characteristics of the women, health workers and facilities in Uttar Pradesh, India.

6.2: Methods

6.2.1: Study setting

This study was nested within a larger research project in three districts of Uttar Pradesh (UP): Kannauj, Kanpur Nagar, and Kanpur Dehat.[359] Amongst Indian states, UP is the most-populous and its maternal mortality (258 per 100,000 live births) was the second highest and neonatal mortality (49 per 1,000 live births) was the third highest in 2012-13.[253] Neonatal mortality rates in the three study districts were high (Kannauj - 55, Kanpur Dehat - 41 and Kanpur Nagar - 24 per 1 000 live births), as was the maternal mortality ratio (240 per 100 000 live births).[253] Up to 39% of deliveries in UP occur at public sector facilities (43% in Kannauj, 46% in Kanpur

Dehat and 34% in Kanpur Nagar).[253] The private sector delivery share is estimated to be 18% in UP (15% in Kannauj, 34% in Kanpur Nagar, and 10% in Kanpur Dehat).[253] There are also widespread inequities across the continuum of care for all reproductive, maternal and newborn health indicators in the three study districts.[253] Primary data on estimated caseloads at our study sites show that the median annual number of deliveries was 2,216 (range: 1,433-5,126) and the caesarean section rate was 6% (range: 0%-34%) in our sample of public sector facilities. For private sector facilities, the median annual number of deliveries was 697 (range: 234-2,392) and the caesarean section rate was 32% (range: 2%-59%).

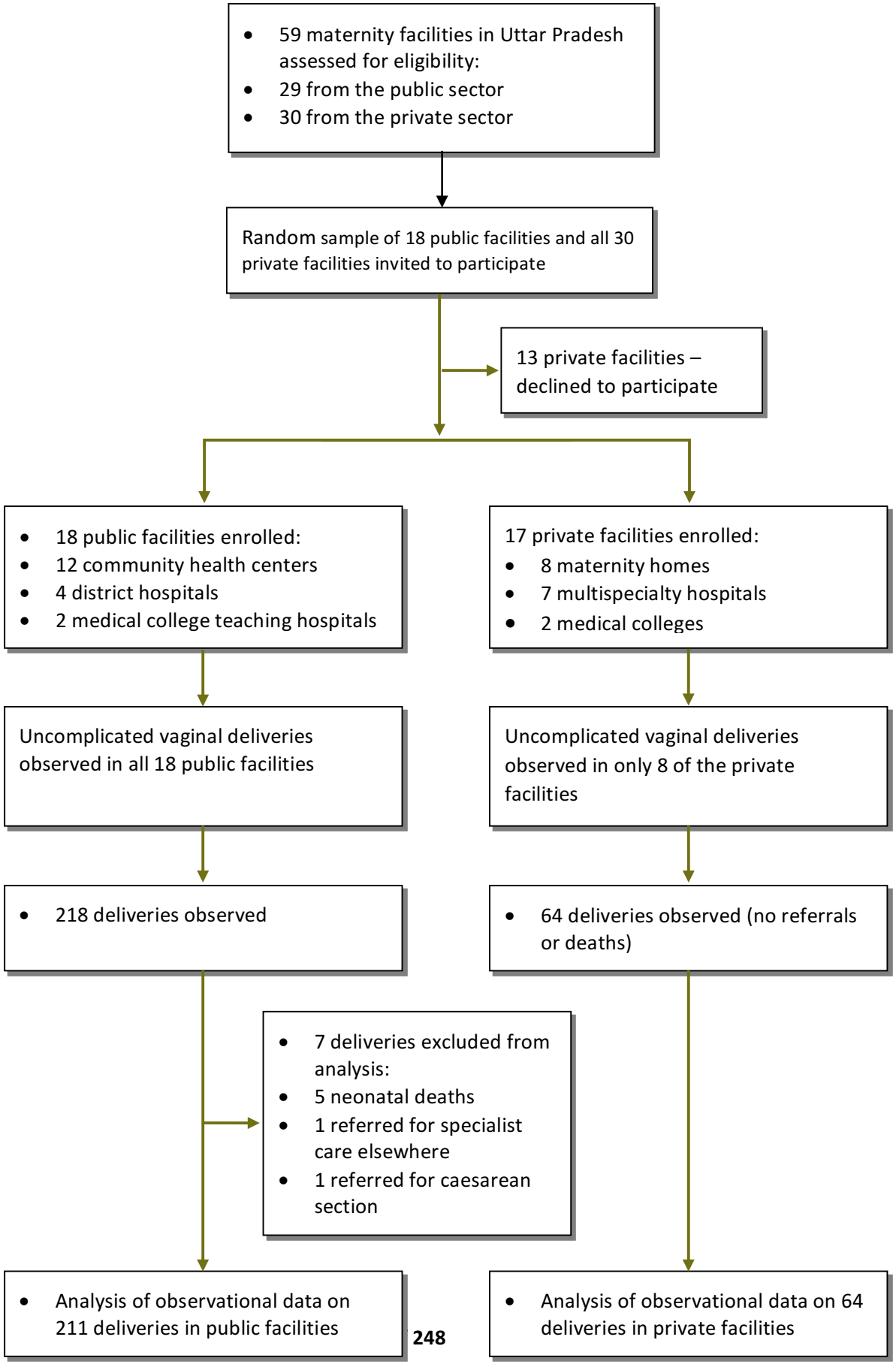
6.2.2: Sampling

We used a multistage stratified sampling methodology. The sampling frame included 29 public sector facilities (obtained from the Department of Health) and 30 private facilities (identified by key informants). The public sector facilities were eligible if they had 200 or more deliveries monthly based on HMIS data[342] and were round-the clock BEmOC sites. There was no sampling frame available for the private sector and a census of all private sector facilities was not feasible. We relied on local knowledge of our collaborating organisation (which has worked in health research in the study districts for years) to draw up a list of private sector facilities providing 24/7 maternity care in the study districts and selected all facilities for inclusion in the study. In the second stage, 18 public facilities were randomly selected stratified by type of facility and all agreed to participate. Amongst the 30 private facilities invited to participate, 13 facilities refused. There were no cases at an additional nine private facilities during the one week that researchers were stationed there. Figure 6 shows the overall study flowchart. Power calculations were done to estimate the required number of observations at each facility (discussed in chapter 5, section 5.6). We expected up to 10 observations in two days per public sector facility and 10 observations per week in private sector facilities and ultimately, could observe an average of 12 and 8 observations in public and private sector facilities, respectively.

6.2.3: Study participants

Study participants included pregnant women with spontaneous, uncomplicated labour operationally defined as women with low-risk, gestational age between 37 and 42 (+0) weeks with singleton pregnancy with vertex presentation admitted to facilities who consented to participate in the study and their newborns.

Figure 6: Study flow diagram for the assessment of QoC during labour and childbirth



6.2.4: Data collection

We developed a QoC assessment tool based on a critical assessment of previously tested instruments[337,360] and WHO guidelines for care during pregnancy and childbirth.[361] Questions capturing educational, demographic and socio-economic status were adapted from the National Family Health Survey questionnaire.[338] The QoC assessment tool is available from Appendix 1. At maternity facilities, 14 trained enumerators with maternal and newborn health backgrounds visited the admissions, emergency, labour room and postnatal wards to identify pregnant women who were likely to undergo uncomplicated vaginal births. Two enumerators were stationed at each facility and observed round-the-clock care provision. Data were collected after obtaining women's informed written consent between 26th of May to 8th of July 2015. Ethical approval was obtained from the Public Healthcare Society Ethics Review Board and the Indian Council for Medical Research in India, and the London School of Hygiene & Tropical Medicine in the UK.

6.2.5: Measures:

Learning from previous quality measurement efforts,[151,153] we operationalized QoC as encompassing clinical care provision and clients' experiences of care. Clinical care provision means application of evidence-based processes including principles of doing no harm and experiences of care relate to woman-centred respectful care practices during the birthing process.[141] We collected data on 42 items for every observation. Each item was coded as 1 if completed, and 0 otherwise. We then aggregated items into clinical practices – nine obstetric care practices, eight newborn care practices and 17 practices overall for essential care at birth (Table 7). Some practices were based on a single item (e.g. early initiation of breastfeeding was coded 1 if the mother was observed to initiate breastfeeding within one hour). Other practices were based on multiple items (e.g. Active Management of Third Stage of Labour was coded as 1 if uterotonic within 1 min, cord clamping and controlled cord traction were all done). Finally, summary scores for obstetric care (nine practices), newborn care (eight practices) and an overall essential care at birth index (17 practices) were calculated as the percentage of practices completed per woman (i.e. the number of practices done divided by the number of practices measured within the quality of care domain).

The exposure variable was public or private sector and the explanatory variables were women's characteristics (parity, age, referral status, caste, wealth, time and day of

admission), health worker characteristics (delivery by qualified personnel, duty hours) and facility characteristics (volume). Principal component analysis was applied to data on ownership of a common set of assets, and quintiles of wealth status were generated.[343]

Table 7: Indices for Quality of Care

Timing	Obstetric	Foetal/ Neonatal
On admission and first stage of labour	Regular monitoring of labour using a partograph (1 item: labour monitored regularly with partograph)	Checks fundal height and foetal presentation (2 items: fundal height checked; foetal presentation checked)
	Maternal infection prevention measures during admission (2 items: hand-washing prior to exam; sterile gloves worn prior to vaginal exam)	Foetal heart rate monitored at regular intervals (1 item: foetal heart rate monitored at regular intervals)
	Preeclampsia / eclampsia screening (2 items: BP monitored and urine tested for proteins)	
During second stage of labour to completion of childbirth	Maternal Infection prevention measures (2 items: health worker wears sterile gloves, cleans the vulva and perineum with an antiseptic)	Health workers prepared for resuscitation if required (2 items: ventilation bag available; newborn mask available and laid out)
	Active management of the third stage of labour (3 items: uterotonic within 1 min; cord clamping; and controlled cord traction)	Neonatal sterile cord care (1 item: sterile cord cutting)
	Maternal blood loss assessment (3 items: completeness of the placenta and membranes; assessing for vaginal tears; and lacerations and monitoring bleeding.)	Appropriate newborn thermal care (3 items: baby dried; skin to skin contact; baby covered with a dry towel)
	Women centred respectful care practices (5 items: process of labour explained to the mother or support person at least once; companion allowed to be with the mother during labour; women informed prior to vaginal examination; visual privacy ensured; mother asked about choice of position)	Apgar score 1 min and 5 minutes (2 items: Apgar score assessed at 1 min after birth; Apgar score assessed at 5 min after birth)
		Initiates early breastfeeding within 1 hour (1 item: mother initiates breastfeeding within 1 hour of birth)
	No harmful or unnecessary interventions done for mother during the labour and childbirth period (6 items: no enema; no pubic shaving; no apply fundal pressure to hasten delivery of baby or placenta; no uterine lavage after delivery; no manual exploration of the uterus after delivery; no use of episiotomy without indication)	No harmful or unnecessary practices for the newborn during the early neonatal period (3 items: no routine aspiration of the nose; no slap the newborn; no holding the newborn upside down)

	No harmful or unnecessary behaviours done to the mother during the labour and childbirth period (3 items: no restrict food and fluid during labour; no shout, insult or threaten the woman during labour and childbirth; no slap, hit or pinch the woman during labour and childbirth)	

6.3: Analysis

Descriptive analyses were carried out at the level of individual women using the Svy command in STATA 14 (http://www.stata.com/) to incorporate weights and account for clustering at the facility level. Post-sampling weights were applied to obtain population-based estimates using data on facility caseload of normal deliveries, the idea being to give greater weight to the QoC provided by facilities with more patients. Prevalence, proportions, frequencies, and means were calculated for covariates disaggregated by sector. A two-level linear mixed effects model was used with a random effect at the facility level to account for clustering.[344] The regression included the explanatory variables previously described as well as a dummy variable for each enumerator to mitigate biases across observers. Estimation was by restricted maximum likelihood. We used a Wald test to generate an overall *p*-value for each categorical variable (e.g. age group) to assess whether there was an association between a given explanatory variable and the quality of care outcome.

6.4: Results

6.4.1: Sample characteristics

Most observations were conducted in the public sector (n=211, 77%) and most women came directly to facilities (92%) (Table 8). Most women were between 20-35 years of age (90%), multi-parous (56%) and belonged to the *other backward caste* category (51%). Women of this caste were in higher proportion at private maternities than the public sector (*p*=0.002). A higher proportion of private sector clients were from the highest quintile and third quintile than public sector patients (*p*=0.07). A greater proportion of deliveries in the private sector (73%) compared to public sector (27%) were performed by qualified personnel (doctors, nurses, and midwives) (*p*=0.01). A greater proportion of cases were admitted to the private sector (99.5%) during daytime work-hours compared to public (93%) maternity facilities (*p*=0.003).

Table 8: Sample characteristics

	Unweighted			Weighted			
	Total (n=275)	Public (n=211)	Private (n=64)	Total (n=52047)	Public n=41512	Private (n=10535)	P value
Women's age							0.85
a. <20 years	16/275 (6%)	12/211 (5.6%)	4/64 (6.2%)	5.5%	6%	4.4%	
b. 20-35 years	247/275 (90%)	191/211 (90.5%)	56/64 (87.5%)	90.4%	90%	90.5%	
c. 35 years or more	12/275 (4%)	8/211 (4%)	4/64 (6.2%)	4.1%	4%	5.1%	
Parity							0.7
a. Primipara	119 (43%	90/ 211 (43%)	29/64 (45.3%)	44%	41.6%	53.4%	
b. Multipara	156 (57%)	121/ 211 (57%)	35/64 (54.7%)	56%	58.4%	46.6%	
Referral status							
a. Patient directly to this facility	243/275 (88.4%)	197/ 211 (93.4%)	46/64 (72%)	91.5%	96%	74%	0.003
b. Patient referred from another facility	32/275 (11.6%)	14/ 211 (6.6%)	18/64 (28%)	8.5%	4%	26%	
Caste							
a. "Scheduled caste"	59/275 (21.4%)	53/ 211 (25.1%)	6/64 (9.4%)	24.2%	29%	6.4%	0.002
b. "Scheduled tribe"	2/275 (0.7%)	0/ 211 (0%)	2/64 (3.1%)	0.3%	0%	1.4%	
c. "Other backward caste"	153/275 (55.6%)	111/ 211 (52.6%)	42/64 (65.6%)	51.4%	49%	61.1%	
d. "General caste"	61/275 (22.2%)	47/ 211 (22.3%)	14/64 (22%)	24.1%	22.3%	31%	
Socio-economic status							
a. 1st quintile (lowest)	56/275 (20.4%)	49/ 211 (23.2%)	7/64 (11%)	22.5%	24.2%	16%	0.07
b. 2nd quintile	54/275 (19.6%)	46/ 211 (22%)	8/64 (12.5%)	18%	19.5%	11%	
c. 3rd quintile	55/275 (20%)	36/ 211 (17%)	19/64 (30%)	18%	18%	18%	
d. 4th quintile	55/275 (20%)	46/ 211(22%)	9/64 (14%)	19.5%	22%	10%	
e. 5th quintile (highest)	55/275 (20%)	34/ 211 (16.1%)	21/64 (33%)	22.5%	17%	45.2%	
Type of birth attendant							
a. Qualified birth attendant	113/275 (41%)	75/211 (35.5%)	38/64 (59.4%)	36%	27%	73%	0.01
b. Unqualified SBA	162/275 (59%)	136/211 (64.5%)	26/64 (40.6%)	64%	73%	27%	
Admission during work hours?							
a. Within work hours (9:00 AM -17:00 PM)	254/275 (92.3%)	191/211 (90.5%)	63/64 (98.4%)	94.4%	93%	99.5%	0.003
b. Out of hours (17:01 PM to 8: 59 am)	21/275 (7.6%)	20/211 (9.5%)	1/64 (1.5%)	5.5%	7%	0.5%	
Admission during weekends?							
a. Admission during weekdays	211/275 (77%)	158/211 (75%)	53/64 (83%)	77%	76%	82%	0.58
b. Admission during weekends.	64/275 (23%)	53/211 (25%)	11/64 (17%)	23%	24%	18%	

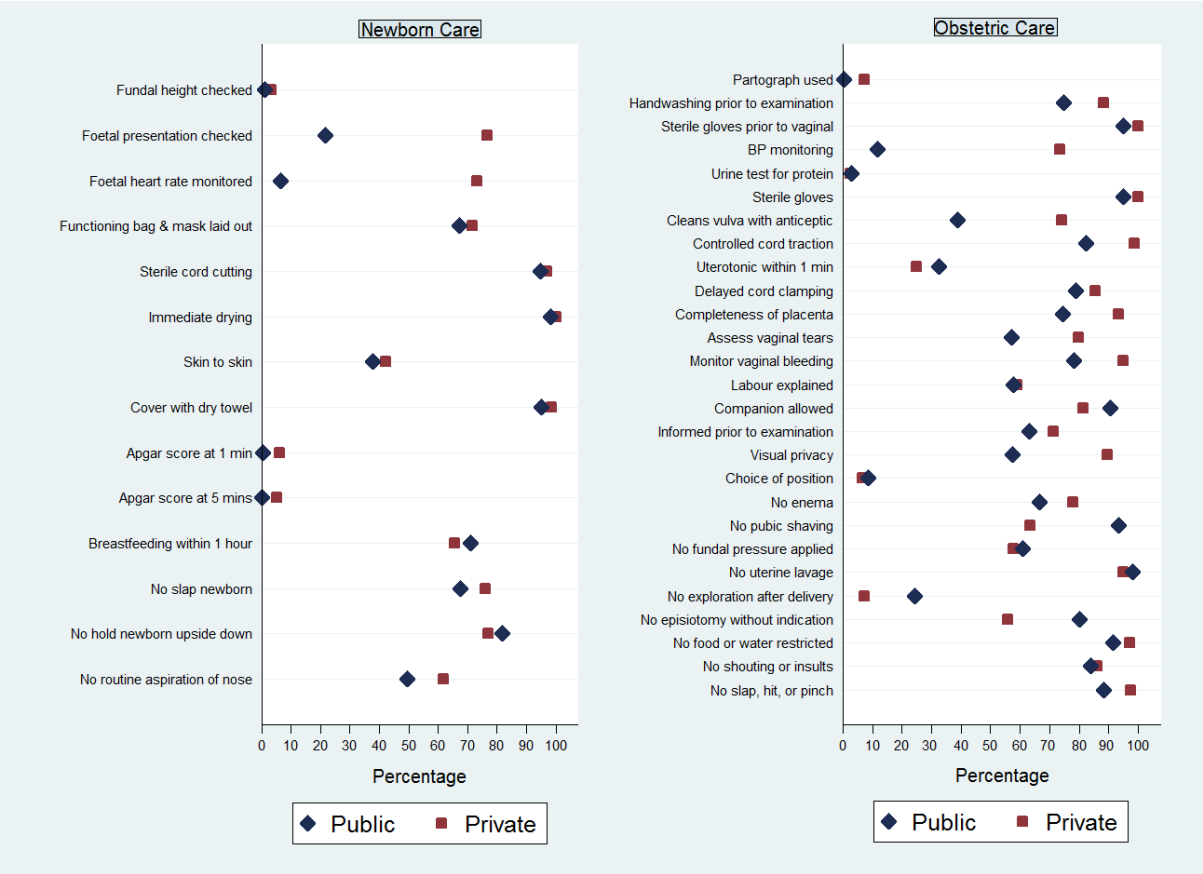
6.4.2: Variations in essential care at birth across public and private sectors facilities

Table 9 below shows the QoC by sector for each of the clinical practices measured. For obstetric care provision, monitoring of labour using partograph (2%), screening for pre-eclampsia/ eclampsia (2%), woman-centred care (4%), no harmful/unnecessary interventions (4%) and AMTSL (24%) were particularly low in both sectors. Facilities in both sectors performed relatively better for maternal infection prevention measures during admission (76%) and no harmful health worker behaviours (74%). However, partograph use (p=<0.001), maternal infection prevention measures during childbirth (*p*=0.05) and maternal blood loss assessment (*p*=0.01) were significantly better in the private sector compared to the public sector. We did not find any significant differences between sectors in use of no harmful or unnecessary maternal care interventions (*p*=0.2) or in harmful health worker behaviours towards mothers (*p*=0.45).

For foetal/neonatal care, foetal heart rate monitoring at regular intervals (20%), assessment of foetal presentation and fundal height (1%), and assessment of Apgar scores at 1 and 5 minutes (1%) were especially poor across both sectors. Facilities in both sectors performed relatively better for resuscitation preparedness (68%), sterile cord care (95%) and support for early initiation of breastfeeding (70%). However, significant differences were seen between public sector (7%) and private sector (73%) for foetal heart rate monitoring (*p*=<0.001). Figure 7 shows data disaggregated further by each of the 42 items observed.

Quality of essential care during labour and childbirth was found to be deficient (36%) across the entire sample of maternity facilities (Table 9). On average, 45% of clinical practices were completed amongst women giving birth in the private sector compared to 33% in public sector facilities (*p*=0.01). For obstetric care, private sector clients received 40% of the recommended obstetric care practices compared to 28% in the public sector (*p*=0.01). Neonatal care was also better in the private sector (p=0.02) where clients received 51% of recommended practices compared to 39% in the public sector.

Figure 7: Quality of care items for obstetric and newborn care by sector using weighted data.



The results from the multivariate analysis reveal that overall QoC was 6 percentage points higher (p=0.03) in private sector facilities than public sector facilities, after controlling for confounders (Table 10). We found no association between use of qualified personnel, facility caseload or client characteristics and overall QoC at the time of birth. Specifically, there were no statistically significant differences in quality of care with respect to the woman's age, parity, referral status, caste, or socio-economic status. However, admission during the weekends was associated with a 3-percentage point poorer standard of care (p=0.03).

We examined adjusted variances between health workers and health facilities and found greater variation within health workers than between health workers for QoC (SD within=0.004, SD between=0.002, intraclass correlation of 0.33). Similarly, there was greater variation within health facilities than between health facilities (SD within= 0.005, SD between =0.002, intraclass correlation of 0.27). We found that QoC did not change significantly by the order of observation, suggesting that health workers were not exerting more effort simply because they were being observed. Graph showing limited Hawthorne effect is presented in Figure 8.

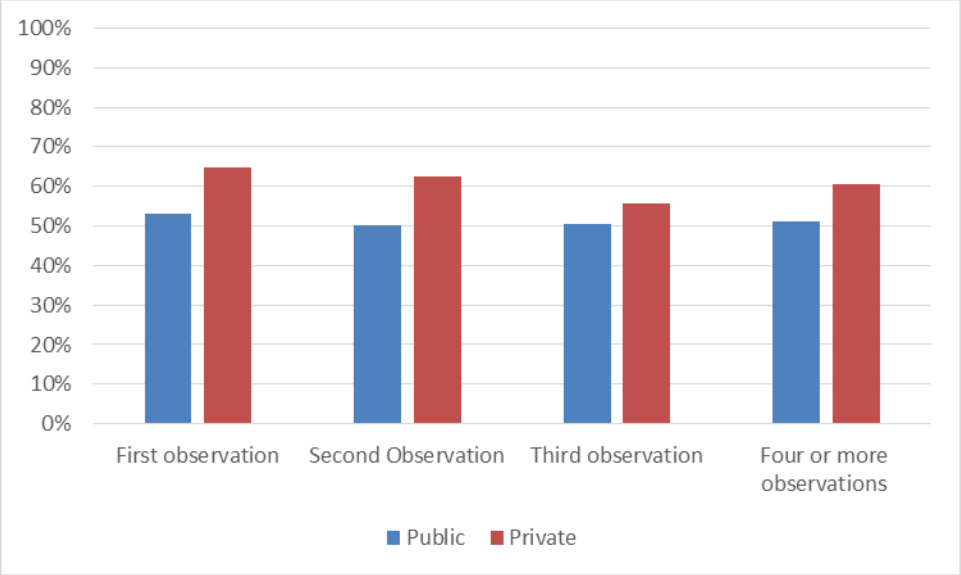
Table 9: Variations in essential care at birth across public and private sectors in Uttar Pradesh, India

Measures	Unweighted estimates (n, %)						Weighted estimates (%)					
	Total (n = 275)	**Public (n = 211)**	**Public sector 95% CI**	**Private (n=64)**	**Private sector 95% CI**	***p value***	**Total (n = 52 047)**	**Public (n = 41 5 12)**	**Public sector 95% CI**	**Private (n = 10 53 5)**	**Private sector 95% CI**	***p value***
Clinical practices for obstetric care												
Regular monitoring of labour using partograph	3 (1.1)	1(0.5)	0.1 to 3.3	2 (3.1)	0.7to 12	0.07	1.6	0.2	0.1 to 1.9	7.2	1.7 to 26	<0.001
Maternal Infection prevention measures during admission	212 (77)	159 (75.4)	69 to 81	53 (83)	71.4 to 90	0.21	76.4	73.4	65 to 80	88.2	77 to 94	0.1
Screening for Preeclampsia/ Eclampsia	3 (1.1)	2 (0.9)	0.2 to 3.7	1 (1.5)	0.2 to10.5	0.67	2.3	2.22	0.5 to 9.3	2.5	0.3 to 16	0.9
Maternal Infection prevention measures during childbirth	115 (42)	76 (36)	30 to 43	39 (61)	48.4 to72.2	<0.001	45.5	38.3	31 to 46%	74.1	59 to 85	0.05
Active management of the third stage of labour	73 (26.5)	58 (27.4)	22 to 34	15(23.4)	14.6 to 35.5	0.52	24.5	25.4	19.3 to 32.5	21	11 to 36	0.7
Maternal blood loss assessment	124 (45.1)	81 (38.4)	32 to 45	43(67.2)	54.7 to 77.6	<0.001	43	34.5	27.4 to 42.4	75.7	61 to 86	0.01
Women centred respectful care practices	12 (4.4)	9 (4.3)	2.2 to 8	3 (4.7)	1.5to 14	0.88	3.4	3	1 to6	5.6	1.1 to 24	0.5
No harmful interventions done to the mother	15 (5.4)	14 (6.6)	4 to 11	1 (1.5)	0.2 to10.5	0.12	4.3	5	3 to 9	1.5	0.2 to 10	0.2
No harmful health worker behaviours towards the mother	215 (78.2)	162 (77)	70.5 to 82	53 (83)	71.4 to 90.3	0.306	74	72.4	64 to 79	81	57 to 93	0.45
Clinical practices for newborn care												
Checks fundal height and foetal presentation	4 (1.4)	1(0.5)	0.1 to 3	3 (4.7)	1.5 to13	0.014	1.1	0.5	0.1 to 3.6	3.4	0.7 to 14	0.08
Foetal heart rate monitored at regular intervals	61 (22.2)	20 (9.5)	6.2 to 14	41 (64)	51 to75	<0.001	20	6.6	45 to10.5	73.3	58 to 84	<0.001
Health workers prepared for resuscitation, if required	179 (65.1)	132 (62.6)	56 to 69	47(73.4)	61.2 to 83	0.11	68	67.2	60 to74	71.5	51 to 86	0.8
Neonatal sterile cord care	265 (96.4)	202 (96)	92 to 98	63(98.4)	89.5 to 99.8	0.3	95.2	94.6	89 to 97.5	97.5	84 to 99	0.5
Appropriate newborn thermal care	84 (30.5)	62 (29.4)	23 to 36	22(34.4)	23.7 to 47	0.4	38	36.5	29 to 45	42.4	26 to 62	0.7
Apgar score 1 min and 5 min	1 (0.36)	0 (0)	0 to 0	1 (1.5)	0.2 to 10.5	0.07	0.9	0	0 to 0	4.7	0.6 to 27	0.08
Initiate early breastfeeding	191 (69.4)	148 (70)	64 to 76	43(67.2)	55 to77	0.6	70	71	62 to 78	65.6	49 to 79	0.6
No harmful or unnecessary practices for the newborn	95 (34.5)	70 (33.2)	27 to 40	25 (39)	28 to 52	0.3	38	35.3	28 to 43.5	49	31 to 67	0.3
Aggregate indices of quality of care at time of birth												
Obstetric care Index	31.2	29.6	28 to 31	36.5	33 to39.5	0.03	30.5	28.2	26 to 30.5	40	35 to 44	0.01
Neonatal care index	40	37.6	36 to 39	48	44 to 51.6	0.02	41.3	38.9	37.2 to 41	51	45 to 57	0.02
Essential care at birth index	35.3	33.4	32 to 35	42	38 to 45	0.01	35.6	33.3	31.6 to 35	45	40 to 49	0.01

Table 10: Results from the multilevel mixed effects linear regression

Outcome: Essential care at the time of birth index	**Coef.**	***p* value**	**95% Conf. interval**
Explanatory variables			
By sector			
• Public sector	Base		
• Private sector	0.06	0.03	0.01- 0.11
Was the admission on a weekend?			
• Weekday admission	Base		
• Weekend admission	-0.03	0.03	-0.06- 0.003
Number of deliveries at maternity facility last year			
• low volume <2000 deliveries/ year	Base		
• average volume (2000-2999 deliveries/year)	0.01	0.77	-0.05- 0.06
• High volume (>3000 deliveries/ year)	-0.02		-0.08- 0.05
Woman's age			
• Less than 20 years	Base		
• 20-34 years	0.01	0.91	-0.04- 0.05
• 35 and greater	0.01		-0.05- 0.08
Parity			
• Primipara	Base		
• Multipara	0.01	0.22	-0.01- 0.03
Referral to the hospital?			
• Patient directly to this facility	Base		
• Patient referred from another facility	0.00	0.84	-0.04- 0.03
Caste			
• Scheduled caste and scheduled tribe	Base		
• Other backward caste	0.02	0.15	-0.01- 0.04
• General caste	0.03		0.00-0.06
Socio-economic status			
• 1st quintile (lowest)	Base		
• 2nd quintile (lower)	0.00		-0.03- 0.03
• 3rd quintile (average)	0.00	0.08	-0.03- 0.03
• 4th quintile (higher)	0.00		-0.03- 0.03
• 5th quintile (highest)	0.04		0.0- 0.07
Admission during work hours?			
• Within work hours (9:00 AM -17:00 PM)	Base		
• Out of hours (17:01 PM to 8: 59 am)	-0.01	0.62	-0.05- 0.03
Who conducted the delivery?			
• Non-qualified birth attendant	Base		
• Qualified birth attendant	0.01	0.61	-0.02- 0.04

Figure 8: Estimated Hawthorne effect across sampled observations in 26 hospitals of Uttar Pradesh



6.5: Discussion

Using data from clinical observations in Uttar Pradesh, we found that essential care at the time of birth provided to women and their newborns was poor quality. There were significant differences amongst sectors, with private facilities outperforming public sector facilities for overall care at birth, obstetric and neonatal care. The private sector also performed better for specific procedures such as maternal blood loss assessment, monitoring of progress of labour and monitoring of foetal heart rate. Preventive measures against major causes of maternal mortality such as haemorrhage, sepsis and hypertensive disorders were frequently not done at facilities in both sectors.

Our study advances the descriptive evidence base on QoC at the time of birth in India, particularly for the private sector which has an increasing market share for maternity care.[33] We used direct observations of clinical practices that offer many advantages over other quality assessment methods. We found no evidence that observing health workers generated a Hawthorne effect. In addition, we provided a comprehensive measure of QoC that includes adherence to evidence-based guidelines, use of harmful and unnecessary interventions and behaviours, and respectful care practices. The essential care at birth, obstetric care and neonatal care indices could be used for monitoring QoC in other settings.

The findings from the multivariate analysis confirmed that the private sector provided a higher standard of care compared to the public sector and QoC was not associated with

characteristics of the patient, facility, or midwifery personnel. However, admission during weekends was associated with poorer quality of care. Our findings are similar to other studies that have found a weekend-effect with poorer obstetric and neonatal care outcomes during weekends. [362,363]

Although care was less likely to be provided by qualified staff in the public sector, qualified personnel attending births was not associated with better quality of care. Previous studies have shown that even when a qualified birth attendant is present they may not be adequately skilled.[78,364]A study using standardized patients in India also found minor differences between trained and untrained providers and QoC, although, this study did not focus on maternal and newborn care.[178]

We did not find any relationship between facility size and QoC at birth. This could perhaps be explained by the fact that our observations were limited to uncomplicated vaginal births and QoC in this setting was deficient across all sampled facilities. Previous studies have found better QoC at higher level facilities, potentially explaining why patients bypass lower level facilities.[348] Although, we do not have robust evidence on factors influencing quality of obstetric and neonatal care at facilities in India, there is evidence from other low income countries which shows that provider effort may be a key determinant for QoC[365] and that the private sector provides better QoC because it has superior operational and management systems including better incentive schemes to attract better qualified and motivated staff.[178] We intend to explore some of these issues in subsequent analyses.

Our findings are similar to other studies from India that have found partograph use to be especially weak and that monitoring often consists of repeated unhygienic vaginal examinations with inadequate attention to either foetal or maternal well-being.[71] We found slightly higher rates of AMTSL compared to a recent study in neighbouring districts of UP.[77] Respectful care was poor in both sector: only 4% woman received rights-based care.[141] Verbal (13%) and physical abuse (8%) was endured by some women. Our informal observations during data collection were consistent with other studies, in Madhya Pradesh[66] and Rajasthan[78], that found labour room environments were chaotic and health workers can be dominant, abusive and threatening on occasions.[66] Some researchers have suggested that inadequate knowledge and skills, staffing shortages, poor quality in-service trainings, lack of enabling environments and limited supportive supervision could be underlying causes of poor

quality care in India.[66,71] We note that the Government of India and its partners are implementing a range of schemes to improve the quality of intrapartum and immediate postpartum care.[366] Given immense shortages of skilled human resources for maternity care, focused efforts to establish a professional cadre of midwives could be beneficial. We found greater variance in QoC within individual health workers than between them. This could indicate that health workers do not follow standard protocols or provide preferential care.

We note several limitations of the study. First, there may have been observer bias due to the general perception in the community that the private sector is superior because it has better infrastructure and better trained personnel, leading to an over-estimation of quality in private facilities. Second, there were challenges to sampling the private sector. Not only did 13 private facilities refuse to participate, we had no official sampling frame from which to select the facilities. It is possible that the QoC of the participating private facilities was different from those that were either not sampled or refused to participate. Third, aggregating numerous indicators masks variations between individual indicators but was essential to report comprehensively on QoC. In developing aggregate measures of quality, we gave equal weight to each indicator as there was no scientific basis for applying intervention-specific weights. The validation of the index was beyond the scope of the present study. On the other hand, there were no refusals by women to recruitment and a strict case-definition was followed which minimises selection bias at the level of participants. Researchers were well-trained and a structured instrument was used which limits subjectivity.

Although, the government has had success in encouraging women to deliver in facilities, we found limited evidence-based care practiced at public and private sector maternity facilities in UP. Our findings suggest three key implications. First, there is a need for authorities to introduce a systematic effort to measure and identify existing quality gaps during labour and childbirth especially in high-burden states. These efforts should include private-sector facilities as they provide a substantial proportion of maternity care in India. Second, reasons for high rates of untrained personnel providing maternity care and widespread non-adherence to recommended protocols should be investigated further. The practice of relying heavily on personnel, not formally-trained, to provide maternity care is a worrying model of service provision in the 21st century, which makes improving QoC particularly difficult because such personnel are invisible within the health system. Third, tailored quality

improvement initiatives[88] must be designed for facilities in both sectors with regular auditing of actual care-processes linked to functional accountability mechanisms.

Chapter 7: An investigation into mistreatment of women during labour and childbirth in maternity care facilities in Uttar Pradesh, India: a mixed methods study

Preface:

Chapter 6 presented results on overall quality of care at the time of birth in public and private sector facilities. Since there is limited research evidence on mistreatment of women in maternity facilities in Uttar Pradesh, I decided to investigate mistreatment in detail.

In this chapter, I report on a mixed-methods study employing structured clinical practice observations and analysis of open-ended observer comments to describe the nature and context of mistreatment of women at public and private sector facilities in Uttar Pradesh India. For the quantitative data, I used a bivariate descriptive analysis technique and for the qualitative data, I used a thematic approach to analyse open-ended observer comments and describe patterns of mistreatment in public and private sector maternity facilities.

The results of the study show a mixed picture of care during labour and childbirth at public and private sector maternity facilities with a high prevalence of certain harmful practices. I demonstrate that mistreatment of women frequently occurs in maternity facilities in Uttar Pradesh as a result of complex factors related to policy, infrastructure and resources, ethics, culture and poor standards at maternity facilities.

www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Gaurav Sharma
Principal Supervisor	Véronique Filippi
Thesis Title	An investigation into quality of care at the time of birth at public and private sector maternity facilities in Uttar Pradesh, India

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

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Reproductive Health
Please list the paper's authors in the intended authorship order:	Gaurav Sharma, Loveday Penn-Kekana, Kaveri Halder, Véronique Filippi
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	As first author on this paper, I developed the idea for the paper, undertook the analysis, wrote the first two draft of the manuscript and incorporated co-author comments

Student Signature: 

Date: _____

7.1: Introduction

The number of maternal deaths remains high in India with 45,000 estimated deaths in 2013.[5] Since 2006, the Government of India has promoted skilled attendance at birth and rapidly expanded the Janani Suraksha Yojana (JSY) programme that now benefits approximately 40% of India's birth cohort.[367] The JSY is a cash transfer programme that provides a monetary incentives to women delivering in health facilities.[332]

However, recent evidence from JSY has been cautionary and highlights the need to improve Quality of Care (QoC), concomitantly with efforts to increase institutional births.[10] Ensuring high QoC at the time of birth encompasses the application of evidence- based obstetric and neonatal care and efforts to ensure positive birth experiences for pregnant woman. [89] Respect, dignity and emotional support, although, integral to ensuring positive birth experiences have been overlooked in research, policy, programmes and practice.[368,15]

There is now increasing research evidence on mistreatment of women during labour and childbirth from both high,[80,128-131] and lower income settings[132-134]. Mistreatment has been previously described as disrespect and abuse,[125] obstetric violence[126] and dehumanised care.[127] However, conceptualising what constitutes mistreatment, and therefore how to measure mistreatment are both complex. A comprehensive definition of mistreatment needs to capture the health, human rights and socio-cultural dimensions of mistreatment, while, measurement efforts need to capture what, where, how and why mistreatment occurs.[81] Freedman *et al.* have highlighted that measurement efforts should also be able to capture whether mistreatment was intentional or not, and the role of local societal norms (for example- women's status, patient-provider dynamics) that influences women's perceptions of mistreatment in different contexts. [81]

Given these challenges, a recent WHO systematic review tried to establish the evidence-base for mistreatment globally.[80] They reviewed 65 studies (53 qualitative and 12 quantitative) from 34 countries and found that most studies have used different operational definitions and measurement approaches.[80] Amongst the quantitative studies, only three studies reported a prevalence of mistreatment at maternity facilities, which varied from 15 to 98%.[80] This review also proposed a typology of items considered mistreatment, and identified the following: physical, verbal or sexual abuse, stigma and discrimination, lack of informed

consent, breaches of confidentiality, neglect and abandonment, refusal to provide pain relief, lack of supportive care, detainment in facilities, bribery and extortion.[80] The review incorporated elements from the work by Bowser and Hill (2010), who proposed seven categories of disrespect and abuse, namely: 1) physical abuse (beating, slapping, punching), 2) non-consented care (prior to vaginal examination or caesarean operation), 3) non-confidential care (lack of privacy), 4) non-dignified care (shouting, scolding, and demeaning care), 5) discrimination (based on age, wealth status, caste group), 6) abandonment during care (being left alone after childbirth), and 7) detention in facilities (if clients cannot pay user fees). [125]

However, a phenomenon often overlooked in the disrespect and abuse discourse relates to the overuse of inappropriate or unnecessary interventions for care at normal birth. There are examples of health workers in both high and low-income settings underusing simple, inexpensive interventions (for example, birth companionship or counselling on breastfeeding) and overusing ineffective interventions that are more technical, lucrative or convenient despite potential for harm (for example: labour augmentation without indications or caesarean sections).[369-371]

For this study, we operationalised mistreatment as those related to the following: 1) disrespect and abuse (no privacy, no birthing position choice, not informing women prior to a vaginal examination, not allowing birth companions, not explaining reasons for augmentation of labour, restricting food and water and informal payments); 2) Overtreatment (routine use of enema, routine use of perineal shaving, application of extreme fundal pressure, routine uterine lavage, routine manual exploration of the uterus and routine episiotomy); and lastly, 3) Under-treatment (deficiencies in infection prevention by individual health workers, deficiencies in hospital environmental hygiene and use of unqualified attendants). Research and programme efforts to improve QoC at the time of birth have largely neglected to examine and address mistreatment in such a comprehensive manner. Further, it is also possible for both under treatment and overtreatment to occur within the same patient and within the same facility [370] which makes interpreting data difficult but this should be considered by researchers working to improve QoC.

Uttar Pradesh (UP) is India's most populous and deprived state.[253] In related work, we previously described overall poor quality of care at the time of birth[47] but did not specifically

examine mistreatment of women at maternity facilities. There are limited number of studies that have described patterns and the context of such care at maternity facilities especially in the private sector which has an estimated 18% of the market share for maternity care in UP. [253] This information is essential for understanding the context of care provision and in developing effective interventions, policy and advocacy approaches for improvement of QoC at the time of birth. Available research evidence indicates that women with previously negative pregnancy outcomes tend to choose private sector.[40] Higher socio-economic status and accessibility are associated with increased private sector use.[40] Scheduled caste and tribe status are negatively associated with use of private facilities.[248] The private sector is thought to be more expensive than the public sector and there is a general perception amongst Indian women that the private sector provides better amenities and a higher standard of care.[248]

Qualitative studies in India have described many challenges to ensuring high QoC during childbirth such as overcrowding of labour rooms, chaotic work environments, poor coordination between health workers, limited skills and competence of health workers in performing routine care procedures.[65,66,372] They have also described situations where labouring women have been left unsupported, were shouted at or slapped, not given information about what procedures were being done and why they were receiving it. [66,239]

In this paper, we report on the nature and context of mistreatment recorded during 275 clinical observations of labour and childbirth in 26 maternity facilities in Uttar Pradesh. This rich observational data helps us in describing the context of care-provision in a low- resource setting including what, how and why mistreatment of women during labour and childbirth occurs at maternity facilities.

7.2: Methods

7.2.1: Study setting

The study was conducted in the districts of Kannauj, Kanpur Nagar and Kanpur Dehat of Uttar Pradesh. In 2012-2013, the maternal mortality across Uttar Pradesh was 240 per 100,000 live births.[253] At this time, the neonatal mortality rate were 55 per 1000 live births in Kannauj, 41 in Kanpur Nagar and 24 in Kanpur Dehat. [253] Despite government schemes to improve rates of institutional births in public sector facilities, approximately 39% of deliveries in UP (43% in Kannauj, 46% in Kanpur Dehat and 34% in Kanpur Nagar) occurred at public sector facilities

in 2012-2013.[253] The private sector delivery share was estimated to be 18% in UP (15% in Kannauj, 34% in Kanpur Nagar, and 10% in Kanpur Dehat) during that time.[253] The National Rural Health Mission has also appointed community health workers known as Accredited Social Health Activists (ASHAs) in every Indian village.[333] Motivating pregnant women, accompanying them to institutions for childbirth and arranging suitable transportation to hospitals at the start of labour also falls under the responsibilities of ASHAs who are paid a small monetary incentive (INR 600-equivalent £7) for these tasks.

7.2.2: Sampling

Our sampling frame included all high-volume public sector facilities (>200 monthly deliveries based on HMIS data[342]) and established private sector facilities providing round-the-clock basic emergency obstetric care identified by Sambodhi Research and Communications (Lucknow, Uttar Pradesh) that has extensive experience of working in health research in the study districts. After mapping of facilities, we selected six public sector facilities per district by conducting a random selection of four community health centres, one medical college and one district hospital and we invited all identified private sector facilities to participate. Since Kanpur Dehat did not have a medical college, we selected an additional district hospital. Amongst the selected facilities, all public-sector facilities agreed to participate while 17 private facilities (out of 30) agreed to participate. At nine of the private facilities that agreed to participate, there were no deliveries while observers were present. Therefore, the observational data that we analysed came from 18 public facilities and 8 private sector facilities. Further details on the sampling methods are described elsewhere.[47] The overall study flow diagram was presented in Figure 6.

