Impacts of an intervention to reduce maternal mortality in Kerala, India

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Grantee Final Report

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Note to readers

This final impact evaluation grantee report has been submitted in partial fulfilment of the requirements of grant PW3.03 awarded under Policy Window 3. 3ie is making it available to the public in this final report version as it was received. The evaluation described in this report has a number of methodological limitations, and the findings should be interpreted in light of these limitations.

The evaluation examines the impact of a pilot programme that trained health workers on delivering quality antenatal care, along with the full rollout of the programme after the pilot. The study finds that the pilot programme was effective in improving maternal care practices, but finds no evidence that the rollout programme spurred such improvements. However, it is unclear how to interpret this pattern given that there were a number of differences between the pilot and rollout programmes (e.g., rollout trainings were shorter and were not supplemented by labour room posters, as was the case in the pilot programme).

Perhaps more importantly, there is a key limitation in the study's core method for identifying the causal impact of the intervention. The evaluation used a difference-in-differences (DiD) approach. Unlike randomised controlled trials, DiD analyses do not rely on the assumption that the treatment and control groups are equivalent at baseline. Rather, the baseline differences are subtracted from the endline differences to identify the portion of the endline difference that is attributable to the programme. However, a key assumption of DiD is that while the baseline levels of the outcome may be different in the treatment and control groups, the groups are following similar trends (e.g., one group is not improving at a faster rate than the other). This is known as the parallel trends assumption. In order for the results of a DiD analysis to be reliable, there should be some test of the parallel trends assumption.

In the case of this study, the authors test the parallel trends assumption by measuring the treatment and control groups at multiple points before the intervention. These tests reveal that for nearly all outcomes, the treatment and control groups displayed different trends in their use of recommended healthcare practices before the intervention began. As a result, the DiD results do not necessarily identify the causal impact of the programme, as they would if the parallel trends assumption held true.

As a result of the above, 3ie considers the results of the study to be inconclusive. It is possible that the programme had a significant impact on healthcare practices, but one cannot confidently draw this conclusion from the data available.

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Executive Summary

Background

IFMR LEAD in collaboration with Professor Shannon Maloney and Rohini Dutta sought to measure the impact of a quality standards training program (QSP) on improving maternal outcomes. These standards were aimed at influencing provider practices in terms of obstetric care delivery. These quality standards consisted of ten evidence-based guidelines to reduce Post-Partum Hemorrhage (PPH) and Pregnancy Induced Hypertension (PIH) which were identified to be the major causes of maternal death in Kerala[1]. To generate these standards, the National Health Mission (NHM) in Kerala with assistance from UK's National Institute for Health and Clinical Excellence (NICE) and Kerala Federation of Obstetricians and Gynecologists (KFOG), convened a task force to develop standards of care most likely to reduce the risk of death due to PPH and PIH. The QSP consisted of a set of trainings for the labor room staff paired with a set of data collection tools (labor register) for those hospitals in which these standards were being implemented.

Research Questions

We aim to answer two questions:

a. How effective has the QSP training been in addressing issues like PPH & PIH through improvements in preventive care outcomes like Active management of third stage of labor (AMTSL), measurement of blood loss and fourth stage monitoring?
b. How effective has the QSP training been in changing provider attitude, knowledge and what were the perceived challenges associated with implementing the guidelines?

Intervention

Beginning with a pilot in eight hospitals in 2013, NHM rolled out the QSP across 22 hospitals that provided antenatal and delivery services. These hospitals were spread across 13 of the 14 districts in Kerala with the exception of Kozhikode. The primary components of the MMR intervention are the ten quality standards and data collection with labor registers. However, the training program underwent significant changes in terms of how it was delivered when it was expanded to the 22 hospitals in the rollout phase. The rollout training program was a single day training session with negligible hospital administrative involvement. This was significantly different from the comprehensive pilot training program which included considerable support in terms of resources and a longer duration.

Analysis

Evidence of a causal impact on the implementation of guidelines by providers to bring down complications related to PPH and PIH was looked into, using a quantitative approach. Additionally, we conducted around 41 qualitative interviews involving separate groups of physicians and nurses. This was aimed at seeking information on the facilitators and barriers that the personnel faced during implementation of the QSP at the hospital level.

Major Findings

In contrast to the comparison hospitals, hospitals that were a part of the pilot phase of the QSP displayed the following effects:

- Participating in the pilot program does not significantly affect the PPH rate.
- Treatment hospitals saw a significant improvement in measurement of blood loss as a quantity and were also more likely to increase the number of case sheets with blood loss measured as a quantity as compared to symbols and phrases.
- Fourth stage blood pressure and pulse recordings were likely to be more in treatment hospitals.
- Post-delivery measurement of pallor was more likely to be not recorded in treatment hospitals
- No significant effects, in terms of rates of administration of oxytocin at birth.

In terms of the impact of the MMR QSP in the rollout phase:

- No impact was detected on PPH rates, PIH, eclampsia or pre-eclampsia for treatment hospitals.
- No impact on any preventive care measures like recording of blood loss as a quantity, administering oxytocin at birth, optimum care in case of excessive blood loss, fourth stage monitoring, prescription or receiving of anti-hypertensive drugs during antenatal and postpartum period was detected for the treatment hospitals.

Factors Impeding Implementation of the QSP

[1] The ten quality standards are Active management of third stage labour, PPH Prevention- Fourth Stage management, Management of PPH with Blood and Blood Products, Obstetric Intensive Care, Placenta Praevia Accreta, Pre-eclampsia, Anti-Hypertensive treatment, Severe Hypertension in Pregnancy and in immediate post-partum period, HELLP, Eclampsia.

Provider Related Barriers	Infrastructural Barriers	Staffing Barriers	Equipment Barriers
• Accustomed to old methods • Lack of confidence • Mistrust in the training • Non-complaint subordinates	• Lack of facilities for blood products • Physical structure and capacity	• Staff shortage • Multiple staff required for certain task at the same time • Staff rotation • Staff lack required qualifications	• Insufficient equipment and supplies to carry out techniques taught in the training

Recommendations

The findings suggest that a single day training is not sufficient to improve the kind of labor and delivery care which was envisaged by the QSP. However, there were positive effects on the care practices of the provider when it was accompanied with infrastructural improvements, supply of medicines and equipment's and monitoring. In this context, we propose the following recommendations.

1. **Invest in supply and maintenance of infrastructure -** Insufficient infrastructure adversely impacts the ability and functioning of the providers. Additionally, providers cannot implement evidence-based guidelines without the associated materials, equipment and administrative support required to do so.

2. **Involve leadership to ensure buy-in** - Staff reported that administrators who were aware and supportive towards the program provided a strong expectation and vision for how the standards could be used in the hospital.