7.2.3: Study participants

Study participants included pregnant women with spontaneous, uncomplicated labour (defined as women with low-risk pregnancy, of gestational age between 37 and 42 weeks and singleton vertex presentation, admitted to facilities who consented to participate in the study) and their newborns.

7.2.4: Data collection

We collected data on 15 potentially harmful interventions as outlined previously. Each item was coded as 1 if observed and 0 otherwise. An aggregate measure of mistreatment was developed which was the mean of observed items of mistreatment for every woman (Range: 0-15). Potential covariates included women's age, parity, referral status, caste, socio-

economic status, delivery by qualified personnel, admission during work-hours, admission during weekends and public or private sector. For socio-economic status, wealth quintiles were generated using principal component analysis using data on ownership of household assets. [343]

We conceptualised mistreatment of women during labour and childbirth as disrespect and abuse, overtreatment and under treatment during the time of birth as described previously. Specifically, our questionnaire captured information on ensuring adequate privacy, explaining the process of labour, restricting food and fluids, informing women prior to vaginal examination and prior to labour augmentation, performing an enema, perineal shaving, not allowing a birth companion, not offering choice of birthing position, routine episiotomy, physical abuse (slapping or hitting), verbal abuse (insult, threaten and shout), routine application of fundal pressure, routine uterine lavage and routine manual exploration of the uterus after childbirth.

Questions capturing educational, demographic and socio-economic status were adapted from the National Family Health Survey questionnaire.[338] At the end of every case, clinical observers with maternal and child health backgrounds were encouraged to record open-ended comments about the QoC they observed, particularly, anything they felt was important to explain the context and things that were particularly striking to them. Observers had been oriented to the principles of respectful maternity care during field-level trainings.[141] A team of 14 clinical observers working in pairs at each facility observed care round the clock. They visited the admissions, emergency, labour room and postnatal wards to identify pregnant women who were likely to undergo uncomplicated vaginal births and observed care provided from admission to one hour postpartum. Data were collected after obtaining women's informed written consent between 26th of May to 8th of July 2015.

7.2.5: Ethics

Ethical approval was obtained from the Public Healthcare Society (PHS) Ethics Review Board in India and the London School of Hygiene and Tropical Medicine in the UK (LSHTM Ethics Ref: 8858). The study also received government clearance from the National Health Mission in Uttar Pradesh.

7.3: Analysis

7.3.1: Measurement

We collected data on 15 potentially harmful interventions as outlined previously. Each item was coded as 1 if observed and 0 otherwise. An aggregate measure of mistreatment was developed which was the mean of observed items of mistreatment for every woman (Range: 0-15). Potential covariates included women's age, parity, referral status, caste, socio-economic status, delivery by qualified personnel, admission during work-hours, admission during weekends and public or private sector. For socio-economic status, wealth quintiles were generated using principal component analysis using data on ownership of household assets. [343]

7.3.2: Quantitative analysis

Descriptive analyses were carried out at the level of individual women using STATA 14 (Stata Corp. LP, College Station, United States of America). Since preliminary analysis showed that all women encountered at least one item of mistreatment (Appendix 6), we categorised the sample into two groups based on the median number of items of mistreatment observed, as shown in Table 11. We then conducted a bivariate analysis to examine the relationship between indicators of mistreatment and socio-demographic characteristics. Means, proportions and a total mistreatment score were calculated for all covariates. Chi square tests were used to assess whether there was a significant difference amongst the use of practices considered mistreatment and the relevant co-variates.

7.3.3: Qualitative analysis

The open-ended comments were transcribed in Hindi and translated to English and analysed using Nvivo 11 software (QSR International). A thematic analysis approach was utilised. Two researchers (GS, LPK) independently reviewed comments line-by-line and then agreed on a set of codes broadly categorised into codes related to the quantitative checklist and codes for other emerging issues. Both researchers then jointly coded all the open-ended comments. In cases where disagreements arose between researchers, further discussion took place until consensus was achieved. Throughout the analysis process, researchers reflected on how their background, training and worldview might influence their interpretation of results and efforts were taken to minimise them. We triangulated the quantitative data with qualitative comments. Comments that summarise common findings across observations are reported.

7.4: Results

We first report on women's socio-demographic characteristics categorised by two overall mistreatment levels. Next, we present bivariate analysis of the prevalence of specific indicators of mistreatment for which quantitative data are available and examine their relationship with socio-demographic characteristics of the sample. Finally, we report our qualitative findings, which provide additional information, and triangulate these to the quantitative results, where possible, to further explain the nature and the context in which mistreatment occurs.

1. Demographic characteristics

The majority of observations were conducted in the public sector (n=211, 77%) and most women came directly to facilities (88%) (Table 11). Amongst our sample, the majority of participants were between 20-35 years of age (90%), multi-parous (53%), belonged to the so-called "other backward class" category (55%) and were from the lowest wealth quintile (20%). Most deliveries were performed by unqualified personnel (59%) during regular work-hours (92%) on weekdays (77%). The only variable significantly different was timing of admission and a greater proportion of mistreatment was observed in cases admitted during work hours compared to observations done beyond regular working hours (p=0.02).

Table 11: Socio-demographic characteristics of the sample by two overall levels of mistreatment

	Total (n=275) N, (%)	**Less than or equal to median number of mistreatment items N, (%)**	**Greater than median number of mistreatment items N, (%)**	**P[a] value**
1. Women's age				
a. <20 years	16 (5.8)	14 (7.5)	2 (2.3)	0.23
b. 20-35 years	247 (89.8)	165 (88.2)	82 (93.2)	
c. 35 years or more	12 (4.4)	8 (4.3)	4 (4.6)	
2. Parity				
a. Primipara	119 (43.3)	76 (40.6)	43 (48.9)	0.32
b. Multipara	145 (52.7)	102 (54.6)	43 (48.9)	
c. Grandmultipara	11 (4.0)	9 (4.8)	2 (2.3)	
3. Referral status				
a. Patient comes directly to this facility	243 (88.4)	164 (87.7)	79 (89.8)	0.62
b. Patient referred from another facility	32 (11.6)	23 (12.3)	9 (10.2)	
4. Caste group[b]				
a. "Scheduled caste and tribe"	61 (22.2)	38 (20.3)	23 (26.1)	0.40
b. "Other backward caste"	153 (55.6)	109(58.3)	44 (50.0)	
c. "General caste"	61 (22.2)	40 (21.4)	21 (23.9)	
5. Socio-economic status				

a. 1st quintile (poorest)	56 (20.4)	41 (21.9)	15 (17.1)	0.56
b. 2nd quintile	54 (19.6)	35 (18.7)	19 (21.6)	
c. 3rd quintile	55 (20.0)	39 (20.9)	16 (18.2)	
d. 4th quintile	55 (20.0)	39 (20.9)	16 (18.2)	
e. 5th quintile (wealthiest)	55 (20.0)	33 (17.7)	22 (25.0)	
6. Delivery by qualified attendants				
a. Qualified attendants [c]	113 (41.1)	78 (41.7)	35 (39.8)	0.76
b. Unqualified attendants [d]	162 (58.9)	109 (58.3)	53 (60.2)	
7. Timing of admission				
a. Within work hours (9:00 AM -17:00 PM)	254 (92.4)	168 (89.8)	86 (97.7)	0.02
b. Out of hours (17:01 PM to 8: 59 am)	21 (7.6)	19 (10.2)	2 (2.3)	
8. Admission day				
a. Admission during weekdays	211 (76.7)	141 (75.4)	70 (79.6)	0.45
b. Admission during weekends	64 (23.3)	46 (24.6)	18 (20.5)	
9. Sector				
a. Public	211 (76.7%)	138 (73.8)	73 (82.9)	0.09
b. Private	64 (23.2%)	49 (26.2)	15 (17.1)	

[a] For the comparison of the proportions for less than or equal to median number of items of mistreatment observed and greater than median number of items of mistreatment that were observed.

[b] The caste system in India is a system of social stratification that places people in occupational groups. Members of *scheduled* castes are the lowest castes in society and protected by the government through special concessions.[373] For caste, we have used the exact language of the various ethnic categories given in Indian national family health survey questionnaires.

[c] Doctors, nurses or nurse-midwives – with at least 5, 4 and 2 years of pre-service training, respectively – who are licensed, regulated and endorsed by the government to provide maternity care at health facilities.

[d] Accredited social health activists, cleaners, hospital porters, other community health workers, traditional birth attendants and others who are not legally allowed by the government to provide maternity care at health facilities.

2. Patterns of mistreatment by socio-demographic characteristics

Figure 9 below shows that amongst mistreatment practices, birthing position choice not offered to the labouring woman (92%), manual exploration of the uterus after delivery (80%) and reason for augmentation not explained (46%) were particularly high at facilities in both sectors.

Figure 9: Quantitative results showing the prevalence of indicators of mistreatment in public and private sector maternity facilities

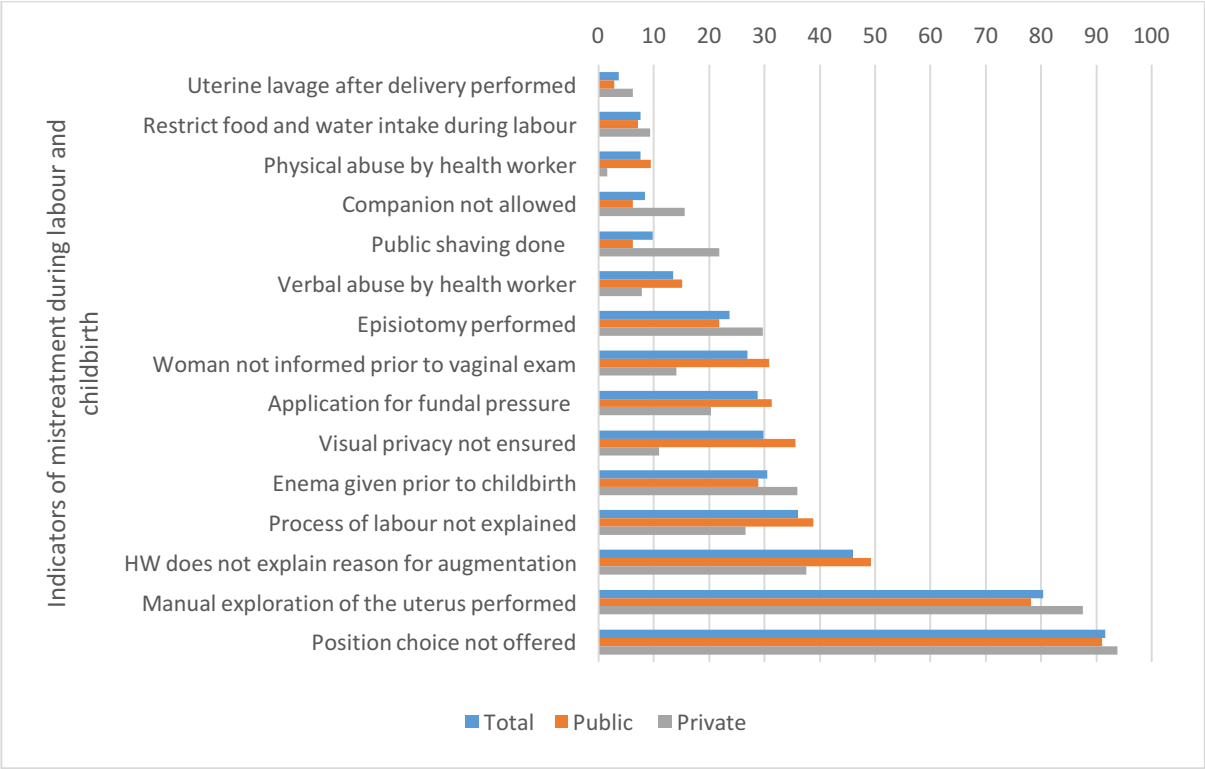


Table twelve below illustrates that amongst all socio-demographic characteristics, the highest mistreatment scores (mean) for women, were found in women above 35 years of age (5.1); primiparous women (5.2); those that were referred from another facility (5.0); amongst women belonging to "scheduled caste and tribes" (5.0); those in the fifth (richest) wealth quintile (5.1), and amongst cases admitted during work-hours (5.0) on weekdays (5.0) in the public sector (4.9). However, the timing of admission (during weekdays or weekends) influenced a greater number of indicators of mistreatment compared to admission during regular work-hours, despite total mistreatment scores being similar across both co-variates. More women admitted during weekdays underwent episiotomies (p=0.04) and enemas (p=0.01) whereas, more women admitted during weekends were not informed prior to vaginal examination (p=0.03) and did not have the process of labour explained to them (p=0.04). We found that more women admitted during regular work-hours delivered without adequate privacy (p=0.01), underwent enemas (p=0.03) and extreme fundal pressure (p=0.01) more frequently.

Table twelve shows that the public sector performed worse than the private sector for not ensuring privacy of the labouring women (p=<0.001), not informing women prior to a vaginal examination (p=0.01) and for physical violence (shout, hit or pinch) towards the labouring woman (p=0.04). On the other hand, the private sector performed worse than the public sector for not allowing birth companions to accompany the labouring woman (*p*=0.02) and for perineal shaving (*p*=<0.001).

Table 12: Bivariate analysis of the significance by socio-demographic factors and the prevalence of observed indicators of mistreatment

	No privacy %	No Position choice %	Woman not informed prior to vaginal exam %	Companion not allowed %	Process of labour not explained %	Reason for augmentation not explained %	Restrict food and water %	Enema %	Public shaving %	Fundal pressure %	Uterine lavage %	Manual uterus exploration %	Episiotomy %	Physical abuse %	Verbal abuse %	Total score (mean)
Total N reporting mistreatment (N=275)	**82**	**252**	**74**	**23**	**99**	**40**	**21**	**84**	**27**	**79**	**10**	**221**	**65**	**21**	**37**	**Range 1-15**
Women's age																
<20 years	18.8%	81.3%	25.0%	0.0%	18.8%	12.5%	0.0%	62.5%	6.3%	18.8%	0.0%	68.8%	43.8%	0.0%	0.0%	4.4
20-35 years	30.4%	92.3%	27.1%	8.9%	36.0%	15.0%	8.5%	28.7%	10.5%	28.7%	4.0%	81.4%	23.1%	7.3%	14.2 %	4.9
35 years or more	33.3%	91.7%	25.0%	8.3%	58.3%	8.3%	0.0%	25.0%	0.0%	41.7%	0.0%	75.0%	8.3%	25.0%	16.7 %	5.1
Chi square	0.59	0.30	0.97	0.46	0.10	0.79	0.28	0.02	0.43	0.42	0.56	0.42	0.08	0.04	0.26	
Parity																
Primipara	26.1%	91.6%	24.4%	9.2%	31.9%	20.2%	6.7%	36.1%	16.%	34.5%	5.0%	80.7%	45.4%	7.6%	16.0 %	5.2
Multipara	33.1%	91.0%	30.3%	8.3%	41.4%	10.3%	7.6%	24.1%	4.8%	25.5%	2.8%	78.6%	7.6%	8.3%	11.7 %	4.7
Grandmultipara	27.3%	100.0 %	9.1%	0.0%	9.1%	9.1%	18.%	54.5%	0.0%	9.1%	0.0%	100.0%	0.0%	0.0%	9.1%	4.3
Chi square	0.45	0.59	0.22	0.57	0.05	0.07	0.39	0.02	0.003	0.10	0.50	0.23	<0.001	0.61	0.55	
Referral status																
Patient comes directly to this facility	29.6%	91.8%	27.2%	7.4%	36.6%	13.2%	7.4%	30.0%	9.9%	30.0%	2.9%	79.8%	21.8%	7.4%	12.3 %	4.9
Patient referred from another facility	31.3%	90.6%	25.0%	15.6%	31.3%	25.0%	9.4%	34.4%	9.4%	18.8%	9.4%	84.4%	37.5%	9.4%	21.9 %	5.0
Chi square	0.85	0.83	0.80	0.11	0.55	0.07	0.69	0.62	0.93	0.19	0.07	0.54	0.05	0.69	0.14	
Caste																
"Scheduled caste and tribe"	32.8%	93.4%	36.1%	8.2%	39.3%	13.1%	9.8%	27.9%	6.6%	34.4%	1.6%	78.7%	19.7%	11.5%	13.1 %	5.0
"Other backward caste"	28.1%	92.2%	24.2%	6.5%	35.3%	13.1%	8.5%	30.1%	10.5%	24.2%	3.9%	82.4%	20.3%	6.5%	15.0 %	4.8
"General caste"	31.1%	88.5%	24.6%	13.1%	34.4%	19.7%	3.3%	34.4%	11.5%	34.4%	4.9%	77.0%	36.1%	6.6%	9.8%	4.9
Chi square	0.77	0.58	0.19	0.11	0.82	0.44	0.33	0.72	0.61	0.18	0.60	0.63	0.04	0.44	0.60	
Socio-economic status																
1st quintile (lowest)	41.1%	89.3%	42.9%	7.1%	46.4%	17.9%	5.4%	25.0%	8.9%	30.4%	0.0%	83.9%	10.7%	3.6%	12.5 %	4.9
2nd quintile	27.8%	90.7%	37.0%	3.7%	33.3%	11.1%	7.4%	29.6%	3.7%	27.8%	5.6%	74.1%	16.7%	14.8%	20.4 %	4.8
3rd quintile	23.6%	96.4%	18.2%	5.5%	43.6%	12.7%	12.7%	38.2%	5.5%	20.0%	9.1%	74.5%	25.5%	3.6%	7.3%	4.7
4th quintile	32.7%	92.7%	21.8%	5.5%	32.7%	12.7%	7.3%	20.0%	5.5%	30.9%	3.6%	83.6%	21.8%	10.9%	16.4 %	4.8
5th quintile (highest)	23.6%	89.1%	14.5%	20.0%	23.6%	18.2%	5.5%	40.0%	25.5%	34.5%	0.0%	85.5%	43.6%	5.5%	10.9 %	5.1
Chi square	0.22	0.62	0.002	0.01	0.09	0.76	0.59	0.11	0.001	0.53	0.05	0.37	0.001	0.10	0.31	
Delivery by qualified attendants *																

Unqualified attendants	30.2%	93.2%	32.7%	4.9%	36.4%	15.4%	9.3%	28.4%	6.2%	29.0%	1.9%	78.4%	17.3%	9.9%	16.0 %	4.8
Qualified attendants	29.2%	89.4%	18.6%	13.3%	35.4%	13.3%	5.3%	33.6%	15.0%	28.3%	6.2%	83.2%	32.7%	4.4%	9.7%	4.9
Chi square	0.85	0.26	0.01	0.01	0.86	0.62	0.23	0.35	0.02	0.90	0.06	0.33	0.003	0.09	0.13	
Admission during work hours[#]																
Within work hours	31.9%	90.9%	28.0%	9.1%	36.2%	15.0%	7.1%	32.3%	10.6%	30.7%	3.9%	80.7%	24.8%	7.9%	13.8 %	5.0
Out of hours	4.8%	100.0 %	14.3%	0.0%	33.3%	9.5%	14.3%	9.5%	0.0%	4.8%	0.0%	76.2%	9.5%	4.8%	9.5%	3.7
Chi square	0.01	0.15	0.18	0.15	0.79	0.50	0.23	0.03	0.12	0.01	0.35	0.62	0.11	0.61	0.58	
Admission during weekends?																
Admission during weekdays	30.8%	90.0%	23.7%	10.0%	32.7%	14.2%	7.1%	34.6%	11.%	29.4%	4.7%	82.0%	26.5%	8.5%	14.7 %	5.0
Admission during weekends.	26.6%	96.9%	37.5%	3.1%	46.9%	15.6%	9.4%	17.2%	4.7%	26.6%	0.0%	75.0%	14.1%	4.7%	9.4%	4.6
Chi square	0.52	0.08	0.03	0.08	0.04	0.78	0.55	0.01	0.12	0.66	0.08	0.22	0.04	0.31	0.28	
Sector																
Public sector	35.5%	91.0%	30.8%	6.2%	38.9%	14.7%	7.1%	28.9%	6.2%	31.3%	2.8%	78.2%	21.8%	9.5%	15.2 %	4.9
Private sector	10.9%	93.8%	14.1%	15.6%	26.6%	14.1%	9.4%	35.9%	21.%	20.3%	6.3%	87.5%	29.7%	1.6%	7.8%	4.7
Chi square	<0.01	0.49	0.01	0.02	0.07	0.90	0.55	0.29	<0.01	0.09	0.20	0.10	0.19	0.04	0.13	

3. Specific patterns of mistreatment that occur at maternity facilities

The section below summarises qualitative information obtained from observers' open-ended comments on mistreatment. It provides contextual insights into the quantitative data presented earlier, as well as additional information on categories and themes of mistreatment such as deficiencies in infection prevention, lack of analgesia for episiotomy, informal payments and poor health facility environmental hygiene which were not captured by the quantitative checklist (Table 13).

Table 13: Themes and their composition- clinical observations of labour and childbirth at maternity facilities

Categories	Themes	Composition
1. Over-treatment	a) Extreme fundal pressure	Occurs frequently and help often sought from others present
	b) Routine episiotomy	Occurs frequently and often conducted without any analgesia.
2. Under-treatment	c) Deficiencies in Infection prevention by individual health workers	Using dirty clothes to clean the perineal and vaginal areas, unhygienic care procedures, conducting unnecessary manual exploration of uterus or uterine lavage and using unsterile gloves and equipment.
	d) Unqualified birth attendants	Chronic staff shortages mean that unqualified health workers are often involved providing maternity care services.
	e) Health facility environmental hygiene	Limited adherence to infection management protocols, no facilities for hand washing, no use of antiseptics, non-availability of protective gear, inadequate sterilisation of equipments, aprons or facemasks, no waste disposal systems and stray animals such as dogs and cows in premises.
3. Disrespect and abuse	f) Physical violence and verbal abuse	Health workers are often anxious and sometimes use physical violence and verbal abuse. Physical abuse ranged from slapping the pregnant woman, to hitting and pinching her thighs or restraining forcefully. Verbal abuse ranged from talking down to the pregnant woman, using foul language and threatening women with caesarean sections, if they did not stop shouting or crying.
	g) Informal payments	Frequent in both public and private sector maternity facilities. These range from Rupees 200 – 2000, equivalent £2.4 to £24

1. Overtreatment by health workers

a) Fundal Pressure:

Our quantitative results (Figure 9) show that the prevalence of fundal pressure was 29%; similar across both sectors (p=0.09) but done more frequently during regular work-hours

(p=0.01) compared to outside regular work hours. The descriptions of fundal pressure recorded by observers in open-ended comments ranged from application of light pressure to extreme pressure on the upper abdomen directed downwards to the birth canal. In a few instances, observers noted that maternity care personnel climbed on top of the bed and use both hands to push down forcefully on the abdomen. Often physical violence was also used while performing fundal pressure. Although, fundal pressure was mostly done by personnel attending to the delivery, help was also sought from others present in the labour room such as mother-in laws and ayahs. The circumstances leading to the decision to apply extreme fundal pressure included to expedite the delivery process, when the woman could not tolerate labour pains or could not bear down or push properly. The quote below illustrate some examples of how fundal pressure was described in the field notes.

> *'The labour room of the district hospital conducts deliveries in a miserable state. They give fundal pressure on the abdomen the way people use pumps for filling air in cycle tyres. They were pressing their abdomen with their elbows during delivery and also slapped the lady badly'.* (Clinical observation of 35-year-old, primiparous at district hospital.)

b) **Episiotomy:**

Quantitative results indicate that episiotomy was done in 24% of cases and that the prevalence was similar across both sectors (p=0.19). However, amongst cases where episiotomy was given, no analgesia was given in 25% of cases, similar across both sectors (p=0.09). Comments recorded by observers corroborate that analgesics were often not given during episiotomies despite women crying and shouting in pain. Anecdotal evidence collected during fieldwork suggests that health workers seem to believe that women do not require analgesia during episiotomy as they are already in so much pain and will not feel any additional pain. The quotes below illustrate two examples of episiotomy recorded in field notes.

> *"Episiotomy was conducted without analgesia because of which the patient was constantly shouting. The nurse consoled her saying it was only a few stitches, but no analgesia was given and instead the nurse scolded her before giving her stitches"* (Clinical observation at a district hospital in a 34-year multigravida woman.)

"Family members were not allowed to enter in the labour room when patient came for delivery. This was her first labour and she looked scared. She was stopping the nurse from doing PV examination. "The pregnant women said that she has been in pain for a long time but no one is paying attention. Inside labour room, when women asked for water, nurse said not to give water as she is just doing drama. Very high pressure was applied on abdomen and episiotomy was done during labour. Stitches were given 2-3 hours later. The woman was crying and said that she won't ever come again to public hospital as nurse insulted her badly." (Clinical observation at a district hospital in a 22-year-old primiparous woman.)

2. Under treatment:

c) Deficiencies in infection prevention:

Deficiencies in infection prevention by individual health workers was also an important theme in the observers' comments. These deficiencies by individual health workers ranged from using dirty clothes to clean the perineal and vaginal areas, pouring oil over the vagina/ perineum, conducting unnecessary manual exploration of uterus, and using unsterile gloves and equipment. Although quantitative data is not available for all of these practices, available quantitative results corroborate a high prevalence (80%) of manual exploration of the uterus which was similar in both sectors (p=0.10). Enemas were also observed in 30% of cases, risking possible faecal contamination. It is encouraging to note that most health workers used sterile gloves; use of unsterile gloves to conduct vaginal examinations was low and happened in just 2.2% of all cases, all in the public sector (3%). Uterine lavage after delivery was also infrequent in both public (3%) and private sectors (6.3%) cases. Observer's comments also indicate that in some facilities, instruments were sterilised once a day and often just dipped in warm water and chlorhexidine solution and reused multiple times. Vaginal examinations were observed to be conducted multiple times by different health workers. In a few instances, observers' comments mention that used syringes were left discarded on the floor, which is a potential hazard for needle-stick injuries.

The quote below illustrates some examples of deficiencies in infection prevention by individual health workers:

"While suturing the episiotomy, ayah accepted a phone call, also touched the bed with her gloved hands and then continued with the suturing. Manual exploration of the

placenta was also done to check whether anything was left inside" (Clinical observation in a community health centre of a 28-year-old multiparous woman)

"Here, gloves are taken out from the powder. I don't know if they use autoclaves. They did not inform me. They just wash instruments with water only. Mostly they dip instruments in warm water, but the blood stains are still there. Cheatle forceps are available but they do not keep it properly." (Clinical observation at a district hospital in a 30-year-old grand multiparous woman).

d) **Health facility environmental hygiene:**

The wider facility environment and hospital infection prevention and control measures were also noted as a serious concern in many of the observers' comments. This theme captures issues beyond the control of the individual health workers, such as those at the institutional level, and has been conceptualised as under-treatment, which constitutes mistreatment of women since it is unethical to allow women to deliver in such unhygienic conditions. Observer's comments frequently describe limited adherence to infection management protocols at facilities, no facilities for hand washing, no use of antiseptics, non-availability of protective gear, inadequate sterilisation of equipments, aprons or facemasks. Systems for segregation of wastes (used injection vials, sharp instruments or wastes such as placenta, other fluids) such as colour-coded bins were non-functional. A frequent finding was that stray animals such as dogs and cows roamed throughout the facility compound and often took shelter in the wards or labour rooms. Clean towels and sterile pads were frequently not available at hospitals; instead, women's old clothes such as old saris were used to wipe the woman and newborn after childbirth. Suction machines and radiant warmers, even when available, were often found to be unused and dirty. Beds sheets were not changed regularly and multiple women were observed giving birth in the same bed. The quotes below illustrate some examples of comments recorded under this theme.

"Instruments here are neither washed properly nor placed in the autoclave. They clean it with water and use them again. Doctor, nurse, ayah - none of them take care of anything. There is no water available in the bathroom. No one cleans the bed after delivery for next patient. Another woman was asked to lay over the same bed where there was blood from the previous delivery." (Clinical observation at a Community health centre of a 25-year-old multiparous woman).

"The hospital is private but it doesn't look like one. Repeated deliveries are conducted without even cleaning the bed properly. In the labour room, the staff chew and spit tobacco and there are stains everywhere. There is a large focus light in the labour room which is covered with dust. There are mice in the labour room. They never use the autoclave machine although it is available." (Clinical observation at a private hospital of 27-year-old multiparous woman.)

e) **Unqualified birth attendants:**

Quantitative data indicate that 59% of all births were attended by unqualified personnel, more frequently in the public (64%) than the private (41%) sector (p=0.001). We conceptualised the use of unqualified personnel as under-treatment. Moreover, it is unethical for women to received care from unqualified personnel at institutions. Our findings indicate that given the chronic staff shortages, the role of unqualified personnel seems important and established in the provision of care during labour and childbirth. The sweeper, traditional birth attendant (dai) and the ayah (helper) tend to be involved in supporting work in the labour room such as bringing instruments or delivery trays when the delivery is imminent. They are often also involved in conducting the deliveries since the doctors and nurses are not available or do not attend all the normal deliveries. The quotes below highlight some examples from field notes.

"After examining the pregnant woman, the nurse asked if any dai had checked her as well. Dais are routinely involved in providing care at this facility. I did not observe any doctors during my shift" (Clinical observation at a community health centre of a 25-year-old multiparous woman).

"Nurses of this private hospital are not trained. They are studying now and are working based on some experience." (Clinical observation in a private hospital of a 26-year-old primiparous woman).

3. Disrespect and abuse

f) Physical violence and verbal abuse

Physical violence and verbal abuse were a common theme in observer's comments. From the quantitative data, the prevalence of physical abuse was 7.6%; and more frequent in the public sector than the private sector (p=0.04) and greater amongst women above 35 years of age

(p=0.04). Although, verbal abuse was also more prevalent in the public sector (15%) than in the private sector (8%), this was not statistically significant (p=0.13). The descriptions of physical violence in the open-ended comments ranged from slapping the pregnant woman to hitting and pinching her thighs while she was bearing down. Slapping often occurred while fundal pressure was being applied. Verbal abuse ranged from talking down to the pregnant woman, using foul language and threatening women with caesarean sections, if they did not stop shouting or crying. In most instances, field-researchers noted that staff appeared anxious at the time of the birth and often used physical violence (such as slapping, forcing woman to bear down or restraining the woman) during the birthing process. There were no instances recorded in the field notes where pregnant woman or their companions stood up to mistreatment or abuse by health workers. The quotes below illustrate physical violence, verbal abuse and mistreatment of pregnant woman encountered during clinical observations.

> *"The nurse said, when you are with your husbands, you don't shout but you are shouting now. You will come again with another baby soon!"* (Clinical observation at a district hospital of a 27-year-old multiparous woman.)

> *"The nurse was badly scolding the pregnant woman. The women appeared restless and was screaming and shouting. The nurse threatened her and said that if she continues to scream, she would operate on her."* (Clinical observation at a district hospital in a 25-year-old primiparous woman)

g) **Informal payments:**

The practice of maternity care personnel asking for informal payments was the most common theme identified from the observers' comments and is a form of disrespect and abuse. However, quantitative data about this phenomenon were not captured during clinical observations. Observers' comments indicate that, in most instances, maternity care personnel demanded money from families for doing activities that are a part of their job description such as drying and wrapping the newborn, weighing the newborn, cleaning blood spills on the delivery bed or labour room floor and cleaning up. Often in public sector hospitals, maternity care personnel demanded money from clients and their families to cover their costs, as they were contractual staff, allegedly, without a regular monthly income

source. In some instances, informal payments were also given to health workers as gratuity payments to express happiness at the birth of newborn.

Field notes also indicate that there is an understanding between the maternity care personnel and community health worker such as ASHA's who often act as the intermediary between the clients and health workers, facilitating the exchange of such payments. In addition, in most observations, families were asked to purchase drugs and commodities such as gloves, baby towels, medicines, delivery kits from outside, although, in principle these items should be provided free of cost at health facilities under the JSY scheme. There were also a few cases where observers documented that newborns were withheld from families until providers received payments from families. If the providers did not receive money, women were more likely to be mistreated during their hospital stay. The amount of informal payments varied between Indian Rupees 200–2000, equivalent UK Pounds Sterling £2.4 - 24. The quotes below illustrate some examples of the practices of informal payments at maternity facilities.

> *The junior nurses ask for money in this hospital. They say, "Give me Rs.2000. We have performed the delivery so well. If we had not done that the child would have died inside you. I will take half of the money and will give the rest to madam."* (Clinical observation at a district hospital of a 22-year-old multiparous woman).
>
> *"Nurse was fighting for money. She conducted delivery only after receiving money. Family members are asked to bring clothes for cleaning mother and child. Money for gloves is also taken from family members."* (Clinical observation at a community health centre of a 23-year-old primiparous woman.)

7.5: Discussion

This study explored the nature and context of mistreatment amongst women attending public and private sector maternity facilities in Uttar Pradesh. All women in the study encountered at least one indicator of mistreatment. Our estimates are similar to another cross-sectional study from a teaching hospital in south-eastern Nigeria where 98% of women reported some kind of mistreatment during childbirth.[374] The prevalence of mistreatment reported across studies varies depending on how mistreatment is conceptualised and measured.[80] A recent cross-sectional study from Uttar Pradesh, India reported that 57% of urban slum-resident women reported some form of perceived mistreatment during childbirth.[375] In Tanzania,

researchers found 19% perceived mistreatment amongst a sample of women while using hospital-exit interviews and up to 28% mistreatment amongst the same women followed-up at home which they attribute to courtesy bias in the exit interviews.[376] However, unlike in our study, both of these studies measured perceived mistreatment rather than direct observations of labour and childbirth.

We found that total mistreatment scores were higher amongst women above than 35 years of age (5.1), primiparous (5.2), those that were referred from another facility (5.0), amongst women belonging to the "scheduled caste and tribe" (5.0), those in the fifth (richest) wealth quintile (5.1), and amongst cases admitted during work-hours (5.0) on weekdays (5.0) in the public sector (4.9). The cross-sectional study from urban slums in Uttar Pradesh, mentioned earlier also found that wealthier women, migrant women and women from lower castes reported higher levels of disrespect and abuse.[375] The importance of caste is well documented in India with many studies reporting inferior care and discrimination against women belonging to these so-called scheduled castes. [377,378] Researchers have suggested that since these women are less empowered, health workers are more likely to think that they can get away with mistreatment of these women.[375]

We found that not offering woman a choice of birthing position (92%), manual exploration of the uterus after delivery (80%) and not explaining the reason for augmentation (46%) were particularly high at facilities in both sectors. There is evidence from a systematic review supporting the benefits of delivering in alternative positions compared to supine positions for normal births such as shorter labour duration, fewer episiotomies and fewer second-degree tears. [379] Manual exploration of the uterus is an important risk factor for puerperal sepsis and shock [114] and should be avoided unless indicated and constitutes overtreatment which is form of mistreatment. Further, it is essential to provide all women with adequate information and obtain an informed consent prior to any invasive clinical procedures such a vaginal examination.[114]

We found that the public sector performed worse than the private sector for not ensuring privacy of the labouring women (p=<0.001), not informing women prior to a vaginal examination (p=0.01) and for physical violence (shout, hit or pinch) towards the labouring woman (p=0.04). There could be many reasons for poor performance of the public sector such as inadequate infrastructure, high-workloads, poor communication skills and

normalisation of disrespect and abuse in actual practice. During fieldwork, we noted that public sector facilities were crowded and that maternity care personnel worked in challenging environments often without basic amenities, limited incentives and these environments were not conducive to practice evidence based maternity care.

On the other hand, the private sector was found to perform worse than the public sector for not allowing birth companions to accompany the labouring woman (p=0.02) and for perineal shaving (p=<0.001). This could perhaps be due to existing institutional polices in private hospital labour rooms which do not allow birth companions. A recent Cochrane review found that that continuous support from a chosen family member or a friend increased women's satisfaction with their childbearing experience.[380] Although, perineal shaving is performed with the belief that it reduces the risk of infection, a systematic review has found no associated clinical benefits of shaving. [381] Perineal shaving is also discouraged in the Indian skilled birth attendance training materials[382], which suggests that, perhaps, private sector health workers may not have received these trainings or that quality of such trainings is poor.

We also found some interesting associations between women's socio-demographic characteristics and the prevalence of specific indicators of mistreatment. Caste was only associated with episiotomy and women in the so-called "general caste" were found to have greater proportions of routine episiotomies (p=0.04) perhaps because they used public sector facilities more often. Women in the first quintile (poorest) were least likely to be informed prior to a vaginal exam (p=0.002) which suggests discriminatory care based on wealth status.[378] However, women in the highest wealth quintile (richest) were more frequently unaccompanied by a birth companions (p=0.01), had higher rates of perineal shaving (p=0.001) and episiotomy (p=0.001) which could perhaps reflect greater use of the private sector and consequent overtreatment of women that attend private sector facilities.

Women who delivered with an unqualified attendant were more frequently not informed prior to a vaginal examination (p=0.01) and these examinations were often conducted with unsterile gloves (p=0.04). However, delivery with a qualified attendant was associated with lower rates of birth companionship (p=0.01), and routine episiotomy (p=0.003) which suggests either unfavourable institutional policies or outdated knowledge of health workers resulting in overtreatment. Interestingly, we found that total mistreatment scores (mean)

were higher for deliveries conducted by qualified attendants (4.9) as compared to unqualified attendants (4.8) which supports the notion of overtreatment by qualified personnel.

Mistreatment was seen to coexist with limited adherence to evidence-based practices in this setting.[47] Saini *et al.* (2017) suggest that the primary drivers for poor care arise out of inequalities of information, wealth, and power. [370] In this context, we suggest that the drivers for mistreatment include resource constraints, shortages of health workers, limited incentives, weak mentorship and supervision, restrictive institutional policies, lack of up-to-date knowledge and unequal power dynamics between health workers and pregnant women.[376,383,384] Some researchers have also articulated that long-standing patterns of poor work conditions, resource scarcity, low skills or overburdened health workers at facilities and limited choice for clients leads to poor QoC. [125] In addition, health workers may often not be aware of rights-based approaches or unable to provide high quality care despite their best intentions due to inherent organizational and work- environment related constraints, which are particularly relevant in this setting.

Another important finding of this study captured through observers' comments was informal payments. Upon reflection, our QoC assessment tool should have specifically captured detailed information on informal payments. Informal payments can range from gratuity payments from appreciative patients, payments to jump the queue, receive better or additional care, to obtain drugs and commodities, or simply to receive any care at all.[385] Informal payments are considered to be inequitable and constitute institutionalised bribery, which may hamper the entire health system.[385,386] Further, they tend to be prevalent in settings where health systems are under-funded, supervisory mechanisms are weak; where women are not empowered or not aware of their rights, and where providers are unlikely to face disciplinary action for their behaviours. [385]

In summary, the literature suggests that mistreatment during labour and childbirth may be the result of many factors such as unfavourable institutional policies, resource and infrastructural constraints, socio-cultural factors, limited knowledge and skills of health workers. We argue that non-adherence to clinical protocols, including under treatment or overtreatment also constitute mistreatment of women at maternity facilities. An important question that emerges from our study is whether it is ethical to allow and encourage women to deliver in conditions where basic standards of evidence-based care, cleanliness, hygiene,

dignity and equity cannot be met. We demonstrated that mistreatment of women often occurs because of over-treatment and under-treatment which constitute a failure to adhere to professional standards of care[80]. Over-treatment and under-treatment should be considered in the global discourse on disrespect and abuse, as they are also a violation of human rights and constitute poor quality of care at maternity facilities. It is possible that some practices such as those related to individual health workers' deficiencies in knowledge or skills are perhaps easier to change compared to long-standing socio-cultural factors that may give rise to mistreatment. Ultimately, mistreatment occurs, at least in part, because governments have not committed to or invested in participatory accountability mechanisms like social audits, community scorecards and others, which ensure that women's experiences and perceptions of care are addressed and that respectful maternity care standards are followed. [81] This is one of the key recommendations emerging from this work.

7.6: Limitations

This study used data from an observational study designed to capture descriptive information on elements of QoC for normal labour and childbirth. The study was not specifically powered to measure and explain mistreatment as a separate category of poor quality of care. Fieldworkers used open-ended comments to capture information that was contextually important or events that were particularly striking to them. Therefore, it is likely that the comments perhaps captured the more extreme events rather than routine care processes. There may also have been an observer bias, for example: comments recorded by observers perhaps reflects their own professional experiences, training and knowledge of respectful care practices. During fieldwork, we also noted that younger observers were more likely to take down detailed notes compared to the older observers, who were more experienced, and perhaps, more inclined to accept mistreatment as a normal occurrence. Our sample of private sector facilities was also limited by the fact that we had no official sampling frame for the private sector facilities in the study districts and that 13 private facilities refused to participate in the study. It is possible that the QoC of participating private sector facilities was different from other private facilities that were either not sampled or those that refused to participate. We have previously shown that any Hawthorne effect was negligible in this study since the aggregate quality scores for individual observers did not change depending on the order of observations.[47] The mixed methods approach taken to triangulate our findings, data

collection round-the-clock on all seven days of the week, and the use of clinical practice observations are key strengths of this study.

7.7: Conclusions

Mistreatment is common in both private and public sectors, albeit of different types. Efforts to expand institutional births in Uttar Pradesh and other high maternal and perinatal mortality settings would benefit from strengthening the quality of maternity care in both sectors so that evidence-based maternity care is provided, and positive births experiences are ensured. There are at least four specific recommendations emerging from this work. First, there needs to be a systematic and context-specific effort to measure mistreatment in high burden states in India in both public and private sectors. Second, a training initiative to orient all maternity care personnel to the principles of respectful maternity care would be useful. Third, systems to promote accountability for the application of respectful, woman-centred, maternity care pathways are needed. Lastly, we note that there needs to be a long-term, sustained investment in health systems so that supportive and enabling work-environments are available to front-line health workers.

CHAPTER 8: Management is not associated with quality of care during labour and childbirth: evidence from a cross-sectional study of maternity facilities in Uttar Pradesh, India.

Preface:

In chapter 6, I described the results from a comprehensive assessment of quality of care at the time of birth in Uttar Pradesh. Chapter 7 described the nature and context of mistreatment of women in maternity facilities, which occurs due to health worker actions, restrictive institutional and labour room policies, and lack of up-to date knowledge and skills among health workers.

In this chapter, I assess and describe management practices at maternity facilities in Uttar Pradesh and examine whether management practices are associated with quality of care. I collected primary data on management practices from interviews with hospital managers in the study sites. I merged two datasets on QoC and management, performed descriptive analyses and then used multi-level mixed effects regression techniques to investigate whether there was a relationship between management practices and QoC during labour and childbirth. Multi-level mixed effects regression techniques are a robust and practical statistical method to analyse clustered data such as data from different hospitals and these techniques account for random effects and fixed effects in the linear regression model.