3. **Look for ways to engage nurses and physicians with learning and test competency** - Physicians displayed reluctance to the material taught in the training program due to them being familiar with the old techniques. Future efforts to train physicians must include practical application along with repeated messaging, evidence of best practices and use case scenarios to reduce the probability of them failing to use evidence-based guidelines.

4. **Implement ongoing monitoring** - Currently, collection of monitoring information by the government is inadequate and this affects the adherence to the QSP. This can be improved by implementing an electronic checklist which will make the process of data collection and compilation easier. This needs to be complemented with adequate monitoring.

5. **Adapt a culture of patient-centeredness and accountability** - It has been noticed that little to no attention is paid to cater to a patients' emotional needs – especially for something as crucial as childbirth. Hence, hospitals should adopt a culture of providing ethical and respectful care to patient.

List of Abbreviations

CME	Continuing Medical Education
H&FWD	Health and Family Welfare Department
HELLP	Haemolysis Elevated Liver Enzymes and Low Platelet Count
ICMR	Indian Council of Medical Research
ICU	Intensive Care Unit
IHME	Institute for Health Metrics and Evaluation
KFOG	Kerala Federation of Obstetrics and Gynecology
LMICs	Low and Middle Income Countries
MMR	Maternal Mortality Rate
NHM	National Health Mission
NICE	National Institute for Health and Clinical Excellence
NITI	National Institution for Transforming India
NRHM	National Rural Health Mission
PHFI	Public Health Foundation of India
PIH	Pregnancy Induced Hypertension
PPH	Postpartum Haemorrhage
SDGs	Sustainable Development Goals
WHO	World Health Organization
WNL	Within Normal Limit

1. Introduction

Rates of maternal death are higher in low- and middle-income countries (LMICs) than in high-income countries (GBD Maternal Mortality Collaborators, 2016 and Graham et al., 2016). This disparity between countries has been partially attributed to differences in medical intervention, with mothers in high-income countries far more likely to receive antenatal care and give birth in the presence of a skilled birth attendant (Shaw et al., 2016). Recognizing low- and middle-income countries as the drivers of high international mortality rates and emphasizing the life-saving role of intervention, much of the strategy to reduce global maternal mortality has focused on increasing births delivered by a skilled birth attendant, preferably in a hospital setting. However, while the rates of delivery in a birth facility increase in LMICs, maternal outcomes continue to fare poorly, turning attention toward the quality of institutional care given during the perinatal period (Miller et al., 2016 and Koblinsky et al., 2016). New strategies to end preventable maternal deaths emphasize quality and access to health care, estimating that removal of these two barriers could avert more than 100,000 preventable maternal deaths by 2020 (Chou et al., 2015).

Emerging evidence of health care delivery in low- and middle-income settings suggests a high degree of inconsistency of care quality within countries. A 2013 systematic review found that hospital level factors were a consistent major factor in maternal mortality in LMICs (Knight et al., 2013). India, which accounts for 15% of the world's maternal mortality burden (WHO, 2015) faces health care quality challenges that are only recently gaining attention. A study using standardized patients to assess care in northern India found that 63 percent of providers in rural public clinics had no medical training and were less likely to adhere to essential care checklists than private providers (Das et al., 2012).

Evidence-based clinical guidelines are an important tool for standardizing care and improving health outcomes in LMICs. Evidence-based obstetric medicine aims to improve the quality of medical care (Olatunbosun et al., 1998) and reduce costs by encouraging the uptake of medical techniques demonstrated to save mothers (Paxton et al., 2005) lives through scientific review (Sackett et al., 1996). Despite the existence of established guidelines for obstetric practices that improve maternal outcomes, implementation of these guidelines in LMICs is variable (Heiby et al., 2014) and insufficient attention is given to adapting guidelines to local context (Mehndiratta et al., 2017). As well, studies suggest that many physicians fail to use evidence-based medicine in their obstetric practice (Olatunbosun et al., 1998; Karolinski et al, 2010).

Well-supported guidelines to reduce maternal complications and death associated with postpartum haemorrhage, a leading cause of maternal mortality in LMICs, exist, but effective and low-cost approaches to promote the uptake of these guidelines in hospital settings is not well understood. Qualitative research with health care providers suggests that training may be an effective approach to improve uptake of evidence-based guidelines in LMICs (Bateganya et al., 2009). A review of barriers to evidence-based maternal medicine among low- and middle- income countries (LMICs) identified inadequate training as a provider-level barrier in all five countries reviewed (Puchalski et al., 2016).

A review of approaches to improve health care delivery in LMICs identified just two studies that studied the effect of training health care providers on guidelines related to delivery of a baby (Dettrick et al., 2013.) One study provided training to traditional birth attendants and focused on hygiene (Goodburn et al., 2000); while the other included hygiene and new-born care in a hospital setting, but did not include guidelines aimed at improving maternal outcomes (Senarath et al., 2007). Neither study examined the impact of active management of third stage labour or fourth stage monitoring on provider behaviour.

This study sought to measure the impact of a quality standards training program on provider practices in obstetric care delivery for the improvement of maternal outcomes. This program, developed through an international partnership between government, academic and practitioner representatives, adapted international guidelines for reducing maternal mortality to fit the local context in Kerala, India. Using a difference in difference estimation technique, we looked for evidence of causal impact on provider implementation of guidelines to reduce complications associated with postpartum haemorrhage. We hypothesized that intervention hospitals would experience an increase in recommended care practices relative to a set of comparison hospitals over an established observation period.

In addition, we sought information from health care providers on their perceptions of barriers and facilitators to implementing the material covered in the quality standards training. A greater understanding of provider perspectives on the uptake of evidence-based CME material will help inform more effective strategies to

promote utilization of evidence based obstetric medicine in low- and middle-income countries. We complement these findings with an assessment of hospital readiness to implement change and a qualitative study of the key factors influencing mothers' choice of birth facility.
Collectively, these efforts support a comprehensive evaluation that tells the story of an effort to improve the care delivery at government hospitals. The following report discusses the promise of this type of Quality Standards training program to improve care delivery in low resource settings and potential modifications to enhance the chances of success. We end with a discussion of the policy implications and next steps to advance the agenda for improving maternity care in India.

2. Intervention, Theory of Change and Research Hypotheses

NRHM is implementing standards of care to reduce maternal mortality in Kerala hospitals. To generate these standards, NRHM, along with the Government of Kerala, NICE International and the Kerala Federation of Obstetricians and Gynaecologists, convened a task force which identified the primary causes of maternal deaths in Kerala and the standards of care most likely to reduce the risk of death due to these causes. The task force identified postpartum haemorrhage (PPH) and pregnancy induced hypertension (PIH) as the leading causes of maternal mortality in Kerala hospitals and generated a list of ten quality standards to adequately diagnose, treat and reduce the risk of death related to these two diseases. Beginning with a pilot in eight hospitals, NRHM planned to roll-out the quality standards of care across all Kerala government hospitals that provide antenatal and labor and delivery services. NRHM pairs the quality standards with an initial training on the standards and a data collection tools (labor registry.) Thus, the primary components of the MMR intervention are: 1) the ten quality standards and 2) data collection with labour registries. The causal pathway for each component and related assumptions are described in the following narrative. Refer to Appendix-D for the pictorial representation of the Theory of Change.