My results indicate that QoC and management practices were both poor in maternity facilities in Uttar Pradesh, India. In this setting, my results indicate management practices at the institutional level do not influence QoC during labour and childbirth. The only management domain that strongly influenced QoC was performance management, which was associated with up to a seven-percentage point higher quality score. These results support the role of performance monitoring activities focussed on quality improvement such as audits which have been found to encourage the use of evidence-based-practices, improve supportive supervision of health workers, encourage regular monitoring, and reporting on key performance indicators.

www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Gaurav Sharma
Principal Supervisor	Véronique Filippi
Thesis Title	An investigation into quality of care at the time of birth at public and private sector maternity facilities in Uttar Pradesh, India

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

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Health affairs
Please list the paper's authors in the intended authorship order:	Gaurav Sharma, Véronique Filippi, John Bradley and Timothy Powell Jackson
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	As first author on this paper, I developed the idea for the paper, undertook the analysis, wrote the first two draft of the manuscript and incorporated co-author comments

Student Signature:  **Date:** _____

8.1: Introduction

Managers of maternity facilities are responsible for implementing appropriate systems and procedures to ensure high-quality care for labouring women from the time of admission to their discharge from facilities after childbirth.[300] Managerial practices are defined as "the set of formal and informal rules and procedures for selecting, deploying, and supervising resources in the most efficient way possible to achieve institutional objectives."[387]

Although we generally assume that management influences quality of care (QoC) at hospitals, empirical evidence examining this relationship is limited. [300]

Since management practices are broad in nature, traditionally researchers have found it hard to measure management practices comprehensively through quantitative methods. However recent methodological advances from studies in high-income countries offer an interesting framework for measuring management practices at hospitals.[42,46,300]

The only systematic review which examined the role of hospital managers in quality and patient safety found limited and inconsistent evidence to support these claims.[300] The modest evidence that exists does suggest that managers' time spent, engagement and work specifically on quality assurance influences indicators of clinical quality and patient-safety positively. [300] Managerial activities thought to improve quality include activities such as establishing goals and strategies to improve QoC, setting the quality agenda, promoting a quality improvement culture and procurement of institutional resources to ensure quality of care. [300]

In low-resource settings, although, inadequate management capacity has been recognised as an important bottleneck for improving maternal and newborn health, research evidence examining this relationship is limited.[388] In addition, the likely relationship between managerial practices and QoC may also be of a lesser magnitude as more fundamental barriers to quality such as unavailability of essential drugs, commodities, poor referral linkages, weak information systems, deficiencies in knowledge, skills and motivation of health workers exist[16] that are often beyond the control of hospital managers.

Many researchers argue that there are a range of management practices originally applied in the manufacturing and service industries that are relevant to health care. [269,389-391] However,

transferring and applying these management practices to hospitals must consider complex healthcare issues such as quality, safety and medical errors. [266]

In the recent decade, there have been important advances in measuring management practices from studies in the field of health economics. For example, in a cross- sectional study at cardiac units in USA, management practices were significantly associated with mortality as well as process of care measures.[312] In another study at substance abuse clinics in the USA, researchers have found a strong association between management practices and client days to treatment and increased revenue generated at these clinics.[313] Similarly, in UK hospitals, management practices had a strong association with both health outcomes (improved survival rates after acute myocardial infarction) and financial indicators. [310]

Other studies that conducted secondary analysis of data conducted as a part of the World Management Survey efforts (http://worldmanagementsurvey.org/), which collects data from over 2,000 hospitals in nine countries have found that hospitals with more effective management practices provide higher-quality care.[46,42,311] One of these studies which restricted analysis to data from hospitals in the USA and England found that when hospital-boards paid more attention to clinical quality, managers were more likely to pay attention to clinical quality and that hospital boards which used clinical quality measures more effectively had higher scores on target management and operations management.[46]

However, it is important to note that most research studies on this topic are from high-income countries, from the private sector, and none of them has specifically focused on examining the relationship between management practices and quality of maternity care. Therefore, examining whether there is a relationship between management practices and QoC in maternity facilities is a key evidence gap.

India has one of the highest burden of maternal and neonatal deaths[352] and, available evidence from high-burden states like Uttar Pradesh indicates significant deficiencies in QoC at maternity facilities particularly around the time of childbirth.[47] Given the increasing rates of institutional births, exploring whether management can drive gains in quality is important to investigate. We collected primary data on management practices at 33 maternity facilities after adaptation of a previously tested survey instrument to our study setting. Our study objectives were: 1) to assess and describe existing management practices at public and

private sector maternity facilitates in three districts of Uttar Pradesh, India; and 2) to examine whether management practices influence quality of care offered during labour and childbirth.

8.2: Methods

8.2.1: Conceptualization of management

The past decade has seen a rise in the innovative measurement efforts that have tried to quantify the relationship between management and QoC outcomes. Most of this research stems from the field of health economics and are primarily from studies in high income countries. [42,46,300] Notable amongst these, is the pioneering work by Bloom *et al.* (2010) who initially studied management practices across manufacturing firms in numerous countries. [307] This work has since been replicated in the health sector and the tools developed by Bloom *et al.* (2010) have now been used for measuring management practices in diverse health system contexts such as in high-income (Australia, Canada, France, Germany, Sweden, UK, USA), upper-middle income (Brazil) and lower-middle income countries (India).[43,282,308,309]

These research efforts have employed a telephone- based interview methodology and assessed management practices under four key dimensions: measures of hospital operations, measures of hospital performance, measures of targets management at hospitals and measures of people management at hospitals.[44,310,311]

Briefly, operations management and performance monitoring sections of the tool assessed how well modern management techniques were introduced at maternity facilities; whether systems for continuous improvement existed; and whether facility performance was regularly tracked with useful indicators. Target management section assessed whether appropriate targets had been set, whether they pushed facilities to improve performance and how well they had been communicated across the hospital. People management section assessed whether emphasis had been placed on good human resource practices, whether mechanism to incentivise high performing staff or reprimand poor performing staff exist.[42]

8.2.2: Study design

Given the paucity of empirical evidence on the relationship between management practices and quality of care, we conducted a cross-sectional survey to collect primary data on management practices and conducted clinical observations of labour and childbirth at maternity facilities in Uttar Pradesh, India.

8.2.3: Settings

This study was conducted in three districts of Uttar Pradesh (UP) in India: Kannauj, Kanpur Nagar and Kanpur Dehat. [359] Kanpur Nagar is predominant urban, with higher literacy and lower mortality than the state average. By contrast, Kannauj and Kanpur Dehat are more typical of the state. The maternal mortality ratio (240 per 100 000 live births) and neonatal mortality rates (Kannauj - 55, Kanpur Dehat - 41 and Kanpur Nagar - 24 per 1 000 live births) were both high in the study districts.[253] Across the continuum of care, large discrepancies in maternal and child health indicators exist across the study districts. For example, 43% of deliveries in Kannauj, 46% in Kanpur Dehat and 34% in Kanpur Nagar occur at public sector facilities. The private sector delivery share is estimated to be 15% in Kannauj, 34% in Kanpur Nagar, and 10% in Kanpur Dehat. [253]

8.2.4: Data collection

We conducted clinical observations of labour and childbirth care at maternity facilities between 26 May and 8 July 2015. Subsequently, we conducted face-to-face, interview-based data collection on management practices from 9 August to 12 of September 2015. We established telephone contact with facility managers early on and set up appointments to ensure a high response rate. The interviews were presented as follow-up activities to the QoC assessments and were confidential conversations about management experiences and challenges. We did not cover sensitive issues, for example, financial earnings of the hospital. The participants were not aware that they were being rated for their responses to the management questionnaire. All interviews were double-scored; while one researcher (GS) conducted all the interviews, another researcher also scored them independently. The researchers had been oriented on management concepts, the survey tool, and the scoring technique over a three-day training session.

8.2.5: Sampling

The overall study flow diagram for this study is illustrated in Figure 10 below. Sampling for the QoC assessments was described in Chapter 6 and the QoC study flow diagram was presented in Figure 6 of chapter 6. Altogether, for the QoC assessments, we could observe care provided to 275 mother-baby pairs at 18 public sector facilities and 8 private sector facilities (n=26). For the management survey, we employed the same sampling strategy as the QoC assessments. However, we received a better response rate for the management survey (n=33) compared to the clinical observations which could only be obtained in 26 facilities. All the surveyed facilities had complex organizational structures- defined as facilities with separate administrative, information, therapeutic, diagnostic and support services and greater than five beds allotted for maternity care.

8.2.6: Survey instrument

We adapted and used a management survey tool that has previously been used for measuring management practices in diverse hospital settings in high-income (Australia, Canada, France, Germany, Sweden, UK, USA), upper-middle income (Brazil) and lower-middle income countries (India)[282,308,309] and tailored it to be applicable to the context of maternity care provision in rural Uttar Pradesh. Specifically, after pre-testing, we removed questions on a category known as target interconnection, which was not applicable in this context and simplified the language so that questions retained their meaning in Hindi.

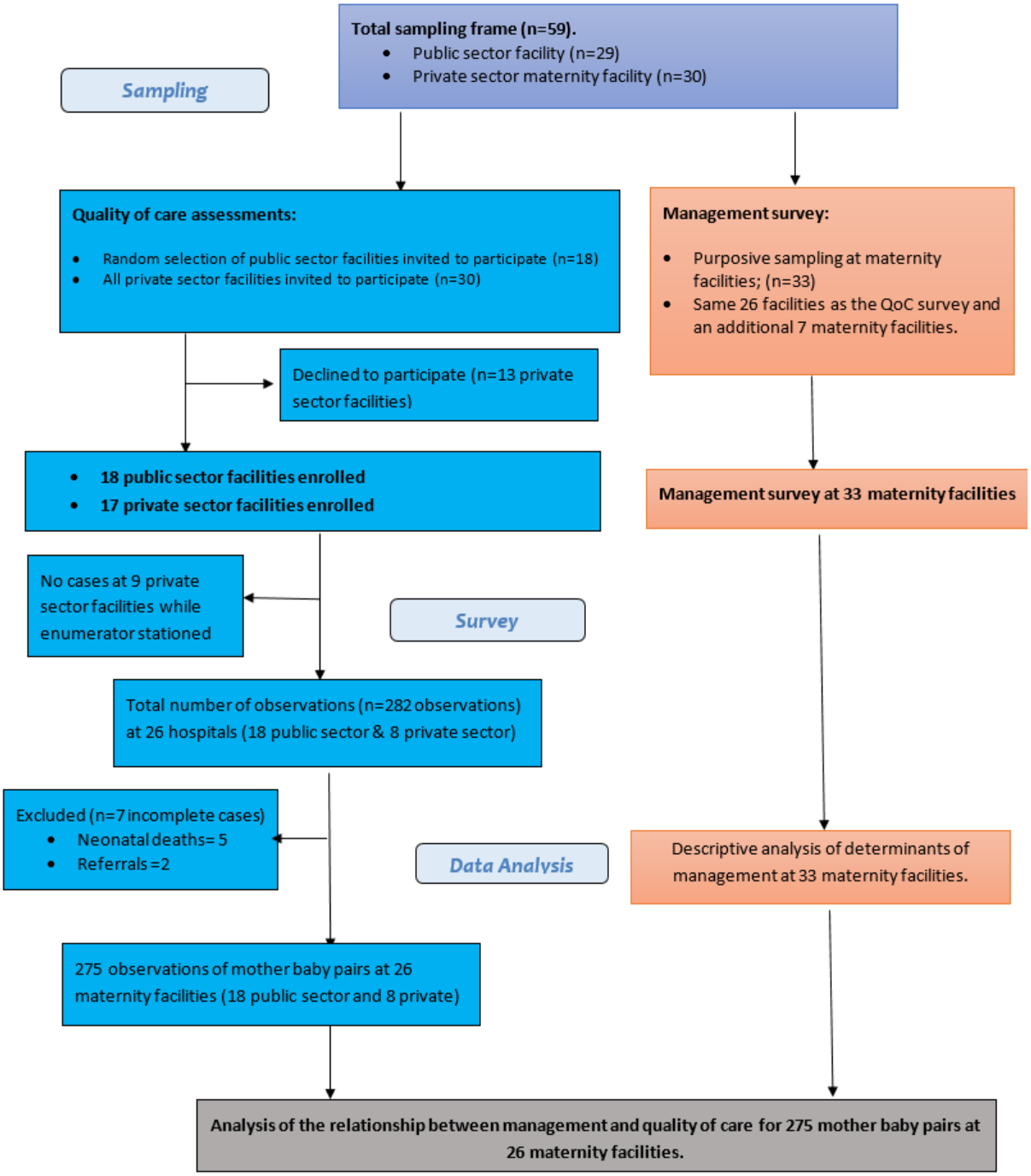
Essentially, this interview-based tool assesses management practices at hospitals through four key domains: operations management, performance management, target management and people management as described previously. The interviewer (GS) asked a series of structured but open-ended questions (up to four questions for every domain) so that sufficient insights to score each management practice were obtained. A scoring grid (between 1 to 5) was used by assessors to give scores for responses to all questions depending on how closely answers matched descriptors for each question. The survey tool is available in appendix 2.

8.2.7: Study participants

Study participants for the management survey included administrators or clinical leaders at 33 maternity facilities (10 private and 23 public sector). Participants for the QoC assessments

included pregnant women and their newborns that consented to the clinical practice observations.

Figure 10: Overall study flow diagram- investigating the relationship between management practices and quality of care during labour and childbirth.



8.2.8: Ethics

Ethical approval was obtained from the Public Healthcare Society (PHS) Ethics Review Board in India and the London School of Hygiene & Tropical Medicine in the UK (LSHTM Ethics Ref: 8610). The study design has also received government clearance from the National Health Mission in Uttar Pradesh.

8.2.9: Measurement

8.2.9.1: Measures of Quality of care

The overall essential care at birth index which measures QoC during labour and childbirth is the outcome variable in our analysis. Details on the development of this indicator have been provided in Chapter 6.

8.2.9.2: Measures of management

Measures of management included scores for overall management and individual management dimensions: operations, performance, targets, and people management. Two independent assessors gave individual ratings for questions asked to managers at 33 maternity facilities. Correlation of scores given by the two independent assessors was high (see Table 14 below) so a mean score was calculated for each variable. As is standard practice, these scores (between 1 to 5) were then converted to Z scores; which express how far a value is from the population mean and expresses this difference in terms of standard deviations by which it differs. Z scores were calculated primarily for the purposes of the regression analysis.[277]

8.2.9.3: Explanatory variables

Other explanatory variables included hospital characteristics such as number of beds, ownership, when the hospital was established and teaching status. A dummy variable for individual observer's quality rating was also used to mitigate concerns relating to observer bias.

8.2.10: Analysis

Analysis was carried out using STATA 14 (Stata Corp. LP, College Station, United States of America). Total scores for overall management and individual management domains were calculated for every facility. Descriptive analyses were performed to examine the determinants of management practices at the 33 sampled maternity facilities. Determinants of management included the number of beds, ownership, teaching status, managers' tenure

in post, when the hospital was established and whether there was external development partner support to the facility.

The relationship between management practices and QoC was investigated after merging the management dataset (facility n=33) with the QoC dataset (facility n=26). Therefore, the data that we analysed were at the level of individual women (n=275) at 26 facilities.

Four multilevel, mixed-effects linear regression models with overall quality index (outcome variable) and Z scores for total management and Z scores for sub-categories of management (explanatory variables) were developed. The first model was the unadjusted model and the second model adjusted for facility characteristics.

All four models included robust standard errors, accounted for clustering at the level of facilities, used sampling weights, included a dummy variable for observer ratings and controlled for random effects at the level of individual facilities and health workers. Sampling weights were applied so that each facility received equal weight in the analysis. Maximum likelihood estimation was used. The coefficients of the multivariate regression were interpreted to show the association of one standard deviation of management Z score on the outcome (QoC).

8.3: Results

8.3.1: Maternity facility sample characteristics

The average hospital in our sample was 10 years old and had 12 beds allocated for maternity services. Most sampled facilities were non-teaching (88%) and in the public sector (70%). Most managers at surveyed facilities had a clinical background (91%); 48% of them had a postgraduate clinical specialisation and 6% reported to have a MBA degree.

The average management score for maternity facilities in our sample was 1.6 (SD $\pm$ 0.7) (See figure 11 below). Figure 12 shows management scores disaggregated by public or private sector. Public sector facilities received a mean score of 1.5 (SD$\pm$ 0.4) compared to the private sector facilities that received a mean score of 2.0 (SD$\pm$ 0.9). Private sector facilities outperformed the public sector for all management dimensions: operations management (private: 2 and public: 1.7), performance management (private: 1.9 and public: 1.5), targets management (private: 1.6 and public: 1.2) and people management (private: 2.4 and public: 1.2).

Table 14: Correlation results between independent assessors ratings for management dimensions

Management scores	Correlation between individual assessors
Total management score	0.9
• Operations management	0.7
• Performance management	0.9
• Targets management	0.7
• People management	0.9

Figure 11: Histogram showing total management scores across sampled facilities (n=33)

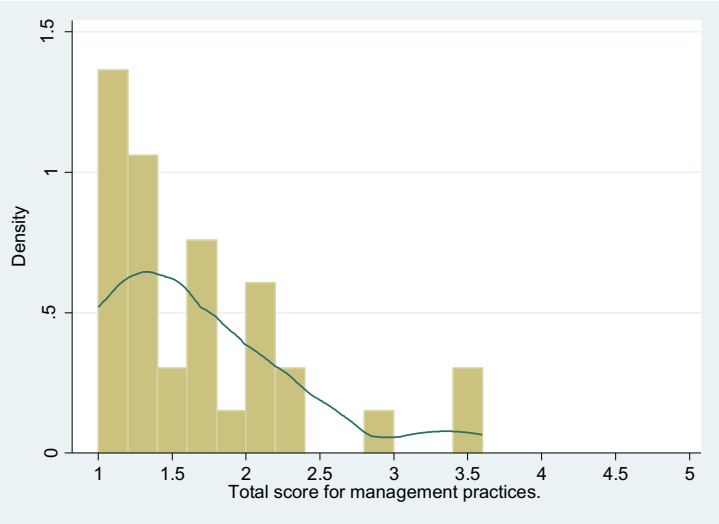


Figure 12: Graph showing scores for total and individual management domains at public and private sector facilities

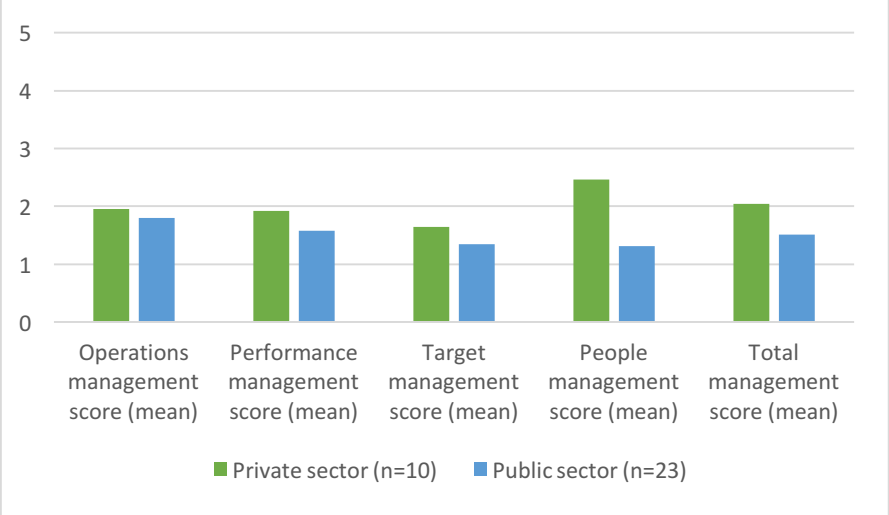


Table 15 shows the descriptive analysis of the relationship between management scores at maternity facilities and their characteristics. We did not find significant differences in characteristics amongst sampled facilities.

Table 15: Maternity facility sample characteristics categorised by their management scores

Characteristics of maternity facilities	Less than or equal to median management score (facility n=17)		Above the median management score (facility n=16)		*p*-value
	n	%	n	%	
1. Bed capacity					
a) Less than 15 beds	10	59%	7	44%	
b) More than 15 beds	7	41%	9	56%	0.38
2. Ownership					
a) Private facility	4	23.5%	6	37.5%	
b) Public facility	13	76.5%	10	62.5%	0.38
3. Teaching status					
a) Non-teaching hospital	16	94%	13	81%	
b) Teaching hospital	1	6%	3	19%	0.25
4. Managers tenure in post					
a) Years in post (<5years)	9	53%	9	56%	
b) Years in post (>5 years)	8	47%	7	44%	0.85
5. Hospital established					
a) Less than 10 years' old	11	65%	7	44%	
b) More than 10 years' old	6	35%	9	56%	0.23
6. Development Partner support					
a) No	6	35%	3	19%	0.28
b) Yes	11	65%	13	81%	

8.3.2: Relationship between management Z score and facility characteristics

Table 16 shows results from a linear regression examining the relationship between total management Z score and facility characteristics. Older facilities (established >10 years) were associated with higher management z scores (p=0.04) and the number of beds was found to be borderline significant (p=0.07). Other characteristics such as ownership, teaching status, manager's tenure in post and support by development partners did not have a statistically significant relationship with total management Z score.

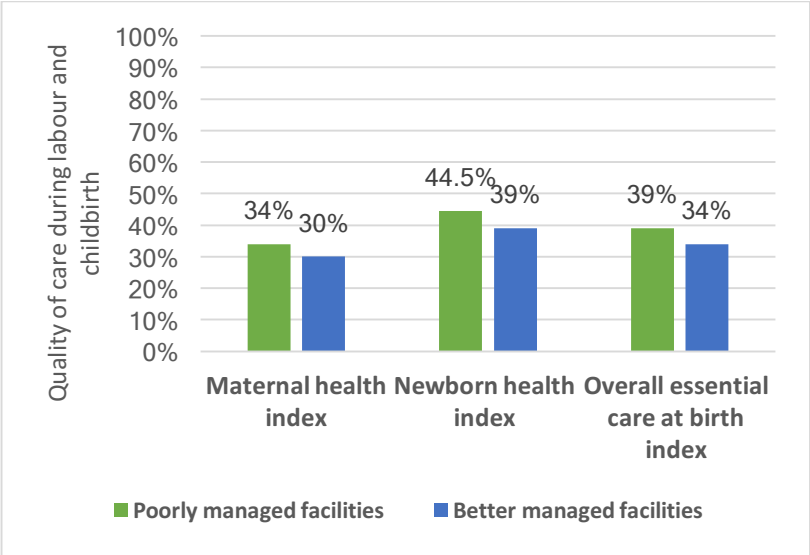
Table 16: Relationship between facility sample characteristics and management scores

Total management z score	Coef.	p value	[95% Conf. Interval]	
1. *Number of beds*				
a) Less than 15 beds	Base			
b) More than 15 beds	0.60	0.07	-0.06	1.25
2. *Ownership*				
a) Private facility	Base			
b) Public facility	-0.63	0.20	-1.59	0.34
3. *Teaching status*				
a) Non-teaching hospital	Base			
b) Teaching hospital	0.87	0.21	-0.52	2.27
4. *Managers tenure*				
a) Years in post (<5years)	Base			
b) Years in post (>5 years)	-0.28	0.41	-0.95	0.40
5. *Hospital established*				
a) Less than 10 years' old	Base			
b) More than 10 years' old	0.67	0.04	0.04	1.29
6. *Development Partner support*				
a) No	Base			
b) Yes	0.30	0.41	-0.43	1.02

8.3.3: Relationship between quality of care during labour and childbirth and management practices

Figure 13 shows variations in QoC at facilities dichotomised based on their management scores. Facilities with below median management scores provided 39% of all recommended interventions compared to 34% by facilities with above median management scores but this difference was not statistically significant (p=0.28). For maternal care, better-managed facilities provided 30% of the recommended interventions compared to 34% for poorly managed facilities but this difference is not statistically significant (p=0.4). For newborn care, better managed facilities provided 39% of the recommended interventions compared to poorly managed facilities that provided 44% of the recommended neonatal care interventions but this difference was also not statistically significant *(p=0.13)*.

Figure 13: Weighted estimates of quality of care at maternity facilities categorised by their management scores



8.3.4: Results from the mixed effects linear regression model

In multivariate analysis (see Table 17 below), there was no statistically significant relationship (p =0.85) between total management Z score and quality of care in the unadjusted model (model 1). This relationship remains statistically insignificant after adjusting for all explanatory variables (Model 2, p= 0.55).

Table 18 shows results from the multivariate analysis investigating the association between the four domains of management and QoC, and we find that, amongst individual management dimensions, performance monitoring (p= 0.02) is the only dimension statistically associated with QoC (outcome). One-unit increase in performance management was associated with a seven-percentage point increase in quality of care. Further, results from both multivariate models (Table 17 &18) show that delivering in private maternity facilities was associated with 7-10 % point higher standard of care for women. However, we found no association between bed capacity, teaching status or duration since establishment of maternity facilities and quality of care.

Table 17: Mixed effects linear regression examining the relationship between overall QoC at birth and Z score index for total management score at 26 maternity facilities

Outcome: Essential care at birth	**Model 1**				**Model 2**			
Variables	**Coef.**	***p value***	**[95% Conf. Interval]**		**Coef.**	***p value***	**[95% Conf. Interval]**	
Management score z index	0.00	0.85	-0.02	0.02	-0.01	0.55	-0.03	0.02
Bed capacity								
• Less than 15 beds	X	X	X	X	Base			
• Greater than 15 beds	X	X	X	X	-0.01	0.76	-0.06	0.05
Ownership								
• Public	X	X	X	X	Base			
• Private	X	X	X	X	0.10	0.003	0.03	0.16
Hospital established								
• Less than 10 years	X	X	X	X	Base			
• More than 10years	X	X	X	X	0.00	0.92	-0.04	0.04
Teaching status								
• Non-teaching hospital	X	X	X	X	Base			
• Teaching hospital	X	X	X	X	-0.03	0.27	-0.09	0.03

Table 18: Mixed effects linear regression examining the relationship between quality of care and z scores indexes for management sub-categories for 26 maternity facilities

Outcome: Essential care at birth	**Model 1**				**Model 2**			
Variables	**Coef.**	***p value***	**[95% Conf. Interval]**		**Coef.**	***p value***	**[95% Conf. Interval]**	
Operations score z index	-0.04	0.03	-0.07	0	-0.03	0.12	-0.06	0.01
Performance score z index	0.08	0.01	0.02	0.15	0.07	0.02	0.01	0.12
Target score z index	-0.01	0.7	-0.07	0.05	-0.02	0.33	-0.06	0.02
People score z index	-0.04	0.02	-0.08	-0.01	-0.03	0.09	-0.07	0.01
Bed capacity								
• Less than 15 beds	X	X	X	X	Base			
• Greater than 15 beds	X	X	X	X	-0.03	0.25	-0.07	0.02
Ownership								
• Public	X	X	X	X	Base			
• Private	X	X	X	X	0.07	0.01	0.02	0.13
Hospital established								
• Less than 10 years	X	X	X	X	Base			
• More than 10years	X	X	X	X	0.00	0.87	-0.04	0.04
Teaching status								
• Non-teaching hospital	X	X	X	X	Base			
• Teaching hospital	X	X	X	X	-0.03	0.29	-0.08	0.03

8.4: Discussion

This paper provides empirical evidence on management practices and their association with quality of care at maternity facilities in Uttar Pradesh, India. Overall, we found that management practices were poor across the surveyed maternity facilities in Uttar Pradesh. We did not find a statistically significant relationship between total management Z scores and QoC. However, amongst management domains, performance monitoring was found to have a significant relationship with QoC (adjusted *p* value = 0.02). One-unit increase in performance monitoring was associated with a 7-percentage point higher quality score.

On a scale of 1 to 5, the average management score for facilities in our sample was 1.6 with facilities in the private sector (2.0) receiving better management scores than public sector facilities (1.5). These findings are in line with previous studies that have found higher management scores in the private sector. [42] Our results are also compatible with the findings reported by a larger Indian survey in 3,892 private sector hospitals that used the survey tool that we adapted but was done through telephone interviews. [44] This study by Lemos *et al.* (2012) reported a total management score of 1.9, which is comparable to our private sector score of 2.0. Similarly, scores for all management dimensions obtained by the private sector samples in our study were in line with those reported by the previously mentioned study, such as: operations score (2.0 to 2.1), performance score (1.9 to 2.0), target management score (1.6 to 1.6) and people management (2.4 to 1.9).[44]

Previous studies utilizing the same tool have found that Indian hospitals were poorly managed compared to hospitals in US (3.1), UK (2.9), Sweden (2.7), Germany (2.6), Canada (2.5), Italy (2.5) and France (2.4).[44] In India, researchers found a wide spread of total management scores across states, ranging from 2.2 (highest) in Haryana, 1.9 in Delhi (median) to 1.7 in Kerala (lowest).[44] Hospitals in Uttar Pradesh were below the median and obtained a total score of 1.8[44] which is 0.2 points higher than our total management score.

In our sample, most managers had a clinical background (91%) rather than a business background (6 %) and 3.0% had a joint degree (MD/ MBA). In the larger Indian study, 30% of managers had an MBA degree or some sort of equivalent business training and 54% had a clinical degree.[44] These differences could perhaps be due to our study setting, which was

predominantly rural with a nascent private sector in two districts or could also indicate limited formal management training amongst administrators. Cross-sectional evidence from high-income settings indicates that hospitals employing clinically trained managers often have better management practices.[308] Research from the United Kingdom using the same survey tool has also found that doctors often make better managers if they have the relevant management skills and understanding of hospital operations. [309]

Previous research in India has found that Indian hospital managers are often unaware of modern management practices.[44] Our data shows that that most public-sector hospital managers have clinical backgrounds and tend to come into their positions based on their tenure through an incremental career progression scheme. Whereas, private sector hospitals were more likely to be family or self-owned, for- profit enterprises and managers at such private sector institutions had formal management qualifications (6%), which may perhaps explain better management scores in the private sector. Our impressions during fieldwork was that managers of public sector facilities are often constrained by bureaucratic procedures that limits financial autonomy, authority for recruitment or dismissal and ability to incentivise high performers. These could perhaps also partly explain poor performance of public-sector facilities compared to the private sector.

We also found that older facilities (established >10 years ago) had higher management scores compared to newly established facilities which could indicate that older facilities perhaps have more standardized and established care pathways compared to newer maternity facilities.

Although we found some variation in overall QoC between better managed and poorly managed facilities, this difference was not statistically significant (p=0.28). Results from the mixed effects model confirmed that there was no statistical association between total management Z score and QoC in both the unadjusted (Model 1; p= 0.85) and adjusted models (Model 2; p = 0.55). This finding is not consistent with previous research evidence from high-income settings,[43,45,308] however, none of these studies were done in low-income settings or specifically focussed on quality of maternity care.

Amongst all management dimensions, performance monitoring was the only dimension that had a significant relationship with QoC (adjusted *p* value = 0.02) with one-unit increase in performance monitoring associated with a 7-percentage point higher quality score. Our findings are in line with previous studies that have shown performance monitoring may encourage the use of evidence-based-practices, improve supportive supervision of health workers, encourage regular monitoring, and reporting on performance indicators.[293] The effectiveness of audits and feedback was evaluated in a Cochrane review, which found that audits and feedback interventions have the potential for a modest improvement (median +4.3%) in health worker compliance with desired practice.[195] In addition, the review found that audits and feedback are particularly effective when baseline performance is low, the source is a supervisor or a colleague, it is done multiple times, delivered in both verbal and written formats and includes explicit targets and an action plan.[195] Since hospitals are often the most expensive component of health systems, performance monitoring has potential to be useful in all settings.[392]

We also found that delivery in a private-sector facility was associated with a 7-10 % point higher standard of care compared to delivering in a public-sector facility. This is in line with our results from the QoC assessments which found better QoC in the private sector.[47] These results indicate that management practices do not fully explain the differences in quality of care between public and private sectors. It is possible that the private sector attracts more competent, better-motivated health workers with higher remuneration who in turn provide better quality of care. Further research using robust methods would be useful to understand whether management influences quality of care during normal labour and childbirth across sectors.

8.5: Limitations

We note the following limitations of the study. First, our sample of private sector facilities for the QoC assessments were limited by the fact that we had no official sampling frame for the private sector and undertaking a comprehensive census of private sector facilities was not feasible. In addition, 13 private facilities refused to participate in the QoC study. Management practices and QoC at facilities that were not sampled or refused to participate may have been different from participating private facilities. Hence, our findings on the relationship between

management practices and QoC are not generalizable to all facilities providing maternity care services in Uttar Pradesh.

Second, we interviewed manager's face-to face unlike previous studies that have employed telephone interviews. Therefore, it is possible that assessors maybe biased by the appearance or the operations of a particular facility. Third, although we adapted a tool that has previously been used in multiple countries including India, the content and construct validity of the tool was not specifically tested which may have implications for findings. Since, correlation between assessors was high and our scores were comparable with the larger Indian study, reliability is less of a concern. However, an additional validation study in a small selection of participants would have been useful to validate the study instruments. Fourth, our sample of 275 observations at 26 hospitals is also small to generate precise estimates on the relationship between management and quality of care. Fifth, our study instrument did not capture any information on contextual determinants (political, social, economic, socio-cultural) that may influence managers and facility performance in this setting. Further research would be useful to examine these issues in detail.

8.6: Conclusions

This study is of interest to the maternal and newborn health academic and research community, policy makers, programme managers and hospital administrators in resource-constrained settings that are interested to improve quality of care during labour and childbirth. Our findings suggest that management best practices are not widely utilised and that considerable gaps in knowledge and implementation exist at both public and private sector maternity facilities. We found that the relationship between management practices and QoC for normal labour and childbirth is complex and may not be apparent in settings where both QoC and management are weak. However, we found a strong association between performance management activities and quality of care. Our findings strengthen the evidence-base on the role of activities such as audits in low-resource settings that have an important role in improving quality of care.

It is likely that QoC during labour and childbirth is dependent on individual health worker's actions, competence and their motivations and health workers who are motivated will provided high quality care despite existing constraints that they face. Further research into

determinants of management practices at hospitals and validation of approaches to measure management practices comprehensively in resource- constrained settings would be useful.

Chapter 9: Discussion of the results of the overall doctoral research

Addressing QoC at the time of birth is an important priority for several global and national efforts that aim to end avoidable maternal deaths, neonatal deaths and stillbirths. [4,103] The results of three studies presented in my PhD provide a useful contribution to the literature on QoC and management practices at maternity facilities in Uttar Pradesh, India. My PhD results will also be useful to inform future maternal newborn health programmes and support the design of quality improvement efforts in the study districts. At the global level, my PhD findings will be of interest to the global research community working to define metrics for quality in maternal newborn health[26] and to define elements of skilled attendance at birth (SAB)[393].

9.1: Summary of key findings

The overall picture of maternity care provision that emerges from the study districts is of a dysfunctional care pathway with limited adherence to evidence-based practices and a high prevalence of certain practices considered to be mistreatment. The QoC at maternity facilities in the three studied districts of Uttar Pradesh in 2015 was found to be generally poor. Amongst all the investigated characteristics of the woman, the health facility and the type of birth attendant, overall quality of care was found to be better in private sector facilities and for women that were admitted during the work week (Monday-Friday).

Although I found that the majority of deliveries in maternity facilities were conducted by unqualified personnel in 2015, there were no statistical differences in care provided by unqualified or qualified birth attendants. Mistreatment of women (defined as presence of indicators of disrespect and abuse, over-treatment and under-treatment) frequently occurred at maternity facilities. From my investigation into the relationship between management practices and QoC, I found that there was no statistical association between total management scores and QoC. The only management dimension that had a significant positive association with QoC was performance management.

The key findings of the results chapters of my PhD are elaborated below.

9.1.1: Quality of care was generally poor across the sampled public and private sector maternity facilities in Uttar Pradesh in 2015

The results of chapter 6 showed that quality of essential care during labour and childbirth was poor in Uttar Pradesh, India. On average, women received just 36% of the recommended seventeen practices for care at the time of birth across the sampled maternity facilities in Uttar Pradesh. The clinical practices that I measured were the most essential and basic care practices recommended during labour and childbirth so in relative terms QoC was found to be very poor.

The overall QoC was found to be better amongst women attending private sector facilities where they received 45% of recommended practices compared to 33% amongst women attending the public sector in 2015. Notwithstanding the limitations of sampling the private sector, I found that private sector provided an overall higher standard of care during labour and childbirth (p=0.01) including for both obstetric (p=0.01) and neonatal care (p=0.02). The results from the multivariate analysis confirmed that overall QoC was 6 percentage points (95% CI: 1-11%) higher (p=0.03) in private sector facilities than corresponding scores in the public sector after controlling for confounders. Although, this result is statistically significant the difference in quality between sectors may not be clinically relevant as the effect can be as small as 1%.

There is mixed research evidence on whether private sector provides better quality health services than the public sector. For example, two systematic reviews employing different review methodologies have reported different results indicating that the underlying evidence base on this topic is weak[394]. In their systematic review (2011) of studies examining quality of care in formal private versus public sector facilities in LMICs, Berendes et al. (2011), concluded that "quality in both provider groups seems poor, with the private sector performing better in drug availability and aspects of delivery of care, including responsiveness and effort, and possibly being more client oriented".[365] However, another systematic review published a year later by Basu et al. (2012) concluded that "studies evaluated in this review do not support the claim that the private sector is usually more efficient, accountable or medically effective than the public sector"[395].

Qualitative studies that have sought to explain the reasons behind poor quality in the public sector have highlighted reasons such as resource constraints, low salaries, high workloads,

poor incentives and conditions of services[396], staff favouring certain patients[397], clients lacking sufficient knowledge about the appropriate use of drugs and their rights to challenge poor services. [398-400]

Specific to India, researchers have suggested that poor quality of care in India can be partly explained by the poor quality of medical trainings and the absence of national continuing medical education and recertification programmes.[178] Other researchers have found that provider effort is a key determinant for quality and health workers in the private sector exert more effort than the public sector.[365] This is also relevant in the context of LMICs where private sector personnel often want to demonstrate that they are providing better value for money and exert greater effort. Research evidence also indicates that provider effort can be improved by providing higher payments, better incentive schemes, strengthening monitoring and providing better support to health workers through peer-networks.[365]

Quality of obstetric care, as measured by an index based on nine of the most important practices, was found to be low (30.5%) across the entire sample. The obstetric care index was found to be lower amongst public sector cases (28%) compared to the private sector cases (40%). Amongst obstetric care practices, regular monitoring of labour using a partograph (1.6%) was rare and partographs were used in just 0.2% of public sector cases compared to 7.2% of private sector cases. My findings are similar to other studies in India which have found poor rates of partograph use with inadequate attention to either foetal or maternal well-being during labour and childbirth.[70,71] In fact a study examining the implementation of partographs in the JSY program in Madhya Pradesh found low rates of partograph use (6%) and poor comptence of health workers in using partographs correctly.[67] In this study, health workers received a mean score of 1.08 (out of 10) on clinical vignettes, indicating substantial deficiences in knowledge of health workers. [67]

Although, the use of partograph is actively promoted by the Indian government and national guidelines also recommend that trainings on partographs and essential supplies should be provided at all birthing facilities, [332,382] my findings demonstrate that partographs are not used routinely. Other research evidence from LMICs has suggested that challenges for routine partograph use include limited knowledge of health workers, limited availability of pre-printed partographs, length of time needed to fully complete a partograph and high workloads of health workers.[16,67] As discussed above, research evidence also indicates that

deficiencies in intra-partum care such as inadequate monitoring of labour through partographs often lead to preventable intra-partum stillbirths in India. [401]

Screening measures for preeclampsia/ eclampsia were found to be low (2.3%) across the entire sample with 2.2% of public sector cases receiving these screening measures compared to 2.5% of private sector cases. These results suggest that simple screening measures such as detection of elevated blood pressure and presence of proteinurea are not routinely assessed at both public and private maternity facilities.

Active management of third stage of labour (AMTSL) was done in less than a quarter of all cases, amongst a greater proportion (25.4%) of public sector cases compared to 21% of private sector cases. These rates of AMTSL were higher than reported by another observational study in a neighbouring district of UP which used the same WHO definition I used. [77] The WHO (2014) defines AMTSL as three components: 1. provision of a uterotonic drug – Oxytocin (10 IU, IV/IM) is recommended; 2. delayed cord clamping and 3. controlled cord traction in settings where SBA are available.[402] Uterine massage is not recommended in WHO guidelines.[402] In fact a recent large clinical trial led by WHO (2012) showed that the most important component of AMTSL was the administration of the uterotonic drug.[403] Encouragingly, I found that administration of uterotonic was high (above 90%) and similar in both sectors.

The neonatal care index, which is a summary index for eight of the most important neonatal care practices, was found to be 41% across the entire sample. The neonatal care index was lower amongst cases in the public sector (38.9%) than comparable rates in the private sector (51%). Assessment of foetal viability after admission by assessing foetal presentation and fundal height was found to be done in 1.1% of all observed cases. More private sector cases (3.4%) received this assessment compared to public sector cases (0.5%). Monitoring of the fetal heart rate at regular intervals was found to be done in 20% of all cases, in a greater proportion (73.3%) of private sector cases compared to 6.6 % of public sector cases.

The monitoring of Apgar score at 1 and 5 minutes was done in just 0.9% of all observed cases, 4.7% amongst private sector compared to none in the public sector. The Apgar score assessment comprises of five components: colour, heart rate, reflexes, muscle tone and respiration, each of which is given a score of 0, 1 or 2. The score is reported at 1 minute and

5 minutes after birth for all neonates and at 5-minute intervals thereafter until 20 minutes for infants with a score less than 7.[404] Essentially, Apgar score is a convenient method for reporting the status of the newborn infant immediately after birth and the response to resuscitation if needed. Although, Apgar score measurement is recommended in WHO guidelines for care at birth[114] and the Indian guidelines [382] as my results demonstrate these are not routinely assessed. However, some researchers have also questioned the validity of the Apgar score indicator since assessment comprises of many subjective elements. [405] In addition, a range of factors including maternal sedation or anaesthesia, congenital malformations, gestational age, trauma, and inter-observer variability can affect the score[405] so these Apgar scores need to be interpreted cautiously.

My results on poor quality of care for routine normal labour and childbirth are in line with other studies from India [70,71,78,406] and from other LMIC settings in Africa (Côte d'Ivoire[407], Burkina Faso, Ghana, Tanzania[408]) and from Arab countries.[118] In India, other researchers have suggested that inadequate knowledge and skills, staffing shortages, poor quality in-service trainings, lack of enabling environments and limited supportive supervision could be underlying causes of poor quality care at facilities.[66,71]

Research evidence from countries such as Thailand, Malaysia and Sri-Lanka that have achieved good progress in improving maternal mortality indicates that programme efforts need to go beyond increasing coverage of interventions and a specific focus on improving quality is required which researchers have referred to as effective coverage. [409,410]

In the study districts, the QoC provided – in either the public or private sector – was not significantly related to the investigated characteristics of the birth attendant, facility or the woman's age, caste, parity, referral status or socioeconomic status. The only covariate associated with QoC was admission at a weekend, which was associated with 3-percentage point poorer standard of care (p=0.03). I will discuss some of these findings in greater detail below.

9.1.1.1: Poorer quality of care during weekends

Many research studies have reported on a "weekend effect" in obstetrics with poor QoC at the time of birth leading to adverse maternal and perinatal outcomes. [362,363,411] For example: a large observational study from the United Kingom found higher rates of stillbirths, early

neonatal deaths, puerperal infections, injuries to the neonate, and increased three-day neonatal admissions to the emergency room during weekends.[362] Another study from Scotland reported a higher adjusted odds ratio for weekend neonatal deaths of 1.3 (1.0 to 1.6) compared with weekday within regular working hours.[363] Specific to LMICs, a large retrospective record review study (2015) from the Gambia found that newborns admitted during weekends were more likely to die than those admitted during the weekdays (38% *vs* 35%, *P* = 0.03). [412] Similarly, the risk of neonatal death was greater for those admitted out of hours than those admitted during during regular working hours (38% *vs* 33%, *P* = 0.004).[412] Other research studies from LMICs have also reported fluctuations in the numbers of staff such as less numbers of doctors or nurses on-site during weekends and at nights, that limits EmOC capability at hospitals. [413] In addition, laboratory, blood transfusion, emergency referral and diagnostic services may also be limited during weekends.[412,414] Reseachers have suggested that deficiencies in structural elements of care, limited resources and poor management of maternity services during the weekends are the reasons behind poorer obstetric and neonatal outcomes during weekends. [362,363]

9.1.1.2: Similar QoC care provided by unqualified and qualified maternity care personnel

My results indicate that the majority of deliveries (59%) were attended by unqualified personnel in maternity facilities in UP. Research evidence from observational studies in Rajasthan, which is another state with a relatively similar health indicators, has also found that unqualified personnel were involved in providing care during labour and childbirth, in up to half of all observed cases, and that there were significant deficiencies in quality. [70,71]

However, in the multivariate analysis, I did not find a significant difference in QoC provided by qualified and unqualified attendants. There could be many reasons that explain this finding. First, my observations were limited to normal vaginal births which are a normal physiological event and had I measured QoC for complications of pregnancy, perhaps, maternity personnel's qualifications may have emerged as a stronger predictor for better quality.

Second, the quality of trainings received by qualified personnel may be poor and they may not be aware of up-to-date technical guidelines and therefore unable to provide high quality care. The quality of medical education in both public and private medical colleges in India is

known to be variable and previous research efforts have found that the technical comptence of health workers can vary depending on where they received their trainings. [178,415]

Third, although, qualified personnel may have received high quality trainings and possess good knowledge and skills, they may not be able to apply these into regular clinical practice as a result of many different factors such as resource-constraints, high work-load, limited incentives and others as highlighted previously.

Fourth, given that there are no existing mechanims for training unqualified maternity care personnel (TBAs, ASHAs, BHWs, BSWs,cleaners) as a part of ongoing government initiatives, perhaps, unqualified personnel learn informally on-the-job. My observations during field work and dialogue with Indian colleagues on this issue confirms this finding. Since, maternity care relies heavily on team work, these unqualified personnel pick up essential skills from qualified personnel as a part of their routine work. It may also be possible that through these informal on-the-job training mechanims, unqualified personnel are able to gain equivalent practical skills, similar to what they would obtained through formal training.

Evidence from a meta-analysis of audit-based studies aiming to identify avoidable factors for maternal and perinatal deaths in low-resource settings has identified deficiencies in care by health workers as the most important factor for avoidable maternal and perinatal deaths. [416] Several studies from LMICs such as Afganistan[417], Nigeria[418], Pakistan[75] have reported gaps in knowledge and skills of SBAs, similar to those reported by Harvey *et.al* (2007) from assessments in Benin, Ecuador, Jamica and Rwanda[364]. A study using standadized patients in India also found limited differences in QoC provided by unqualified and qualified health workers, although this study was not specifically focussed on maternity services. [178] Furthermore, it can be assumed that qualifications on paper do not guarantee that health workers have adequate skills, up-to-date knowledge and clinical competence for proving maternity services. Similarly, just because a doctor, nurse or a midwife meets the WHO defined criteria for SBAs does not mean that they are adequately skilled.[364] Receving a skilled birth attendant training course, feeling competent about their expertise and applying these knowledge and skills to daily clinical practice are separate issues.

As demonstrated by the LMIC studies mentioned earlier, even trained SBAs often have gaps in their comptence and this may result in feeling under-qualified or uncomfortable in

managing conditions during labour and childbirth. Although, shortages of adequate numbers of SBAs and the absence of formal midwifery cadres are important issues for India, ensuring competence of existing SBAs also seems to be an important barrier for improving QoC at the time of birth in India. However, it is encouraging to note that the Government of India and its partners are implementing a range of schemes to improve the quality of intrapartum and immediate postpartum care.[366]

9.1.1.3: No association between QoC and characteristics of the women and hospital

I did not find a significant relationship between facility size and QoC at the time of birth which could be explained by the fact that my clinical observations were limited to uncomplicated vaginal births and QoC in this setting was deficient across all sampled facilities. Previous cross-sectional studies from Africa (Tanzania) and South Asia (Nepal and Srilanka) have found better QoC at higher level facilities, potentially explaining why patients bypass lower level facilities.[348,419,420] In the study from Nepal (2013), the most popular reasons identified for bypassing smaller birthing centres to deliver at larger urban hospitals, despite incurring additional costs, were found to be non-availability of operating theatres and inadequate drugs and equipment at smaller birthing centres.[420]

I also did not find a significant relationship between women's age, caste, socio-economic or referral status and QoC in the multivariate analysis. However, I did find a greater variance in QoC within individual health workers than between them which suggests that health workers may not systematically follow standard protocols or provide preferential care to some women.

9.1.2: Mistreatment of women frequently occurred at maternity facilities in Uttar Pradesh in 2015

Chapter 7 examined the nature and context of mistreatment amongst women attending public and private sector maternity facilities in Uttar Pradesh. I found that all pregnant women encountered at least one practice defined as mistreatment. My estimates are similar to another cross-sectional study from a teaching hospital in south-eastern Nigeria where 98% of women reported some kind of mistreatment during childbirth.[374] Similarly, another cross-sectional study in Ethiopia also found a high prevalence of mistreatment where 100% of women that went to a teaching hospital and 89.4% that went to peripheral health centres encountered some form of mistreatment.[421]

As mentioned previously, there is now substantial research evidence which indicates that mistreatment is widespread in both high and low income countries. [80,128-134] Further, newer research evidence is also emerging including from Uttar Pradesh which suggests that mistreatment may also be associated with maternal health complications during delivery and the post-partum period.[422] Hence, mistreatment is not just a rights-based issue but also a medical and poor QoC issue. Moreover, we know that women who are mistreated are less likely to come to facilities for future deliveries[80] so this is an important issue that needs to be addressed.

9.1.2.1: Common practices of mistreatment in public and private sector facilities

I found a higher prevalence of verbal abuse (shout, threaten, talk-down) than physical abuse at health facilities. However, physical abuse was particularly higher among women above 35 years of age and those attending the public sector facilities. My informal observations during data collection were consistent with other studies in Madhya Pradhesh[66] and Rajasthan[78], that found labour room environments were chaotic and health workers can be dominant, abusive and threatening on occasions.[66] My impressions during field work also suggest that verbal abuse occurs much more frequently than physical abuse.

I found that the most prevalent practices of mistreatment were not offering women a choice of birthing position (92%) and performing routine manual exploration of the uterus (80.4%) which were similar across facilities in both sectors. My estimates on health workers not offering women a choice of birthing position are in line with other cross-sectional studies in Africa and Asia. [421 423] Bohren *et al*.'s systematic review on barriers to institutional deliveries identified that women being asked to adopt unfamiliar positions and not having control over their position during childbirth are important reasons for women choosing to deliver at home. [79] In qualitative studies from Bangladesh and Uganda, researchers have reported that since health workers are not trained to deliver women in positions other than lying on their backs, they are not comfortable with offering alternative birthing positions. [424,425]

Interpersonal communication between birth attendants and labouring women was largely non-existent as demonstrated by the high prevalence of cases where explanations were not provided to women prior to invasive procedures. These findings are similar to those reported in other Indian states such as in Rajasthan and Madhya Pradesh. [66,70]

9.1.2.2: Mixed patterns of mistreatment in public and private sector facilities

Private sector facilities were found to perform worse than the public sector for not allowing birth companions and for perineal/ pubic shaving. This could be because of existing labour room policies in private hospitals which do not allow birth companions as they may not be aware of the latest recommendations on birth companionship or perhaps they think that limiting the number of people in the labour room is better for infection prevention and control. It may also be possible that health workers in private hospitals feel that since they already provide personalised and comprehensive maternity care, birth companions are not needed. In the Indian setting, birth companions generally tend to be family members such as mothers, mother-in-laws, sisters or the husband. As mentioned previously, evidence from a systematic review indicates that continuous support from a chosen family member or a friend increases women's satisfaction with their childbearing experience.[380]

Perineal/ pubic shaving has no associated clinical benefits [381] and is not recommended in the Indian skilled birth attendance training materials[382], which suggests that, perhaps, private sector health workers may not have received these trainings or that quality of such trainings is poor.

On the other hand, the public sector was found to perform worse than the private sector for not ensuring adequate privacy, not informing woman prior to a vaginal examination, and for physical violence towards pregnant women. There could be many reasons such as infrastructure-related deficiences (limited number of beds or screens), larger number of clients, poor communication, normalisation of disrespect and abuse[79,80] in the public sector in Uttar Pradesh.

Research evidence from LMICs has identified factors such as unfavourable institutional policies, resource and infrastructural constraints, socio-cultural factors, poor working conditions, limited mentorship and supervision, limited knowledge and skills of health workers of health workers as underlying causes for mistreatment of women which are relevant in this setting too.[79,80,368]

9.1.2.3: Some socio-demographic characteristics are risk factors for mistreatment

I found that total mistreatment scores were higher amongst women above than 35 years of age (5.1), primiparous (5.2), those that were referred from another facility (5.0), amongst

women belonging to the "scheduled caste and tribe" (5.0), those in the fifth (richest) wealth quintile (5.1), and amongst cases admitted during regular work-hours (5.0) on weekdays (5.0) in the public sector (4.9). A cross-sectional study from urban slums in Uttar Pradesh similarly found that wealthier women, migrant women and women from lower castes self-reported higher levels of disrespect and abuse, although this study was not based on actual observations.[375]

The importance of caste is well documented in India and researchers have suggested that since "scheduled caste and tribe" women are less empowered, health workers are more likely to think that they can get away with mistreatment of these women.[375] However, in the bivariate analysis, caste was only associated with episiotomy and women in the higher "general caste" categories were found to have greater proportions of routine episiotomies perhaps because they used private sector facilities more often. Women in the first quintile (poorest) were least likely to be informed prior to a vaginal examination (p=0.002) which suggests discriminatory care based on wealth status.[378] However, women in the highest wealth quintile (richest) were more frequently unaccompanied by a birth companions (p=0.01), had higher rates of perineal shaving (p=0.001) and episiotomy (p=0.001) which could perhaps reflect greater use of the private sector and consequent overtreatment of women that attend private sector facilities.

9.1.2.4: Under-treatment and over-treatment of women at maternity facilities is also mistreatment

In Chapter 7, I demonstrated and argued that under-treatment such as through the use of unqualified personnel who may not be capable of providing essential care practices or of deliveries taking place in unhygienic conditions are against the rights of childbearing women[141] and therefore should be considered mistreatment. Similarly, overtreatment such as through non-adherence to evidence-based protocols or routine use of harmful practices (uterine lavage, episiotomy or enemas) also occurs frequently that are against the rights of childbearing women[141]. Essentially, mistreatment intersects quality of maternal health care and relates to care that is both Too Little Too Late and Too Much Too Soon[83].

The recent WHO statement on disrespect and abuse (2014) indicates that mistreatment is now considered a serious issue at the global level.[123] The United Nations has also issued a resolution on preventable maternal mortality as a human rights violation[426] and issued a technical guidance on the application of a human rights-based approach to reduce maternal

deaths in 2012.[427] In addition, bodies such as FIGO, ICM, WHO and others have also initiated a "Mother and Baby Friendly Birthing Facilities" initiative which amongst other things states that "Every woman and every newly born baby should be protected from unnecessary interventions, practices, and procedures that are not evidence-based, and any practices that are not respectful of their culture, bodily integrity, and dignity".[428]

9.1.2.5: Mistreatment and type of maternity care personnel

Although I found that the majority of pregnant women were cared for by unqualified attendants (unweighted estimate: 59%) and they were more prevalent in the public sector, the aggregate scores for mistreatment were higher for deliveries conducted by qualified attendants (4.9) as compared to unqualified attendants (4.8) which supports the notion of overtreatment by qualified personnel.

Upon closer examination, unqualified personnel were more likely not to inform women prior to a vaginal examination (p=0.01) and use unsterile gloves (p=0.04). This indicates poor interpersonal communication and lack of knowledge amongst unqualified personnel. However, qualified personnel were more likely conduct unnecessary procedures such pubic/ perineal shaving (p=0.02) and episiotomy (p=0.003) which suggests either unfavourable institutional policies or outdated knowledge of health workers resulting in overtreatment.

An important issue to note at this time, relates to the problems in conceptualising and measuring mistreatment. For example, these practices outlined above such as pubic/ perineal shaving or routine episiotomy or fundal pressure are not evidence based and can be harmful.[83] However, health workers are often trained to do these things and they may genuinely believe that these practices are for the woman's benefit. Therefore, it is important think further about measurement of mistreatment, and whether the act or the harmful practice was intentional or not. I will elaborate on these issues later in the section on future recommendations for research. Moreover, the research community will need to think carefully about how to address mistreatment comprehensively and take a balanced approach without blaming health workers who also work in difficult situations.

9.1.2.6: Informal payments as also form of mistreatment of women in maternity facilities.

I found that informal payments were routinely demanded by health workers in the public sector. These informal payments often determined the QoC received by women in public

sector maternity facilities in 2015. Informal payments can range from gratuity payments from appreciative patients, payments to jump the queue, receive better or additional care, to obtain drugs and commodities, or simply to receive any care at all.[385] Informal payments are considered to be inequitable and constitute institutionalised bribery, which may hamper the entire health system.[385,386] Further, they tend to be prevalent in settings where health systems are under-funded, supervisory mechanisms are weak; where women are not empowered or not aware of their rights, and where providers are unlikely to face disciplinary action for their behaviours. [385]

9.1.3: Overall management score was not associated with QoC at maternity facilities in Uttar Pradesh in 2015

In chapter 8, I measured and described management practices at maternity facilities in Uttar Pradesh and examined whether management practices were associated with quality of labour and childbirth care. The results from this investigation found that the QoC and management practices were both poor in maternity facilities in Uttar Pradesh, India. In this setting, my results indicate management practices at the institutional level do not influence QoC during labour and childbirth. The only management dimension that had a significant association with QoC was performance management which was found to be associated with up to a seven percentage point higher quality score. The key results from my investigation into management practices and quality of care at the studied facilities in 2015 is summarised below.

9.1.3.1: Management practices were poor at the studied maternity facilities in Uttar Pradesh

I found that the overall management scores received by maternity facilities in Uttar Pradesh was low (1.6 on a scale of 1 to 5). Public sector facilities received a lower score of 1.5 compared to the private sector facilities which received a score of 2.0. The private sector also outperformed the public sector for all management dimensions; operations management (private: 2 and public: 1.7), performance management (private: 1.9 and public: 1.5), targets management (private: 1.6 and public: 1.2) and people management (private: 2.4 and public: 1.2).

The low performance of the public sector suggests that various bottlenecks exists for the implementation of these management best-practices in the public sector. These bottlenecks could include issues such as limited autonomy of managers in the public sector with budgets,

human-resource management decisions, and limited ability to incentivise better performance in the public sector. These findings are in line with previous studies that have found higher management scores in the private sector. [42] Although, my descriptive results showed higher scores for all management dimensions and quality of care in the private sector, I did not find an overall statistical association between management and quality of care in the multivariate analysis.

My results are also compatible with the findings reported by a larger Indian survey in 3,892 private sector hospitals that used the survey tool that we adapted but was done through telephone interviews. [44] This study by Lemos *et al.* (2012) reported a total management score of 1.9, which is comparable to our private sector score of 2.0. Similarly, scores for all management dimensions obtained by the private sector samples in our study were in line with those reported by the Lemos *et al* study (2012). For example, operations score (2.0 to 2.1), performance score (1.9 to 2.0), target management score (1.6 to 1.6) and people management (2.4 to 1.9). [44]

The scores obtained by the facilities in UP in 2015 were found to be poorer than corresponding scores obtained by hospitals in US (3.1), UK (2.9), Sweden (2.7), Germany (2.6), Canada (2.5), Italy (2.5) and France (2.4) that were done using a similar tool. [44] Specific to Uttar Pradesh, my scores were 0.2 points lower than what others have found in Uttar Pradesh using the same tool [44], however, I surveyed more public sector facilities which may explain the difference.

9.1.3.2: Performance management was the only management dimension associated with better quality of care at the studied maternity facilities in 2015

I found that facilities with below median management scores provided an average of 39% of all recommended seventeen interventions to women compared to 34% by facilities with above median management scores but this difference was not statistically significant (P=0.28). Similarly, for obstetric care, better managed facilities were found to provide 30% of the recommended interventions compared to 34% of recommended interventions in poorly managed facilities but this difference was not statistically significant (p=0.4). For newborn care, better managed facilities provided 39% of the recommended interventions compared to poorly managed facilities that provided 44% of the recommended neonatal care interventions but this difference was also not statistically significant *(p=0.13)*.

Results from the mixed effects models confirmed that there was no statistical association between total management Z score and QoC in both the unadjusted (p= 0.85) and adjusted models (p = 0.55). This finding is not consistent with previous research from high-income settings[43,45,308]; however, none of these studies were done in low-income settings or specifically focussed on quality of maternity care.

Amongst all management dimensions, performance monitoring was the only dimension that had a significant relationship with QoC (adjusted p value = 0.02) with one-unit increase in performance monitoring associated with a 7-percentage point higher quality score. Our findings are in line with previous studies that have shown performance monitoring may encourage the use of evidence-based-practices, improve supportive supervision of health workers, encourage regular monitoring, and reporting on performance indicators.[293]

The effectiveness of audits and feedback was evaluated in a Cochrane review, which found that audits and feedback interventions have the potential for a modest improvement (median +4.3%) in health worker compliance with desired practice.[195] In addition, the review found that audits and feedback are particularly effective when baseline performance is low, the source is a supervisor or a colleague, it is done multiple times, delivered in both verbal and written formats and includes explicit targets and an action plan. [195] As hospitals or health facilities are the most expensive and important components of any health system whether in LMICs or in HIC, performance monitoring has potential to be useful in all settings. [392]

Lastly, after accounting for confounders in the multivariate analysis, I also found that women attending private maternity facilities received a 7-10 % point higher standard of care which is consistent with the results reported in chapter 6.

9.2: Plans for dissemination

Upon completion of clinical observations in individual health facilities, the research team and I routinely debriefed with the health facility manager and/ or senior clinical staff. During these debriefing meetings, we discussed our overall impressions of QoC at these facilities. We also discussed specific cases where grossly negligent care (for example mistreatment of women) or cases where life threatening maternal and neonatal complications (such as PPH or birth

asphyxia) were observed by the research team. Hospital authorities were also informed that if they were interested, I would be happy to send them preliminary results from clinical observational data collected at their facility. These results could potentially be useful for initiating quality improvement work at individual facilities.

I also received an opportunity to present paper one of my PhD at a policy seminar at the World Health Organization, Switzerland on June 14, 2017. My paper was included in the Bulletin of the World Health Organization's special theme issue on quality of care in the era of the Sustainable Development Goals (SDGs). Further details on the policy seminar are available here. https://www.wider.unu.edu/event/policy-seminar-launch-who-bulletin-theme-issue-measuring-quality-care

My overall research findings were also shared with the funder and implementing partners in a workshop in September 2017 and other periodic meetings. There is a national dissemination event planned in February 2018 where the results of the studies reported in my PhD will be widely disseminated amongst national and state level stakeholders in India. I hope that this event is able to highlight the urgent need to improve existing maternity care standards in Uttar Pradesh and other states in India. As mentioned previously, dissemination of evidence-based guidelines and the concepts of respectful maternity care amongst all front-line workers would be useful in improving quality of maternity care.

Lastly, there are on-going discussions about a dissemination event in London, planned for April 2018, where the learning from all MET projects will be synthesized and disseminated to the academic and research community.

9.3: Reflections, strengths and limitations

9.3.1: For objective 1: QoC during labour and childbirth at maternity facilities in UP

9.3.1.1: Reflections

In chapter 6, I assessed and described processes of care during labour and childbirth that were investigated using clinical observations conducted at 26 maternity facilities in Uttar Pradesh. An important consideration while measuring QoC is how far to go when defining and selecting appropriate QoC indicators. Although, conceptually, QoC has been thought by some to encompass multiple levels from patients to health systems and health policies[86], for the

purposes of measuring actual services at health facilities, it is not ideal to measure bottlenecks in health systems[16] but rather preferable to focus on elements of direct service provision and experiences of clients.

Hence, for the QoC assessments in my PhD study, I only measured processes of care which I defined as the application of evidence-based guidelines and provision of respectful woman-centred maternity care. Although other aspects of quality such as those related to structure (measured through an inventory assessment of medicines, infrastructure and supplies) or outcomes (measured through hospital-based data or special studies) are important, they do not provide a comprehensive picture of quality of care during labour and childbirth that women receive. In addition, the contribution of my PhD is to advance the thinking around measurement of processes of care for normal labour and childbirth which included the development of three innovative indices.

To develop the QoC indices, I had to think carefully about how to group various clinical items into clinical practices and then decide on how to develop different aggregate indices. While developing these indices, I grouped individual items into clinical practices based on their inherent clinical logic and their purpose rather than their relative importance in avoiding adverse outcomes as there was no scientific basis for doing so. For example, I did not apply weights to interventions since many interventions used for labour and childbirth do not have evidence of efficacy as trials on these practices would be unethical for example: monitoring of post-partum bleeding or sterile cord cutting. Therefore, to keep the indices transparent, I gave equal weight to all individual clinical practices. If there had been evidence for applying intervention-specific weights, the indices would perhaps have been more robust. Another option would have been to generate a consensus on the importance of specific clinical practices by undertaking a modified Delphi-method approach, as others have done, [201] but such methods are also known to be subjective[429]. I will elaborate on these issues further in recommendations for future research.

9.3.1.2: Strengths

Some of the strengths of this QoC study were that I developed a comprehensive assessment tool which allowed for an integrated assessment of both maternal and newborn care practices around the time of birth, which is often lacking in many of the other available assessment tools. This tool is a direct output from this study and has also been used in Uganda and

Rajasthan. It is hoped that it will also be useful for future research efforts to measure QoC in other high-burden settings. Since it focuses on normal births, its applicability also extends to smaller birthing centres in LMIC settings. I also selected all women who came to deliver in the study facilities and there were no refusals by women to recruitment which is a strength of the study. Other strengths of the QoC study were that I did not rely on self-reported behaviours or facility records and conducted clinical observations round-the clock on all seven days of the week.

To overcome measurement errors, QoC assessment tool was developed as a structured, standardized tool and was pre-tested and piloted prior to field application. Time and effort was invested into training of observers so that they were competent in using the study instruments. This limited subjectivity by observers. Further, all observers used at individual maternity facilities were external to that facility to minimise any inherent biases. To prevent misclassification of pregnancies as normal, all observers had been trained to follow a strict case definition of normal vaginal births and cases that did not fulfil this case definition were excluded from the study. Data quality was assured through daily quality checks.

The essential care at birth index is an innovative analytical framework that captures the use of evidence-based interventions, use of respectful, woman-centred care practices as well as patterns of harmful care. All the indices- the essential care at birth index, neonatal care index and obstetric care index can also be used individually for monitoring maternal and newborn health programme efforts. The strengths of creating such aggregate indices include the ability to communicate a large amount of information and convey a comprehensive picture of QoC in a succinct manner. Since I wanted these indices to be useful for programme improvement efforts, I decided to develop three separate indices. Depending on the specific area of concern for quality improvement, interested researchers and programme managers may use these indices individually, as appropriate. However, interested researchers who use the methodology described in my PhD to conduct clinical observations have to be careful while interpreting results from such aggregate indices. They will have to think carefully about what are the specific practices that make up the aggregate index have a weak(er) or high(er) score. For example: woman centred respectful care practices may be the weakest elements that bring down the entire obstetric care index or establishing skin to skin contact may be one of the practices that brings down the entire neonatal care index.

Lastly, since the sampling for the public-sector facilities was done using a stratified random sampling methodology, and the analysis also used population based weights, I am confident that the estimates obtained reflect the real situation in public sector facilities in the study districts.

9.3.1.3: Limitations

My measurement approach is resource and time-consuming so it may not be possible to scale this up beyond dedicated research projects. However, efforts to improve measurement of QoC at the time of birth are evolving rapidly despite the fact that WHO guidance on measurement of QoC during labour and childbirth does not exist till date.

My study was only conducted in three districts of Uttar Pradesh within the framework of an external evaluation of the "Matrika" project so my findings may not be representative of the overall situation in Uttar Pradesh.

Observer bias: There may have been observer bias in the study due to the popular perception that the private sector is superior since it has better infrastructure, better trained personnel who are also better paid, leading to an over-estimation of quality in private facilities.

Selection bias: There were challenges to sampling the private sector. Not only did 13 private facilities refuse to participate, I had no official sampling frame from which to select the facilities. Therefore, it is possible that the QoC of the participating private facilities was different from those that were either not sampled or refused to participate. Although, I had the necessary permissions from the government and ensured confidentiality of any data collected; as privately owned facilities, they were not obliged to participate in my study. In addition, obtaining detailed information from the private sector on their staff, their qualifications, extra hours of work, numbers of caesarean sections and others was particularly problematic even at facilities that consented to the clinical observations. As reported by a qualitative study that interviewed private sector obstetricians in the states of Uttar Pradesh and Jharkhand in India, there is often a trust deficit between the private sector and the government.[430] My overall impressions during field work was that the private sector authorities were very cautious with external entities given the volatile socio-political environment and media sting operations that frequently occur in Uttar Pradesh.

I also had limited number of cases in the private sector compared to the public sector as most private sector births resolved as caesarean sections and this is an important limitation. My research focussed on examination of normal labour and childbirth and I did not measure quality of care for complications of pregnancy such as post-partum haemorrhage or severe eclampsia or for CEmOC procedures like caesarean operations. It is possible that a different picture of quality may have emerged between public and private sectors had I measured QoC for these issues. Perhaps, the public sector may have performed better for being able to manage pregnancy complications or have fewer non-indicated caesarean operations compared to the private sector.

However, there are many challenges associated with measuring QoC for complications of pregnancies. Some of these include limited availability of appropriate, valid assessment tools, problems in recruiting specialists such as obstetricians and gynaecologists to work as clinical observers throughout the duration of the study, a longer time frame is required to get the optimal number of observations and there is potential for observer bias, as with any clinical observation. A recent study from Afghanistan that used mixed-methods including clinical observations of caesarean deliveries reported that direct observations were a feasible and effective method for assessing QoC of caesarean deliveries in low resource settings.[431] However, in this study, researchers recommend that along with clinical observations, others methods such as record reviews and interviews with health workers should be undertaken so that a comprehensive picture of quality can be obtained. [431]

Using aggregate indices is useful to report comprehensively on QoC but it masks differences between individual indicators. Also, another limitation is the difficultly in identifying why a particular index has a low score or a particular practice is weak, beyond common individual or facility based determinants. In order to choose the necessary actions required to improve QoC, researchers will need to identify the exact reasons behind poor scores. For example, poor rates of uterotonic drug use within 1 minute may be due to many problems such as non-availability, incorrect formulation, incorrect timing, lack of knowledge, poor injection technique, poorly motivated staff, poor working conditions, no refrigerator to store oxytocin and others.

The Hawthorne effect refers to a phenomenon where subjects under observation may alter their behaviour precisely because they are being observed.[181] The concern in this study was

that health workers may have performed better when being observed than under normal conditions. To help address this problem, maternity care personnel were blinded to the details of the primary measures of the study. Information sheets provided to maternity care personnel as part of the consent procedures emphasised that observations were not meant to assess their personal performance, information collected will not be liked to individual providers and study findings will not result in punitive action. During the analysis, I did not examine individual performance of any specific maternity care personnel. However, all observations were time-stamped so that I could explore the presence of Hawthorne effect during analysis. It is encouraging to note that any Hawthorne effect is negligible in this study.[47]

Lastly, I did not look at maternal and perinatal outcomes in my study as that would have required larger sample sizes, larger time period for data collection and additional funding. As highlighted previously, improved processes of care do not guarantee better maternal and perinatal health outcomes. However, the global maternal health community is eagerly awaiting the results of a cluster-randomized controlled trial in Uttar Pradesh known as the better birth trial.[432] In this trial, researchers are evaluating the impact of a safe childbirth checklist embedded within a quality improvement programme with a nurse "mentor" providing supportive supervision and real-time feedback on QoC at health facilities.[432] As per their protocol, researchers are expected to report on a range of outcomes including composite measures of maternal deaths, maternal severe morbidity, intrapartum-related stillbirths, and newborn death occurring within 7 days after birth.[432]

In summary, my overall experience with clinical observations of labour and childbirth was promising and, as my results have shown, with careful design and planning, it is possible to conduct a robust observational study.

9.3.2: For objective 2: Mistreatment of women at maternity facilities in UP.

9.3.2.1: Reflections

To measure and describe mistreatment of women at maternity facilities, I used a mixed-methods approach using quantitative data obtained from clinical observations and qualitative data from unstructured observers comments. Other researchers have also measured

mistreatment by asking women questions about their maternity experiences during hospital-exit interviews or household surveys.[376]

Upon reflection, it may have been useful to conduct some in-depth interviews amongst a sample of recently delivered woman and health workers as a part of my PhD study. Understanding women's insights and perceptions of mistreatment would have been useful to understand the cultural and contextual issues around mistreatment in UP. Interviews with health workers would have provided me with additional information on whether health workers understand what mistreatment is, what they perceive as mistreatment and whether they understand that poor experiences of women might affect future utilisation of their services. However, the innovative aspect of my PhD study is that data are based on actual clinical observations of mistreatment including in the private sector.

Upon reflection, from a measurement point of view, it can be hard to distinguish mistreatment from receiving care which is not evidence-based, since the boundaries between these often overlap. For example: is delivery by an unqualified person or in an unhygeinic settings without basic amenities considered mistreatment of women since it is against the rights of childbearing women[141] or is it just an indicator of lack of resources or both?.

Lynn Freedman has suggested that a definition of mistreatment should try to capture individual disrespect and abuse – that is specific behaviours of the health workers that are intended to be disrespectful or humiliating such as slapping or scolding the woman. But also the role of systemic deficiencies that may create a disrespectful and abusive environment, for example, an overcrowded and understaffed maternity ward where women deliver on the floor, alone, in unhygienic conditions.[81]

While defining and measuring mistreatment, we also need to think about whether mistreatment was intentional or not. For example, some practices, such as fundal pressure or routine episiotomy are not evidence based and can be harmful,[83,114] but often health workers have been trained to do these things and think they are for the woman's benefit. Are these indicators of mistreatment or of poor quality of care? Although, health workers may have been taught to use these interventions in the past, these harmful interventions are no longer recommended. Hence, this concept of intentionality complicates measurement efforts.[83,114]

Therefore, further conceptual clarity on the boundaries between mistreatment and poor quality of care may be needed.

I also had limited qualitative data from the observer's comments and upon reflection, it may have been better to have a dedicated observer assigned specifically for taking detailed field notes as employed by other qualitative studies. [433]

Lastly, my QoC assessment tool should have specifically captured detailed information on informal payments in the public sector which seem to be widespread despite the presence of programmes such as JSY which should in theory ensure that there are no financial implications to women that choose to deliver at institutions.

9.3.2.2: Strengths

I conducted a comprehensive assessment of mistreatment of women at maternity facilities using actual clinical observations. My PhD findings advances the understanding and measurement of mistreatment at maternity facilities. I operationalised indicators of mistreatment as those related to intentional disrespect and abuse, overtreatment and under-treatment by using a rights-based approach to conceptualise mistreatment. This comprehensive approach to measurement is a strength of the study

Rather than take a strict quantitative approach as I did in Chapter 6, I felt that in chapter 7 it would be more insightful to explore the nature and context of care provision using the available information from open-ended comments. This provides a useful contribution to the literature on mistreatment particularly because data are based on actual observations and were more objective compared to self-reported perceptions of women as employed by the vast majority of studies. [375,376]

I also looked at public and private sector differences in the nature and patterns of mistreatment which is a key strength and innovation of this PhD.

The mixed methods approach taken to triangulate qualitative and quantitative findings, data collection round-the-clock on all seven days of the week, and the use of clinical practice observations were some of the key strengths of the study.

9.3.2.3: Limitations

This study used data from an observational study designed to capture descriptive information on elements of QoC for normal labour and childbirth. The study was not specifically powered to measure and explain mistreatment as a separate category of poor quality of care which is a key limitation of this study.

It is also hard to interpret data from a limited set of unstructured observers' comments . While using unstructured comments, it is important to note that findings may be hard to replicate, since observers may only record events that were interesting or particularly striking to them, which is a key limitation of my methodology. These limitations could have been overcome if I had used multiple observers[433] or additional data collection methods as discussed above.

In a few instances, I also found that it was hard for observers to find a private space to record down their observations. Sometimes health workers at the studied facilities would try to look at what the observers had written down. In such cases, observers had to wait until they were alone or wait till the end of the day and rely on their memory to note down their observations

Observer bias could also occur if observers become too involved or affected by the hospital enviorenment or details of a particular case. I anticipated many of these issues and in the trainings focussed on the importance of being silent observers and not interfering or being involved with any aspects of care provision. In addition, comments recorded by observers perhaps reflects their own professional experiences, training and knowledge of respectful care practices which is a limitation. During fieldwork, I also noted that younger observers were more likely to take down detailed notes compared to the older observers, who were more experienced, and perhaps, more inclined to accept mistreatment as a normal occurrence.

9.3.3: For objective 3: Management and its relationship with QoC

9.3.3.1: Reflections

In chapter 8, I assessed and described management practices at maternity facilities in Uttar Pradesh and examined whether management practices are associated with quality of care. Measuring management practices at hospitals is an emerging field and there are widespread opinions about the definitions, scope and measurement of different management practices. As discussed earlier, my starting point was a pre-existing tool for the management survey which I used because of the wide application of the tool which supports comparisons and an

opportunity to undertake this work soon after the QoC assessments in the studied facilities. I also piloted and further adapted this tool prior to using it for data collection which provided many useful insights.

The key reflection from the management study is that if I had the time and the resources available, I would have undertaken a much more thorough exploration of the concepts and determinants of management practices particularly in the public sector. Detailed formative research would have provided me with better insights into the nature and determinants of management practices in Uttar Pradesh. As a result of this, my assessment tool may not have captured information on the contextual determinants of management for example local politics, socio- economic factors and others, which may drive public-sector performance in LMIC settings. This could mean that I may not have measured all the determinants of management at hospitals in Uttar Pradesh which has implications for the results obtained by my study.

I found that the research-assistants (field-supervisor qualifications) often struggled with the fundamentals of hospital management, perhaps because none of us had any academic training in hospital management or business adminstration. This is why I decided to conduct all of the interviews myself, although, it is encouraging to note that there was a high correlation between scores given by me and scores given by the second silent rater. While orienting the research-assistants to the management tool, I also found that they struggled to conceptualise hospital management as a separate entity from wider health systems management, perhaps because in many ways hospitals are also health systems themselves.

The scoring methodology for individual questions could also have also been simplified. For example, instead of asking open- ended questions and providing a rating between 1 to 5, I could have simplified the response to a yes or no response which may have been easier to implement.

I found that the study instrument was comprehensive and tried to measure all the practices that represent good management in both public and private sectors. However, it is important to note that the tool originates from manufacturing sector and its main purpose has been to make cross-country and cross-sector comparisions. Therefore, there is some benefit in designing a tailored tool that is much more relevent for maternity care provision in LMIC

settings. For example, the new assessment tool could specifically examine management practices associated with implementing a seamless maternity care pathway including drug and supply chain management, organisation of clinical teams and others.

Many of the questions in the assessment tool for example those related to the layout of patient flow, performance management and target management, human resource management and incentives management were comparatively poorer in the public sector. This raises some deeper questions on what it means for a public sector institution to be well managed, particularly in LMICs settings where there is no autonomy or authority given to the manager to implement some of these management best practices.

I found that most hospitals in Uttar Pradesh do not have standardized maternity care pathways. Although, protocols for labour and childbirth are available in most public sector hospitals, they are not specifically kept in the labour rooms, and these tend to be absent in private hospitals. Monitoring the use of standardised protocols was not routinely done in both sectors and managers were often not sure whether staff were following the relevant protocols. I also found that while specialists such as doctors tend not moved across specialities, nurses are frequently moved across specialities which has implications for quality of services. The public sector was found to be inflexible in terms of deployment of staff and often struggled with recruitment, selection and retention of staff.

Although, the private sector was found to be relatively better for human-resource management, managers frequently complained that finding qualified staff to come and work in these rural areas was challenging. I did not find systems for tracking performance indicators routinely in the public sector, whereas the larger private sector hospitals often tracked indicators related to financial earnings such as outpatient quantitity, surgery quantitity, bed turnover rates and length of stay. Conversations about hospital performance were not regularly done and processes for exposing operational problems were rare in both sectors.

During my interviews with the managers, I also found that there are no immidiate or direct consequences of poor performance for staff in the public sector. For targets, the private sector only had targets for revenue and not for quality whereas in the public sector, targets were limited to the ones prescribed by the central government.

9.3.3.2: Strengths

Key strengths of the management study included obtaining data on management practices from facilities where actual clinical observations had taken place. To the best of my knowledge, no study to date has investigated the relationship between management and QoC in such a LMIC setting, primarily because of the difficulties in obtaining such primary data.

We also double scored all responses to the interview questions and found good correlation between scores given by two different assessors which strengthens the internal validity of my study.

I could also obtain better response rates for the management survey and interviewed all administrators and clinical leaders at 33 maternity facilities (10 private and 23 public sector) unlike in the QoC study where I could just get observations at 26 facilities. Managers were also appreciative of the fact that I went back to engage with them on this issue after the completion of QoC assessments which is a strength.

I adapted a previously used survey instrument which supported comparability of results across different settings. In addition, my results particularly from private sector samples were similar to those reported by the larger study in India which is encouraging in terms of external validity. The previous study by Lemos *et al*(2013) [44] in India was only conducted in the private sector. Therefore, my study makes a useful contribution to the literature on management practices and quality of care in both private and public sectors. This is a key contribution of my PhD.

9.3.3.3: Limitations

For the management survey, limitations included purposive sampling of maternity facilities in three districts in UP because of which my findings are not generalizable to all districts of Uttar Pradesh.

I also interviewed manager's face-to face unlike previous studies that have employed telephone-interviews. Therefore, it is possible that other assessors and I may have been biased by the appearance or the operations of a particular facility. However, face-to-face interviews rather than telephone-based interviews are a good research practice. Personal face-to face interviews were also essential to ensure that I obtained a good response rate and managers also appreciated the follow up visit.

Although I adapted a tool that has previously been used in multiple countries including India, the content and construct validity of the tool was not specifically tested which may have implications for findings. Since, correlation between assessors was high and our scores were comparable with the larger Indian study, reliability is less of a concern. However, an additional validation study in a small selection of participants would have been useful to validate the study instruments.

Lastly, my sample of 275 observations at 26 hospitals is also small to generate precise estimates on the relationship between management and quality of care and therefore, follow-up study with a larger sample size would be useful.

9.4: Implications of the doctoral study

My PhD study advances the evidence-base on quality of care during labour and childbirth in in at least four ways with important implications, as I will discuss. First, I conducted a comprehensive assessment of QoC for normal labour and childbirth including in private sector facilities and this is one of the first efforts to do so in Uttar Pradesh, which is a high-priority state for the Indian government. My findings of poor QoC at both public and private sector maternity facilities shines an important light on this issue and demands a strong policy response to improve QoC during labour and childbirth in UP.

Second, I demonstrated that given the high prevalence of mistreatment of women in maternity facilities it is important to consider disrespect and abuse, over-treatment and under-treatment in national and global debates on poor quality of care. Regardless of the terminology used, mistreatment of women falls under poor quality of care and it is both a rights-based and a medical issue.

Third, this PhD advances measurement efforts by developing three transparent indices which can be used to evaluate and monitor overall QoC during normal labour and childbirth, and QoC for obstetric and neonatal care. These indices could be utilised by other quality improvement projects and researchers.

Fourth, I demonstrate that management best practices are not utilised at maternity facilities in Uttar Pradesh and in such settings, performance management activities such as audits have

a positive impact on quality of care. To the best of my knowledge, this is also one of the first efforts to investigate the role of management practices on QoC during labour and childbirth at maternity facilities in a low-resource setting.

The specific recommendations of my doctoral study on research, programmes and policies is discussed in the sections below.

9.4.1: Recommendations for the future research agenda

The results from my PhD show that QoC was poor in both public and private sector maternity facilities in Uttar Pradesh. Therefore, a systematic effort to measure and identify existing quality gaps during labour and childbirth is required, especially in India's high-burden states and in similar settings elsewhere. These research efforts should also include private-sector facilities, which provide a substantial and increasing proportion of the maternity care in India and in other LMICs.

Since, I was not able to obtain a sampling frame for the private sector and conducting a large census of private sector facilities was not feasible within the timeframe of my PhD, my private sector estimate may not be precise. Therefore, there is a need to conduct a census of private sector facilities in UP so that future research and government efforts to engage with the private sector can be more effective. Researchers working in India widely acknowledge that obtaining participation from the private sector in research is a fundamental challenge. Therefore, the research community will need to think carefully about innovative research strategies to improve participation of the private sector in future research efforts. It is important to highlight that involving the private sector in future large-scale research activities may only be possible through robust governmental regulation, or as a part of government purchasing of private sector services or private-led initiatives amongst insurers or large hospital groups.

There are many benefits of conducting a larger study using the methods described in my QoC study. A larger study will provide estimates that are more representative for the whole of Uttar Pradesh and in particular for the private sector. Future research efforts should also anticipate the difficulties of sampling associated with the private sector; invest additional

resources and have a longer period for data collection so that a greater number of normal labour and childbirth cases can be recruited, especially in the private sector.

My PhD findings showed that the quality of care was generally poor during labour and childbirth and that being qualified did not guarantee provision of a higher standard of care. These results suggest that improving the knowledge, skills and competence of qualified health workers is important. Mixed-methods implementation research studies can be utilised to investigate the extent to which the quality of existing trainings influence health workers knowledge, skills and actual performance on-the job. Kirkpatrick's model of training programme evaluation recommends a comprehensive assessment of reaction (of the trainees to the training program), learning (the knowledge/skill gain), behaviour (the actual change in practice) and results (the final outcome due to the training) [434].

Other innovative research questions include examining the effectiveness of innovative training approaches like simulation-based trainings/ obstetric skills and drills methods [435] in improving health workers knowledge, skills and confidence. Similarly, implementation research to investigate whether training and retraining of health workers linked to re-accreditation or certification with professional councils (medical or nursing councils) have the potential to improve QoC at health facilities could also be investigated further.

Criterion-based clinical audits are considered as a useful method to audit quality in maternal and newborn health. Process indicators used during these audits can help to assess the adherence to evidence-based practices.[436] Audit approaches can often use a structured problem-solving methodology (for example: Plan, Do, Study, Act cycles) where teams of providers are organized and supported to identify and test changes in the processes they wish to improve and to measure the impact of the changes against quantitative indicators of quality.[388] These methods have not been utilised extensively in hospitals in Uttar Pradesh. Therefore, there is scope for future research on examining the effectiveness of introducing such approaches in Uttar Pradesh. Moreover, the trial by Dumont et al. (2013) in Senegal and Mali offers an interesting example that researchers could replicate in India[226]. Additional implementation research questions could also include issues such as feasibility, cost-effectiveness and sustainability of these audit mechanisms.

Since, I found that there was a high prevalence of unqualified personnel in maternity facilities in UP in 2015, it is important to understand the reasons behind this phenomenon. What are the contextual factors and determinants that lead to such a high reliance on unqualified personnel in maternity facilities? Is this caused by staffing shortages, monetary issues, sociocultural factors, deficiencies in knowledge, skills or competence of qualified health workers or are qualified health workers overburdened? Understanding these issues in detail, will be useful to formulate appropriate policy responses, therefore further research on this issue would be useful. There is also an important global evidence gap around optimal staffing levels and SBA staffing models in hospitals.[437] Further research on identifying optimal staffing levels would also be very useful to support safe motherhood in India.

As demonstrated in my PhD study, clinical observations are a feasible way to assess process measures of quality of care for labour and childbirth. Future research efforts could also employ clinical observations to investigate the QoC for complications of pregnancies and caesarean sections[431] in both public and private sector facilities in LMIC settings. The differences in QoC for managing complications amongst qualified and unqualified personnel would also be an interesting question for research.

There should also be future research on characterising and improving organizational culture to enhance patient safety at maternity facilities.[438] These research efforts could employ multidisciplinary approaches to investigate the effectiveness of interventions to improve patient and provider safety such as interventions to improve hand-hygiene, improve adherence to evidence-based practices or adherence to infection prevention and control procedures and others. [439,432]

Further conceptual work is required around measurement of mistreatment of women during labour and childbirth in India, particularly, as I found a high prevalence of certain harmful practices which were also associated with socio-demographic characteristics of women. Defining the boundaries for measurement between poor quality and mistreatment is also required since some indicators of over-treatment and under-treatment are against the rights of child bearing women[141] but also considered indicators of poor QoC. Identifying improved ways to incorporate the concept of intentionality in measurement efforts of mistreatment as described earlier is also required.