2.1 Ten Quality Standards:

The quality standards include five standards targeted at reducing risk of death related to postpartum haemorrhage; including preventing excessive blood loss with drugs, monitoring blood loss, transfusion for cases of excessive blood loss, intensive care treatment for complications due to excessive blood loss and referrals for specialized care for women with placenta praevia. The remaining five standards target pregnancy induced hypertension: testing and diagnosis of preeclampsia during antenatal check-ups, antihypertensive therapy for women showing signs of hypertension during pregnancy, parenteral antihypertensives for severe cases of hypertension during postpartum period, monitoring for signs of HELLP syndrome and use of magnesium sulphate to treat severe preeclampsia and eclampsia. For each standard, clear dosage and/or protocols for treatment or testing are specified.

At the start of the initiating the standards in a new hospital, NRHM convenes a training session, typically two full days, for all labor and delivery associated hospital staff. During this session, NRHM explains the standards and expectations in detail. NRHM then provides the hospital with poster-size flow charts, one for each standard, which are to be hung in a visible and easily accessible location for labor and delivery staff. The posters are to serve as reminders for providers to recollect and adhere to the guidelines taught during the training. The immediate expected outputs of these activities are that hospital staff understand the new standards, hospitals hang posters in appropriate locations and that hospitals maintain adequate staffing and materials to implement the quality standards effectively. As well, it is expected that hospital staff will apply the quality standards in 100 percent of cases and care for these conditions will be standardized both within and across hospitals. In the short term, it is expected that proper implementation of these standards will lead to increased cases of PPH and PIH which are properly diagnosed and treated. In the long term, it is expected that this will cause fewer complications and death due to postpartum haemorrhage and fewer complications and due to pregnancy induced hypertension.

The main assumptions along this pathway are that: 1) the training, posters and materials provided are adequate preparation for hospital staff to properly apply the ten quality standards; 2) delivery staff are sufficiently motivated to utilize the quality standards; 3) the ten quality standards will increase proper diagnosis and treatment of PPH and PIH; 4) proper diagnosis and treatment of PPH and PIH will reduce the risk of complication and death associated with PPH and PIH; 5) the quality standards selected will in fact reduce risks of complication and death associated with PPH and PIH; and 6) by reducing the risks associated with PPH and PIH, the overall mortality rate in Kerala will decrease.

2.2 Data Collection with Labour registries:

NRHM has incorporated data collection of hospital processes and patient outcomes as part of the MMR reduction intervention. NRHM designed a labour room registry, which collects detailed information about the patient, procedure performed and outcomes. This is to replace the current registers used by hospitals, which collect less detailed information. Blank copies of the NRHM registry are provided to the hospital. Hospital staff are expected to complete the registries in real time and capture relevant information in a report, which they are to submit to NRHM monthly. NRHM is currently considering the best uses for the data it receives and has asked for our assistance in how to best interpret and use this data. A conceivable approach would be to provide reports to each hospital, which show hospital performance on maternal mortality outcomes and relative performance against other labor and delivery hospitals. The immediate expected outputs from the data collection component of the intervention are that hospitals complete one record per patient, hospitals submit monthly reports to NRHM and that NRHM analyses and prepares reports based on this data. Expected short term outcomes are that hospitals and NRHM increase their awareness of hospital performance on maternal mortality outcomes and that hospitals are more motivated to improve their performance on the quality standards. Specifically, it is expected that labor register data will be used by NRHM for continuous quality improvement. Meaning, NRHM will collect the data at regular intervals and use this data to provide feedback and recommendations to hospitals. In turn, hospitals staff are expected to be motivated by this quality improvement process and respond by changing their care practices. This is expected to contribute to the long term outcome of reduced complications and deaths due to PPH and PIH.

Main assumptions along this data collection pathway include: 1) NRHM has sufficient resources to distribute blank copies of labor room registries and collect reports regularly from hospitals; 2) hospital staff have adequate time, motivation and knowledge to accurately complete the labor room registry an submit reports; 3) performance reports and relative comparisons to other hospitals motivate hospitals to improve their performance; and 4) that again, proper application of the ten quality standards will lead to reductions in complications and death due to PPH and PIH.

3. Context

New strategies to end preventable maternal deaths emphasize quality and access to health care, estimating that removal of these two barriers could avert more than 100,000 preventable maternal deaths by 2020 (Chou et al., 2015). India, which accounts for 15% of the world's maternal mortality burden (WHO, 2015) faces health care quality challenges that are only recently gaining attention. A study using standardized patients to assess care in northern India found that 63 percent of providers in rural public clinics had no medical training and that government health care providers were less likely to adhere to essential care checklists than private providers (Das et al., 2012).

In 2016, over 65 million mothers died from complications related to pregnancy (ICMR, PHFI and IHME, 2017). The WHO (2015) Global Burden of Disease tasks force reports that India's maternal mortality ratio has gone from 482.1 maternal deaths per 100,000 live births in 1990 to 247.5 maternal deaths per 100,000 live births in 2015, representing an annual reduction of 2.7 percent during this time period. While this reduction is encouraging, India's 2015 maternal mortality ratio falls above the global average and is far above the Sustainable Development Goals target of 70 maternal deaths per 100,000 live births (SDGs 2016). Considerable work is required for India to achieve this target by 2030.

Kerala has been a consistent positive story in India's generally poor performance on maternal and child health indicators. Indeed, Kerala's maternal mortality ratio most recent is reportedly 61 maternal deaths per 100,000 live births (NITI.) A confidential review of maternal deaths in Kerala was conducted in 2014. This review reports that 98 percent of mothers given birth in a hospital or clinic, 94 percent of mothers are literate and a low fertility rate of 1.6 births per woman (Paily et al., 2014).

Accordingly, one might expect Kerala to perform well on indicators of maternal mortality and maternal health. To some extent, this is true. Kerala is the highest performing state in India on this indicator. However, while the maternal mortality ratio in India is low for India, it is four times higher than the average maternal mortality ratio of 16.9 maternal deaths per 100,000 live births found in high-income countries (WHO, 2015). As well, Kerala's maternal mortality rates have remained stagnant or slightly increased since 2004 (Paily et al., 2014), suggesting that Kerala's social indicators cannot be solely relied upon to keep its mothers safe.