For ensuring respectful maternity care, further research is required to identify, test and scale up effective accountability mechanisms. Many promising pilots of accountability mechanisms such as social audits, public hearings, citizen's report cards, verbal and social autopsies and partnership-defined-quality have been utilised but these require further implementation research in order to support scale-up in high burden countries. [440-442] In addition, we still need further research to identify effective interventions for various contexts particularly to identify interventions needed to improve interpersonal care and social support for women at maternity facilities, without blaming health workers who are also working under difficult situations.

Future research could also examine the prevalence and determinants of informal payments at maternity facilities in India. Informal payments seem widespread despite national schemes such as the JSY scheme in India. This also relates to a larger research agenda on corruption in the health sector in India. Detailed information on level and nature of informal payments can be collected through observations, household surveys, focus groups with women or from reports of other health providers[385]. Additional research questions could also explore effective approaches to empower women and families so that they can refuse informal payments in facilities.

Future research efforts could examine ways to assign intervention-specific weights to different elements of care provided during normal labour and childbirth. These research efforts could employ methods for establishing and developing consensus such as Delphi techniques, consensus panels, or nominal group processes.[429] These approaches are often used in combination and use both quantitative and qualitative methods. Essentially, a group of experts in a particular field are convened and asked to decide on the importance of specific issues of interest.[429] However, some critics have argued that there is selection bias with these consensus methods.[429] For example, experts invited to participate may not be representative of the wider research community or may not be front-line health workers. There is also debate about the validity and reliability of these consensus methods and no agreement about which method is the most appropriate.[429] The current thinking appears to be that the results of consensus methods should be interpreted cautiously and tested for their validity against observations which are considered the gold standard for measuring processes of care.[429] To illustrate this point in an example, in order to undertake such an exercise for care during

routine labour and childbirth, experts would be convened and asked to rank items for various dimensions of care. What do they think are the most important interventions for evidence-based obstetric or neonatal care, for interpersonal care or for harmful care procedures? Based on their ratings of the importance of specific items, indicators would then grouped and candidate indices developed based on expert's rankings.[201]

The global community has now recognized the importance of QoC in achieving further reductions in maternal and neonatal mortality and stillbirths. In order to achieve this, we need valid ways to assess QoC at the time of birth. Validation of the indices developed in this PhD study could be undertaken - face validity assessed through expert feedback. Content and criterion validity assessed by using data collected from clinical observations.[201] Additional research questions could also focus on feasibility, reliability, and perception of these indices by end- users such as programme managers and national monitoring and evaluation experts in high-burden settings. Other researchers that have employed a similar methodology have found good specificity and sensitivity of indices developed on quality of care during labour and childbirth. [201]

There are also statistical methods like principal component analysis that could be used to develop such indices. Principal component analysis (PCA) have generally been used to construct measures of socio-economic status from household ownership of assets.[443] PCA essentially employs mathematical algorithms to retain variations in the data set [444] and are used to reduce a large volume of indicators to a single index appropriately constructed from the common variance of a specific set of indicators. [443] One example of this approach has been used by researchers investigating health service readiness by using data from a service provision assessment survey in Tanzania. [443] However, there are also limitations of this approach since PCA may give low importance to indicators that are commonest in the dataset regardless of their clinical importance. For example, uterotonic within 1 minute is an important clinical indicator but since it was relatively common in my dataset, PCA will not give adequate importance to that indicator.

As shown by my results, performance management activities have a positive effect on quality of care at the time of birth. Therefore, further implementation research on ways to institutionalise and implement mechanism such as criterion-based audits, maternal death

reviews, confidential enquiries, near-miss audits and maternal or perinatal death surveillance and response mechanisms, is important for all high burden settings. These activities can provide powerful information that can guide actions to end preventable maternal and neonatal deaths in high-burden settings.

9.4.2: Recommendation for programmes

Currently, knowledge about best practices during normal labour and childbirth in LMIC settings is limited. Assessment of the QoC during labour and childbirth needs to be instituted systematically in all high-burden states of India. The availability of assessment tools, such as those developed in this study may be useful. Programmes should target their resources to improve measurement and improve existing QoC at facilities in both public and private sectors. As highlighted in this study, quality improvement efforts needs to be central in all efforts to end preventable maternal, neonatal deaths and stillbirths in maternity facilities.

Dissemination of evidence-based guidelines and concepts of respectful maternity care needs to be done extensively amongst all front-line workers in India and other similar settings. This is particularly important since I found that QoC and levels of mistreatment were similar for both qualified and unqualified personnel. This could be an innovative area of work to develop suitable training programmes for both qualified and unqualified personnel, design appropriate skill-development activities and improve linkages with specialists and higher-centres.

Since, I found that QoC during weekends and outside normal working hours was poor compared to weekdays and within regular working hours. Managers at maternity facilities should ensure that optimal staffing levels and ancillary resources are available during these times. Overall, given the poor quality of care in maternity facilities in UP, improving the knowledge and competence of all maternity care personnel is urgently needed. Use of appropriate training methods with adequate opportunities for supervised practical training sessions and further on-the-job supportive supervision and refresher trainings would be useful, as described earlier.

Innovative projects to improve deficiencies in knowledge and skills amongst health workers, improvement of the quality of trainings, mechanism to address health worker shortages and

development of innovative mentorship and supervision mechanisms would help in advance the evidence-base on these issues and support further declines in maternal and newborn mortality.

9.4.3: Recommendations for policy

My results indicate that unqualified personnel such as TBAs, sweepers, dais, ASHAs were frequently involved in providing care in maternity facilities in UP in 2015. This is a troublesome finding with many important global and national implications. First, it may be possible that the maternal health community in India and globally, is over-estimating the proportion of women that deliver with SBAs particularly in high-focus states of India such as Uttar Pradesh. Global monitoring efforts often employ advanced mathematical modelling methods that rely on indicators such as population coverage of SBA births, therefore, it is possible that global estimates for MMR declines in India could be under-estimating the actual burden of maternal mortality.

The Indian Government recommends provision of maternity services by appropriately trained and qualified skilled birth attendants at health facilities. However, given various context specific challenges described earlier, the prospect of all births being cared for by qualified personnel at health facilities is an important challenging, particularly in rural areas. Therefore, it is important for policy makers to issue clear and comprehensive guidance on the role of unqualified providers at maternity facilities.

If national authorities decide against using unqualified personnel to provide institutional services, they must design and implement robust monitoring mechanisms to ensure that unqualified personnel are not involved in service delivery. Up-to date job descriptions are required, so that there is no confusion about roles and responsibilities. Women that go to institutions have a right to expect care from qualified personnel irrespective of public or private sector and it is the duty of the government to ensure and protect that right for women.

Policymakers must invest in designing appropriate career development pathways for young doctors, nurses and midwives so that they join the public sector. This will also require better remuneration packages to attract and retain qualified health workers particularly those serving in rural areas. Ultimately, there is a need to develop comprehensive national human

resource plans with strategies to ensure adequate recruitment, rational deployment, ongoing retention and capacity building of qualified health workers providing maternity care services.[16]

Policymakers should consider the importance of long-term investments in strengthening health systems and improving work conditions for front-line health workers. Given the immense shortages of skilled human resources for maternity care in India, focused efforts to establish a professional cadre of midwives could be beneficial and long-terms investments are required to increase production of qualified maternity care personnel.

Policymakers also need to tackle the widespread existence of informal payments by designing better polices for supervision, disseminate patient charters, and institute disciplinary mechanisms for health workers involved in such corrupt practices.

Policy makers need to invest in participatory accountability mechanisms as highlighted in the recommendations for research section earlier so that evidence-based and respectful care is provided to all woman and their babies at maternity facilities.

Finally, there is now increasing realisation that governments alone may not be able to deliver all services to meet their population's needs. Further, some women often prefer to seek care in the private sector and therefore it is quite important to regulate and improve quality in the private sector as well. Comprehensive regulation on the private sectors' role in providing health services including detailed quality standards expected in private sector facilities for maternity care need to be developed. Once regulations and quality standards have been finalised, permissive policies will be required to implement and test innovative public- private partnership models to improve efficiency, effectiveness and QoC of maternity services.

Chapter 10: Conclusions

The results of my PhD study indicate that in maternity facilities in Uttar Pradesh, the personnel providing normal labour and childbirth care were often unqualified; adherence to evidence-based obstetric and neonatal care protocols was generally poor; and, all women encountered at least one practice considered to be mistreatment. Mistreatment of women at maternity facilities falls under poor quality of care and needs greater attention in national and global debates.

My PhD results indicate that a systematic and urgent effort is needed to measure and improve QoC at the time of birth in public and private sector facilities in high-burden states in India. Appropriate context-specific strategies and interventions need to be developed for improving care during labour and childbirth.

Lastly, I did not find an association between overall management scores and quality of care during labour and childbirth. The only management dimension that positively influenced quality was performance management and hence, performance management activities such as different types of audits should be implemented in all maternity facilities in high-burden settings.

11. List of references

1. Akachi Y, Kruk ME. Quality of care: measuring a neglected driver of improved health. *Bulletin of the World Health Organization* 2017; **95**(6): 465-72.
2. Graham W, Woodd S, Byass P, et al. Diversity and divergence: the dynamic burden of poor maternal health. *Lancet* 2016; **388**(10056): 2164-75.
3. Horton R. Offline: Ensuring healthy lives after 2015. *Lancet* 2013; **381**(9882): 1972-.
4. World Health Organization. Strategies towards ending preventable maternal mortality (EPMM). 2015.
5. Alkema L, Chou D, Hogan D, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. *Lancet* 2016; **387**(10017): 462-74.
6. Every Woman Every Child. The Global Strategy for Women's, Children's And Adolescents'health (2016-2030). *Sustainable Development Goals* 2015.
7. Kruk ME, Larson E, Twum-Danso NA. Time for a quality revolution in global health. *Lancet Glob Health* 2016; **4**(9): e594-6.
8. World Health Organization. World Health Statistics 2015.: WHO Press; 2015.
9. United Nations. The Millennium Development Goals Report 2014. *New York: United Nations* 2014.
10. Powell-Jackson T, Mazumdar S, Mills A. Financial incentives in health: New evidence from India's Janani Suraksha Yojana. *J Health Econ* 2015; **43**: 154-69.
11. Lim SS, Dandona L, Hoisington JA, James SL, Hogan MC, Gakidou E. India's Janani Suraksha Yojana, a conditional cash transfer programme to increase births in health facilities: an impact evaluation. *Lancet* 2010; **375**(9730): 2009-23.
12. Okeke E, Chari AV. Can Institutional Deliveries Reduce Newborn Mortality? Evidence from Rwanda. Santa Monica, CA: RAND Corporation, 2014.
13. Leslie HH, Fink G, Nsona H, Kruk ME. Obstetric Facility Quality and Newborn Mortality in Malawi: A Cross-Sectional Study. *PLoS Med* 2016; **13**(10): e1002151.
14. Hodgins S. Achieving better maternal and newborn outcomes: coherent strategy and pragmatic, tailored implementation. *Glob Health Sci Pract* 2013; **1**(2): 146-53.
15. Campbell OM, Calvert C, Testa A, et al. The scale, scope, coverage, and capability of childbirth care. *Lancet* 2016; **388**(10056): 2193-208.
16. Sharma G, Mathai M, Dickson KE, et al. Quality care during labour and birth: a multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy Childbirth* 2015; **15 Suppl 2**(Suppl 2): S2.
17. Dickson KE, Simen-Kapeu A, Kinney MV, et al. Every Newborn: health-systems bottlenecks and strategies to accelerate scale-up in countries. *Lancet* 2014; **384**(9941): 438-54.
18. Lawn JE, Blencowe H, Oza S, et al. Every Newborn: progress, priorities, and potential beyond survival. *Lancet* 2014; **384**(9938): 189-205.
19. Bhutta ZA, Das JK, Bahl R, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? *The Lancet* 2014; **384**(9940): 347-70.
20. WHO Essential Interventions. Commodities and Guidelines for Reproductive, Maternal, Newborn and Child Health: A global review of the key interventions related to reproductive, maternal, newborn and child Health. *Geneva: WHO* 2011.
21. World Health Organization. Make Every Mother and Child Count: The World Health Report 2005.
22. UNFPA; WHO and UNICEF. AMDD: Monitoring emergency obstetric care: a handbook. . 2009.
23. Gabrysch S, Simushi V, Campbell OM. Availability and distribution of, and geographic access to emergency obstetric care in Zambia. *Int J Gynaecol Obstet* 2011; **114**(2): 174-9.

24. Lumbiganon P, Laopaiboon M, Gulmezoglu AM, et al. Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007-08. *Lancet* 2010; **375**(9713): 490-9.
25. Shah A, Fawole B, M'Imunya J M, et al. Cesarean delivery outcomes from the WHO global survey on maternal and perinatal health in Africa. *Int J Gynaecol Obstet* 2009; **107**(3): 191-7.
26. Madaj B, Smith H, Mathai M, Roos N, van den Broek N. Developing global indicators for quality of maternal and newborn care: a feasibility assessment. *Bulletin of the World Health Organization* 2017; **95**(6): 445-52I.
27. Mills A, Brugha R, Hanson K, McPake B. What can be done about the private health sector in low-income countries? *Bulletin of the World Health Organization* 2002; **80**.
28. Hanson K, Gilson L, Goodman C, et al. Is private health care the answer to the health problems of the world's poor? *PLoS Medicine* 2008; **5**(11): e233.
29. Rosenthal G, Newbrander W. Public policy and private sector provision of health services. *Int J Health Plann Manage* 1996; **11**(3): 203-16.
30. Jakovljevic MB. Resource allocation strategies in Southeastern European health policy. Springer; 2013.
31. Morgan R, Ensor T. The regulation of private hospitals in Asia. *Int J Health Plann Manage* 2016; **31**(1): 49-64.
32. Madhavan S, Bishai D, Stanton C, Harding A. Engaging the private sector in maternal and neonatal health in low and middle income countries: Future health systems (FHS); 2010.
33. Campbell OM, Benova L, MacLeod D, et al. Family planning, antenatal and delivery care: cross-sectional survey evidence on levels of coverage and inequalities by public and private sector in 57 low- and middle-income countries. *Trop Med Int Health* 2016; **21**(4): 486-503.
34. Afifi NH, Busse R, Harding A. Regulation of health services. *Private participation in health services* 2003: 219-334.
35. Almeida Sd, Bettiol H, Barbieri MA, Silva AAMd, Ribeiro VS. Significant differences in cesarean section rates between a private and a public hospital in Brazil. *Cadernos de Saúde Pública* 2008; **24**(12): 2909-18.
36. Sharma G. The changing paradigm of labour and childbirth in Indian cities: an enquiry into increasing rates of caesarean deliveries. *Int J Epidemiol* 2016; **45**(5): 1390-3.
37. Sarker BK HJ, Mridha MK, et al. . Caesarean delivery in urban slums of Dhaka City: indications and consequences. . 2012. ; **Manoshi Working Paper 18.**
38. Parkhurst JO, Rahman SA. Life saving or money wasting? Perceptions of caesarean sections among users of services in rural Bangladesh. *Health Policy* 2007; **80**(3): 392-401.
39. Neuman M, Alcock G, Azad K, et al. Prevalence and determinants of caesarean section in private and public health facilities in underserved South Asian communities: cross-sectional analysis of data from Bangladesh, India and Nepal. *BMJ Open* 2014; **4**(12): e005982.
40. Pomeroy A, Koblinsky M, Alva S. Who gives birth in private facilities in Asia? A look at six countries. *Health policy and planning* 2014; **29**(suppl 1): i38 - i47.
41. Daire J, Gilson L, Cleary S. Developing leadership and management competencies in low and middle-income country health systems: a review of the literature. *Cape Town: Resilient and Responsive Health Systems (RESYST)* 2014.
42. Bloom N, Genakos C, Sadun R, Van Reenen J. Management Practices Across Firms and Countries. *Academy of Management Perspectives* 2012; **26**(1): 12-33.
43. Dorgan S, Layton D, Bloom N, Homkes R, Sadun R, Van Reenen J. Management in healthcare: why good practice really matters. *London: McKinsey and Company/London School of Economics* 2010.
44. Lemos R, Scur D. Could poor management be holding back development? Describing practices in the public and private sectors in India: IGC Working Paper, 2013.
45. Agarwal R, Green R, Agarwal N, Randhawa K. Benchmarking management practices in Australian public healthcare. *J Health Organ Manag* 2016; **30**(1): 31-56.

46. Tsai TC, Jha AK, Gawande AA, Huckman RS, Bloom N, Sadun R. Hospital board and management practices are strongly related to hospital performance on clinical quality metrics. *Health Aff (Millwood)* 2015; **34**(8): 1304-11.
47. Sharma G, Powell-Jackson T, Haldar K, Bradley J, Filippi V. Quality of routine essential care during childbirth: clinical observations of uncomplicated births in Uttar Pradesh, India. *Bulletin of the World Health Organization* 2017; **95**(6): 419-29.
48. UN-IGME. Levels and trends in child mortality - report 2013. 2013.
49. Lawn J, Blencowe H, Pattinson R, et al. Stillbirths: Where? When? Why? How to make the data count? *Lancet* 2011; **377**(9775): 448 - 1463.
50. Lawn JE, Blencowe H, Kinney MV, Bianchi F, Graham WJ. Evidence to inform the future for maternal and newborn health. *Best Pract Res Clin Obstet Gynaecol* 2016; **36**: 169-83.
51. You D, Hug L, Ejdemyr S, et al. Global, regional, and national levels and trends in under-5 mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Inter-agency Group for Child Mortality Estimation. *The Lancet* 2015; **386**(10010): 2275-86.
52. Lawn JE, Blencowe H, Waiswa P, et al. Stillbirths: rates, risk factors, and acceleration towards 2030. *Lancet* 2016; **387**(10018): 587-603.
53. Souza JP, Gulmezoglu AM, Vogel J, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): a cross-sectional study. *Lancet* 2013; **381**(9879): 1747-55.
54. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Global Health* 2014; **2**(6): E323-E33.
55. WHO Global Health Observatory. *[Internet]* 2014.
56. UN Inter-agency Group for Child Mortality Estimation (IGME). Report : Levels and trends in child mortality 2015.
57. Graham WJ, Varghese B. Quality, quality, quality: gaps in the continuum of care. *Lancet* 2012; **379**(9811): e5-6.
58. Storeng KT, Baggaley RF, Ganaba R, Ouattara F, Akoum MS, Filippi V. Paying the price: the cost and consequences of emergency obstetric care in Burkina Faso. *Social science & medicine (1982)* 2008; **66**(3): 545-57.
59. van den Broek NR, Graham WJ. Quality of care for maternal and newborn health: the neglected agenda. *BJOG* 2009; **116 Suppl 1**(Suppl 1): 18-21.
60. Nesbitt RC, Lohela TJ, Manu A, et al. Quality along the continuum: a health facility assessment of intrapartum and postnatal care in Ghana. *PLoS One* 2013; **8**(11): e81089.
61. Erim DO, Kolapo UM, Resch SC. A rapid assessment of the availability and use of obstetric care in Nigerian healthcare facilities. *PLoS One* 2012; **7**(6): e39555.
62. Sabde Y, Diwan V, Randive B, et al. The availability of emergency obstetric care in the context of the JSY cash transfer programme in Madhya Pradesh, India. *BMC Pregnancy Childbirth* 2016; **16**(1): 116.
63. Randive B, Chaturvedi S, Mistry N. Contracting in specialists for emergency obstetric care-does it work in rural India? *BMC Health Serv Res* 2012; **12**: 485.
64. Randive B, Diwan V, De Costa A. India's Conditional Cash Transfer Programme (the JSY) to promote institutional birth: Is there an association between institutional birth proportion and maternal mortality? *PLoS One* 2013; **8**(6): e67452.
65. Chaturvedi S, Upadhyay S, De Costa A. Competence of birth attendants at providing emergency obstetric care under India's JSY conditional cash transfer program for institutional delivery: an assessment using case vignettes in Madhya Pradesh province. *BMC Pregnancy Childbirth* 2014; **14**(1): 174.
66. Chaturvedi S, De Costa A, Raven J. Does the Janani Suraksha Yojana cash transfer programme to promote facility births in India ensure skilled birth attendance? A qualitative study of intrapartum care in Madhya Pradesh. *Global health action* 2015; **8**.

67. Chaturvedi S, Upadhyay S, De Costa A, Raven J. Implementation of the partograph in India's JSY cash transfer programme for facility births: a mixed methods study in Madhya Pradesh province. *BMJ Open* 2015; **5**(4): e006211.
68. Adair-Rohani H, Zukor K, Bonjour S, et al. Limited electricity access in health facilities of sub-Saharan Africa: a systematic review of data on electricity access, sources, and reliability. *Glob Health Sci Pract* 2013; **1**(2): 249-61.
69. Making Pregnancy Safer. Making pregnancy safer: the critical role of the skilled attendant-Joint Statement by WHO, ICM and FIGO. *World Health Organization: Geneva* 2004.
70. Iyengar SD, Iyengar K, Suhalka V, Agarwal K. Comparison of domiciliary and institutional delivery-care practices in rural Rajasthan, India. *J Health Popul Nutr* 2009; **27**(2): 303-12.
71. Iyengar K, Jain M, Thomas S, et al. Adherence to evidence based care practices for childbirth before and after a quality improvement intervention in health facilities of Rajasthan, India. *BMC Pregnancy Childbirth* 2014; **14**: 270.
72. Hussein J, Bell J, Nazzar A, et al. The Skilled Attendance Index: Proposal for a new measure of skilled attendance at delivery. *Reproductive Health Matters* 2004; **12**(24): 160-70.
73. ten Hoope-Bender P, Campbell J, Fauveau V, Matthews Z. The state of the world's midwifery 2011: delivering health, saving lives. *Int J Gynaecol Obstet* 2011; **114**(3): 211-2.
74. Adegoke A, Utz B, Msuya SE, Van Den Broek N. Skilled Birth Attendants: who is who? A descriptive study of definitions and roles from nine Sub Saharan African countries. *PloS one* 2012; **7**(7): e40220.
75. Ariff S, Soofi SB, Sadiq K, et al. Evaluation of health workforce competence in maternal and neonatal issues in public health sector of Pakistan: an Assessment of their training needs. *BMC Health Serv Res* 2010; **10**(1): 319.
76. Footman K, Benova L, Goodman C, et al. Using multi-country household surveys to understand who provides reproductive and maternal health services in low- and middle-income countries: a critical appraisal of the Demographic and Health Surveys. *Trop Med Int Health* 2015; **20**(5): 589-606.
77. Stanton CK, Deepak NN, Mallapur AA, et al. Direct observation of uterotonic drug use at public health facility-based deliveries in four districts in India. *Int J Gynaecol Obstet* 2014; **127**(1): 25-30.
78. Iyengar SD, Iyengar K, Martines JC, Dashora K, Deora KK. Childbirth practices in rural Rajasthan, India: implications for neonatal health and survival. *J Perinatol* 2008; **28 Suppl 2**: S23-30.
79. Bohren MA, Hunter EC, Munthe-Kaas HM, Souza JP, Vogel JP, Gulmezoglu AM. Facilitators and barriers to facility-based delivery in low- and middle-income countries: a qualitative evidence synthesis. *Reprod Health* 2014; **11**(1): 71.
80. Bohren MA, Vogel JP, Hunter EC, et al. The Mistreatment of Women during Childbirth in Health Facilities Globally: A Mixed-Methods Systematic Review. *PLoS Med* 2015; **12**(6): e1001847; discussion e.
81. Freedman LP, Ramsey K, Abuya T, et al. Defining disrespect and abuse of women in childbirth: a research, policy and rights agenda. *Bulletin of the World Health Organization* 2014; **92**(12): 915-7.
82. Campbell OM, Cegolon L, Macleod D, Benova L. Length of Stay After Childbirth in 92 Countries and Associated Factors in 30 Low- and Middle-Income Countries: Compilation of Reported Data and a Cross-sectional Analysis from Nationally Representative Surveys. *PLoS Med* 2016; **13**(3): e1001972.
83. Miller S, Abalos E, Chamillard M, et al. Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide. *Lancet* 2016; **388**(10056): 2176-92.
84. Murray CJ, Frenk J. A framework for assessing the performance of health systems. *Bulletin of the World Health Organization* 2000; **78**(6): 717-31.

85. Berwick DM. Continuous improvement as an ideal in health care. *N Engl J Med* 1989; **320**(1): 53-6.
86. Peabody JW, Taguiwalo MM, Robalino DA, Frenk J. Improving the quality of care in developing countries. *Disease control priorities in developing countries* 2006; **2**: 1293-308.
87. Silimperi DR, Franco LM, Veldhuyzen van Zanten T, MacAulay C. A framework for institutionalizing quality assurance. *Int J Qual Health Care* 2002; **14 Suppl 1**(suppl 1): 67-73.
88. Barker PM, Reid A, Schall MW. A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. *Implement Sci* 2016; **11**(1): 12.
89. Tuncalp, Were WM, MacLennan C, et al. Quality of care for pregnant women and newborns-the WHO vision. *BJOG* 2015; **122**(8): 1045-9.
90. Borchert M, Goufodji S, Alihonou E, et al. Can hospital audit teams identify case management problems, analyse their causes, identify and implement improvements? A cross-sectional process evaluation of obstetric near-miss case reviews in Benin. *BMC pregnancy and childbirth* 2012; **12**(1): 109.
91. Thaddeus S, Maine D. Too far to walk: maternal mortality in context. *Soc Sci Med* 1994; **38**(8): 1091-110.
92. Adegoke AA, Hofman JJ, Kongnyuy EJ, van den Broek N. Monitoring and evaluation of skilled birth attendance: a proposed new framework. *Midwifery* 2011; **27**(3): 350-9.
93. Adegoke AA, van den Broek N. Skilled birth attendance-lessons learnt. *BJOG* 2009; **116 Suppl 1**(s1): 33-40.
94. Yanqiu G, Ronsmans C, Lin A. Time trends and regional differences in maternal mortality in China from 2000 to 2005. *Bulletin of the World Health Organization* 2009; **87**(12): 913-20.
95. Campbell C, Gipson R, Issa AH, et al. National maternal mortality ratio in Egypt halved between 1992-93 and 2000. *Bulletin of the World Health Organization* 2005; **83**(6): 462-71.
96. Li J, Luo C, Deng R, Jacoby P, de Klerk N. Maternal mortality in Yunnan, China: recent trends and associated factors. *BJOG* 2007; **114**(7): 865-74.
97. McClure EM, Goldenberg RL, Bann CM. Maternal mortality, stillbirth and measures of obstetric care in developing and developed countries. *Int J Gynaecol Obstet* 2007; **96**(2): 139-46.
98. World Health Organization. Making Pregnancy Safer: the Critical Role of the Skilled Attendant. Joint Statement by WHO, ICM and FIGO. Geneva: WHO; 2004.
99. Freedman LP, Kruk ME. Disrespect and abuse of women in childbirth: challenging the global quality and accountability agendas. *Lancet* 2014; **384**(9948): e42-4.
100. Harvey S. Are skilled birth attendants really skilled? A measurement method, some disturbing results and a potential way forward. *Bulletin of the World Health Organization* 2007; **85**(10): 783-90.
101. Harvey SA, Ayabaca P, Bucagu M, et al. Skilled birth attendant competence: an initial assessment in four countries, and implications for the Safe Motherhood movement. *Int J Gynaecol Obstet* 2004; **87**(2): 203-10.
102. UNICEF. Countdown to 2015: a decade of tracking progress for maternal, newborn and child survival—the 2015 report. WHO Press, World Health Organization, Geneva, Switzerland; 2015.
103. WHO, UNICEF. Every Newborn: An action plan to end preventable newborn deaths.
104. UNICEF M. Multiple indicator cluster survey (MICS). 2000.
105. MEASURE DHS. Demographic and health surveys: Calverton: MEASURE DHS; 2013.
106. World Health Organization. The 2014 update. Global Health Workforce Statistics 2014.
107. Koblinsky M, Matthews Z, Hussein J, et al. Going to scale with professional skilled care. *Lancet* 2006; **368**(9544): 1377-86.
108. Gerein N, Green A, Pearson S. The implications of shortages of health professionals for maternal health in sub-saharan Africa. *Reprod Health Matters* 2006; **14**(27): 40-50.
109. Lehmann U, Dieleman M, Martineau T. Staffing remote rural areas in middle- and low-income countries: a literature review of attraction and retention. *BMC Health Serv Res* 2008; **8**(1): 19.

110. Bustreo F, Say L, Koblinsky M, Pullum TW, Temmerman M, Pablos-Mendez A. Ending preventable maternal deaths: the time is now. *Lancet Global Health* 2013; **1**(4): E176-E7.
111. Althabe F, Bergel E, Cafferata ML, et al. Strategies for improving the quality of health care in maternal and child health in low- and middle-income countries: an overview of systematic reviews. *Paediatr Perinat Epidemiol* 2008; **22 Suppl 1**(s1): 42-60.
112. Pronovost PJ. Enhancing physicians' use of clinical guidelines. *JAMA* 2013; **310**(23): 2501-2.
113. Neilson JP. Evidence-based intrapartum care: evidence from the Cochrane library. *Int J Gynaecol Obstet* 1998; **63 Suppl 1**(S1): S97-102.
114. World Health Organization. Care in Normal Birth: A Practical Guide. Geneva: World Health Organization; 1996.
115. Eason E, Labrecque M, Wells G, Feldman P. Preventing perineal trauma during childbirth: a systematic review. *Obstet Gynecol* 2000; **95**(3): 464-71.
116. Ludka LM, Roberts CC. Eating and drinking in labor. A literature review. *J Nurse Midwifery* 1993; **38**(4): 199-207.
117. Turan JM, Bulut A, Nalbant H, Ortaylı N, Erbaydar T. Challenges for the adoption of evidence-based maternity care in Turkey. *Social Science & Medicine* 2006; **62**(9): 2196-204.
118. Khalil K, Elnoury A, Cherine M, et al. Hospital Practice Versus Evidence-Based Obstetrics: Categorizing Practices for Normal Birth in an Egyptian Teaching Hospital. *Birth* 2005; **32**(4): 283-90.
119. Sandin-Bojo A-K, Kvist L. Care in Labor: A Swedish Survey Using the Bologna Score. *Birth* 2008; **35**(4): 321 - 8.
120. Group S-OS, Laopaiboon M, Lumbiganon P, et al. Use of evidence-based practices in pregnancy and childbirth: South East Asia Optimising Reproductive and Child Health in Developing Countries project. *PLoS One* 2008; **3**(7): e2646.
121. Neilson JP. Evidence-based intrapartum care: evidence from the Cochrane library. *Int J Gynaecol Obstet* 1998; **63 Suppl 1**: S97-102.
122. International Federation of G, Obstetrics, International Confederation of M, et al. Mother-baby friendly birthing facilities. *Int J Gynaecol Obstet* 2015; **128**(2): 95-9.
123. World Health Organization. The prevention and elimination of disrespect and abuse during facility-based childbirth: WHO statement. 2014.
124. Renfrew MJ, McFadden A, Bastos MH, et al. Midwifery and quality care: findings from a new evidence-informed framework for maternal and newborn care. *Lancet* 2014; **384**(9948): 1129-45.
125. Bowser D, Hill K. Exploring evidence for disrespect and abuse in facility-based childbirth: report of a landscape analysis. USAID-TRAction Project, Washington, DC; 2010.
126. D'Gregorio RP. Obstetric violence: a new legal term introduced in Venezuela. Elsevier; 2010.
127. Misago C, Kendall C, Freitas P, et al. From 'culture of dehumanization of childbirth'to 'childbirth as a transformative experience': changes in five municipalities in north-east Brazil. *International Journal of Gynecology & Obstetrics* 2001; **75**: S67-S72.
128. Vedam S, Stoll K, Rubashkin N, et al. The Mothers on Respect (MOR) index: measuring quality, safety, and human rights in childbirth. *SSM - Population Health* 2017; **3**: 201-10.
129. Declercq E, Sakala C, Corry M, Applebaum S, Herrlich III A. Listening to Mothers III: Report of the Third National US Survey of Women's Childbearing Experiences. New York: Childbirth Connection; 2013. 2013.
130. Baker SR, Choi PYL, Henshaw CA, Tree J. 'I felt as though I'd been in jail': Women's experiences of maternity care during labour, delivery and the immediate postpartum. *Feminism & Psychology* 2005; **15**(3): 315-42.
131. Ishola F, Owolabi O, Filippi V. Disrespect and abuse of women during childbirth in Nigeria: A systematic review. *PLoS One* 2017; **12**(3): e0174084.
132. Warren C, Njuki R, Abuya T, et al. Study protocol for promoting respectful maternity care initiative to assess, measure and design interventions to reduce disrespect and abuse during childbirth in Kenya. *BMC Pregnancy Childbirth* 2013; **13**: 21.

133. Sheferaw ED, Mengesha TZ, Wase SB. Development of a tool to measure women's perception of respectful maternity care in public health facilities. *BMC Pregnancy Childbirth* 2016; **16**(1): 67.
134. Chadwick RJ, Cooper D, Harries J. Narratives of distress about birth in South African public maternity settings: a qualitative study. *Midwifery* 2014; **30**(7): 862-8.
135. Hulton L, Zoë Matthews, and R. William Stones. . A framework for the evaluation of quality of care in maternity services. 2000.
136. Calnan M. Lay evaluation of medicine and medical practice: report of a pilot study. *Int J Health Serv* 1988; **18**(2): 311-22.
137. Okafor CB, Rizzuto RR. Women's and health-care providers' views of maternal practices and services in rural Nigeria. *Studies in family planning* 1994; **25**(6 Pt 1): 353-61.
138. Bruce J. Fundamental elements of the quality of care: a simple framework. *Stud Fam Plann* 1990; **21**(2): 61-91.
139. Lohr KN, Donaldson MS, Walker AJ. Medicare: a strategy for quality assurance, III: Beneficiary and physician focus groups. *QRB Quality review bulletin* 1991; **17**(8): 242-53.
140. Vera H. The client's view of high-quality care in Santiago, Chile. *Studies in family planning* 1993; **24**(1): 40-9.
141. White Ribbon Alliance. Respectful maternity care: the universal rights of childbearing women. *Available at :* http://whiteribbonallianceorg/wp-content/uploads/2013/10/Final_RMC_Charterpdf 2012; **Accessed on 4.12.2016**.
142. Mannava P, Durrant K, Fisher J, Chersich M, Luchters S. Attitudes and behaviours of maternal health care providers in interactions with clients: a systematic review. *Global Health* 2015; **11**(1): 36.
143. J OV, Bate P, Cleary P, et al. Quality collaboratives: lessons from research. *Quality & safety in health care* 2002; **11**(4): 345-51.
144. Institute of Medicine ; Committee on Quality of Health Care in America. Crossing the quality chasm: A new health system for the 21st century, : National Academies Press; 2001.
145. Donabedian A. The quality of care: How can it be assessed? *Jama* 1988; **260**(12): 1743-8.
146. Donabedian A. Explorations in Quality Assessment and Monitoring: The Definition of Quality and Approaches to its Assessment. . 1980.
147. Roemer MI, Carlos Montoya-Aguilar, and World Health Organization. Quality assessment and assurance in primary health care. 1988.
148. Lohr KN, Institute of Medicine Medicare: a strategy for quality assurance. Vol. 1. . *National Academies Press* 1990.
149. Wilson LL. Quality and its measurement. *J Qual Clin Pract* 1998; **18**(3): 163-70.
150. Godlee F. Effective, safe, and a good patient experience. *Bmj* 2009; **339**: b4346.
151. Donabedian A. The quality of care: How can it be assessed? *Jama* 1988; **260**(12): 1743 - 8.
152. Medicine Io, America CoQoHCi. Crossing the quality chasm: A new health system for the 21st century. 2001.
153. Hulton L, Matthews Z, Stones R. A framework for the evaluation of quality of care in maternity services. 2000.
154. Raven JH, Tolhurst RJ, Tang S, Van Den Broek N. What is quality in maternal and neonatal health care? *Midwifery* 2012; **28**(5): e676-e83.
155. Germain A;Ordway J. Population Control and Women's Health: Balancing the Scales. 1989.
156. EngenderHealth. COPE handbook : a process for improving quality in health services. . 2003.
157. Maxwell RJ. Dimensions of quality revisited: from thought to action. *Quality in health care : QHC* 1992; **1**(3): 171-7.
158. Srivastava A, Avan BI, Rajbangshi P, Bhattacharyya S. Determinants of women's satisfaction with maternal health care: a review of literature from developing countries. *BMC Pregnancy Childbirth* 2015; **15**: 97.

159. Mendoza Aldana J, Piechulek H, al-Sabir A. Client satisfaction and quality of health care in rural Bangladesh. *Bulletin of the World Health Organization* 2001; **79**(6): 512-7.
160. Goodman P, Mackey MC, Tavakoli AS. Factors related to childbirth satisfaction. *Journal of advanced nursing* 2004; **46**(2): 212-9.
161. Harvey S, Rach D, Stainton MC, Jarrell J, Brant R. Evaluation of satisfaction with midwifery care. *Midwifery* 2002; **18**(4): 260-7.
162. Waldenstrom U, Hildingsson I, Rubertsson C, Radestad I. A negative birth experience: prevalence and risk factors in a national sample. *Birth* 2004; **31**(1): 17-27.
163. World Health Organization. Standards for maternal and neonatal care. 2007.
164. World Health Organization. Everybody's business--strengthening health systems to improve health outcomes: WHO's framework for action. 2007.
165. World Health Organization. Keeping Promises, Measuring Results: Commission on Information and Accountability for Women's and Children's Health. . 2012.
166. Munos MK, Stanton CK, Bryce J, Core Group for Improving Coverage Measurement for M. Improving coverage measurement for reproductive, maternal, neonatal and child health: gaps and opportunities. *J Glob Health* 2017; **7**(1): 010801.
167. Donabedian A. The quality of care: How can it be assessed?. *Jama* 1988; **260**(no. 12): 1743-8.
168. World Health Organization. Service availability and readiness assessment (SARA): an annual monitoring system for service delivery: reference manual. 2013.
169. MEASURE DHS. Demographic and Health Surveys. The Service Provision Assessment (SPA). . 2011.
170. MEASURE Evaluation; USAID. Health Facility Assessment Technical Working Group (2005) Profiles of health facility assessment methods. . 2005.
171. Wang W, Winner M, Burgert-Brucker CR. Limited Service Availability, Readiness, and Use of Facility-Based Delivery Care in Haiti: A Study Linking Health Facility Data and Population Data. *Global Health: Science and Practice* 2017: GHSP-D-16-00311.
172. USAID and MCHIP. Maternal and Newborn Quality of Care Surveys. .
173. Peabody JW, Luck J, Glassman P, et al. Measuring the quality of physician practice by using clinical vignettes: A prospective validation study. *Annals of Internal Medicine* 2004; **141**(10): 771-80.
174. Austin A, Langer A, Salam RA, Lassi ZS, Das JK, Bhutta ZA. Approaches to improve the quality of maternal and newborn health care: an overview of the evidence. *Reprod Health* 2014; **11 Suppl 2**(Suppl 2): S1.
175. Aung T, Montagu D, Schlein K, Khine TM, McFarland W. Validation of a new method for testing provider clinical quality in rural settings in low- and middle-income countries: the observed simulated patient. *PLoS One* 2012; **7**(1): e30196.
176. Mohanan M, Vera-Hernandez M, Das V, et al. The know-do gap in quality of health care for childhood diarrhea and pneumonia in rural India. *JAMA Pediatr* 2015; **169**(4): 349-57.
177. Kwena ZA, Sharma A, Muga C, Wamae N, Bukusi EA. Management of simulated patients with sexually transmitted infections by staff of retail pharmacies in Kibera slums of Nairobi. *East Afr Med J* 2008; **85**(9): 419-24.
178. Das J, Holla A, Das V, Mohanan M, Tabak D, Chan B. In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps. *Health Aff (Millwood)* 2012; **31**(12): 2774-84.
179. Peabody JW, Luck J, Glassman P, Dresselhaus TR, Lee M. Comparison of vignettes, standardized patients, and chart abstraction: a prospective validation study of 3 methods for measuring quality. *JAMA* 2000; **283**(13): 1715-22.
180. Daniels B, Dolinger A, Bedoya G, et al. Use of standardised patients to assess quality of healthcare in Nairobi, Kenya: a pilot, cross-sectional study with international comparisons. *BMJ Global Health* 2017; **2**(2): e000333.

181. Wickström G, Bendix T. The" Hawthorne effect"—what did the original Hawthorne studies actually show? *Scandinavian journal of work, environment & health* 2000: 363-7.
182. Peabody JW, Tozija F, Munoz JA, Nordyke RJ, Luck J. Using vignettes to compare the quality of clinical care variation in economically divergent countries. *Health Serv Res* 2004; **39**(6 Pt 2): 1951-70.
183. Styles M, Cheyne H, O'Carroll R, Greig F, Dagge-Bell F, Niven C. The Scottish Trial of Refer or Keep (the STORK study): midwives' intrapartum decision making. *Midwifery* 2011; **27**(1): 104-11.
184. Luck J, Peabody JW, Lewis BL. An automated scoring algorithm for computerized clinical vignettes: evaluating physician performance against explicit quality criteria. *Int J Med Inform* 2006; **75**(10-11): 701-7.
185. Leonard KL, Masatu MC. The use of direct clinician observation and vignettes for health services quality evaluation in developing countries. *Soc Sci Med* 2005; **61**(9): 1944-51.
186. Rethans JJ, Sturmans F, Drop R, van der Vleuten C, Hobus P. Does competence of general practitioners predict their performance? Comparison between examination setting and actual practice. *Bmj* 1991; **303**(6814): 1377-80.
187. Landry E, Pett C, Fiorentino R, Ruminjo J, Mattison C. Assessing the quality of record keeping for cesarean deliveries: results from a multicenter retrospective record review in five low-income countries. *BMC Pregnancy Childbirth* 2014; **14**(1): 139.
188. World Health Organization. Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer: World Health Organization; 2004.
189. Pattinson R, Kerber K, Waiswa P, et al. Perinatal mortality audit: counting, accountability, and overcoming challenges in scaling up in low- and middle-income countries. *Int J Gynaecol Obstet* 2009; **107 Suppl 1**(Supplement): S113-21, S21-2.
190. Filippi V, Ronsmans C, Gohou V, et al. Maternity wards or emergency obstetric rooms? Incidence of near-miss events in African hospitals. *Acta Obstet Gynecol Scand* 2005; **84**(1): 11-6.
191. Hutchinson C, Lange I, Kanhonou L, Filippi V, Borchert M. Exploring the sustainability of obstetric near-miss case reviews: a qualitative study in the South of Benin. *Midwifery* 2010; **26**(5): 537-43.
192. Filippi V, Richard F, Lange I, Ouattara F. Identifying barriers from home to the appropriate hospital through near-miss audits in developing countries. *Best Practice & Research in Clinical Obstetrics & Gynaecology* 2009; **23**(3): 389-400.
193. Filippi V, Brugha R, Browne E, et al. How to do (or not to do) ... Obstetric audit in resource-poor settings: lessons from a multi-country project auditing 'near miss' obstetrical emergencies. *Health Policy and Planning* 2004; **19**(1): 57-66.
194. Crombie I, Davies H, Abraham S, Florey CdV. The audit handbook. Improving health care through audit. New York: John Wiley & Sons; 1997.
195. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012; (6): CD000259.
196. Birch L, Jones N, Doyle PM, et al. Obstetric skills drills: evaluation of teaching methods. *Nurse Educ Today* 2007; **27**(8): 915-22.
197. Cro S, King B, Paine P. Practice makes perfect: maternal emergency training. *British Journal of Midwifery* 2001; **9**(8): 492-6.
198. Harden RM, Gleeson FA. Assessment of Clinical Competence Using an Objective Structured Clinical Examination (Osce). *Medical Education* 1979; **13**(1): 41-54.
199. de Graft-Johnson J, Vesel L, Rosen HE, et al. Cross-sectional observational assessment of quality of newborn care immediately after birth in health facilities across six sub-Saharan African countries. *BMJ Open* 2017; **7**(3): e014680.
200. Rosen HE, Lynam PF, Carr C, et al. Direct observation of respectful maternity care in five countries: a cross-sectional study of health facilities in East and Southern Africa. *BMC Pregnancy Childbirth* 2015; **15**(1): 306.