The Kerala government recently announced a goal to cut the maternal mortality ratio in Kerala in half – to 30 maternal deaths per 100,000 live births (Nair, 2017). Kerala also hopes to increase the utilization of government facilities for delivery of a baby. The results of this report are directly relevant to the current goals of the Kerala government and the recommendations provide guidance for how Kerala can achieve its maternal health goals. As well, the lessons learned from the Kerala MMR Quality Standards program can be applied to all Indian states wishing to reduce their much higher maternal mortality ratios. The challenges faced by government hospitals are common across Indian states. By observing the impacts of the quality standards program in a relatively ideal setting of Kerala, and identifying challenges to success, we can identify lessons applicable to all Indian states.

4. Timeline

The timeline for each phase of the MMR quality standards program is shown in Tables 1 and 2 below. In 2012, NHM, NICE International and KFOG worked to finalize the care guidelines which would for the 10 quality standards of care to reduce maternal mortality through prevention of death and complication due to postpartum haemorrhage and pregnancy induced hypertension. The MMR quality standards were published in January 2013. Four labor and delivery hospitals located within or near to Trivandrum, plus others, were then recruited to participate a pilot phase of the program, which ran from March 2013 through February 2014. It was envisioned that the rollout phase, during which the quality standards program would go to all districts in Kerala, would proceed within a few months after the pilot phase. However, changes in leadership, and therefore priorities, delayed and changed this process.

After the end of the pilot year, in 2014, the Chief Secretary of Health and Welfare in Kerala changed. The new Health Secretary was less supportive of the Kerala MMR Quality Standards program than the previous Health Secretary, who had been one of the program's founders. The new Health Secretary attended an MMR Quality Standards Evaluation workshop, put on by the evaluation team responsible for this report, and announced his priorities were focused on reducing lifestyle diseases. We took this as a strong signal that maternal mortality was not a major focus area for this new Health Secretary. In addition, the National Health Mission Director changed three times during the evaluation time period. The NHM director involved in the MMR Quality Standards pilot left in 2014. She was replaced by a director who then left the post in late 2015. A new, current NHM director joined in May 2016.

Our conclusion is that the above changes were directly related to the MMR Quality Standards program being stalled for over one year. Our evaluation team reached out to the key partners involved in the MMR Quality Standards program on several occasions over this period. Our evaluation team believes that we influenced the eventual rollout of the MMR Quality Standards program through our presence and continued reminders to these partners regarding the importance of the program and expectations related to evaluation. Eventually, the first rollout training did occur in September 2015.

Our evaluation team attended the rollout trainings, spoke with the partners involved in the training sessions and took notes. Through this effort, we learned that that rollout program differed considerably from the original pilot program. The training was shorter and included additional components which were not part of the 10 Quality Standards. As well, we did not see evidence of labor room posters or labor room registers being passed out to hospital administration or staff. We confirmed these observations during focus group discussions with hospital physicians and nurses. Through these focus group discussions we also learned that hospitals were no longer receiving delivery kits, intended to aid the MMR Quality Standards Program and that hospitals faced supply constraints which impacted their ability to implement many of the Quality Standards.

Aside from the impact these changes in leadership had on the shape of the MMR Quality Standards program, the evaluation plan also faced changes. The original rollout plan was scheduled to take place slowly, with 1-2 hospitals being trained each month over nearly one year, allowing the evaluation team to plan a unique difference in difference analysis comparing changes between early receivers and late receivers. We planned to complement this with a within hospital analysis, comparing changes in the labor room to changes in other hospital wards. However, two changes impacted this: 1) the rollout plan was condensed over a shorter period, with the majority of hospitals receiving the training between October to December 2015; and 2) In January 2013[2] Kerala rolled out a state-wide accreditation system for its

[2] The second edition of the Kerala Accreditation Standards for Hospitals (KASH) was implemented on 17th January 2013. To receive accreditation through this program, hospitals must demonstrate meeting minimum criteria for safety and quality, determined

hospitals, impacting care practices across all wards. Therefore, the final evaluation plan included a standard difference in difference model, comparing time-invariant changes between trained hospitals and a comparison set of untrained hospitals.

Table 1: Timeline for Phase 1: Pilot Training Sessions (4 government hospitals)

		Time of training (Delivery of the intervention)	
	Project Activity	2013	Project Activity
	12 months pre-training (data collection only)	March	12 months post-training with monitoring (data collection only)
Number of hospitals trained during Pilot Phase		4	

Table 2: Timeline for Phase 2: Rollout Training Sessions (22 government hospitals)

		Time of training (Delivery of the intervention)							
	Project Activity	2015				2016			Project Activity
	12 months pre-training (data collection only)	Sep	Oct	Nov	Dec	Jan	Feb	Mar	12 months post-training (data collection only)
Number of hospitals trained during Rollout Phase		1	4	4	7	1	1	4	

Note: the 12 months pre-training and post-training periods refer to the observation period for data collection and analysis. No intervention related activities occurred during this time. Numbers within boxes refer to the number of hospitals trained during that month.

5. Evaluation: Design, Methods and Implementation

5.1 Ethical Considerations and Permissions

The project was reviewed for human subjects' protection and approved by the Institutional Review Board at the University of Nebraska Medical Center and the Institute for Financial Management and Research Human Subjects Committee. In addition, the project proceeded under the approval of the National Health Mission and under the Government Order No. 1273/2015/H&FWD of the Health and Family Welfare Department of the Government of Kerala.

5.2 Evaluation Questions

We proposed the following set of evaluation questions, in accordance with the Donabedian (1980) framework for assessing quality of health care in hospital settings:

Hospital Structural questions:

1. Do hospitals maintain adequate structures (unexpired relevant medications and supplies, flow charts, etc.) to support implementation of the MMR quality standards?

Hospital Process questions:

2. Do the MMR quality standards improve quality of care for mothers with PPH and PIH, as measured by adherence to the quality standards?

by the Kerala National Health Mission. Hospital application for KASH accreditation is voluntary. A hospital may apply and receive KASH accreditation any time after January 2013.

3. What barriers do hospitals face in implementing the intervention? How can these be overcome?

Health Care Outcomes questions:

4. Do the MMR quality standards reduce complications and deaths due to postpartum haemorrhage (PPH)?

5. Do the MMR quality standards reduce complications and deaths due to pregnancy induced hypertension (PIH)?

Other questions:

6. How can the labour registry data be used effectively by NRHM to improve care quality and maternal outcomes?

7. Which factors do women list as barriers or reasons for not utilizing government delivery facilities for birth and or antenatal care?

To answer these questions, this project employed a mixed methods approach, with four main data sources:

- *Hospital Survey and Direct Observation:*
  - Purpose: to obtain baseline characteristics of hospital policies, procedures, structures, staffing and patient load
- *Focus Group Discussions with Labor Ward Obstetricians and Nurses*
  - Purpose: to characterize hospital staff perceptions of the barriers and facilitators to implementing the quality standards program
- *Interviews with Mothers*
  - Purpose: to better understand mothers' perceptions of institutional delivery in Government and Private hospitals and major factors in choosing a birth facility
- *Medical Record Abstraction:*
  - Purpose: to measure the impact of the quality standards program on changing health care provider behavior

We review the sampling plan, data collection process and analytic strategy, followed by results, for Medical Record Abstraction (our main outcome analysis) below. Results and methods for the other data collection elements are available upon request.

5.3 Medical Record Abstraction

Hospital medical records were used as the primary data source for our analysis of impact of the MMR quality standards program on changes in health care quality and health care outcomes for women. As noted in our proposal, our study was not powered to detect significant changes in pregnancy related death; however, we did look for changes in postpartum hemorrhage and complications associated with pregnancy induced hypertension.

We originally proposed a difference in difference analysis using two methods: comparison of changes over time in care between wards within hospitals and comparison of changes over time between hospitals that received the intervention early and hospitals that received the intervention late. This second comparison is similar to the step-wedge design used in randomized controlled trials; however, in our case the government was choosing the order in which hospitals received the MMR Quality Standards program. The government changed its plans for rollout of the MMR Quality Standards program, which required our research team to adapt a new approach.

We maintained a difference in difference analytical strategy. However, the government informed us that they no longer intended to rollout the training to all hospitals. Instead, they planned to rollout to a smaller set of 22 hospitals; most of which would be trained within a space of 3 months. We also learned that the government had changed the MMR Quality Standards Program from the original version used during the pilot phase. The pilot version of the MMR Quality Standards Program was a more robust and stronger

program; therefore, we thought it was important to capture impacts of the pilot program as well as the rollout program.

The medical record abstraction proceeded in two phases: 1) a pilot program phase and 2) the rollout program phase. The data collection process and analytic strategy were identical for the pilot and rollout phases. We will describe the process only once in each of those two sections. The sample differed between the two phases; therefore we present two descriptions of the sample in that section.

5.4 Sampling Plan

5.4a Pilot

We identified five government hospitals that participated in the pilot phase which met the study criteria: 1) was not a university or teaching hospital; 2) fully participated in the pilot phase of the MMR Quality Standards Program; 3) the hospital is at least a taluk level, non-Aryuvedic facility; and 4) the facility had at least 20 deliveries per year.

Each of these hospitals was matched to a comparison facility that did not receive treatment. Hospitals were matched on three criteria: geographic location, caseload and facility type (Women and Children, general, district, taluk.) Priority was given to matching by caseload, as this was the main predictor of hospital infrastructure and patient profiles. Whenever possible, comparison hospitals were chosen from the same district. In cases where this was not possible, a match was drawn from a neighboring district of similar composition. Similarly, whenever possible, hospitals were matched to a hospital of the same type. In cases where this wasn't possible, hospitals were matched to a similar facility type.

We included all women who were admitted to the institution for delivery and gave birth to a single baby in our sampling frame. We drew a random sample of 10 percent of case records from each hospital for medical record abstraction. Kerala government hospitals store medical records in paper files, sorted by medical record number. The medical record is assigned according to hospital admission date. No registry of medical records is maintained, but record numbers are generated anew each year and align with progression of time over one year. Therefore, to gather a 10 percent random sample, we randomly selected 3 days per month for each of 24 months in the observation period. This equaled 72 days for which all medical records of women admitted for delivery were reviewed.

For each hospital, we instructed the medical record librarian to pull all records from the randomly selected 3 days for each month in our 24 month time period. We additionally added all cases of pregnancy induced hypertension and non-secondary postpartum hemorrhage that occurred during our 24 month observation period, identified through the labor room registers.

After commencing the data analysis, we discovered one hospital and its match had fewer than two medical records per month in the sample. We could not obtain a reliable estimate with such a small sample. These two hospitals were dropped from the sample. We were left with four "treated" hospital and four comparison hospitals, for a total sample of 8 hospitals. Pilot hospitals and their matches are shown in Table 3.

Table 3: Number of Medical Records captured for each Pilot Phase hospital and Matched Comparison hospital

Hospital	No. of Medical Records in the Pre-Treatment Period	No. of Medical Records in the Post-Treatment Period	Total
Pilot – Taluk	214	206	2,468
Pilot – District	108	133	
Pilot – General	181	248	
Pilot – Women and Children	645	733	
Comparison – District	101	145	1,994
Comparison – District	96	145	
Comparison – General	310	408	
Comparison – Women and Children	389	400	
Total	2044	2418	4,462

5.4b Rollout

The government provided our research team with a list of 22 hospitals for which it planned to deliver the rollout phase, which met the study criteria: 1) was not a university or teaching hospital; 2) fully participated in the pilot phase of the MMR Quality Standards Program; 3) the hospital is at least a taluk level, non-Ayurvedic facility; and 4) the facility had at least 20 deliveries per year. We followed the same matching strategy as employed during the pilot phase. Matching hospitals were also chosen from a set of hospitals that met the study criteria.

Initially, we identified 22 matches for the 22 treated hospitals. However, the government changed their rollout procedure during the course of the rollout. Initially, they had planned to offer the rollout only to the hospitals identified as treatment hospitals. At the time of rollout, they opened the training up to any hospital that wanted to send its staff to attend the training. This decision allowed an additional 39 hospitals to attend the rollout MMR Quality Standards training, for a total of 61 treated hospitals. Kerala has a finite set of government hospitals that offer labor and delivery services; therefore, we were left with just 20 untreated hospitals that met our study criteria. These were matched to the treated hospitals as closely as possible, with 2 treated hospitals left without a match.

We had already begun data collection on the pre-intervention period and our budget constraints did not allow for an additional inclusion of treatment hospitals to our sample. As well, we did not expect to gain any meaningful power by adding additional treatment observations to the sample. The deficiency existed in the set of comparison hospitals.

Our evaluation met an additional setback during the data collection phase. The comparison hospitals were heavily skewed toward the smaller, more rurally located facilities than the treatment hospitals. This was intentional on the part of the government, as they wanted to train hospitals which were more likely to experience a bigger impact from the training – both in terms of number of patients affected and in presence of infrastructure to support the implementations of the standards. A consequence of this decision is that our comparison hospitals were also more likely to stop serving pregnant women and were less likely to keep adequately maintained medical records. One of our comparison hospitals had stopped delivering babies during the post-treatment phase and removed from the sample. Another comparison hospital had such poorly maintained records that we were not able to locate any records from a large chunk of the observation period. Both of these hospitals had missing observations for 6 months or more. The final set of hospitals by type is shown in Table 4.