201. Tripathi V, Stanton C, Strobino D, Bartlett L. Development and Validation of an Index to Measure the Quality of Facility-Based Labor and Delivery Care Processes in Sub-Saharan Africa. *PLoS One* 2015; **10**(6): e0129491.
202. Singhal N, Lockyer J, Fidler H, et al. Helping Babies Breathe: global neonatal resuscitation program development and formative educational evaluation. *Resuscitation* 2012; **83**(1): 90-6.
203. Sholkamy H KK, Cherine M, Elnoury A, Breebaart M, Hassanein N. . An Observational Checklist for Facility-Based Normal Labour and Delivery Practices: The Galaa Study. *Monographs in Reproductive Health No 5*
204. Organization WH. Integrated management of pregnancy and childbirth. 2003.
205. Lindback C, Kc A, Wrammert J, Vitrakoti R, Ewald U, Malqvist M. Poor adherence to neonatal resuscitation guidelines exposed; an observational study using camera surveillance at a tertiary hospital in Nepal. *BMC Pediatr* 2014; **14**(1): 233.
206. Linder-Pelz S, Struening EL. The multidimensionality of patient satisfaction with a clinic visit. *J Community Health* 1985; **10**(1): 42-54.
207. Sitzia J, Wood N. Patient satisfaction: a review of issues and concepts. *Social science & medicine* 1997; **45**(12): 1829-43.
208. Sawyer A, Ayers S, Abbott J, Gyte G, Rabe H, Duley L. Measures of satisfaction with care during labour and birth: a comparative review. *BMC Pregnancy Childbirth* 2013; **13**(1): 108.
209. Agha S, Karim AM, Balal A, Sosler S. The impact of a reproductive health franchise on client satisfaction in rural Nepal. *Health Policy Plan* 2007; **22**(5): 320-8.
210. Bramadat IJ, Driedger M. Satisfaction with childbirth: theories and methods of measurement. *Birth* 1993; **20**(1): 22-9.
211. Avis M, Bond M, Arthur A. Satisfying solutions? A review of some unresolved issues in the measurement of patient satisfaction. *Journal of advanced nursing* 1995; **22**(2): 316-22.
212. Staniszewska S, Ahmed L. The concepts of expectation and satisfaction: do they capture the way patients evaluate their care? *Journal of advanced nursing* 1999; **29**(2): 364-72.
213. Waldenstrom U, Rudman A, Hildingsson I. Intrapartum and postpartum care in Sweden: women's opinions and risk factors for not being satisfied. *Acta Obstet Gynecol Scand* 2006; **85**(5): 551-60.
214. Hodnett ED. Pain and women's satisfaction with the experience of childbirth: a systematic review. *American journal of obstetrics and gynecology* 2002; **186**(5): S160-S72.
215. Brown S, Lumley J. Satisfaction with care in labor and birth: a survey of 790 Australian women. *Birth* 1994; **21**(1): 4-13.
216. Lomas J, Dore S, Enkin M, Mitchell A. The Labor and Delivery Satisfaction Index: the development and evaluation of a soft outcome measure. *Birth* 1987; **14**(3): 125-9.
217. Knapp L. Childbirth satisfaction: the effects of internality and perceived control. *The Journal of Perinatal Education* 1996; **5**(4): 7-16.
218. Wilde-Larsson B, Larsson G, Kvist LJ, Sandin-Bojo AK. Womens' opinions on intrapartal care: development of a theory-based questionnaire. *J Clin Nurs* 2010; **19**(11-12): 1748-60.
219. Britton JR. The assessment of satisfaction with care in the perinatal period. *J Psychosom Obstet Gynaecol* 2012; **33**(2): 37-44.
220. Rudman A, El-Khouri B, Waldenstrom U. Women's satisfaction with intrapartum care - a pattern approach. *Journal of advanced nursing* 2007; **59**(5): 474-87.
221. Green JM, Coupland VA, Kitzinger J. Great expectations: a prospective study of women's expectations and experiences of childbirth. Cambridge: University of Cambridge; 1988.
222. Redshaw M, Martin CR. Validation of a perceptions of care adjective checklist. *J Eval Clin Pract* 2009; **15**(2): 281-8.
223. Graham WJ, Ahmed S, Stanton C, Abou-Zahr C, Campbell OM. Measuring maternal mortality: an overview of opportunities and options for developing countries. *BMC Med* 2008; **6**: 12.
224. AbouZahr C, Wardlaw T. Maternal mortality at the end of a decade: signs of progress? *Bulletin of the World Health Organization* 2001; **79**(6): 561-73.

225. Shakur H, Roberts I, Fawole B, et al. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. *Lancet* 2017; **389**(10084): 2105-16.
226. Dumont A, Fournier P, Abrahamowicz M, et al. Quality of care, risk management, and technology in obstetrics to reduce hospital-based maternal mortality in Senegal and Mali (QUARITE): a cluster-randomised trial. *Lancet* 2013; **382**(9887): 146-57.
227. Rao KD, Shahrawat R, Bhatnagar A. Composition and distribution of the health workforce in India: estimates based on data from the National Sample Survey. *WHO South East Asia J Public Health* 2016; **5**(2): 133-40.
228. Rao M, Rao KD, Kumar AK, Chatterjee M, Sundararaman T. Human resources for health in India. *Lancet* 2011; **377**(9765): 587-98.
229. Sathpathy S VS. Human resources for health in India's national rural health mission: dimensions and challenges. . *Regional Health Forum* 2006; (10:29–37.).
230. Rao KD, Bhatnagar A, Berman P. So many, yet few: Human resources for health in India. *Hum Resour Health* 2012; **10**(1): 19.
231. Rao KD BA, Berman P. India Health Beat, Volume 1. India's health workforce: size, composition and distribution. ; 2009.
232. Banerjee A, Deaton A, Duflo E. HEALTH, HEALTH CARE, AND ECONOMIC DEVELOPMENT: Wealth, Health, and Health Services in Rural Rajasthan. *Am Econ Rev* 2004; **94**(2): 326-30.
233. Naryana K. The Unqualified Medical Practitioners Methods of Practice and Nexus with the Qualified Doctors, 2008.
234. Mavalankar D, Vora K, Prakasamma M. Achieving millennium development goal 5: is India serious? *Bulletin of the World Health Organization* 2008; **86**(4): 243-A.
235. Jhpiego. Addressing India's Human Resource for Health (HRH) Challenge: Global Evidence, Local Efforts.
236. Gill K. A primary evaluation of service delivery under the National Rural Health Mission (NRHM): findings from a study in Andhra Pradesh, Uttar Pradesh, Bihar and Rajasthan. *Planning Commission of India, Government of India* 2009.
237. Directorate of Family Welfare and SIFPSA. Gap Analysis of First Referral Units (FRUs) in UP by SIFPSA. . 2013.
238. Ghodki PS, Sardesai SP. Obstetric hemorrhage: Anesthetic implications and management. *Anaesth Pain Intensive Care* 2014; **18**: 405-14.
239. Hulton LA, Matthews Z, Stones RW. Applying a framework for assessing the quality of maternal health services in urban India. *Soc Sci Med* 2007; **64**(10): 2083-95.
240. Sabde Y, De Costa A, Diwan V. A spatial analysis to study access to emergency obstetric transport services under the public private "Janani Express Yojana" program in two districts of Madhya Pradesh, India. *Reprod Health* 2014; **11**(1): 57.
241. Stanton C, Armbruster D, Knight R, et al. Use of active management of the third stage of labour in seven developing countries. *Bull World Health Organ* 2009; **87**(3): 207-15.
242. Stanton CK, Deepak NN, Mallapur AA, et al. Direct observation of uterotonic drug use at public health facility-based deliveries in four districts in India. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics* 2014; (0).
243. Iyengar K, Jain M, Thomas S, et al. Adherence to evidence based care practices for childbirth before and after a quality improvement intervention in health facilities of Rajasthan, India. *Bmc Pregnancy and Childbirth* 2014; **14**(1): 270.
244. Iyengar SD, Iyengar K, Martines JC, Dashora K, Deora KK. Childbirth practices in rural Rajasthan, India: implications for neonatal health and survival. *Journal of perinatology : official journal of the California Perinatal Association* 2008; **28 Suppl 2**((Suppl 2)): S23-30.

245. Alehagen SA, Finnstrom O, Hermansson GV, et al. Nurse-based antenatal and child health care in rural India, implementation and effects - an Indian-Swedish collaboration. *Rural Remote Health* 2012; **12**(3): 2140.
246. Sodani P, Sharma K. Training needs assessment of public health professionals in maternal and neonatal care. *Indian Journal of Maternal and Child Health* 2011; **13**(4): 8.
247. Afsana K BM, Cross S, Mavalankar D, Rahman A, Roy T, etal. . Clean delivery: a situation analysis of hygiene on maternity wards in India and Bangladesh. . 2014.
248. Thind A, Mohani A, Banerjee K, Hagigi F. Where to deliver? Analysis of choice of delivery location from a national survey in India. *BMC Public Health* 2008; **8**(1): 29.
249. Ferrinho P, Bugalho AM, Van Lerberghe W. Is there a case for privatising reproductive health? Patchy evidence and much wishful thinking. *Safe Motherhood Strategies: a Review of the Evidence* 2000.
250. Sharan M, Strobino D, Ahmed S. Intrapartum oxytocin use for labor acceleration in rural India. *Int J Gynaecol Obstet* 2005; **90**(3): 251-7.
251. Jeffery P, Das A, Dasgupta J, Jeffery R. Unmonitored Intrapartum Oxytocin Use in Home Deliveries: Evidence from Uttar Pradesh, India. *Reproductive Health Matters* 2007; **15**(30): 172-8.
252. Baqui AH, Williams EK, Darmstadt GL, et al. Newborn care in rural Uttar Pradesh. *Indian J Pediatr* 2007; **74**(3): 241-7.
253. Office of the Registrar General & Census Commissioner. Annual Health Survey 2012-2013 Fact Sheet, Uttar Pradesh. . 2012-2013.
254. UNICEF India. Coverage evaluation survey 2009. *New Delhi: United Nations Children Fund* 2010.
255. Registrar General of India. Special Bulletin on Maternal Mortality in India 2010-12. New Delhi, India: Government of India; 2013.
256. Social Statistics Division MoSaPI, Government of India. Millennium Development Goals, India Country Report 2014. . 2014.
257. Registrar General of India. Sample Registration System: Maternal Mortality in India 1997-2003; Trends, Causes and Risk Factors, . 2006.
258. Liu L, Oza S, Hogan D, et al. Global, regional, and national causes of child mortality in 2000-13, with projections to inform post-2015 priorities: an updated systematic analysis. *Lancet* 2015; **385**(9966): 430-40.
259. India. RGo. Sample registration system (SRS) statistical report 2013, . 2013.
260. Sankar MJ, Neogi SB, Sharma J, et al. State of newborn health in India. *J Perinatol* 2016; **36**(s3): S3-S8.
261. WHO-MCEE estimates for child causes of death. 2000-2015.
262. Korde-Nayak VN GP. Causes of Stillbirth. . *J Obstet Gynecol India* 2008.
263. McClure EM, Wright LL, Goldenberg RL, et al. The global network: a prospective study of stillbirths in developing countries. *Am J Obstet Gynecol* 2007; **197**.
264. World Health Organization. Building leadership and management capacity in health: Aide memoire. WHO/EIP/health systems/2005.1. 2005.
265. Smith R. The scientific basis of health services. *BMJ* 1995; **311**(7011): 961-2.
266. Bloom N, Sadun R, Van Reenen J. Does management really work? *Harvard business review* 2012; **90**(11): 76-82.
267. Berta WB, Baker R. Factors that impact the transfer and retention of best practices for reducing error in hospitals. *Health Care Management Review* 2004; **29**(2): 90-7.
268. Kollberg B, Dahlgaard JJ, Brehmer P-O. Measuring lean initiatives in health care services: issues and findings. *International Journal of Productivity and Performance Management* 2006; **56**(1): 7-24.
269. Kujala J, Lillrank P, Kronström V, Peltokorpi A. Time-based management of patient processes. *Journal of Health Organization and Management* 2006; **20**(6): 512-24.

270. Li LX, Benton W, Leong GK. The impact of strategic operations management decisions on community hospital performance. *Journal of Operations Management* 2002; **20**(4): 389-408.
271. Tucker AL, Edmondson AC. Why hospitals don't learn from failures: organizational and psychological dynamics that inhibit system change. *California management review* 2003; **45**(2): 55-72.
272. Goldstein SM, Ward PT. Performance effects of physicians' involvement in hospital strategic decisions. *Journal of Service Research* 2004; **6**(4): 361-72.
273. Rambani R, Okafor B. Evaluation of factors delaying discharge in acute orthopedic wards: a prospective study. *European Journal of Trauma and Emergency Surgery* 2008; **34**(1): 24-8.
274. Scott I, Poole P, Jayathissa S. Improving quality and safety of hospital care: a reappraisal and an agenda for clinically relevant reform. *Internal medicine journal* 2008; **38**(1): 44-55.
275. Proudlove N, Boaden R. Using operational information and information systems to improve in-patient flow in hospitals. *Journal of health organization and management* 2005; **19**(6): 466-77.
276. Rotter T, Kinsman L, James E, et al. Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. *Cochrane Database Syst Rev* 2010; **3**(3).
277. Bloom N, Propper C, Seiler S, Van Reenen J. Management practices in hospitals. *Manuscript, London School Econ* 2009.
278. Ministry of Health and Family Welfare GoI, Maternal health division. . Maternal and Newborn Health Toolkit. Jan 2013
279. Satpathy SK. Indian public health standards (IPHS) for community health centres. *Indian J Public Health* 2005; **49**(3): 123-6.
280. Boyne GA, Chen AA. Performance targets and public service improvement. *Journal of Public Administration Research and Theory* 2007; **17**(3): 455-77.
281. Micheli P, Neely A. Performance Measurement in the Public Sector in England: Searching for the Golden Thread. *Public Administration Review* 2010; **70**(4): 591-600.
282. Agarwal R, Green R, Agarwal N, Randhawa K. Benchmarking management practices in Australian public healthcare. *Journal of health organization and management* 2016; **30**(1): 31-56.
283. Chun YH, Rainey HG. Goal ambiguity and organizational performance in US Federal agencies. *Journal of Public Administration Research and Theory* 2005; **15**(4): 529-57.
284. Mannion R, Davies HT, Buetow S. Pay-for-performance in New Zealand primary health care. *Journal of Health Organization and Management* 2008; **22**(1): 36-47.
285. Kabene SM, Orchard C, Howard JM, Soriano MA, Leduc R. The importance of human resources management in health care: a global context. *Hum Resour Health* 2006; **4**(1): 20.
286. West MA, Borrill C, Dawson J, et al. The link between the management of employees and patient mortality in acute hospitals. *International Journal of Human Resource Management* 2002; **13**(8): 1299-310.
287. Patterson M, Rick J, Wood SJ, Carroll C, Balain S, Booth A. Systematic review of the links between human resource management practices and performance. 2010.
288. Adzei FA, Atinga RA. Motivation and retention of health workers in Ghana's district hospitals: addressing the critical issues. *Journal of Health Organization and Management* 2012; **26**(4): 467-85.
289. Borrill C, West M, Shapiro D, Rees A. Team working and effectiveness in health care. *British Journal of Healthcare Management* 2000; **6**(8): 364-71.
290. Hunter E, Nicol M. Systematic review: evidence of the value of continuing professional development to enhance recruitment and retention of occupational therapists in mental health. *The British Journal of Occupational Therapy* 2002; **65**(5): 207-15.
291. Brooks RG, Walsh M, Mardon RE, Lewis M, Clawson A. The roles of nature and nurture in the recruitment and retention of primary care physicians in rural areas: a review of the literature. *Academic Medicine* 2002; **77**(8): 790-8.
292. Wang Y, Collins C, Tang SL, Martineau T. Health systems decentralization and human resources management in low and middle income countries. *Public Administration and Development* 2002; **22**(5): 439-53.

293. Smith PC. Performance measurement for health system improvement: experiences, challenges and prospects: Cambridge University Press; 2009.
294. Hafner JM, Williams SC, Koss RG, Tschurtz BA, Schmaltz SP, Loeb JM. The perceived impact of public reporting hospital performance data: interviews with hospital staff. *Int J Qual Health Care* 2011; **23**(6): 697-704.
295. Mannion R, Davies HT, Gross R, Elhaynay A, Friedman N, Buetow S. Pay-for-performance programs in Israeli sick funds. *Journal of health organization and management* 2008; **22**(1): 23-35.
296. Ferguson B, Lim JN. Incentives and clinical governance: money following quality? *J Manag Med* 2001; **15**(6): 463-87.
297. Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *Jama* 2006; **295**(16): 1912-20.
298. Chang L-c, Lin SW, Northcott DN. The NHS performance assessment framework: a "balanced scorecard" approach? *Journal of management in medicine* 2002; **16**(5): 345-58.
299. Giuffrida A, Gravelle H, Roland M. Measuring quality of care with routine data: avoiding confusion between performance indicators and health outcomes. *British Medical Journal* 1999; **319**(7202): 94-8.
300. Parand A, Dopson S, Renz A, Vincent C. The role of hospital managers in quality and patient safety: a systematic review. *BMJ Open* 2014; **4**(9): e005055.
301. Conway J. Getting boards on board: engaging governing boards in quality and safety. *Jt Comm J Qual Patient Saf* 2008; **34**(4): 214-20.
302. Gautam KS. A call for board leadership on quality in hospitals. *Qual Manag Health Care* 2005; **14**(1): 18-30.
303. Goeschel CA, Wachter RM, Pronovost PJ. Responsibility for quality improvement and patient safety: hospital board and medical staff leadership challenges. *Chest* 2010; **138**(1): 171-8.
304. Øvretveit J. Leading improvement effectively: review of research. 2009. *London: The Health Foundation London Google Scholar*.
305. Flin R, Yule S. Leadership for safety: industrial experience. *Qual Saf Health Care* 2004; **13 Suppl 2**(suppl 2): ii45-51.
306. West E. Management matters: the link between hospital organisation and quality of patient care. *Quality in Health Care* 2001; **10**(1): 40-8.
307. Bloom N, Van Reenen J. Why Do Management Practices Differ across Firms and Countries? *Journal of Economic Perspectives* 2010; **24**(1): 203-24.
308. Bloom N, Sadun R, Van Reenen J. Does management matter in healthcare. *London School of Economics Working paper* 2013.
309. Castro PJ, Dorgan SJ, Richardson B. A healthier health care system for the United Kingdom. *McKinsey Quarterly* 2008.
310. Bloom N, Propper, C., Seiler, S. & Reenen, J. V. . The Impact of Competition on Management Quality: Evidence from Public Hospitals *National Bureau of Economic Research Inc* 2010; **NBER Working Papers: 16032**.
311. Bloom N, Sadun R, Van Reenen J. Does management really work? How three essential practices can address even the most complex global problems. *Harvard business review* 2012; **90**(11): 76-82.
312. McConnell KJ, Lindrooth RC, Wholey DR, Maddox TM, Bloom N. Management practices and the quality of care in cardiac units. *JAMA Intern Med* 2013; **173**(8): 684-92.
313. McConnell KJ, Hoffman KA, Quanbeck A, McCarty D. Management practices in substance abuse treatment programs. *Journal of Substance Abuse Treatment* 2009; **37**(1): 79-89.
314. Registrar General of India. Population projections for India and States: 2001-2026. 2010.
315. Registrar General of India. Census of India (2011). 2011.
316. Registrar General & Census Commissioner. Annual Health Survey Bulletin 2011- 2012 UTTAR PRADESH. 2011. .
317. Registrar General of India. Sample Registration System, (2007-09). 2007

318. India RGo. Sample Registration System. 2009
319. Registrar General of India. Sample Registration System, . 2008.
320. IIPS and Macro International. National Family Health Survey (NFHS-3), 2005-06, India: Key Findings. . 2007.
321. Singh S, Doyle P, Campbell OM, Mathew M, Murthy GV. Referrals between Public Sector Health Institutions for Women with Obstetric High Risk, Complications, or Emergencies in India - A Systematic Review. *PLoS One* 2016; **11**(8): e0159793.
322. MOHFW India. Rural Health Statistics in India 2013–14. . 2014.
323. MOHFW India. NUHM: Implementation framework. 2013.
324. Mackintosh M, Channon A, Karan A, Selvaraj S, Cavagnero E, Zhao H. What is the private sector? Understanding private provision in the health systems of low-income and middle-income countries. *The Lancet* 2016; **388**(10044): 596-605.
325. Bhate-Deosthali P KR, Wagle S. . Poor standards of care in small, private hospitals in Maharashtra, India: implications for public-private partnerships for maternity care. . *Reproductive Health Matters* 2011; **19**(37).
326. Government of India; Ministry of Health and Family Welfare. Operational guidelines on Maternal & Newborn Health , . 2010, .
327. Srivastava A, Bhattacharyya S, Clar C, Avan BI. Evolution of quality in maternal health in India: Lessons and priorities. *International Journal of Medicine and Public Health* 2014; **4**(1): 33.
328. Ministry of Health and Family Welfare. National Population Policy. . 2000.
329. Ministry of Women and Child Development. National Policy for Empowerment of Women. . 2001.
330. Ministry of Health and Family Welfare. National Health Policy. . 2002
331. Ministry of Health and Family Welfare. Executive Summary of NRHM programme. 2015.
332. Ministry of Health and Family Welfare. Janani SurakshaYojana: Revised Guidelines for implementation 2006. New Delhi: Government of India; 2006.
333. Nagarajan S, Paul VK, Yadav N, Gupta S. The National Rural Health Mission in India: its impact on maternal, neonatal, and infant mortality. *Semin Fetal Neonatal Med* 2015; **20**(5): 315-20.
334. White Ribbon Alliance. Respectful maternity care: the universal rights of childbearing women. *Available: Accessed* 2012; **3**.
335. Donabedian A. The quality of medical care. *Science* 1978; **200**(4344): 856-64.
336. World Health Organization. Managing complications in pregnancy and childbirth: a guide for midwives and doctors. 2000.
337. Choices, Challenges in Changing Childbirth Research N. Routines in facility-based maternity care: evidence from the Arab World. *BJOG* 2005; **112**(9): 1270-6.
338. International Institute for Population Sciences (IIPS) and Macro International. National Family Health Survey (NFHS-4), 2014-2015. 2014.
339. National Institute for Clinical Excellence. Intrapartum care. Care of healthy women and their babies during childbirth. *Clinical Guideline* 2007; **6**.
340. Hayes R, Moulton L. Cluster randomised trials. Taylor & Francis; 2009.
341. Vozdolska R, Sano M, Aisen P, Edland SD. The net effect of alternative allocation ratios on recruitment time and trial cost. *Clin Trials* 2009; **6**(2): 126-32.
342. Ministry of Health and Family Welfare. NHM Health management information system (HMIS) portal (https://nrhm-mis.nic.in/). 2015.
343. Vyas S, Kumaranayake L. Constructing socio-economic status indices: how to use principal components analysis. *Health Policy Plan* 2006; **21**(6): 459-68.
344. Snijders TA. Multilevel analysis: Springer; 2011.
345. UNICEF. UNICEF Data: Monitoring the Situation of Children and Women 2016.
346. Hinderaker SG, Olsen BE, Bergsjo PB, et al. Avoidable stillbirths and neonatal deaths in rural Tanzania. *BJOG* 2003; **110**(6): 616-23.

347. Abouchadi S, Alaoui AB, Meski FZ, Bezad R, De Brouwere V. Preventable maternal mortality in Morocco: the role of hospitals. *Trop Med Int Health* 2013; **18**(4): 444-50.
348. Kruk ME, Mbaruku G, McCord CW, Moran M, Rockers PC, Galea S. Bypassing primary care facilities for childbirth: a population-based study in rural Tanzania. *Health Policy Plan* 2009; **24**(4): 279-88.
349. Parkhurst JO, Ssengooba F. Assessing access barriers to maternal health care: measuring bypassing to identify health centre needs in rural Uganda. *Health Policy Plan* 2009; **24**(5): 377-84.
350. Rowe AK, de Savigny D, Lanata CF, Victora CG. How can we achieve and maintain high-quality performance of health workers in low-resource settings? *The Lancet* 2005; **366**(9490): 1026-35.
351. World Health Organization. Strategies for assisting health workers to modify and improve skills: developing quality health care: a process of change. 2000.
352. World Health Organization. Trends in maternal mortality: 1990-2015: estimates from WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015.
353. Ministry of Health and Family Welfare. Maternal and Newborn Health Toolkit. New Delhi, India: Maternal Health Division, Government of India; 2013.
354. Singh A, Mavalankar DV, Bhat R, et al. Providing skilled birth attendants and emergency obstetric care to the poor through partnership with private sector obstetricians in Gujarat, India. *Bulletin of the World Health Organization* 2009; **87**(12): 960-4.
355. Evans CL, Maine D, McCloskey L, Feeley FG, Sanghvi H. Where there is no obstetrician--increasing capacity for emergency obstetric care in rural India: an evaluation of a pilot program to train general doctors. *Int J Gynaecol Obstet* 2009; **107**(3): 277-82.
356. Potter JE, Berquo E, Perpetuo IHO, et al. Unwanted caesarean sections among public and private patients in Brazil: prospective study. *British Medical Journal* 2001; **323**(7322): 1155-8.
357. Murray SF, Hunter BM, Bisht R, Ensor T, Bick D. Effects of demand-side financing on utilisation, experiences and outcomes of maternity care in low- and middle-income countries: a systematic review. *BMC Pregnancy Childbirth* 2014; **14**: 30.
358. Phadungkiatwattana P, Tongsakul N. Analyzing the impact of private service on the cesarean section rate in public hospital Thailand. *Arch Gynecol Obstet* 2011; **284**(6): 1375-9.
359. Pereira SK, Kumar P, Dutt V, et al. Protocol for the evaluation of a social franchising model to improve maternal health in Uttar Pradesh, India. *Implement Sci* 2015; **10**(1): 77.
360. Getachew A, Ricca J, Cantor D, et al. Quality of care for prevention and management of common maternal and newborn complications: a study of Ethiopia's hospitals. *Baltimore: Jhpiego* 2011.
361. World Health Organization. Integrated management of pregnancy and childbirth: World Health Organization.; 2003.
362. Palmer WL, Bottle A, Aylin P. Association between day of delivery and obstetric outcomes: observational study. *BMJ* 2015; **351**: h5774.
363. Pasupathy D, Wood AM, Pell JP, Fleming M, Smith GC. Time of birth and risk of neonatal death at term: retrospective cohort study. *Bmj* 2010; **341**: c3498.
364. Harvey SA, Blandón YCW, McCaw-Binns A, et al. Are skilled birth attendants really skilled? A measurement method, some disturbing results and a potential way forward. *Bulletin of the World Health Organization* 2007; **85**(10): 783-90.
365. Berendes S, Heywood P, Oliver S, Garner P. Quality of private and public ambulatory health care in low and middle income countries: systematic review of comparative studies. *PLoS Med* 2011; **8**(4): e1000433.
366. Press Information Bureau Ministry of Health and Family Welfare. Achievements under millennium development goals. 2015.
367. Ng M, Misra A, Diwan V, Agnani M, Levin-Rector A, De Costa A. An assessment of the impact of the JSY cash transfer program on maternal mortality reduction in Madhya Pradesh, India. *Glob Health Action* 2014; **7**: 24939.

368. Vogel JP, Bohren MA, Tuncalp O, et al. How women are treated during facility-based childbirth: development and validation of measurement tools in four countries - phase 1 formative research study protocol. *Reprod Health* 2015; **12**(1): 60.
369. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *JAMA* 1998; **280**(11): 1000-5.
370. Saini V, Brownlee S, Elshaug AG, Glasziou P, Heath I. Addressing overuse and underuse around the world. *Lancet* 2017.
371. Oscarsson ME, Amer-Wahlin I, Rydhstroem H, Kallen K. Outcome in obstetric care related to oxytocin use. A population-based study. *Acta Obstet Gynecol Scand* 2006; **85**(9): 1094-8.
372. Coffey D. Costs and consequences of a cash transfer for hospital births in a rural district of Uttar Pradesh, India. *Soc Sci Med* 2014; **114**: 89-96.
373. Ambedkar BR. Castes in India: Their mechanism, genesis and development. *Readings in Indian Government And Politics Class, Caste, Gender* 2004: 131-53.
374. Okafor, II, Ugwu EO, Obi SN. Disrespect and abuse during facility-based childbirth in a low-income country. *Int J Gynaecol Obstet* 2015; **128**(2): 110-3.
375. Sudhinaraset M, Treleaven E, Melo J, Singh K, Diamond-Smith N. Women's status and experiences of mistreatment during childbirth in Uttar Pradesh: a mixed methods study using cultural health capital theory. *BMC Pregnancy Childbirth* 2016; **16**(1): 332.
376. Kruk ME, Kujawski S, Mbaruku G, Ramsey K, Moyo W, Freedman LP. Disrespectful and abusive treatment during facility delivery in Tanzania: a facility and community survey. *Health Policy and Planning* 2014: czu079.
377. Mitra A. The status of women among the scheduled tribes in India. *The Journal of Socio-Economics* 2008; **37**(3): 1202-17.
378. Subramanian SV, Davey Smith G, Subramanyam M. Indigenous health and socioeconomic status in India. *PLoS Med* 2006; **3**(10): e421.
379. Gupta J, Hofmeyr G, Smyth R. Position in the second stage of labour for women without epidural anaesthesia (Review). 2007.
380. Hodnett ED, Gates S, Hofmeyr GJ, Sakala C. Continuous support for women during childbirth. *Cochrane Database Syst Rev* 2013; **7**: CD003766.
381. Basevi V, Lavender T. Routine perineal shaving on admission in labour. *Cochrane Database Syst Rev* 2014; (11): CD001236.
382. Ministry of Health and Family Welfare. Skilled Birth Attendance-A Handbook for Auxiliary Nurse Midwives/Lady Health Visitors and Staff Nurses. 2010.
383. Amoran O, Omokhodion F, Dairo M, Adebayo A. Job satisfaction among primary health care workers in three selected local government areas in southwest Nigeria. *Nigerian journal of medicine: journal of the National Association of Resident Doctors of Nigeria* 2004; **14**(2): 195-9.
384. Bosch-Capblanch X, Garner P. Primary health care supervision in developing countries. *Trop Med Int Health* 2008; **13**(3): 369-83.
385. Lewis M. Informal payments and the financing of health care in developing and transition countries. *Health Aff (Millwood)* 2007; **26**(4): 984-97.
386. Gaal P, Belli PC, McKee M, Szocska M. Informal payments for health care: definitions, distinctions, and dilemmas. *J Health Polit Policy Law* 2006; **31**(2): 251-93.
387. Over M, Watanabe N. Evaluating the impact of organizational reforms in hospitals. *Innovations in Health Service Delivery: The Corporatization of Public Hospitals Human Development Network* 2003.
388. Hanson C, Waiswa P, Marchant T, et al. Expanded Quality Management Using Information Power (EQUIP): protocol for a quasi-experimental study to improve maternal and newborn health in Tanzania and Uganda. *Implement Sci* 2014; **9**(1): 41.
389. Laing AW, Shiroyama C. Managing capacity and demand in a resource constrained environment: lessons for the NHS? *J Manag Med* 1995; **9**(5): 51-67.

390. Butler TW, Leong GK, Everett LN. The operations management role in hospital strategic planning. *Journal of Operations Management* 1996; **14**(2): 137-56.
391. Trisolini MG. Applying business management models in health care. *The International journal of health planning and management* 2002; **17**(4): 295-314.
392. l'Europe OmdlsBrd, Shaw CR. How can hospital performance be measured and monitored?: WHO Regional Office for Europe; 2003.
393. Duff E. International news–June 2017. *Midwifery* 2017; **49**: A1-A5.
394. Coarasa J, Das J, Gummerson E, Bitton A. A systematic tale of two differing reviews: evaluating the evidence on public and private sector quality of primary care in low and middle income countries. *Global Health* 2017; **13**(1): 24.
395. Basu S, Andrews J, Kishore S, Panjabi R, Stuckler D. Comparative performance of private and public healthcare systems in low- and middle-income countries: a systematic review. *PLoS Med* 2012; **9**(6): e1001244.
396. Lindelow M, Serneels P. The performance of health workers in Ethiopia: results from qualitative research. *Soc Sci Med* 2006; **62**(9): 2225-35.
397. Turan JM, Bulut A, Nalbant H, Ortayli N, Akalin AA. The quality of hospital-based antenatal care in Istanbul. *Stud Fam Plann* 2006; **37**(1): 49-60.
398. Hoa NQ, Ohman A, Lundborg CS, Chuc NTK. Drug use and health-seeking behavior for childhood illness in Vietnam - A qualitative study. *Health Policy* 2007; **82**(3): 320-9.
399. Paphassarang C, Philavong K, Boupha B, Blas E. Equity, privatization and cost recovery in urban health care: the case of Lao PDR. *Health Policy Plan* 2002; **17 Suppl**(suppl_1): 72-84.
400. Schneider H, Palmer N. Getting to the truth? Researching user views of primary health care. *Health Policy Plan* 2002; **17**(1): 32-41.
401. McClure EM, Pasha O, Goudar SS, et al. Epidemiology of stillbirth in low-middle income countries: a Global Network Study. *Acta Obstet Gynecol Scand* 2011; **90**(12): 1379-85.
402. World Health Organization. Active management of the third stage of labour: new WHO recommendations help to focus implementation. 2014.
403. Gulmezoglu AM, Lumbiganon P, Landoulsi S, et al. Active management of the third stage of labour with and without controlled cord traction: a randomised, controlled, non-inferiority trial. *Lancet* 2012; **379**(9827): 1721-7.
404. American Academy of Pediatrics and American Heart Association. Textbook of Neonatal Resuscitation. . 6th edition ed; 2011.
405. Pediatrics AAo. Neonatal encephalopathy and neurologic outcome. *Pediatrics* 2014; **133**(5): e1482-e8.
406. Nagpal J, Sachdeva A, Sengupta Dhar R, Bhargava VL, Bhartia A. Widespread non-adherence to evidence-based maternity care guidelines: a population-based cluster randomised household survey. *BJOG* 2015; **122**.
407. Delvaux T, Ake-Tano O, Gohou-Kouassi V, Bosso P, Collin S, Ronsmans C. Quality of normal delivery care in Cote d'Ivoire. *Afr J Reprod Health* 2007; **11**(1): 22-32.
408. Duysburgh E, Zhang WH, Ye M, et al. Quality of antenatal and childbirth care in selected rural health facilities in Burkina Faso, Ghana and Tanzania: similar finding. *Trop Med Int Health* 2013; **18**(5): 534-47.
409. Pathmanathan I, Liljestrand J. Investing in maternal health: learning from Malaysia and Sri Lanka: World Bank Publications; 2003.
410. Bryce J, Arnold F, Blanc A, et al. Measuring coverage in MNCH: new findings, new strategies, and recommendations for action. *PLoS Med* 2013; **10**(5): e1001423.
411. Mathers CD. Births and perinatal deaths in Australia: variations by day of week. *J Epidemiol Community Health* 1983; **37**(1): 57-62.
412. Okomo UA, Dibbasey T, Kassama K, et al. Neonatal admissions, quality of care and outcome: 4 years of inpatient audit data from The Gambia's teaching hospital. *Paediatr Int Child Health* 2015; **35**(3): 252-64.

413. Hossain J, Ross SR. The effect of addressing demand for as well as supply of emergency obstetric care in Dinajpur, Bangladesh. *International Journal of Gynecology & Obstetrics* 2006; **92**(3): 320-8.
414. Kim YM, Tappis H, Zainullah P, et al. Quality of caesarean delivery services and documentation in first-line referral facilities in Afghanistan: a chart review. *BMC Pregnancy Childbirth* 2012; **12**(1): 14.
415. Bhat R. Characteristics of private medical practice in India: a provider perspective. *Health Policy Plan* 1999; **14**(1): 26-37.
416. Merali HS, Lipsitz S, Hevelone N, et al. Audit-identified avoidable factors in maternal and perinatal deaths in low resource settings: a systematic review. *BMC Pregnancy Childbirth* 2014; **14**(1): 280.
417. Partamin, Kim YM, Mungia J, Faqir M, Ansari N, Evans C. Patterns in training, knowledge, and performance of skilled birth attendants providing emergency obstetric and newborn care in Afghanistan. *International Journal of Gynecology & Obstetrics* 2012; **119**(2): 125-9.
418. Ijadunola KT, Ijadunola MY, Esimai OA, Abiona TC. New paradigm old thinking: The case for emergency obstetric care in the prevention of maternal mortality in Nigeria. *BMC Womens Health* 2010; **10**: 6.
419. Leonard KL, Mliga GR, Mariam DH. Bypassing health centres in Tanzania: Revealed preferences for quality. *Journal of African Economies* 2002; **11**(4): 441-71.
420. Karkee R, Lee AH, Binns CW. Bypassing birth centres for childbirth: an analysis of data from a community-based prospective cohort study in Nepal. *Health policy and planning* 2013; **30**(1): 1-7.
421. Asefa A, Bekele D. Status of respectful and non-abusive care during facility-based childbirth in a hospital and health centers in Addis Ababa, Ethiopia. *Reprod Health* 2015; **12**(1): 33.
422. Raj A, Dey A, Boyce S, et al. Associations Between Mistreatment by a Provider during Childbirth and Maternal Health Complications in Uttar Pradesh, India. *Matern Child Health J* 2017.
423. Sheferaw ED, Bazant E, Gibson H, et al. Respectful maternity care in Ethiopian public health facilities. *Reprod Health* 2017; **14**(1): 60.
424. Afsana K, Rashid SF. The challenges of meeting rural Bangladeshi women's needs in delivery care. *Reprod Health Matters* 2001; **9**(18): 79-89.
425. Kyomuhendo GB. Low use of rural maternity services in Uganda: Impact of women's status, traditional beliefs and limited resources. *Reproductive Health Matters* 2003; **11**(21): 16-26.
426. United Nations High Commissioner. Report of the Office of the United Nations High Commissioner for Human Rights on preventable maternal mortality and morbidity and human rights. 2010.
427. United Nations High Commissioner. Technical guidance on the application of a human rights-based approach to the implementation of policies and programmes to reduce preventable maternal morbidity and mortality. 2012.
428. Miller S, Lalonde A. The global epidemic of abuse and disrespect during childbirth: History, evidence, interventions, and FIGO's mother-baby friendly birthing facilities initiative. *Int J Gynaecol Obstet* 2015; **131 Suppl 1**: S49-52.
429. Bowling A. Research methods in health: investigating health and health services: McGraw-Hill Education (UK); 2014.
430. Yadav V, Kumar S, Balasubramaniam S, et al. Facilitators and barriers to participation of private sector health facilities in government-led schemes for maternity services in India: a qualitative study. *BMJ Open* 2017; **7**(6): e017092.
431. Evans CL, Kim YM, Yari K, Ansari N, Tappis H. Using direct clinical observation to assess the quality of cesarean delivery in Afghanistan: an exploratory study. *BMC Pregnancy Childbirth* 2014; **14**(1): 176.
432. Semrau KE, Hirschhorn LR, Kodkany B, et al. Effectiveness of the WHO Safe Childbirth Checklist program in reducing severe maternal, fetal, and newborn harm in Uttar Pradesh, India: study protocol for a matched-pair, cluster-randomized controlled trial. *Trials* 2016; **17**(1): 576.

433. Lange IL, Kanhonou L, Goufodji S, Ronsmans C, Filippi V. The costs of 'free': Experiences of facility-based childbirth after Benin's caesarean section exemption policy. *Social Science & Medicine* 2016; **168**: 53-62.
434. Kirkpatrick Donald. Great Ideas Revisited. Techniques for Evaluating Training Programs. Revisiting Kirkpatrick's Four-Level Model. *Training and Development* 1996; **50**(1): 54-9.
435. Utz B, Kana T, van den Broek N. Practical aspects of setting up obstetric skills laboratories--a literature review and proposed model. *Midwifery* 2015; **31**(4): 400-8.
436. Graham WJ. Criterion-based clinical audit in obstetrics: bridging the quality gap? *Best Pract Res Clin Obstet Gynaecol* 2009; **23**(3): 375-88.
437. Das JK, Kumar R, Salam RA, Lassi ZS, Bhutta ZA. Evidence from facility level inputs to improve quality of care for maternal and newborn health: interventions and findings. *Reprod Health* 2014; **11 Suppl 2**(Suppl 2): S4.
438. Singer SJ, Falwell A, Gaba DM, et al. Identifying organizational cultures that promote patient safety. *Health Care Management Review* 2009; **34**(4): 300-11.
439. Gon G, Ali SM, Towriss C, et al. Unpacking the enabling factors for hand, cord and birth-surface hygiene in Zanzibar maternity units. *Health Policy and Planning* 2017.
440. Puri M, Lahariya C. Social audit in health sector planning and program implementation in India. *Indian J Community Med* 2011; **36**(3): 174-7.
441. Joshi A. Do they work? Assessing the impact of transparency and accountability initiatives in service delivery. *Development Policy Review* 2013; **31**(s1).
442. Waiswa P, Kalter HD, Jakob R, Black RE, Social Autopsy Working G. Increased use of social autopsy is needed to improve maternal, neonatal and child health programmes in low-income countries. *Bulletin of the World Health Organization* 2012; **90**(6): 403-A.
443. Jackson EF, Siddiqui A, Gutierrez H, Kante AM, Austin J, Phillips JF. Estimation of indices of health service readiness with a principal component analysis of the Tanzania Service Provision Assessment Survey. *BMC Health Serv Res* 2015; **15**(1): 536.
444. Jolliffe I. Principal component analysis: Wiley Online Library; 2002.

12. List of Appendices

Appendix 1: QoC assessment tool for normal labour and childbirth in Uttar Pradesh in 2015

Part 1: IDENTIFICATION	
I01.NAME AND CODE OF DISTRICT _____ I02. NAME AND CODE OF BLOCK _____ I03. FACILITY TYPE 1. COMMUNITY HEALTH CENTRES (CHCs) 2. DISTRICT HOSPITAL (DH) 3. MEDICAL COLLEGE AND TEACHING HOSPITAL 4. PRIVATE MATERNITY CENTRE I04. OWNER / MANAGER NAME _____ I05. HEALTH WORKER NAME (Attending nurse/ doctor who is conducting the delivery) _____	[___] [___] [___] [___] [___][___]
RESEARCHER VISITS	
I06. DATE	
I07. TIME OBSERVATION STARTED	
I08. TIME OBSERVATION FINISHED	
I09. INTERVIEWER'S NAME	
I10. SUPERVISOR'S NAME	

Part2: Summary Sheet

CIRCLE ALL THAT APPLIES

I11. Unique Identification code	Facility Number(FF): ☐☐ Observation Number: ☐☐	
I12. Participation	Agreed to participate	A.
	Refused to participate	B.
	Did not fulfil eligibility criteria	C.
	Developed a complication after enrolment and observation ended (Please specify reason)	D.
I13. Accompanying person	Yes	1

	No	2
I14. Consent received?	Witten consent by woman	A.
	Written consent family	B.
	Oral consent by researcher	C.
	Thumb Print	D.

Section A: Screening questionnaire

Instructions to the researcher: Approach the ward nurses to identify all pregnant women in the labour wards, admissions department, or other places where pregnant woman may be admitted. From their medical records, complete Section A to assess their eligibility for inclusion in the study. Even if the woman is deemed eligible she may develop a complication during labour and childbirth. In such a case observe care provided up to that point in time.