Table 4: Distribution of hospitals by type and treatment status

Type of Hospital	No. of Treatment Hospitals	No. of Comparison Hospitals	Total
District	6	2	8
Taluk	7	15	22
Women and Children	1	1	2
General	8	0	8
Total	22	18	40

The sampling strategy for case records was the same for the rollout as described above in the pilot phase. Two hospitals were dropped during the data collection phase. No hospitals were dropped during analysis, but several comparison hospitals had fewer than 24 months of data available. The final sample of case records for each hospital type, by treatment status, is shown in Table 5.

Table 5: Number of Medical Records captured for each Rollout Phase Treatment hospital and Matched Comparison hospital

Hospital	No. of Medical Records in the Pre-Treatment Period	No. of Medical Records in the Post-Treatment Period	Total
Rollout - Taluk	892	795	6300
Rollout - District	1,307	1,007	
Rollout – General	1,043	889	
Rollout – Women and Children	149	218	
Comparison – District	1058	685	2350
Comparison – District	266	270	
Comparison – Women and Children	44	27	
Total	4759	3891	8,650

5.5 Data Collection Process

Data was collected using a medical record abstraction tool developed for this project. Data collectors had obtained or were in the process of obtaining a medical, nursing or pharmacy degree and were trained on the study protocol by the research team. Patient records were paper format, typically stored at the hospital site in a medical records library. Most hospitals did not have a consistent process for recording patient care and health information in the case record; accordingly, data collection teams were trained on thorough review to extract all relevant information. They were instructed not to make any assumptions or draw any conclusions that were not clearly and unambiguously supported by information contained in the patient record. All data were reviewed for discrepancies and a sample of records were back-checked for quality control.

5.6 Analytic Strategy

5.6a Outcome Measures

We separate the outcome measures into those related to the postpartum hemorrhage quality standards and those related to the pregnancy induced hypertension quality standards.

5.6aa Postpartum Care and Postpartum hemorrhage

The postpartum hemorrhage analysis focused on care practices related to prevention of postpartum haemorrhage, which could be derived from the patient record, and were recommended practices taught in the quality standards training. The care practices included: 1) whether oxytocin was administered at the time of delivery, 2) fourth stage management, 3) management of PPH with blood and blood products, 3) referral to ICU for uncontrolled PPH cases, 4) prenatal testing for signs of preeclampsia. We also tested the change in incidence of PPH over time between treatment and comparison hospitals.

Postpartum haemorrhage: We constructed a dummy variable equal to 1 if the patient had been identified as a postpartum haemorrhage case through the labor room register or if the medical record indicated that the woman had blood loss greater than normal by any measure or if her blood loss exceeded 500 mL for vaginal and 1000mL for Caesarean delivery. All others were assigned a value of 0 for this variable.

Active Management of Third Stage of Labor: The variable to capture oxytocin administration at time of delivery was constructed by first subtracting the time of oxytocin administration from the time of delivery of the foetus. Elapsed times were converted to a variable that captured whether absolute value of the elapsed time between oxytocin administration and birth was less than or equal to one minute. Oxytocin delivered within one minute before or after delivery was assigned a value of 1; all other non-missing time elapses were assigned a value of zero.

Postpartum Hemorrhage Prevention - 4th Stage Management: One item on the medical record abstraction tool instructed data collectors to indicate whether blood loss was recorded as a quantity (in millilitres). Blood loss recorded as a quantity was used as a proxy measure to capture whether a hospital used the weighing method or visual estimation method to assess blood loss. For example, blood loss visually estimated as normal was often recorded as “bleeding within normal limits,” or “WNL;” while blood loss visually estimated as excessive was typically recorded as “bleeding ++” or “bleeding above normal.” This measure specifically compared blood loss recorded as a quantity to blood loss recorded as a word or symbol. Case records that recorded blood loss as a quantity were assigned a value of 1; those that recorded blood loss with words or symbols were assigned a value of 0.

The medical record abstraction tool captured the number of fourth stage measurements that were taken for each of the five recommended vital measurements: blood pressure, pulse, blood loss, pallor and tonicity of the uterus. The number of measurements post-delivery for each could range from zero to six. We compared whether any measurement was recorded for each of the vitals across pilot and comparison hospitals. Case records that included a measurement was assigned a value of 1, while case records that included no measurement was assigned a value of 0, for each of the five recommended vital measurements. We then compared the difference in number of measurements recorded between comparison and treatment hospitals, for each of the give recommended vital measurements.

Management of Post-Partum Hemorrhage with Blood and Blood Products: Two items on the medical record abstraction tool captured information about blood and blood products. One was whether the attending physician prescribed any blood or blood products and the other was whether the patient was given blood or blood products. For each, we constructed a dummy variable [“prescribed” and “given_blood”] equal to 1 if the medical record showed the patient had been prescribed for the prescribed variable [or given for the given_blood variable] and equal to 0 for if not. The analysis for this variable was restricted to patients that had a designation of PPH, as defined in the PPH measure above.

Obstetric Intensive Care: One item in the medical record abstraction tool captured information on whether or not the patient had been referred to the ICU and another item captured information about whether or not the patient had been transferred to the ICU. For each, we constructed a dummy variable [“referred” and “transferred”] equal to 1 if the medical record showed the patient had been referred to the

ICU [or transferred to an ICU] and equal to 0 for if not. The analysis for this variable was restricted to patients that had a designation of PPH, as defined in the PPH measure above.

5.6ab Care for Pregnancy Induced Hypertension and Incidence of Preeclampsia

The hypertension related analysis focused on care practices related to prevention of complications associated with pregnancy induced hypertension, which could be derived from the patient record, and were recommended practices taught in the quality standards training. The care practices included: 1) urine tests for preeclampsia during the prenatal period; 2) treatment of hypertension with anti-hypertensive medication during the prenatal period; 3) treatment of hypertension with anti-hypertensive medication during the postpartum period; and 4) treatment of eclampsia with magnesium sulfate. We also tested for differences in the change in incidence of HELLP syndrome and eclampsia over time between treatment and comparison hospitals, as these are considered complications of PIH that may be prevented or reduced through medical intervention. PIH itself is not preventable through medical care.

HELLP syndrome: One item on the abstraction tool asked if the patient had headache, blurred vision, edema and/or seizures. These are the symptoms of HELLP syndrome. We generated a dichotomous variable equal to 1 if the patient had the first three or seizure and any 1 of the other symptoms. The variable was set to 0 for all others.

Eclampsia: We constructed a dichotomous variable equal to 1 if the patient's medical record included a diagnosis of preeclampsia or eclampsia and 0 for all others.

Pre-eclampsia: One item on the medical record abstraction tool measured whether urine test for signs of preeclampsia was tested during the prenatal period. Specifically, this question asks whether any urine test was given at any point during the prenatal period. This variable was recorded as a dichotomous dummy variable, with 1 indicated that at least 1 urine test was given and 0 indicating that no urine test was given.