Case definition:

A normal vaginal delivery is one that is:

- Spontaneous in onset
- Low-risk at the start of labour (no history of medical conditions in the past or problems in the current pregnancy, no history of previous obstetric and neonatal complications, no foetal complications in current pregnancy and no previous gynaecological history)
- A single infant is born spontaneously in a vertex position
- Gestational age between 37 and 42 (+0) completed weeks of pregnancy.
- The woman should be between 18-49 years of age.

Unique ID:								

A1.	Age of the woman	Complete in years_____		
A2.	Gestational age of the women, indicate in weeks and days Verify with medical records	_____/Weeks_____Days		
A3.	Gravidity 1. Number of babies born alive 2. Number of babies born dead? 3. Number of abortions/Miscarriage	1. 2. 3.		
A4.	Parity (1+2)			
A5.	Is the labour spontaneous	Yes	No	DK
A6.	Was induction of labour conducted?	Yes	No	DK
A7.	If yes in A6, please provide details of the method used? (Specify drug or procedures used)			
A8.	Is there any history of medical/ obstetric complications in previous pregnancies?	Yes	No	DK
A9.	If yes, Please specify:			

A10.	Are there any foetal complications in the current pregnancy?	Yes	No	DK
A11.	Is this a singleton pregnancy?	Yes	No	DK
A12.	Is the baby in vertex position?	Yes	No	DK
A13.	Cervical dilation	(_____cms)		
A14.	Was the woman's Blood pressure measured? If yes, please specify the reading. _____(mm/hg)	Yes	No	DK
A15.	Was the woman's temperature measured? If yes, please specify the reading. / _____(Degree Celsius)	Yes	No	DK
A16.	Was urine tested for presence of protein?	Yes	No	DK
A17.	Did the health worker perform the following steps for abdominal examination			
	a. Checks fundal height with a measuring tape	Yes	No	DK
	b. Checks fetal presentation by palpation of abdomen	Yes	No	DK
	c. Checks Foetal Heart Rate	Yes	No	DK

Section B: Demographic, Socio-economic and Educational Status

Instructions to the observer: If the woman is in active labour, approach companions or family members of the pregnant woman to complete this section after obtaining consent. If the woman doesn't have any accompanying person, collect information directly from her at a suitable time after delivery.

No.	QUESTION	CATEGORIES	CODE (Circle)
B1.	Client hospital medical number		
B2.	Address of the client		
B3.	Are you a booked case?	Yes	1
		No	2
B4.	Where is the client coming from?	Directly to facility	1
		Referred from another facility	2
B5.	How much time did the client/ family take to travel from home/elsewhere to this facility		
	a. From home to first facility or this facility if coming directly.	(___/___) Time in hh/mm	
	b. From referral facility to this facility	(___/___) Time in hh/mm	
	c. Total time to reach facility	(___/___) Time in hh/mm	
B6.	What is your religion?	Hindu	1.

No.	QUESTION	CATEGORIES	CODE (Circle)
		Muslim	2.
		Christian	3.
		No religion	4.
		Other	5.
		Don't Know	6.
B7.	What is your caste/ category?	Brahmin	1.
		Rajput/ Thakur	2.
		Kayasthi/ Srivastava/ Lala	3.
		Chamar	4.
		Dusadh	5.
		Musahar	6.
		Pasi	7.
		Dhobi	8.
		Chaupal	9.
		Yadav	10.
		Vaishya/ Bania	11.
		Kurmi/ Katiyar	12.
		Shah	13.
		No caste/ Tribe	14.
		Other य	15.
		Don't Know	16.
B8.	Note: if the caste is a scheduled caste, scheduled tribe, other backward caste	Scheduled caste	1.
		Scheduled tribe	2.
		Other backward caste	3.
		General Caste	4.
		Other	5.
B9.	Does the woman or her family have a Below Poverty Line Card (verify BPL card)?	Yes	1.
		No	2.
		Don't Know	3.
B10.	What is the occupation of the pregnant woman?	Self- employed, Agriculture	1.
		Wage employed	2.
		Agricultural labourer	3.
		Salaried worker	4.
		Self/ Employed, Business	5.
		Skilled worker	6.
		Retired	7.
		Looking for work	8.
		Not working and not looking for work	9.
		Other य	10.
		Don't Know	11.
B11.		Kachha	1.

No.	QUESTION	CATEGORIES	CODE (Circle)
	How has your (the woman's house) been constructed?	Semi-Pucca	2.
		Pucca	3.
		Don't Know	4.
B12.	What is the main source of drinking water for the members of woman's household?	Piped water into dwelling	1.
		Piped into yard/ plot	2.
		Public taps/ Stand pipe	3.
		Public Hand-pump	4.
		Private hand-pump	5.
		Tube well or borehole	6.
		Dug well	7.
		Rainwater	8.
		Tanker/ truck	9.
		Surface water (Rover, Lake, Pond, Stream, Canal, Irrigation channel)	10.
		Don't Know	11.
B13.	What kind of toilet facilities does the household have? Probe in detail	Flush or pour flush toilet	1.
		Flush to piped sewer system	2.
		Flush to septic tank	3.
		Flush to pit latrine	4.
		Flush to somewhere else	5.
		Pit Latrine	6.
		Ventilated improve pit biogas latrine	7.
		Pit latrine with slab / open pit	8.
		Twin put/ Composting toilet	9.
		Dry Toilet	10.
		No facilities/ used open space or field	11.
		Don't Know	12.
		Other (Please specify)…….	
B14.	What kind of fuel does the household use for cooking most of the time? Select only one option	Electricity	1.
		LPG/Natural gas	2.
		Biogas	3.
		Kerosene	4.
		Wood	5.
		Agriculture crop waste	6.
		Dung cakes	7.
		Others (Please specify)	8.
		Don't know	9.
B15.	Does the pregnant woman's household have? (circle all as appropriate)	Mattress	1.
		Pressure cooker	2.
		Chair	3.
		Cot/ Bed	4.

No.	QUESTION	CATEGORIES	CODE (Circle)
		Table	5.
		Almirah/ Dressing table	6.
		Electric fan	7.
		Radio/transistor	8.
		Colour TV	9.
		VCR/ VCD/ DVD/CD player	10.
		Sewing machine	11.
		Mobile telephone	12.
		Any other telephone	13.
		Computer/ Laptop	14.
		Refrigerator	15.
		Watch/ clock	16.
		Bicycle	17.
		Motorcycle/ scooter	18.
		Animal- drawn cart	19.
		Car	20.
		Water pump	21.
		Tractor	22.
B16.	Does your household have electricity	Yes	1.
		No	2.
		Don't Know	3.
B17.	What is the highest level of education the woman has attained?	Literate without formal education	1.
		Literate with Formal Education Below Primary	2.
		Primary (Upto 5th standard)	3.
		Middle (6th to 8th Standard)	4.
		Secondary/Metrics Class X	5.
		Hr. Secondary/ Sr. Secondary/ Pre-University (Class XII)	6.
		Graduate/BBA/ B.TECH/ Equivalent	7.
		Post Graduate/MBA/Equivalent or Higher	8.
		Technica Diploma	9.
		Non-technical/Certificate Course	10.
		Other	96
		Illiterate	00

Section C: Direct Observation of normal vaginal deliveries

Instructions to the researcher:

Find the health worker involved in the provision of care to the woman. If this is not a new respondent, proceed directly to part 2. Please obtain informed consent from both the client and the health worker before beginning the clinical practice observations. Ensure that the provider knows that you are not there to evaluate him or her and that you are not an expert to be consulted during the session.

Provide Information and Consent sheets to the health worker.

C1. Consent Given by health worker:
☐ Yes: After completing the Part One proceed to Part 2.
☐ No: Finish the interview.

Part 1:

C2.Who is conducting the delivery? (Circle as appropriate; several responses possible)

Health worker qualification	Category code	Health worker qualification	Category code
Doctor (MBBS)	1	Nursing professionals (post- bachelor)	7
Doctor (BAMS)	2	Midwifery professionals (post- bachelor)	8
Obstetrician and gynaecologists	3	Auxiliary Nurse Midwife	9
Paediatricians and neonatologists	4	General Nurse Midwife	10
Anaesthetists	5	Neonatal nurse	11
Nursing professional (Bachelor)	6	Others (specify): ……..	12

Instructions to the researcher: Provide the information sheet and consent form to the client, next of kin or family member prior to beginning Part 2. Did the client/ family/ accompanying person provide an informed consent and agree to let the researcher be present during labour and delivery?

C3. Consent Given by woman:
☐ Yes: Continue to Part 2.
☐ No: Finish interview.

Part 2: Clinical practice Observation First stage of Labour	Yes	No	DK
C4. Did a health worker explain the process of labour to the woman or companion at least once before the start of active labour?	**1**	**2**	**8**
C5. Observer: Was a companion allowed to be with the woman during labour?	**1**	**2**	**8**
C6. Vaginal Examination performed using sterile gloves?	**1**	**2**	**8**
C7. Woman informed before vaginal examination performed?	**1**	**2**	**8**
C8. Was partograph used to monitor labour? **If No, then skip to C11**.	**1**	**2**	**8**
C9. If action line reached on partograph, was any definitive action taken?	**1**	**2**	**8**
C10. What definitive action was taken: (circle as appropriate)			
a. Consult with specialist	**1**	**2**	**8**
b. Refer to other facility for specialist	**1**	**2**	**8**

c. Prepare for assisted delivery	**1**	**2**	**8**
d. Prepare for C-section	**1**	**2**	**8**
e. Other (please specify_____)			
C11. Was Foetal heart beat monitored at regular intervals?	**1**	**2**	**8**
C12. If foetal heart beat indicated, write in the box?	……../bpm		
C13. Oral fluid offered to the woman on request?	**1**	**2**	**8**
C14. Visual Privacy of the pregnant woman ensured?	**1**	**2**	**8**
C15. Women encouraged to move around by the provider	**1**	**2**	**8**
C16. Was labour augmentation done? **If No, then skip to C20**.	**1**	**2**	**8**
C17. Why was labour augmentation performed?			
a) Inefficient uterine activity	**A**		
b) Cervical dilatation of less than 2 cm in 4 hours	**B**		
c) Not known	**C**		
d) Other (Please specify)……..			
C18. Did a health worker explain to the mother why labour augmentation was being done?		**2**	**8**
C19.How was labour augmentation done?			
a) Artificial rupture of the membranes	**1**	**2**	**8**
b) Use of syntocinon/Oxytocin	**1**	**2**	**8**
c) Others (Please Specify the name of the injection apart from syntocinon/Oxytocin)			
Questions on examination and procedures			
C20. Hand washing done prior to any examination of the woman	**1**	**2**	**8**
C21. Health worker wears sterile surgical gloves	**1**	**2**	**8**
C22. Cleans the vulva and perineum with antiseptic solution	**1**	**2**	**8**
C23. Drapes woman (one drape under buttocks, one over abdomen)	**1**	**2**	**8**
Preparation for delivery			
Check to see if the following equipment and supplies are laid out in preparation for delivery. If some supplies are in a delivery kit, look/ ask to determine what items are included.			
C24. Prepares uterotonic(Oxytocin) for Active management of third stage of labour	**1**	**2**	**8**
C25. Timer (clock or watch with seconds hand)	**1**	**2**	**8**
C26. Self-inflating ventilation bag (250 or 500 mL)	**1**	**2**	**8**
C27. Newborn face mask (size 0, 1)	**1**	**2**	**8**
C28. Mucus Extractor, suction tube/ Suction bulb	**1**	**2**	**8**
C29. Catheter	**1**	**2**	**8**
C30Radiant Warmer	**1**	**2**	**8**
C31. Weighing Scale			
C32. At least two cloths/blankets for new born (one to dry; one to cover)	**1**	**2**	**8**
C33. Umblical cord ties or clamps	**1**	**2**	**8**
C34. Sterile scissors or blade	**1**	**2**	**8**
C35. Has the woman completed the first stage of labour?	**1**	**2**	**8**
Ensure that the first stage of labour is complete before moving down to Section D below.			
Section D: Observation of Second & Third Stage of Labour			
PREPARATION FOR DELIVERY			
D1. Mother informed of the stage of labour	**1**	**2**	**8**

D2. Was episiotomy performed	**1**	**2**	**8**
D3. Was a local anesthetic injection administered before the episiotomy	**1**	**2**	**8**
D4. Position of the woman during childbirth			
a) Lithotomy (on her back)		**A**	
b) Squatting		**B**	
c) Left lateral		**C**	
d) Other (Please specify)		**D**	
D5. Mother asked about choice of position for delivery	**1**	**2**	**8**
D6. Who performed the delivery			
a) Doctor		**A**	
b) Nurse		**B**	
c) Midwife		**C**	
d) Intern doctor		**D**	
e) Student nurse		**E**	
f) Student midwife		**F**	
g) Other (please specify)……			
DELIVERY & UTEROTONIC (OXYTOCIN)			
D7. As baby's head is delivered, supports perineum	**1**	**2**	**8**
D8. Record time of the delivery of the baby	**1**	**2**	**8**
D9. Checks for another baby prior to giving the uterotonic (Oxytocin)	**1**	**2**	**8**
D10. Administers uterotonic(oxytocin)? **If No, then skip to D13**	**1**	**2**	**8**
D11. Which uterotonic was given? (circle as appropriate) **VERIFY**			
a) Oxytocin		**A**	
b) Ergometrine		**B**	
c) Syntometrine		**C**	
d) Misoprostol		**D**	
D12. Timing of administration of uterotonic/oxytocin (circle as appropriate)			
a) At delivery of anterior shoulder		**A**	
b) Within 1 min of delivery of baby		**B**	
c) Within 3 min of delivery of baby		**C**	
d) More than 3 min after delivery of baby		**D**	
D13. Ties or clamps cord when pulsations stop, or by 2-3 minutes after birth (not immediately after birth)	**1**	**2**	**8**
D14. Cuts cord with sterile blade or sterile scissors	**1**	**2**	**8**
D15. Applies traction to the cord while applying suprapubic counter traction	**1**	**2**	**8**
D16. Performs uterine massage immediately following the delivery of the placenta	**1**	**2**	**8**
D17. Assesses completeness of the placenta and membranes	**1**	**2**	**8**
D18. Assesses for perineal and vaginal lacerations	**1**	**2**	**8**
D19. Was vaginal bleeding monitored after the delivery?	**1**	**2**	**8**
D20. Was any drug given to prevent PPH? If Yes, Please Specify (_____)	**1**	**2**	**8**
D21. Woman informed about the sex of the newborn	**1**	**2**	**8**

D22. Outcome of the baby	**Alive**	**Complications**	**Dead**
D23. Outcome of the woman	**Alive**	**Complications**	**Dead**
POTENIALLY HARMFUL PRACTICES			
D24. Did you observe any of the following harmful practices done by any health worker involved in the provision of care? (Circle all that apply)			
a. Use of enema		**A**	
b. Pubic shaving		**B**	
c. Apply fundal pressure to hasten the delivery of the baby or the placenta		**C**	
d. Uterine lavage after delivery		**D**	
e. Slap the newborn		**E**	
f. Hold the newborn upside down		**F**	
g. Shout insult or threaten the woman at any time during labour and childbirth		**G**	
h. Slap, hit or pinch the woman at any time during labour and childbirth		**H**	
D25. Did you see any of the following practices that were done without appropriate indication (Circle all that apply)			
a) Manual exploration of the uterus after delivery	**A**		
b) Use of episiotomy	**B**		
c) Aspiration of the mouth and nose as soon as the newborn is born	**C**		
d) Restrict food and fluid during labour	**D**		
e) None of the above.	**E**		
ESSENTIAL NEWBORN CARE			
D26. Immediately dries baby with towel	**1**	**2**	**8**
D27. Discards the wet towel	**1**	**2**	**8**
D28. Is the baby breathing or crying?	**1**	**2**	**8**
D29. Places baby on mother's abdomen "skin to skin"	**1**	**2**	**8**
D30. Covers baby with dry towel	**1**	**2**	**8**
D31. Apgar score checked after one minute, If yes, please indicate in the box ASK AND VERIFY FROM RECORDS	**1**	**2**	**8**
D32. Apgar score checked after five minutes? If yes, indicate in the box ASK AND VERIFY FROM RECORDS	**1**	**2**	**8**
D33. Mother and newborn kept in same room after delivery (rooming-in)	**1**	**2**	**8**
D34. Was breastfeeding initiated within the first hour after birth	**1**	**2**	**8**
D35. Was the weight of the baby measured? If yes, then Specify (_____)	**1**	**2**	**8**
Field notes:			

Appendix 2: Tool for assessment of management practices in maternity facilities in Uttar Pradesh in 2015

Interview Details	Hospital and Manager's Information
a) Hospital Name:	b) Name:
c) Hospital ID	d) Position:
e) Interviewer Name:	f) Specialty:
g) Date (DD/MM/YY):	h) Tenure in post (number of years):
i) Time (24-hour clock):	j) Tenure in hospital (number of years):
k) Running interview ☐ Listening to interview	l) How old is your hospital (number of years)?

Management Questions

1. Layout of Patient Flow

Tests how well the maternity care pathway is configured at the facility and whether staff pro-actively improve their own work-place organization Score: 1 ☐2 ☐3 ☐4 ☐5☐99☐	a) Can you briefly describe the pregnant women's journey at the facility? b) How closely located are wards, theatres, diagnostics centres and consumables? c) How often do you run into problems with the current layout and pathway management?		
	Score 1: Lay-out of hospital and organization of workplace is not conducive to patient flow (e.g. ward is on different level from theatre or consumables are often not available in the right place at the right time)	*Score 3: Lay-out of hospital has been thought-through and optimized as far as possible; work place organisation is not regularly challenged/ changed (or vice versa)*	*Score 5: Hospital layout has been configured to optimize patient flow; workplace organization is challenged regularly and changed whenever needed*

2) Is there a standardised maternity care pathway at the facility? If yes, what was the rationale for Introducing Standardisation/Pathway Management?

Tests the motivation and impetus behind changes to operations and what change story was communicated Score:	a) How did you make improvements to the maternity care pathway? Can you describe a recent example to me? b) How often do you change the maternity care pathway? c) What factors led to the adoption of these practices? d) Who typically drives these changes?		
	Score 1: Changes were imposed top- down or because other departments were	*Score 3: Changes were made because of financial pressure and the need to save money*	*Score 5: Changes were made to improve overall performance, both clinical and*

1☐2☐3☐ 4☐ 5☐99☐	*making (similar) changes; rationale was not communicated or understood by all.*	*or as a (short-term) measure to achieve government and/ or external targets*	*financial, with buy-in from all affected staff groups; the changes were communicated in a coherent change story.*
3) Standardisation and Protocols *Tests if there are standardised procedures, guidelines and protocols for management of labour and childbirth that are applied and monitored systematically* Score: 1☐2☐3☐4 ☐5☐99☐	a) How standardised are the main clinical processes? b) How clear are clinical staffs on how specific procedures should be carried out? c) What tools and resources does the clinical staff employ (e.g. checklists) to quality care during labour and childbirth? d) How are managers able to monitor whether clinical staff are following established protocols?		
	Score 1: Little standardisation and few protocols exists	Score 3: Protocols have been created, but are not commonly used because they are too complicated, haven't been disseminated and not monitored adequately	Score 5: Protocols are known and used by all clinical staff and regularly followed up on through some form of monitoring or oversight
4) Good use of Human Resources *Tests whether staff are deployed to do what they are best qualified for, but nevertheless help out elsewhere when needed* Score: 1☐2☐3☐4☐5☐-99☐	a) With respect to your staff, what happens when there is a high volume of women coming to deliver at your hospital? b) How do you know which tasks are best suited to different staff? For e.g.: who conducts normal deliveries or caesareans or provides anaesthesia?		
	Score 1: Staff often end up undertaking tasks for which they are not qualified or over-qualified when they could be used elsewhere; staff are not utilised effectively, and tend to be generally underutilised	Score 3: Senior staff try to use the right staff for the right job, but do not go to great lengths to ensure this; staff may move but often in an uncoordinated manner	Score 5: Staff recognise effective human resource deployment as a key issue and will go to some lengths to make it happen; shifting staff from less busy to busy areas is done routinely and in a coordinated manner, based on the documented skills

<table>
<tr><td rowspan="2">5) Continuous Improvement
Tests processes for and attitudes towards continuous improvement, and whether learnings are captured and documented

Score:
1☐2☐3☐4 ☐5☐-99☐</td><td colspan="3">a) How do problems typically get exposed and fixed at this maternity facility?
b) Can you talk me through the process for a recent problem that you faced?
c) When processes do change, what is the main driver of change?
d) Who within the hospital typically gets involved in changing or improving? How do/ can different staff groups get involved in this process? Can you think of any examples?</td></tr>
<tr><td>Score 1: Process improvements are made only when problems occur, or only involve one staff group</td><td>Score 3: Improvements are made in irregular meetings involving all staff groups, to improve performance in their area of work (e.g. ward or theatre)</td><td>Score 5: Exposing problems in a structured way is integral to an individuals responsibilities and resolution involves all staff groups, along the entire patient pathway; exposing and resolving problems is a part of a regular business process rather than being the result of extraordinary efforts</td></tr>
<tr><td colspan="4">6) Who decides how work is allocated across clinical staff? All managers ☐Mostly managers☐ About the same☐ Mostly clinical leaders ☐All clinical leaders☐-9☐</td></tr>
<tr><td rowspan="2">7) Performance Tracking:
Tests whether performance is tracked using meaningful metrics and with appropriate regularity
Score:
1☐2☐3☐ 4☐ 5☐-99☐</td><td colspan="3">a) What kind of performance or quality indicators would you use for performance tracking?
b) How frequently are these measured?
c) Who gets to see these data?
d) If I were to walk through your hospital wards and operating rooms, could I tell how you were doing against your performance goals?</td></tr>
<tr><td>Score 1: Measures tracked do not indicate directly if overall objectives are being met (only government targets are tracked); tracking is an ad-hoc process (certain processes aren't tracked at all)</td><td>Score 3: Most important performance or quality indicators are formally tracked and overseen by senior staff</td><td>Score 5: Performance or quality indicators are continuously tracked and communicated against most critical measures, both formally and informally,</td></tr>
</table>

			to all staff using a range of visual management tools
8) Performance Review: *Tests whether performance is reviewed with appropriate frequency and communicated to staff* Score: 1☐2☐3☐4☐5☐-99☐	a) How do you review your main performance indicators? b) Can you tell me about a recent review meeting? c) Who is involved in these meetings? Who gets to see the results of this review? d) What is a typical follow-up plan that results from these meetings?		
	Score 1: Performance is reviewed infrequently or in an un-meaningful way (e.g. only success or failure is noted)	Score 3: Performance is reviewed periodically with both successes and failures identified; results are communicated to senior staff; no clear follow up plan is adopted	Score 5: Performance is continually reviewed, based on the indicators tracked; all aspects are followed up on, to ensure continuous improvement; results are communicated to all staff
9) Performance Dialogue: *Tests the quality of review meetings.* Score: 1☐2☐3☐4☐5☐-99☐	a) How are these review meetings structured? How is the agenda determined? Could you give me a recent example? b) During these meetings, do you find that you generally have enough information for review? c) How useful do you find these meetings? What type of feedback occurs in these meetings? d) For a given problem, how do you generally identify the root cause?		
	Score 1: The right information for a constructive discussion is often not present or the quality is too low; conversations focus overly on data that is not meaningful; a clear agenda is not known and purpose is not explicitly stated; next steps are not clearly defined	Score 3: Review conversations are held with the appropriate data present; objectives of meetings are clear to all participating and a clear agenda is present; conversations do not drive to the root causes of the problems; next steps are not well defined	Score 5: Regular review/ performance conversations focus on problem solving and addressing root causes; purpose, agenda and follow-up steps are clear to all; meetings are an opportunity for constructive feedback and coaching

10) Consequence Management: *Tests whether differing levels of performance (NOT personal but plan/ process based) lead to different consequence.* Score: 1☐2☐3☐4☐5☐-99☐	a) Let's say you've agreed to a follow-up plan at one of your meetings, what would happen if the plan weren't enacted? b) How long is it between when a problem is identified to when it is solved? Can you give me a recent example? c) How do you deal with repeated failures in obstetric care?		
	Score 1: Failure to achieve agreed objectives does not carry any consequences	Score 3: Failure to achieve agreed results is tolerated for a period before action is taken	Score 5: A failure to achieve agreed targets drives retraining in identified areas of weakness or moving individuals to where their skills are appropriate
11) Target Balance: *Tests whether targets cover a sufficiently broad set of metrics* Score: 1☐2☐3☐4☐5☐-99☐	a) What types of targets are set for the maternity unit? b) Are there any goals that are not set externally (e.g. by the government, regulators)?		
	Score 1: Goals focused only on government targets and achieving the budget	Score 3: Goals are balanced set of targets (including quality, waiting time, operational efficiency, and financial balance); goals form part of the appraisal for senior staff only or do not extend to all staff groups; real inter dependency is not well understood	Score 5: Goals are a balanced set of targets covering all four dimensions (see Score 3); interplay of all four dimensions is understood by senior and junior staff (clinicians as well as nurses and managers)
12) Target Inter-Connection *Tests whether maternity units targets are tied to overall hospital objectives and cascade down to different staff groups or members.* Score: 1☐2☐3☐4☐5☐-99☐	a) What is the motivation behind these goals? b) How are these goals cascaded down to the different staff groups or to individual staff members? c) How are maternity unit targets linked to overall hospital performance and its goals?		
	Score 1: Goals do not cascade down the organisation	Score 3: Goals do cascade, but only to some staff groups (e.g. nurses only)	Score 5: Goals increase in specificity as they cascade, ultimately defining individual expectations for all staff groups

13) Time Horizon of Targets Tests whether hospital has a '3 horizons' approach to planning and targets Score: 1☐2☐3☐4☐5☐-99☐	a) What kind of time scale are you looking at with your targets? b) Which goals receive the most emphasis? c) Are the long-term and short-term goals set independently? d) Could you meet all your short-run goals but miss your long-run goals?		
	Score 1: The staff's main focus is on achieving short-term targets	Score 3: There are short and long-term goals for all levels of the organisation; goals are set independently and therefore are not necessarily linked to one another	Score 5: Long-term goals are translated into specific short-term targets so that short-term targets become a 'staircase' to reach long-term goals
14) Target Stretch: Tests whether targets are appropriately difficult to achieve Score: 1☐2☐3☐4☐5☐-99☐	a) How tough are your targets for maternity care? How pushed are you by the targets? b) On average, how often would you say that you meet your targets? How are your targets benchmarked?		
	Score 1: Goals are either too easy or impossible to achieve, at least in part because they are set with little clinician involvement (e.g. simply off historical performance)	Score 3: Senior staff push for aggressive goals based on external benchmarks but with little buy-in from clinical staff.	Score 5: Goals are genuinely demanding for all parts of the organisation and developed in consultation with senior staff (e.g. to adjust external benchmarks appropriately)
15) Clarity and Comparability of Targets: *Tests how easily understandable performance measures are and whether performance is openly communicated* Score: 1☐2☐3☐4☐5☐-99☐	a) If I asked someone on your staff directly about individual targets, what would he or she tell me? b) Does anyone complain that the targets are too complex? c) How do people know how their own performance compares to other people's performance? Is this published or posted in any way?		
	Score 1: Performance measures are complex and not clearly understood, or only relate to government/ regulator targets; individual performance is not made public	Score 3: Performance measures are well defined and communicated; performance is public at all levels but comparisons are discouraged	Score 5: Performance measures are well defined, strongly communicated and reinforced at all reviews; performance and rankings are made public to induce competition

16) Rewarding High Performers *Tests whether good performance is rewarded proportionately* Score: 1☐2☐ 3☐ 4☐ 5☐-99☐	a) How does your staff appraisal system work? Can you tell me about your most recent one? b) How does your staff's pay relate to the results of this review? How does the bonus system work? c) Are there non-financial rewards for the best performers across all staff groups? d) How does your reward system compare to that at other comparable hospitals?		
	Score 1: Staff members are rewarded in the same way irrespective of their level of performance	Score 3: There is an evaluation system for the awarding of performance related rewards that are non-financial at the individual level; rewards are always or never achieved	Score 5: There is an evaluation system which rewards individuals based on performance; the system includes both personal financial and non-financial awards; rewards are awarded as a consequence of well-defined and
17) Removing Poor Performers *Tests whether hospital is able to deal with underperformers* Score: 1☐2☐3☐4☐5☐-99☐	a) If you had a clinician or a nurse who could not do his/her job, what would you do? Could you give me a recent example? b) How long is under-performance tolerated? How difficult is it to terminate a nurse/ clinician?		
	Score 1: Poor performers are rarely removed from their positions	Score 3: Suspected poor performers stay in a position for more than a year before action is taken	Score 5: We move poor performers out of the unit or to less critical roles as soon as a weakness is identified
18) Promoting High Performers Tests whether promotion is performance based Score: 1☐2☐3☐4☐5☐-99☐	a) Can you tell me about your career progression/ promotion system within the hospital? b) How do you identify and develop your star performers? What types of professional development/training opportunities are provided? c) How do you make decisions regarding progression/ promotions within the unit/ hospital?		
	Score 1: People are promoted primarily on the basis of tenure (years of service)	Score 3: People are promoted upon the basis of performance	Score 5: We actively identify, develop and promote our top performers

19) Managing HR/Talent *Tests what emphasis is put on talent/Human resource management* Score: 1☐2☐3☐4☐5☐-99☐	a) Do you have authority to hire or dismiss additional health workers? b) How do you ensure you have enough staff/ nurses of the right type in the hospital? c) How do senior managers show that attracting talented individuals and developing their skills is a top priority? d) Do senior staff members get any rewards for bringing in and keeping talented people in the hospital?		
	Score 1: Senior staff do not communicate that attracting, retaining and developing talent throughout the organisation is a top priority	Score 3: Senior staff believe and communicate that having top talent throughout the organisation is key to good performance	Score 5: Senior staff are evaluated and held accountable on the strength of the talent pool they actively build
20) Retaining Talent: *Tests whether hospital will go out of its way to keep its top talent* Score: 1☐2☐3☐4☐5☐-99☐	a) If you had a top performing manager, nurse or clinician that wanted to leave, what would the hospital do? b) Could you give me an example of a star performer being persuaded to stay after wanting to leave? c) Could you give me an example of a star performer who left the hospital without anyone trying to keep them?		
	Score 1: We do little to try and keep our top talent	Score 3: We usually work hard to keep our top talent	Score 5: We do whatever it takes to retain our top talent across all staff groups
21) Attracting Talent *Tests the strength of the employee value proposition* Score: 1☐2☐3☐4☐5☐-99☐	a) What makes it attractive to work at this hospital, as opposed to other similar hospitals? b) If I was a top nurse/clinician and you wanted to persuade me to work at your hospital, how would you do this? c) What do you think people may not like about working at your hospital?		
	Score 1: Competing hospitals offer stronger reasons for talented people to join their organizations	Score 3: Our value proposition is comparable to those offered by other hospitals	Score 5: We provide a unique value proposition to encourage talented individuals to join our hospital compared to our competition
	a) Can you tell me about the role that clinicians (e.g. doctors/ consultants) have in improving performance and achieving targets? b) How are individual clinicians responsible for delivery of targets? Does this apply to cost targets as well as quality		

22) Clearly Defined Accountability for Clinicians *Tests whether there is formal leadership roles and accountability among clinicians for delivery of hospital targets*	Score 1: Formal accountability for clinical performance (quality) only	Score 3: There is some accountability for delivery beyond clinical quality but this might be diffused within a team or not carry significant consequences; clinical performance still considered to be the main part of the job	Score 5: Formal accountability across quality service and cost dimensions with effective performance management and consequences for good/ poor performance
Post - Interview			
23) Interview duration (minutes) _____			
24) Interviewee knowledge of management practices Score:1☐2☐3☐4☐5☐	Score 1: Some knowledge about management of maternity facilities.	Score 3: Expert knowledge management of maternity unit	Score 5: Expert knowledge about his specialty and also the rest of the hospital.
25) Interviewee willingness to reveal information Score:1☐2☐3☐4☐5☐	Score 1: Very reluctant to provide more than basic information	Score 3: Provides all basic information and some more confidential information	Score 5: Totally willing to provide any information about the hospital!
26) Interviewee patience Score:1☐2☐3☐4☐5☐	Score 1: Little patience - wants to run the interview as quickly as possible. I felt heavy time	Score 3: Some patience - willing to provide richness to answers but also time constrained. I felt moderate time pressure	Score 5: Lot of patience - willing to talk for as long as required. I felt no time pressure
27) Did the manager mention that the hospital was a teaching hospital?	28) Age of interviewee (don't ask) - guess if not told	29) Number of times rescheduled (0=never rescheduled)	30) Gender of interviewee: Male ☐Female ☐
31) Seniority of interviewee: 1. CEO ☐ 2. Multi-specialty manager☐ 3. Specialty Manager ☐		32) Did the interviewee have a degree - guess if not told	33) Interview language Hindi ☐ English ☐

4. Within specialty management 5. Technician without management role (e.g. nurse or junior doctor)☐		

Appendix 3: Information sheets and consent forms

3.1: Information Sheet for health workers for clinical practice observation

Dear Madam/Sir,

We are conducting a study to understand the quality of maternal and newborn health services provided at several health facilities in UP, India including this health facility. This sheet provides you with information about this research. This study has been approved by the Public Healthcare Society (PHS) Ethics Review Board in India and the London School of Hygiene & Tropical Medicine in the UK (LSHTM Ethics Ref: 8858). The study protocol also received clearance from the National Health Mission in Uttar Pradesh. We have also obtained permission from the facility in charge/ hospital director to observe the care provided at this facility today.

Why is this important?

As you know, many women and babies die due to complications during pregnancy and childbirth in UP. Hence, we are conducting this research to understand more about the quality of services offered at health facilities so that we can improve the quality of obstetric and neonatal care services.

Who is carrying out the study?

This study is funded by Merck for Mothers. It is being run by a small team of researchers from Sambodhi and the London School of Hygiene and Tropical Medicine (LSHTM).

What is involved?

A clinically qualified researcher will observe the quality of services offered to women and neonates during labour and childbirth and the immediate postnatal period. The observer is not there to support you or interfere with any aspects of clinical care provision.

Is this research confidential?

Yes. Any information obtained from this research is confidential and will only be seen by the members of the research team. All information will be stored securely. This means any findings obtained from the clinical observations will not be linked to any individual health worker or facility.

What are the benefits of taking part in this research?

There are no direct benefits to you for participating in this research. However, we will use the information obtained from this survey to improve the healthcare services at selected health facilities in UP, India.

What are the risks in taking part?

There are no risks because of taking part in this research. Your personal identity will be protected at all times and this will have no impact on your work at this health facility.

Do I have to take part in this research?

No. If you decide not to participate in the study, it will not have any effect on any of the services that you receive.

How will the research findings be used?

The findings of the research will be used to develop a report which will highlight the existing quality of maternal and neonatal health services provided at selected health facilities in three districts in Uttar Pradesh, India.

Thank you for taking the time to read this information. We really appreciate your participation in this research.

The research will only proceed once you have asked any other questions that you may have and have signed the relevant consent forms. You can keep this information sheet with you.

If you have any questions or opinions about this study, please contact:

LSHTM: GAURAV SHARMA, + +918601882687; Gaurav.Sharma@lshtm.ac.uk

3.2: Consent form for health worker on clinical practice observation

Instructions: When health worker arrives to conduct a delivery, please provide him or her with the information sheet. It is essential that you obtain an informed consent from the health worker before beginning the observation. Please ask the health worker to sign and date the consent form once they have read the information below and agree to participate in the study.

I _____agree to take part in this study on the quality of maternal and newborn care services provided at this health facility.

I understand that:

- I am agreeing to allow a clinically qualified researcher to observe aspects of clinical care provision.
- All the findings from this research are confidential and will not be linked to my name or any personal information.
- My participation is completely voluntary and refusal to participate will not have any implications on me or my work at this health facility.
- I have been provided with the necessary information about this research and have also had an opportunity to clarify all my questions.

My questions have been answered by _____

Signature of the health worker _____

Date: _____

3.3: Woman consent form for clinical practice observation
चिकित्सीय व्यवहार आब्जर्वेशन के लिए सेवाग्राही (क्लाएंट) की सहमति

INSTRUCTIONS TO OBSERVER

आब्जर्वर के लिए निर्देश

When a pregnant woman arrives at the emergency room or waiting room of the labour and delivery ward, please provide her the information sheet before enrolling her in the study. It is essential that you obtain an informed consent from the client before beginning the observation. If the client cannot read a thumb print should be obtained. Consent for client cannot be given by health worker or facility in-charge.

जब कोई गर्भवती महिला आपात्कालीन कक्ष में या प्रसव और प्रसूति वार्ड के प्रतीक्षा कक्ष में आये तो यइस अध्ययन में नामांकित करने से पहले उसे यह जानकारी शीट दें। यह आवश्यक है कि आब्जर्वेशन (पर्यवेक्षण) करने से पहले आप सेवाग्राही (क्लाएंट) की जानकारीयुक्त सहमति प्राप्त कर लें। अगर सेवाग्राही पढ़ लिख नहीं सकती तो उसके अंगूठे का निशान लिया जाना चाहिए। क्लाएंट के लिए स्वास्थ्य कार्यकर्ता या स्वास्थ्य सुविधा का प्रभारी सहमति नहीं दे सकता।

I understand that:

मैं समझती हूं कि:

I am agreeing to allow a clinically qualified researcher to observe the quality of services that I receive at this health facility today.

मैं एक चिकित्सीय रूप से योग्य शोधकर्ता को आज इस सुविधा में मुझे प्राप्त होने वाली सेवाओं की गुणवत्ता को आब्जर्व करने या देखने की अनुमति दे रही हूं।

All the findings from this research are confidential and will not be linked to my name or any personal information.

इस शोध के सभी निष्कर्ष गोपनीय हैं और उन्हें मेरे नाम या किसी व्यक्तिगत जानकारी से नहीं जोड़ा जायेगा।

My participation is completely voluntary and will not have any implications on the services that I receive today.

मेरी भागीदारी पूरी तरह से स्वैच्छिक है और मैं जो सेवाएं प्राप्त कर रही हूं उन पर इसका कोई प्रभाव नहीं पड़ेगा।

I have been provided with the necessary information about this research and have also had an opportunity to clarify all my questions.

मुझे इस शोध के बारे में आवश्यक जानकारी दे दी गई है और मुझे प्रश्न पूछने का अवसर भी मिला है।

My questions have been answered by _____
मेरे प्रश्नों के उत्तर

Thumb print _____
अंगूठे का निशान

Signed _____
हस्ताक्षर

Date: _____
तिथि

I attest that I read the consent form to the participant and she has agreed to participate.
मैं यह प्रमाणित करता हूं कि मैंने सहभागी को सहमति पत्र पढ़कर सुनाया है और वह भाग लेने के लिए सहमत है।

Researcher's signature: _____
शोधकर्ता के हस्ताक्षरः

Date: _____
तिथिः

Appendix 4: Ethical approval letters and permissions

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

LSHTM

18 May 2015

Dear

Study Title: Quality of Care for normal labour and childbirth at maternity facilities in Uttar Pradesh, India: A Cross-Sectional Study

LSHTM Ethics Ref: 8858

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Covering Letter	Covering letter after resubmission 14.5.15	14/05/2015	2
Protocol / Proposal	Consent and info sheet combined 5.5.15	14/05/2015	2
Information Sheet	Consent and info sheet combined 5.5.15	14/05/2015	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Approval Letter

PHS
Public Healthcare Society

22nd May 2015

To

Mr. Kultar Singh
Principal Investigator
Chief Executive Officer
Sambodhi Research and Communications Pvt. Ltd.
O2, 2nd and 3rd Floor, Lajpat Nagar-II
New Delhi - 110024

Dear Mr. Singh,

PHS-SRB has reviewed and discussed your application to conduct the proposed study entitled **"Evaluation of the Sky Social Franchising Model In Uttar Pradesh (QOC for Normal Labour and Childbirth at Maternity Facilities in Uttar Pradesh, India: A Cross Sectional Study)"** on **22nd May 2015**.

The following documents were reviewed:

a. Research Protocol, Version 2.0 dated 08/Apr/2015
b. Informed Consent Form (Hospital Director on Staffing Characteristics and Clinical Practice Observations, Health Worker on Clinical Practice Observation and Client Clinical Practice Observation): English, Version 2.0 dated 08/Apr/2015
c. Informed Consent Form (Hospital Director on Staffing Characteristics and Clinical Practice Observations, Health Worker on Clinical Practice Observation and Client Clinical Practice Observation): Hindi, Version 2.0 dated 12/Apr/2015,
d. Informed Consent Form (Hospital Director on Staffing Characteristics and Clinical Practice Observations, Health Worker on Clinical Practice Observation and Client Clinical Practice Observation): English- Back Translation, Version 2.0 dated 15/Apr/2015
e. Questionnaire on Staffing Characteristics, English, Version 2.0 dated 08/Apr/2015
f. Questionnaire on Staffing Characteristics, Hindi, Version 2.0 dated 12/Apr/2015
g. Questionnaire on Staffing Characteristics, English- Back Translation, Version 2.0 dated 15/Apr/2015
h. Translation Certificates

The PHS-SRB decision on your study proposal/documents is as follows:

☑ Approval (valid from 22nd May 2015 until next amendment)
☐ Conditional Approval _____
☐ Disapproval
☐ Modification before approval _____
☐ Discontinuation of previously approved project

The following members of the PHS-SRB were present at the meeting held on 22nd May 2015 at 03:45 PM in the Board Room, Hotel Tulip Inn, Hari Nagar, New Delhi.