Anti-hypertensive Treatment: For this measure, we first constructed a dichotomous variable equal to 1 if the pregnant women had blood pressure 140/90 or higher and equal to 0 if the blood pressure was less than this. We then constructed a variable equal to 1 if the woman was given any of several acceptable anti-hypertensive medications and 0 if not. Another variable was created in the same way for prescriptions of anti-hypertensives. We restricted this analysis to women with blood pressure greater than 140/90 during the prenatal period.

Treatment Severe Hypertension in Pregnancy and in Immediate Postpartum Period: For this measure, we first constructed a dichotomous variable equal to 1 if the postpartum woman had blood pressure 160/100 or higher and equal to 0 if the blood pressure was less than this. We then constructed a variable equal to 1 if the woman was given any of several acceptable anti-hypertensive medications and 0 if not. Another variable was created in the same way for prescriptions of anti-hypertensives. We restricted this analysis to women with blood pressure greater than 160/100 during the postpartum period.

Treatment of Eclampsia: One item measured whether the patient was prescribed magnesium sulfate and another item measured whether the patient was given magnesium sulfate. We constructed a dichotomous dummy variable for each, with 1 indicated an affirmative response and 0 indicating a negative response. We restricted this analysis to women with a diagnosis of preeclampsia or preeclampsia in their medical record. women with pre-eclampsia and eclampsia are given magnesium sulfate

5.6b Statistical Analysis

We estimated a multivariate regression specification of the difference in difference model in which care recorded in an individual's patient record is regressed against a dummy variable indicating whether the facility received training (in March 2013 for pilot hospitals and various dates for rollout hospitals), a dummy variable indicating whether the individual was admitted for delivery at the hospital prior to or after (March 2013 for pilot comparisons and the matched hospital training date for rollout comparison hospitals), and an interaction term that multiplied the values of the first and second variable. Difference in difference models estimate the differences in change over time between a group of interest and a comparison group. They are useful for establishing evidence of a causal impact in the absence of randomized assignment into treatment, because they do not require similar baseline profiles. Difference

in difference models establish strong evidence of a causal impact in the presence of baseline differences, so long as there is no evidence of a change in trend over time, often called the “parallel paths” assumption (Imbens and Wooldridge, 2009).

All regressions were run as linear models, regardless of whether the outcome variable was continuous or categorical, as the coefficient of the interaction term cannot be interpreted as an unbiased treatment effect in nonlinear difference in difference models (Puhani, 2012). We calculated robust standard errors, clustered at the hospital level to correct for correlation of the error terms across patients within facilities. All statistical analyses were done using Stata (version 14). Significance testing uses a cut-off of $p<.05$ for all significant results reported.

6. Programme or Policy: Design, Methods and Implementation

The Department of Health at the Directorate of Health Services in Kerala, in partnership with the Kerala National Rural Health Mission (NRHM), the Kerala Federation of Obstetricians and Gynaecologists (KFOG), and the Global Health & Development at Imperial College London[3], developed a set of ten quality standards for the management of postpartum hemorrhage and hypertensive disorders of pregnancy (Vlad et al, 2016). These standards aimed to establish guidelines for health care delivery among Kerala’s government labor and delivery institutions and some private hospitals during the intrapartum and postpartum periods. The parties intended that this program would standardize care practices among labor and delivery hospitals, aligned with the current accepted protocols for evidence based maternity care. More specifically, the organizers hoped that fewer women would die in hospital settings from pregnancy related causes, causing maternal mortality rates to fall overall. The organizers focused on the leading causes of maternal death in Kerala and globally – postpartum hemorrhage and pregnancy induced hypertension. Death due to both causes is highly preventable through swift and appropriate medical intervention.

6.1 The 10 quality standards were:

- **Active Management of Third Stage of Labor:** administration of oxytocin or other recommended uteronic drug within 1 minute of delivery
- **Postpartum Hemorrhage Prevention - 4th Stage Management:** monitoring of vital signs, including blood pressure and pulse, every 30 minutes for the first 2 hours after delivery
- **Management of Post-Partum Hemorrhage with Blood and Blood Products**: any woman with signs of excess postpartum hemorrhage is treated with blood and blood products
- **Obstetric Intensive Care:** any woman with uncontrolled postpartum hemorrhage is transferred to an Intensive Care Unit or higher-level facility within 24 hours
- **Placenta Accreta:** pregnant women with previous placenta accrete is referred to a higher-level facility for care at 32 weeks’ gestation
- **Pre-eclampsia:** tests for signs of pre-eclampsia are done during prenatal visits
- **Anti-hypertensive Treatment:** pregnant women with blood pressure 140/90 or higher are offered anti-hypertensive medications
- **Severe Hypertension in Pregnancy and in Immediate Postpartum Period:** women in the immediate postpartum period with blood pressure 160/100 or greater, and other signs of pre-eclampsia are offered specific anti-hypertensive medications
- **HELLP:** women with hypertension during pregnancy are monitored for signs of HELLP syndrome during labor and delivery
- **Eclampsia:** women with pre-eclampsia and eclampsia are given magnesium sulfate

6.2 Implementation Design

The quality standards program proceeded in two phases. During Phase 1, select hospitals were invited to participate in a pilot of the quality standards with the intention of monitoring progress and refining the program over an one-year observation period. During Phase 2, the quality standards program was rolled out to government hospitals across all 14 of Kerala’s districts.

[3] Formerly NICE International

Phase 1: Pilot Standards Program	Phase 2: Rollout Standards Program
• 4 government hospitals • 1 government medical college • 2-day on-site training session • Supply inventory and replacement • Delivery kits • Labor room posters • Modified labor room register • One year monitoring with in-person meetings	• 61 government hospitals • 5 government medical colleges • 1-day off-site training session

6.2a Phase 1: Pilot Standards Program

Substantial effort and investment were put into the pilot phase of the quality standards program. With the active support of all partners, the program recruited hospitals in the Trivandrum (Kerala capitol) area to participate in the pilot program. The partners chose hospitals based on their perceived ability to implement the care guidelines proposed and to engage in a yearlong monitoring and review process. National Health Mission personnel visited each hospital at the start of the program. During this visit, hospital needs were discussed and NHM subsequently made available materials and supplies required to support the program. KFOG staff introduced the quality standards and taught techniques to medical staff during a 2-day on-site training session at each hospital. As a developer of the quality standards and leaders in the obstetric field in Kerala, KFOG was well qualified to deliver the training. Hospitals were then given laminated posters describing the steps for each quality standard with instruction to hang the posters in the labor ward.

NHM produced a labor room register designed to quickly capture key process measures and outcomes related to the mother and baby. NHM provided each pilot hospital with printed sheets and a binder to maintain the new labor room register. The new labor room register would replace the older, less informative registers. NHM requested hospitals to share mortality and PPH/PIH data monthly. NHM also produced delivery kits to maintain sanitation during labor and delivery. One key component of these kits were disposable blankets intended to aid in measuring blood loss in the postpartum period. The blankets absorbed blood and could be weighed to obtain a reliable estimate of measurable blood loss.