प्रेषक,

मिशन निदेशक,
राष्ट्रीय स्वास्थ्य मिशन,
उत्तर प्रदेश, लखनऊ।

सेवा में,

मुख्य चिकित्साधिकारी,
जनपद–कानपुर नगर, कानपुर देहात, कन्नौज औरैया, फतेहपुर व इटावा।

पत्र संख्या–एन0आर0एच0एम0/एस0पी0एम0यू0/99/14–15/4027-6 दिनांक–11.12.2014

विषय– पाथफाइंडर इंटरनेशनल एवं वर्ल्ड हेल्थ पार्टनर्स द्वारा क्रियान्वित **"मातृका"** परियोजना पर शोध व मूल्यांकन किये जाने के सन्दर्भ में।

महोदय,

अवगत कराना है कि प्रदेश के तीन जनपदों–कानपुर नगर, कानपुर देहात एवं कन्नौज में गुणवत्तापूर्ण मातृ स्वास्थ्य सेवाएं प्रदान कर मातृ मृत्यु दर और रूग्णता को कम करने के लिये पाथफाइंडर इंटरनेशनल एवं वर्ल्ड हेल्थ पार्टनर्स द्वारा **"मातृका"** परियोजना का संचालन किया जा रहा है। इस परियोजना का मुख्य लक्ष्य मौजूदा सरकारी एवं निजी मातृ स्वास्थ्य सेवाओं को विस्तृत करना एवं उनकी कार्यक्षमता में वृद्धि करना है। यह परियोजना ब्लॉक स्तर पर **"स्काई सेन्टर"** के माध्यम से निःशुल्क/न्यूनतम शुल्क पर सरकारी एवं निजी स्वास्थ्य प्रदाताओं के बीच समन्वय स्थापित कर प्रसव पूर्व देखभाल, परिवार नियोजन सुरक्षित संस्थागत प्रसव एवं जननी सुरक्षा योजना अथवा आपातकालीन मातृ प्रसूति सेवाओं को सही समय से माताओं तक पहुँचाने के लिये एक नया रेफरल नेटवर्क बना रही है।

परियोजना की गुणवत्ता का मूल्यांकन करने के लिये **"सम्बोधि रिसर्च एवं कम्यूनीकेशनस् प्रा0 लि0"** द्वारा **"लंदन स्कूल ऑफ हाइजीन एण्ड ट्रापिकल मेडिसिन"** के सहयोग से 03 परियोजना जनपदों (कानपुर नगर, कानपुर देहात, कन्नौज) एवं 03 कन्ट्रोल जनपदों (औरैया, फतेहपुर व इटावा) में शोध एवं मूल्यांकन गतिविधि आरम्भ की जानी है। इस शोध एवं मूल्यांकन गतिविधि में परियोजना द्वारा लाभान्वित परिवारों एवं परियोजना से जुड़े विभिन्न सरकारी अधिकारियों से बातचीत के माध्यम से परियोजना की उपयोगिता के बारे में जानकारी ली जायेगी।

कृपया संस्था को अपने जनपद में आवश्यक सहयोग प्रदान करने का कष्ट करें।

भवदीय,

10/12/14

(अमित कुमार घोष)
मिशन निदेशक

पत्रसंख्या–एन0आर0एच0एम0/एस0पी0एम0यू0/99/14–15/4026-6-3 तद्दिनांक।

प्रतिलिपि– निम्नलिखित को आवश्यक कार्यवाही हेतु सूचनार्थ प्रेषित।

1. महानिदेशक, परिवार कल्याण, परिवार कल्याण महानिदेशालय, उ0प्र0।
2. मण्डलीय अपर निदेशक, कानपुर मण्डल एवं इलाहाबाद मण्डल।
3. डॉ0 नेहा सिंह, राज्य कार्यक्रम प्रबन्धक, पाथफाइंडर इंटरनेशनल।

10/12/14

(अमित कुमार घोष)
मिशन निदेशक

प्रेषक,

मुख्य चिकित्साधिकारी,
कानपुर नगर।

सेवा में,

प्रमुख चिकित्सा अधीक्षिका,
ए0एच0एम0 एण्ड डफरिन चिकित्सालय,
कानपुर नगर।

प्रमुख चिकित्सा अधीक्षक,
एल0एल0आर0 एवं सम्बद्ध चिकित्सालय
कानपुर नगर।

मुख्य चिकित्सा अधीक्षक,
के0पी0एम0 एवं मा0 कांशीराम संयुक्त चिकि0,
कानपुर नगर।

चिकित्सा अधीक्षक,
समस्त सामु0स्वा0केन्द्र,
कानपुर नगर।

पत्रांक : मु0चि0अ0 / मातृका परि0 / सरकुलर / 2015 / दिनांक : 06.06.2015

विषय : पाथफाइडर इंटरनेशनल एवं वर्ल्ड हेल्थ पार्टनर्स द्वारा कियान्वित "मातृका" परियोजन पर शोध व मूल्यांकन किये जाने के संदर्भ में।

महोदय / महोदया,

उपरोक्त विषयक मिशन निदेशक, राष्ट्रीय स्वास्थ्य मिशन, उ0प्र0 लखनऊ के पत्र संख्या एन0आर0एच0एम0 / एस0पी0एम0यू0 / 99 / 14–15 / 4027–6 दिनांक 11.12.2014 को संलग्न कर आपको इस आशय के साथ प्रेषित किया जा रहा है कि पत्र में दिये गये निर्देशानुसार सम्बन्धित संस्था के प्रतिनिधि आपके चिकित्सालय में उपस्थित होने पर इनका पूर्ण सहयोग प्रदान करने का कष्ट करें।

संलग्नक : उपरोक्तानुसार।

भवदीय

मुख्य चिकित्साधिकारी,
कानपुर नगर।

पत्रांक : मु0चि0अ0 / मातृका परि0 / सरकुलर / 2015 / 3776-4 तद्दिनांक।

प्रतिलिपि निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित–

1. मिशन निदेशक, राष्ट्रीय स्वास्थ्य मिशन, उ0प्र0 लखनऊ।
2. महानिदेशक, परिवार कल्याण महानिदेशालय, उ0प्र0 लखनऊ।
3. डा0 नेहा सिंह, राज्य कार्यक्रम प्रबन्धक, पाथफाइडर इंटरनेशन।
4. अपर निदेशक, चिकित्सा स्वास्थ्य एवं परिवार कल्याण, कानपुर मण्डल कानपुर।
5. अपर मुख्य चिकित्साधिकारी (आरसीएच / प्रतिरक्षण), कानपुर नगर।

6/6/15

मुख्य चिकित्साधिकारी,
कानपुर नगर।

कार्यालय,मुख्य चिकित्सा अधिकारी,कानपुर देहात।

पत्रांक – मु0चि0अधि0 / मातृका / शोध एवं मूल्यांकन गतिविधि / 2015 /1920 दिनांक 29.05.2015

विषय :– परियोजना द्वारा लाभान्वित परिवारो एवं परियोजना से जुडे विभिन्न सरकारी अधिकारियों से बातचीत के माध्यम से परियोजना की उपयोगिता की जानकारी के सम्बन्ध में।

श्री हसन मेहदी,फील्ड मैनेजर,
सम्बोधि रिसर्च एवं कन्सूनिकेशनस् प्रा0लि0
द्वारा – लंदन स्कूल ऑफ हाइजीन एण्ड ट्रापिकल मेडिसिन।

आपके पत्र दिनांक 20.05.2015 के क्रम में आपको **पाथ फाइन्डर इन्टरनेशनल एवं वर्ल्ड हेल्थ पार्टनर्स** के सहयोग से संचालित मातृका परियोजना पर पैरामेडिकल टीम के साथ चयनित स्थानो पर शोध कार्य करने की अनुमति इस स्तर से प्रदान की जाती है।

मुख्य चिकित्सा अधिकारी,
कानपुर देहात।

पत्रांक – पत्रांक – मु0चि0अधि0 / मातृका / शोध एवं मूल्यांकन गतिविधि / 2015 तद्दिनांक
प्रतिलिपि – निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित।

1. महानिदेशक,परिवार कल्याण,परिवार कल्याण महानिदेशालय,उ0प्र0।
2. अपर निदेशक,चिकित्सा स्वास्थ्य एवं परिवार कल्याण,कानपुर मण्डल कानपुर।
3. डा0नेहा सिंह,राज्य कार्यक्रम प्रबन्धक,पाथ फाइंडर इन्टरनेशनल।

मुख्य चिकित्सा अधिकारी,
कानपुर देहात।

Appendix 5: Published manuscript for Chapter 6

Quality of routine essential care during childbirth: clinical observations of uncomplicated births in Uttar Pradesh, India

Gaurav Sharma,[a] Timothy Powell-Jackson,[a] Kaveri Haldar,[b] John Bradley[a] & Véronique Filippi[a]

Objective To evaluate the quality of essential care during normal labour and childbirth in maternity facilities in Uttar Pradesh, India.
Methods Between 26 May and 8 July 2015, we used clinical observations to assess care provision for 275 mother–neonate pairs at 26 hospitals. Data on 42 items of care were collected, summarized into 17 clinical practices and three aggregate scores and then weighted to obtain population-based estimates. We examined unadjusted differences in quality between the public and private facilities. Multilevel linear mixed-effects models were used to adjust for birth attendant, facility and maternal characteristics.
Findings The quality of care we observed was generally poor in both private and public facilities; the mean percentage of essential clinical care practices completed for each woman was 35.7%. Weighted estimates indicate that unqualified personnel provided care for 73.0% and 27.0% of the mother–neonate pairs in public and private facilities, respectively. Obstetric, neonatal and overall care at birth appeared better in the private facilities than in the public ones. In the adjusted analysis, the score for overall quality of care in private facilities was found to be six percentage points higher than the corresponding score for public facilities.
Conclusion In 2015, the personnel providing labour and childbirth care in maternity facilities were often unqualified and adherence to care protocols was generally poor. Initiatives to measure and improve the quality of care during labour and childbirth need to be developed in the private and public facilities in Uttar Pradesh.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

The quality of care offered at maternity facilities not only affects pregnant women – both emotionally and physically – but also has an impact on the long-term health and survival of mothers and neonates.[1,2] An increased focus on care during childbirth can lead to reductions in disability, maternal and neonatal mortality and stillbirths.[2,3]

An estimated 72% of all deliveries – including 69% of those in South Asia – now occur in health facilities.[4] Even in health facilities, however, failures in the processes of care can result in bad obstetric and neonatal outcomes[5,6] and care of poor quality often leads to low demand for maternal health services.[7,8] Some routine interventions can be ineffective or even harmful.[9]

Despite substantial efforts to promote evidence-based obstetrics, the uptake of recommended interventions into clinical practice has been limited.[10–12] Clinical practices can be difficult to change because they are influenced by health worker and patient characteristics, the complexity of the tasks involved and the institutional and sociocultural environments.[13,14]

In 2015, the estimated number of maternal deaths in India was higher than that in any other country apart from Nigeria.[15] India has to make rapid improvements in its levels of maternal mortality if the Global Strategy for Women's, Children's and Adolescents' Health's targets are to be met by 2030.[16] Maternity services in India are available from an enormous range of health providers. Maternity care in the public sector is provided through a network of primary, secondary and tertiary facilities that, in principle, provide routine care, basic emergency obstetric care and comprehensive emergency obstetric care, respectively.[17] In the private sector, maternity care is provided by a heterogeneous collection of facilities that range from small maternity homes to large multispecialty medical colleges and tertiary hospitals.

An analysis of the results of Demographic and Health Surveys conducted in 57 countries between 2000 and 2013 revealed that, in the various regions of the world, the private sector accounted for 9–56% of deliveries.[18] In 2003–2005, an estimated 22% of all deliveries in India occurred in the private sector.[19] Among Indian women, previous negative pregnancy outcomes and relatively high socioeconomic status are positively associated with use of private facilities[19] whereas belonging to a so-called scheduled caste or tribe is negatively associated with such use.[20] The private sector is more expensive than the public sector but most Indians associate the private sector with better amenities and a higher standard of care.[20]

Although much information exists on the quality of emergency obstetric care in India,[21,22] there appears to have been little research on the quality of normal labour and childbirth care, particularly in private facilities. The results of a few relevant qualitative studies on the public sector have generally revealed care of poor quality, often characterized by high rates of labour augmentation, routine episiotomies, no choice of position, non-adherence to protocols, limited monitoring, early discharge from the hospital and poor neonatal care.[23–25] In most areas of the world, deliveries in the private sector are much more likely to be by caesarean section than deliveries in the public sector.[26–29] This paper reports findings from clinical observations that were used to describe and investigate the quality of care provided routinely, for uncomplicated labour and childbirth, in maternity facilities in Uttar Pradesh, India.

Methods

Study setting

This study was conducted in three districts of Uttar Pradesh: Kannauj, Kanpur Dehat and Kanpur Nagar.[30] In 2012–2013,

[a] London School of Hygiene & Tropical Medicine, Keppel Street, London, WC1E 7HT, England.
[b] Sambodhi Research and Communications, New Delhi, India.
Correspondence to Gaurav Sharma (email: drsharmag@gmail.com).
(*Submitted: 14 June 2016 – Revised version received: 30 December 2016 – Accepted: 3 January 2017 – Published online: 24 April 2017*)

Uttar Pradesh was the Indian state with the largest population and the second and third highest levels of maternal and neonatal mortality, respectively.[31] At this time, the estimated number of neonatal deaths per 1000 live births was 55 deaths in Kannauj, 41 deaths in Kanpur Dehat and 24 deaths in Kanpur Nagar. The estimated percentage of deliveries occurring in public and private facilities, respectively, was 43% and 15% in Kannauj, 46% and 10% in Kanpur Dehat, and 34% and 34% in Kanpur Nagar.[31] Also widespread inequities across the continuum of care existed – in terms of the recorded indicators of maternal, neonatal and reproductive health – in the three study districts.[31]

Sampling

We used a multistage sampling method. The initial sampling frame included 59 facilities in Uttar Pradesh that provided maternity services: all 29 of the larger public facilities listed by the Indian Department of Health – i.e. facilities that reported at least 200 deliveries per month[32] and, in theory, provided basic emergency obstetric care at all hours of the day and night – plus the 30 private facilities that, in theory, provided continuous maternity care. The private facilities were identified by key informants from Sambodhi Research and Communications (Lucknow, India) – an organization that has worked in health research in the study districts for several years.

In the second stage of sampling, we attempted to select six public facilities per district – i.e. a random selection of four of the community health centres, one of the medical colleges and one of the district hospitals. Since Kanpur Dehat did not have a medical college, we had to select an additional district hospital. Although we invited the 18 selected public facilities and all 30 private facilities to participate in our study, 13 facilities – all private – refused to participate. At nine of the facilities that agreed to participate – again all from the private sector – no deliveries occurred while observers were present. The observational data that we analysed therefore came from 18 public facilities and eight private (Fig. 1). Power calculations were used to estimate the number of observations required at each facility (available from the corresponding author). We expected observations of up to 10 deliveries to be completed either over the two days of observation at each public facility or over the week of observation at each private facility. The 211 observed deliveries from 18 public sector facilities are a sample of an estimated 41 512 annual deliveries that occurred in 18 public sector facilities in 2015. The 64 observed deliveries from eight private sector facilities represented 3 579 deliveries from 8 private sector facilities in 2015. These data on annual caseloads were self-reported by health facilities and collected by us during the study. The larger household survey in three study districts found that public sector deliveries account for 54.8% ($n = 1943$), private sector account for 13.7% ($n = 486$) and home deliveries account for 31.5% ($n = 1117$) annually. The public sector was found to be 3.98 times larger than the private sector. Therefore, to get a representative sample of births by health facility, we multiplied the private sector births by a factor of 2.94 to get a total of 10 535.

Study participants and sites

Study participants were pregnant women with spontaneous, uncomplicated labours who gave their written informed consent. Pregnant women were enrolled if they had a gestational age between 37 and 42 weeks and a singleton pregnancy with vertex presentation. We observed the post-admission care provided to these women and their neonates until one hour postpartum.

Data collection

We developed an assessment tool (available from the corresponding author) based on a critical assessment of previously tested instruments[12,33] and the relevant World Health Organization guidelines.[34] Questions capturing demographic, educational and socioeconomic status were adapted from the National Family Health Survey questionnaire.[35] At maternity facilities, 14 trained

Fig. 1. **Flowchart showing the selection and investigation of participants for the study of the quality of maternal and neonatal care at birth, Uttar Pradesh, India, 2015**

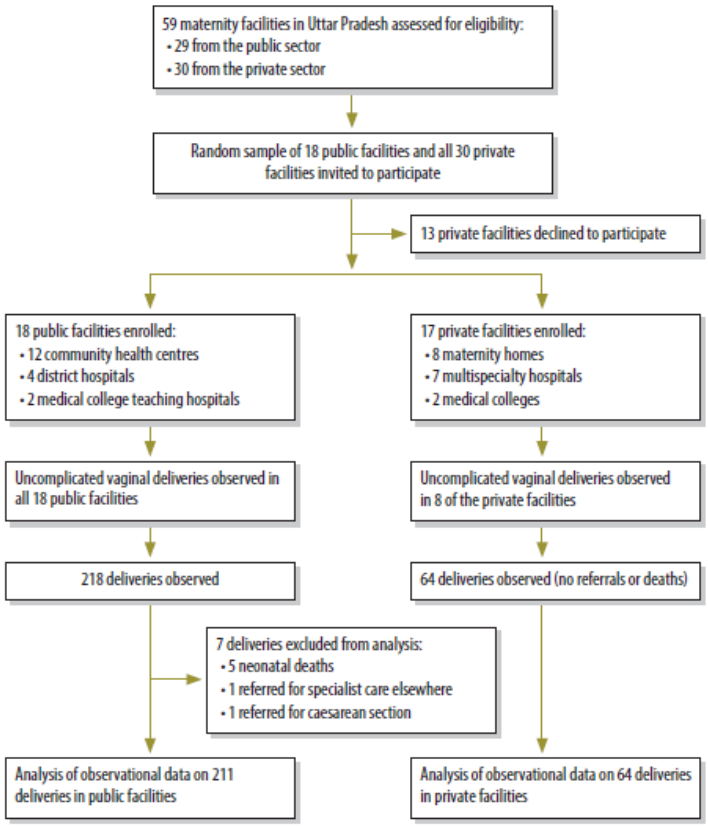


Table 1. **Framework used for the assessment of essential care at birth, India, 2015**

Timing	Obstetric care		Fetal or neonatal care	
	Clinical practice	Observed items	Clinical practice	Observed items
On admission and during first stage of labour	Regular monitoring of labour using a partograph	Is labour monitored regularly with partograph?	Check fundal height and fetal presentation	Is fundal height checked and is fetal presentation checked?
	Measures for the prevention of maternal infection during admission	Are hands washed before examination and are sterile gloves put on before vaginal examination?	Regular monitoring of fetal heart rate	Is fetal heart rate monitored at regular intervals?
	Screening for pre-eclampsia and eclampsia	Is blood pressure monitored and urine tested for proteins?		
From second stage of labour to completion of childbirth	Measures for the prevention of maternal infection during childbirth	Are sterile gloves put on before vaginal examination and are vulva and perineum cleaned with antiseptic?	Health workers prepared for resuscitation if required	Is ventilation bag available and is neonatal mask available and laid out?
	Active management of the third stage of labour	Is uterotonic given within minute of birth, is the cord clamped and is there controlled cord traction?	Neonatal cord care	Is cord cut with a sterile instrument?
	Assessment of maternal blood loss	Are the placenta and membranes checked for completeness, is the vagina checked for tears and is there monitoring of bleeding postpartum?	Appropriate thermal care of neonate	Is neonate dried properly; is skin-to-skin contact between neonate and mother initiated and is the neonate covered with a dry towel?
	Use of woman-centred respectful care practices	Is process of labour explained to the mother or support person at least once, is companion allowed to be with the mother during labour, is mother informed before vaginal examination, is visual privacy ensured and is mother asked about choice of position?	Assessment of Apgar score	Is the Apgar score assessed one minute after birth and is it assessed five minutes after birth?
			Initiation of early breastfeeding	Did the mother initiate breastfeeding within hour of birth?
	Avoidance of harmful or unnecessary interventions for mother	Is an enema given, is the pubic area shaved, is fundal pressure applied to hasten delivery of baby or placenta, is there uterine lavage after delivery, is there manual exploration of the uterus after delivery and is there use of episiotomy without any indication?	Avoidance of harmful or unnecessary practices for neonate	Is their routine aspiration of neonate's nose, is the neonate slapped and is the neonate held upside down?
	Avoidance of harmful or unnecessary health worker behaviour	Does the health worker restrict mother's fluid and food intake during labour; do they insult, shout or threaten the mother during labour and childbirth; and, do they hit, pinch or slap the mother during labour and childbirth?		

Note: We assessed nine obstetric care and eight neonatal care practices.

enumerators with a clinical background visited the admissions, emergency, labour and postnatal wards to identify pregnant women who were likely to undergo uncomplicated vaginal births. Two enumerators were then stationed at each facility for either two days – if the facility was in the public sector – or a week – if the facility was in the private sector – and they observed round-the-clock provision of care for mothers and their neonates. Data were collected between 26 May and 8 July 2015.

Ethics

We obtained ethical approval from the Ethics Review Board of the Public Health-care Society and the Indian Council for Medical Research in India, and the London School of Hygiene & Tropical Medicine in the United Kingdom of Great Britain and Northern Ireland.

Measures

Learning from previous quality measurement efforts,[36,37] our assessments of quality of care encompassed not only the provision of clinical care but also clients' experiences of care. We investigated both the application of evidence-based practices – including use of potentially harmful interventions – and woman-centred respectful care practices during the birthing process.[38] We collected data on 42 items of care for each observation (Table 1). Each item was coded 1 if completed and 0 if not. We then aggregated the items into 17 care practices – i.e. nine obstetric and eight neonatal – and

scored each practice 1 if fully completed and 0 if not (Table 1). Some practices were based on a single item and some were based on multiple items. Finally, summary scores for obstetric care, neonatal care and overall essential care at birth – based on the relevant nine, relevant eight and all 17 clinical practices, respectively – were calculated as the percentage of the practices measured that were completed for each woman.

For each woman investigated, data on household ownership of a common set of assets were collected and then used, in principal components analysis, to generate quintiles of wealth status.[39] We recorded the age, caste, day and time of admission, parity, referral status and wealth quintile of each woman, whether the birth attendants were qualified or unqualified and the facilities' maternity caseloads – i.e. the numbers of deliveries recorded in 2014.

Analysis

Descriptive analyses were carried out at the level of individual women. We used the *svy* command in Stata version 14 (StataCorp. LP, College Station, United States of America) to account for clustering and to incorporate weights based on each facility's maternity caseload. All of the percentages shown in the Results section are weighted estimates. Frequencies, means, prevalence and proportions were calculated for covariates disaggregated by sector. A two-level linear mixed-effects model was used – with a random effect at the facility level to account for clustering.[40] The exposure variable was public or private sector. The explanatory variables were the birth attendant's and women's characteristics and the maternity caseloads that we had recorded and – to reduce the effects of

Table 2. **Characteristics of pregnant women with uncomplicated births investigated in public and private maternity facilities, Uttar Pradesh, India, 2015**

Characteristic	Unweighted numbers (%)			Weighted percentages[a]			*P*[b]
	Total (*n* = 275)	Public (*n* = 211)	Private (*n* = 64)	Total (*n* = 52 047)	Public (*n* = 41 512)	Private (*n* = 10 535)	
Age in years							0.85
< 20	16 (5.8)	12 (5.6)	4 (6.2)	5.5	5.7	4.4	
20 to 34	247 (89.8)	191 (90.5)	56 (87.5)	90.4	90.4	90.5	
≥ 35	12 (4.3)	8 (3.7)	4 (6.2)	4.1	3.8	5.1	
Parity							0.3
Primipara	119 (43.2)	90 (42.6)	29 (45.3)	44.0	41.6	53.4	
Multipara	156 (56.7)	121 (57.3)	35 (54.7)	56.0	58.4	46.6	
Referral status							0.003
Came directly to study facility	243 (88.4)	197 (93.4)	46 (71.9)	91.5	95.9	74.1	
Referred from another facility	32 (11.6)	14 (6.6)	18 (28.1)	8.5	4.0	25.9	
Caste category							0.002
Scheduled caste	59 (21.4)	53 (25.1)	6 (9.4)	24.2	28.7	6.4	
Scheduled tribe	2 (0.7)	0 (0.0)	2 (3.1)	0.3	0.0	1.4	
Other backward caste	153 (55.6)	111 (52.6)	42 (65.6)	51.4	48.9	61.1	
General caste	61 (22.2)	47 (22.3)	14 (21.8)	24.1	22.3	31.0	
Wealth quintile							0.07
First (poorest)	56 (20.4)	49 (23.2)	7 (11.0)	22.5	24.2	15.9	
Second	54 (19.6)	46 (21.8)	8 (12.5)	17.7	19.5	10.6	
Third	55 (20.0)	36 (17.0)	19 (29.6)	17.7	17.6	18.2	
Fourth	55 (20.0)	46 (21.8)	9 (14.0)	19.5	21.9	9.9	
Fifth (wealthiest)	55 (20.0)	34 (16.1)	21 (32.8)	22.5	16.7	45.3	
Type of birth attendant							0.01
Qualified[c]	113 (41.1)	75 (35.5)	38 (59.4)	36.2	27.0	73.0	
Unqualified[d]	162 (58.9)	136 (64.5)	26 (40.6)	63.8	73.0	27.0	
Timing of admission							0.003
Within daytime work-hours[e]	254 (92.3)	191 (90.5)	63 (98.4)	94.4	93.1	99.5	
Out of hours	21 (7.6)	20 (9.5)	1 (1.5)	5.5	6.9	0.5	
Admission day							0.58
Weekday	211 (76.7)	158 (74.8)	53 (82.8)	77.2	75.9	81.9	
Saturday or Sunday	64 (23.3)	53 (25.1)	11 (17.1)	22.8	24.0	18.1	

[a] Weighted according to the reported maternity caseload of the study facilities in 2014.
[b] For the comparison of the weighted percentages for the private sector with the corresponding values for the private sector.
[c] Doctors, nurses or nurse-midwives – with at least 5, 4 and 2 years of pre-service training, respectively – who are licensed, regulated and endorsed by the government to provide maternity care at health facilities.
[d] Accredited social health activists, cleaners, hospital porters, other community health workers, traditional birth attendants and others who are not legally allowed by the government to provide maternity care at health facilities.
[e] That is, between 09:00 and 17:00.

Table 3. **Clinical practices and overall measures of quality in public and private maternity facilities in Uttar Pradesh, India, 2015**

Practice	Unweighted numbers (%)						Weighted percentages[a]					
	Total ($n = 275$)	Public ($n = 211$)	Public sector 95% CI[b]	Private ($n = 64$)	Private sector 95% CI	P[c]	Total ($n = 52\,047$)	Public ($n = 41\,512$)	Public sector 95% CI	Private ($n = 10\,535$)	Private sector 95% CI	P[c]
For obstetric care												
Regular monitoring of labour using a partograph	3 (1.1)	1 (0.5)	0.1 to 3.3	2 (3.1)	0.8 to 11.8	0.07	1.7	0.3	0.0 to 2.0	7.2	1.7 to 25.9	< 0.001
Measures for the prevention of maternal infection during admission	212 (77.0)	159 (75.4)	69.0 to 80.7	53 (82.8)	71.4 to 90.3	0.21	76.4	73.4	65.5 to 80.0	88.2	76.8 to 94.4	0.1
Screening for pre-eclampsia and eclampsia	3 (1.1)	2 (0.9)	0.2 to 3.7	1 (1.5)	0.2 to 10.5	0.67	2.3	2.2	0.5 to 9.3	2.5	0.3 to 15.9	0.9
Measures for the prevention of maternal infection during childbirth	115 (41.8)	76 (36.0)	29.8 to 42.8	39 (60.9)	48.4 to 72.2	< 0.001	45.6	38.3	31.0 to 46.2	74.1	59.3 to 84.9	0.05
Active management of the third stage of labour	73 (26.5)	58 (27.4)	21.9 to 33.9	15 (23.4)	14.6 to 35.5	0.52	24.5	25.4	19.3 to 32.5	21.2	11.4 to 36.1	0.7
Assessment of maternal blood loss	124 (45.1)	81 (38.4)	32.0 to 45.2	43 (67.2)	54.7 to 77.6	< 0.001	42.8	34.5	27.4 to 42.4	75.7	60.7 to 86.2	0.01
Use of woman-centred respectful care practices	12 (4.4)	9 (4.3)	2.2 to 8.0	3 (4.7)	1.5 to 13.7	0.88	3.5	2.9	1.4 to 5.8	5.6	1.1 to 24.7	0.5
Avoidance of harmful or unnecessary interventions for mother	15 (5.4)	14 (6.6)	4.0 to 10.9	1 (1.5)	0.2 to 10.5	0.12	4.3	5.0	2.9 to 8.6	1.5	0.2 to 10.2	0.2
Avoidance of harmful or unnecessary health worker behaviour	215 (78.2)	162 (76.7)	70.6 to 82.0	53 (82.8)	71.4 to 90.3	0.30	74.2	72.4	64.2 to 79.3	81.2	57.3 to 93.3	0.45
For fetal or neonatal care												
Check of fundal height and fetal presentation	4 (1.4)	1 (0.5)	0.1 to 3.3	3 (4.7)	1.5 to 13.7	0.014	1.1	0.5	0.1 to 3.7	3.4	0.8 to 14.1	0.08
Regular checking of fetal heart rate	61 (22.2)	20 (9.5)	6.2 to 14.3	41 (64.0)	51.5 to 74.9	< 0.001	20.1	6.6	4.1 to 10.5	73.3	58.5 to 84.2	< 0.001
Health workers prepared for resuscitation if required	179 (65.1)	132 (62.6)	55.8 to 68.9	47 (73.4)	61.2 to 82.9	0.11	68.1	67.2	60.0 to 73.7	71.6	51.2 to 85.8	0.8
Neonatal cord care	265 (96.4)	202 (95.7)	92.0 to 97.8	63 (98.4)	89.5 to 99.8	0.3	95.2	94.6	88.7 to 97.6	97.5	84.0 to 99.7	0.5
Appropriate thermal care of neonate	84 (30.5)	62 (29.4)	23.6 to 35.9	22 (34.4)	23.7 to 46.9	0.4	37.7	36.5	29.0 to 44.8	42.4	24.8 to 62.1	0.7
Assessment of Apgar score	1 (0.36)	0 (0.0)	0.0 to 0.0	1 (1.5)	0.2 to 10.5	0.07	0.9	0.0	0.0 to 0.0	4.7	0.7 to 26.8	0.08
Initiation of early breastfeeding	191 (69.4)	148 (70.1)	63.6 to 76.0	43 (67.2)	54.7 to 77.6	0.6	69.8	70.9	62.4 to 78.1	65.6	48.7 to 79.3	0.6
Avoidance of harmful or unnecessary practices for neonate	95 (34.5)	70 (33.2)	27.1 to 39.8	25 (39.0)	27.8 to 51.6	0.3	38.0	35.3	27.9 to 43.6	48.8	31.3 to 66.6	0.3

(*continues. . .*)

(...*continued*)

Practice	Unweighted numbers (%)						Weighted percentages[a]					
	Total (n = 275)	Public (n = 211)	Public sector 95% CI[b]	Private (n = 64)	Private sector 95% CI	P[c]	Total (n = 52 047)	Public (n = 41 512)	Public sector 95% CI	Private (n = 10 535)	Private sector 95% CI	P[c]
Aggregate indices of quality of care												
Obstetric care	275 (31.2)	211 (29.6)	27.9 to 31.3	64 (36.5)	33.4 to 39.6	0.03	30.6	28.3	25.9 to 30.5	40.0	35.4 to 44.0	0.01
Neonatal care	275 (40.0)	211 (37.6)	36.1 to 39.2	64 (47.8)	44.1 to 51.6	0.02	41.4	39.0	37.2 to 40.7	51.0	44.8 to 57.0	0.02
Essential care at birth	275 (35.3)	211 (33.4)	32.0 to 34.7	64 (41.8)	38.9 to 44.7	0.01	35.7	33.3	31.6 to 35.0	45.0	40.5 to 49.5	0.01

CI: confidence interval.
[a] Weighted according to the reported maternity caseload of the study facilities in 2014.
[b] Percentage values.
[c] For the comparison of the estimates for the private sector with the corresponding values for the private sector.

any inter-observer bias – a dummy variable for each enumerator. Estimation was by restricted maximum likelihood. We used a Wald test to generate an overall P-value for each categorical variable – e.g. age group – and assess whether there was a significant association between a given explanatory variable and the quality of care that had been observed.

Results

Sample characteristics

Of the 275 observations, 211 were conducted in public facilities and most pregnant women had come directly to the study facilities (91.5%), were 20 to 34 years of age (90.4%), multiparous (56.0%) and belonged to the caste category known as 'other backward' (51.4%; Table 2). Compared with those in the public sector, higher proportions of pregnant women in the private sector belonged to the caste category known as 'other backward' (P = 0.002) and – although not statistically significant – to the wealthiest quintile (P = 0.07) (Table 2). According to the weighted estimates, qualified personnel performed 73.0% of deliveries in the private sector but only 27.0% of those in the public sector (P = 0.01) and 99.5% of maternity cases seen in the private sector but only 93.1% of those seen in the public sector were admitted during daytime workhours (P = 0.003; Table 2).

Care quality by sector

Table 3 shows the quality of care by sector – in terms of each of the clinical practices measured. In the overall provision of obstetric care, in both sectors, monitoring of labour using a partograph (1.7%), screening for pre-eclampsia or eclampsia (2.3%), woman-centred care (3.5%), avoidance of harmful and/or unnecessary interventions (4.3%) and the active management of the third stage of labour (24.5%) were relatively rare whereas measures for the prevention of maternal infection during admission (76.4%) and health worker avoidance of behaviours harmful to the mothers (74.2%) were common. In the provision of obstetric care, assessment of maternal blood loss (P = 0.01), measures for the prevention of maternal infection during childbirth (P = 0.05) and partograph use (P < 0.001) were observed significantly more frequently in the private sector than in the public sector.

In the provision of fetal or neonatal care across both sectors, assessment of Apgar scores one and five minutes after birth (0.9%), assessment of fetal presentation and fundal height (1.1%) and the regular monitoring of fetal heart rate (20.1%) were rare whereas resuscitation preparedness (68.1%), sterile cord care (95.2%) and support for early initiation of breastfeeding (69.8%) were relatively common. One clinical practice – the regular monitoring of fetal heart rate – was observed much more frequently in the private sector than in the public sector (73.3% vs 6.6%; P < 0.001). Observational data disaggregated by each of the 42 items of care that were observed are available from the corresponding author.

Quality of essential care during labour and childbirth was found to be deficient (mean: 35.7%) across our entire sample of facilities (Table 3). Overall, 45.0% of recommended clinical practices were completed among women giving birth in the private sector compared with 33.3% in the public sector (P = 0.01). Private-sector clients received 40.0% of the recommended obstetric care practices and 51.0% of the recommended neonatal care practices – compared with 28.3% (P = 0.01) and 39.0% (P = 0.02), respectively, in the public sector.

The results from the multivariate analysis revealed that, after controlling for confounders, the overall quality of care score was six percentage points higher (P = 0.03) in the private sector than in the public sector (Table 4). We found no association between use of qualified personnel, facility caseload or the woman's age, caste, parity, referral status or socioeconomic status and the overall quality of care at the time of birth. However, compared with admission on a weekday, admission during the weekends was associated with a quality of care score that was three percentage points lower (P = 0.03).

When we examined adjusted variances, for quality of care, between health workers, we found greater variation within health workers (standard deviation, SD: 0.004) than between them (SD: 0.002; intraclass correlation: 0.33). Similarly, there was greater variation, for quality of care, within health facilities (SD: 0.005) than between them (SD: 0.002; intraclass correlation: 0.27). We found no evidence that birth attendants were exerting more – or less – effort sim-

ply because they were being observed and there was, therefore, no significant Hawthorne effect (available from the corresponding author).

Discussion

Using clinical observations, we found that, in Uttar Pradesh, essential care provided to women and their neonates – during labour and childbirth – was generally of poor quality. The private facilities generally outperformed the public facilities in terms of both obstetric and neonatal care. Measures to prevent some major causes of maternal mortality – e.g. haemorrhage, hypertensive disorders and sepsis – were rare in both the private and public sectors.

Our study advances the descriptive evidence base on quality of care at the time of birth in India – particularly for the private sector, which has an increasing share of the market for maternity care.[18] Direct observations of clinical practices offer advantages over other methods of quality assessment, especially when – as in our study – there is no evidence of a Hawthorne effect. We developed a comprehensive measure of quality of care that included adherence to evidence-based guidelines, respectful care practices, harmful and unnecessary interventions and harmful health worker behaviours. The methods we used to calculate separate indices for neonatal care, obstetric care and overall essential care at birth could be used for monitoring quality of care in other settings.

Our multivariate analysis confirmed that, in our study districts, private maternity facilities generally provided a higher standard of care than those in the public sector and that the quality of care provided – in either sector – was not significantly related to the investigated characteristics of the birth attendant, facility or the woman's age, caste, parity, referral status or socioeconomic status. However, compared with admission at other times, admission at a weekend was associated with poorer quality of care. Other studies have also revealed poorer neonatal and obstetric care during weekends than at other times.[41,42]

Care during labour and childbirth in the public sector was less likely to be provided by qualified staff than such care in the private sector. However, we did not find that care provided by qualified personnel was significantly better than that provided by unqualified personnel. Even qualified birth attendants may not be adequately skilled.[25,43] In a study from India using standardized patients, only minor differences were found between the quality of care given by trained providers and that given by untrained providers – although this study did not focus on maternal and neonatal care.[44]

We did not find any relationship between facility size and quality of care at birth – perhaps because our observations were limited to uncomplicated vaginal births and quality of care for such births was generally poor irrespective of the facility caseload. Previous studies have found a relatively better quality of care at large high-level facilities and this may explain why patients may sometimes bypass small low-level facilities.[7] Although, we do not have robust evidence on the factors influencing quality of care at maternity facilities in India, evidence from low-income coun-

Table 4. **Investigation of the association between the index for the quality of essential care at birth and the characteristics of the birth attendants, maternity facilities and mothers, Uttar Pradesh, India, 2015**

Explanatory variable	Coefficient[a] (95% CI)	*P*
Characteristics of birth attendant		0.61
Unqualified	Base	
Qualified	0.01 (−0.02 to 0.04)	
Characteristics of facility		
Facility sector		0.03
Public	Base	
Private	0.06 (0.01 to 0.11)	
No. of deliveries at facility in 2014		0.77
< 2000	Base	
2000 to 2999	0.01 (−0.05 to 0.06)	
≥ 3000	−0.02 (−0.08 to 0.05)	
Characteristics of mother		
Day of admission		0.03
Weekday	Base	
Saturday or Sunday	−0.03 (−0.06 to 0.003)	
Age in years		0.91
< 20	Base	
21 to 34	0.01 (−0.04 to 0.05)	
≥ 35	0.01 (−0.05 to 0.08)	
Parity		0.22
Primipara	Base	
Multipara	0.01 (−0.01 to 0.03)	
Referral status		0.84
Came directly to study facility	Base	
Referred from another facility	0.00 (−0.04 to 0.03)	
Caste		0.15
Scheduled caste or scheduled tribe	Base	
Other backward caste	0.02 (−0.01 to 0.04)	
General caste	0.03 (0.00 to 0.06)	
Wealth quintile		0.08
First (poorest)	Base	
Second	0.00 (−0.03 to 0.03)	
Third	0.00 (−0.03 to 0.03)	
Fourth	0.00 (−0.03 to 0.03)	
Fifth	0.04 (0.00 to 0.07)	
Timing of admission		0.62
Within daytime work-hours[b]	Base	
Out of hours	−0.01 (−0.05 to 0.03)	

CI: confidence interval.
[a] Results from a multilevel mixed-effects linear regression.
[b] That is, between 09:00 and 17:00.

tries indicates that provider effort could be a key determinant.[45] Evidence also exists that the private sector generally provides better quality of care because it has superior management and operational systems – including better incentive schemes that attract more motivated and better qualified staff.[44]

Our findings are similar to those of some other studies in India. In a study based in Rajasthan, partograph use was found to be especially weak and monitoring was found often to consist only of repeated unhygienic vaginal examinations.[24] We found active management of the third stage of labour to be more common in the facilities we surveyed than reported in some neighbouring districts of Uttar Pradesh.[23] We found respectful rights-based maternity care[38] to be rare. Our informal observations during data collection – of labour room environments that often appeared chaotic and of some health workers that could be abusive, dominating and threatening on occasions (available from the corresponding author) – were consistent with those previously found in Madhya Pradhesh[46] and Rajasthan.[25] Inadequate knowledge and skills, lack of enabling environments, limited supportive supervision, staffing shortages and the poor quality of in-service training could all be underlying causes of the generally poor quality of maternity care in India.[24,46] The Indian government is currently implementing a range of schemes to improve the quality of intrapartum and immediate postpartum care.[47] Given the shortages of skilled human resources for maternity care in India, focused efforts to establish a professional cadre of midwives could be beneficial. We found greater variance in quality of care within individual health workers than between them. This could indicate that health workers do not follow standard protocols and/or provide preferential care.

Our study had several limitations. First, there may have been observer bias – e.g. due to the general perception that the private sector is superior because it has better infrastructure and better trained personnel. Second, there were challenges in sampling the private sector. Not only did 13 private facilities refuse to participate but also we had no official sampling frame from which to select private facilities. It is possible that the quality of care provided by the participating private facilities was different to that provided by the other private facilities in Uttar Pradesh. Third, although it provided useful summary measures, our aggregation of numerous indicators into broader indices will have masked variation between individual indicators. Also, in developing our aggregate measures of quality, we gave equal weight to each indicator because there was no scientific basis for applying intervention-specific weights. All of the women who were invited to participate in the study agreed to participate and, by following a strict case-definition, we hoped to minimize any selection bias at participant level. To limit subjectivity, our observers were well trained and used a structured questionnaire to record their observations.

Our findings have at least three key implications. First, a systematic effort to measure and identify existing quality gaps during labour and childbirth, is warranted, especially in India's high-burden states. Such research should include private-sector facilities, which provide a substantial and increasing proportion of the maternity care in India. Second, the reasons for the high prevalence of maternity care provided by untrained personnel and the widespread non-adherence to recommended protocols should be investigated further. Third, tailored quality-improvement initiatives[48] must be designed for facilities in both sectors – with the regular auditing of the actual processes of care linked to functional accountability mechanisms. ■

Acknowledgements
We thank the adult participants, their families, health providers, the data collection team at Sambodhi Research and Communications and Pathfinder International and World Health Partners in Uttar Pradesh, India.

Funding: The activities in this manuscript were supported by funding from MSD – an initiative of Merck & Co, Inc. (Kenilworth, United States of America) – through its MSD for Mothers programme.

Competing interests: None declared.

ملخص

جودة الرعاية الروتينية الضرورية أثناء الولادة: الملاحظات السريرية لعمليات الولادة غير المعقدة في ولاية أوتار براديش بالهند

الغرض تقييم جودة الرعاية الضرورية المقدمة أثناء المخاض العادي والولادة في مراكز الأمومة في ولاية أوتار براديش بالهند.

الطريقة في الفترة ما بين 26 مايو/ أيار، و8 يوليو/ تموز 2015، استخدمنا الملاحظات السريرية لتقييم توفير الرعاية لعدد 275 أمًا وأطفالهن في 26 مستشفى. تم جمع البيانات الخاصة بـ 42 عنصرًا من عناصر الرعاية، وتلخيصها في 17 ممارسة سريرية وثلاث نتائج مجمعة ثم ترجيحها للحصول على تقديرات تعتمد على الشرائح السكانية. وقمنا بفحص الاختلافات غير المعدلة في مستوى الجودة ما بين المرافق العامة والخاصة. كما تم استخدام نماذج خطية متعددة المستويات ذات تأثيرات مختلطة لتعديل خصائص المولدة والمرافق الصحية والأمهات.

النتائج كانت جودة الرعاية التي لاحظناها سيئة بوجه عام في المرافق العامة والخاصة على حدٍ سواء؛ حيث بلغت النسبة المئوية لممارسات الرعاية السريرية الضرورية المقدمة لكل امرأة 35.7٪. وتشير التقديرات الموزونة إلى أن نسبة العاملين غير المؤهلين من مقدمي الرعاية بلغت 73.0٪ و27.0٪ للأم وطفلها في المرافق العامة والخاصة على التوالي. وظهرت رعاية أمراض النساء والولادة، ورعاية المواليد نسبة وإجمالي الرعاية عند الولادة بشكل أفضل في المرافق الخاصة عن مثيلاتها العامة. في التحليل المعدّل، وُجد أن النتيجة الإجمالية للرعاية المقدمة في المرافق الصحية أعلى بست درجات مئوية من الدرجة المماثلة الخاصة بالمرافق العامة.

الاستنتاج في 2015، كان أغلب العاملين من مقدمي رعاية المخاض والولادة في مرافق الأمومة غير مؤهلين وكان الالتزام ببروتوكولات الرعاية ضعيفًا بوجه عام. ويلزم طرح مبادرات لقياس الجودة المقدمة أثناء المخاض والولادة في المرافق الخاصة والعامة بولاية أوتار براديش.

Appendix 6: Table showing frequency of mistreatment by sector

Items of mistreatment	Public sector	Private sector
	N (%)	N (%)
1. Any item of mistreatment	211 (100.0)	64(100.0)
2. Two items of mistreatment	10 (4.7)	3 (4.7)
3. Three items of mistreatment	41 (19.4)	10 (15.6)
4. Four items of mistreatment	44 (20.9)	17 (26.6)
5. Five items of mistreatment	43 (20.4)	19 (29.7)
6. Six items of mistreatment	32 (15.2)	9 (14.1)
7. Seven items of mistreatment	21 (10.0)	4 (6.3)
8. Eight items of mistreatment	14 (6.6)	0 (0.0)
9. Nine items of mistreatment	3 (1.4)	2 (3.1)
10. Ten items of mistreatment	3 (1.4)	0 (0.0)