Throughout the year long pilot phase, NHM convened administrators from the participating hospitals each month for a review of morbidity and mortality related to PPH and PIH. NHM staff analyzed each hospital's data and shared the results during the meeting. Hospital administrators discussed contextual factors related to the results for their hospital and generally discussed progress of implementation of the quality standards. In the last months of the pilot phase, hospital administrators contributed to discussed about the success and potential the refinement of the quality standards guidelines. NHM published the first edition of the quality standards in January 2013, prior to the pilot phase. We are not aware of any subsequent editions of this document. Thus, the January 2013 guidelines continued to serve as the quality standards for the rollout program.

6.2b Phase 2: Rollout Standards Program

As described earlier, several changes in leadership affected the quality standards program in the interim period between the pilot phase (March 2013-February 2014) and rollout phase (commencing in September 2015.) In the rollout phase, the training was held off-site with multiple hospitals in attendance. The training session was shortened to one day. No labor room registers were provided to hospitals and no labor room posters were given. NHM did not monitor hospital implementation of the quality standards guidelines during phase 2. While we initially intended to conduct the impact evaluation on the rollout phase only; we were persuaded by these substantial changes to conduct a separate analysis of the pilot phase as well. We thought it particularly important to document differences in effectiveness across the two versions of implementation.

In the rollout phase, KFOG-trained staff introduced the quality standards through a full-day off-site training session. Kerala convened a training of the trainers session prior to the quality standards training to ensure trainers were equipped to deliver the sessions. As well, KFOG personnel attended and delivered

components of the quality standards training. The training session was divided into two parts: a lecture-based portion and a series of demonstration workstations. All content was directed toward obstetric care practices in a hospital setting, including: active management of third stage labor; fourth stage monitoring; safe induction of labor; signs, symptoms and treatment of preeclampsia; sepsis prevention and management; and appropriate use and handling of blood and blood products.

Labor ward nurses and doctors from intervention hospitals were invited to attend via a circular issued by NHM. Participation in the training program was voluntary. To encourage attendance, health care providers were not charged any fees for attending the training and they were provided compensation for time and travel. Aside from financial support for staff to attend the training, hospitals did not receive any additional support, mandate or monitoring to implement the quality standards program.

A total of 19 training sessions were held between September 2015 and March 2016. More than one hospital attended each session. One session was held in September, 5 in October, 3 in November, 5 in December, and 1 each in January, February, and March. On average, 40 participants attended each training session. The dates and number of participants for each training session is shown in Table 6. As discussed elsewhere, the number of hospitals attending the training changed from the original plan discussed with NHM. NHM opened the training to any interested hospital in the district. Therefore, the original set of 22 treatment hospitals attended the training, but an additional 39 hospitals also attended the training. A total of 61 (non-teaching) government hospitals attending one of the 19 training sessions. Training sessions and participants are shown in Table 6.

Table 6: Rollout Phase Training Sessions

Serial No.	**District**	**Date**	**No. of Participants**
1	Alappuzha	23rd Sep, 2015	43
2	Ernakulam	2nd Mar, 2016	38
3	Idukki	20th Feb, 2016	unknown
4	Kannur	18th Dec, 2015	39
5	Kasaragode	2nd Mar, 2016	46
6	Kasaragode	1st Mar, 2016	55
7	Kollam	11th Dec, 2015	46
8	Kollam	13th Dec, 2015	39
9	Kottayam	23rd Nov, 2015	41
10	Kozhikode	11th Dec, 2015	50
11	Malappuram	21st Nov, 2015	40
12	Palakkad	29th Oct, 2015	42
13	Pathanamthitta	8th Oct, 2015	35
14	Pathanamthitta	1st Oct, 2015	40
15	Thrissur	11th Nov, 2015	33
16	Thrissur	28thOct, 2015	35
17	Thrissur	28th Oct, 2015	35
18	Trivandrum	5th Dec, 15	40
19	Wayanad	30th Jan, 2016	31

7. Impact Analysis and Results of the Key evaluation Questions

7.1 Medical Record Abstraction

7.1a Pilot Results

Hospitals that participated in the pilot phase of the MMR Quality Standards program had significantly fewer cases of postpartum haemorrhage before and after treatment, as compared to their matched comparison hospitals. Participating in the pilot program did not significantly affect the postpartum haemorrhage rate; however, it is unlikely that any true effect on postpartum haemorrhage would have been detectable given the overall low incidence. Results for PPH are shown in Table 7.

Table 7: Number of PPH Cases Before and After Intervention by Treatment Status

	Number of Pilot PPH Cases	Number of Comparison PPH Cases
Before Intervention*	10	43
After Intervention*	12	47
Total	22	90

*Chi-square p-value <0.001

Effect of Pilot Quality Standards Program on Preventive Care Outcomes are shown in Table 8. There was a significant improvement in measurement of blood loss as a quantity instead of a phrase or symbol in hospitals that participated in the quality standards program. Pilot hospitals were significantly more likely to increase the number of case records with a quantified blood loss recording than comparison hospitals. The number of case record with fourth stage blood pressure recordings were significantly more likely to increase in pilot hospitals than in comparison hospitals. There were no significant effects for changes in rates of administration of oxytocin at birth or in the likelihood of having any fourth stage measurement recorded between pilot and comparison hospitals. Shown in Table 9, the number of case records with fourth stage pulse recordings was also significantly more likely to increase for pilot hospitals than for comparison hospitals after the intervention. However, pilot hospitals were significantly more likely to experience a decrease the number of case records with a post-delivery measurement of pallor after participating in the intervention.

Table 8: Effect of Pilot Quality Standards Program on Preventive Care Outcomes

Standard errors in parentheses

+ p<.10, * p<.05, ** p<.01, *** p<.001

	Blood Loss Recorded as Quantity	Oxytocin at Birth	# of Blood Pressure Measurements	# of Pulse Measurements	# of Blood Loss Measurements	# of Pallor Measurements	# of Uterus Tonicity Measurements
Time	-0.00129	-0.0453	-0.0331	0.0197	0.517	0.498**	0.897
	(0.000832)	(0.0792)	(0.147)	(0.113)	(0.363)	(0.114)	(0.566)
Treatment	-0.000364	0.338	-1.325**	-1.296**	-0.127	-0.280*	-0.0819
	(0.000955)	(0.181)	(0.313)	(0.282)	(0.675)	(0.0843)	(0.451)
Time*Treatment	0.309*	0.170	0.586*	0.508*	0.507	-0.466**	0.465
	(0.120)	(0.0985)	(0.176)	(0.162)	(0.444)	(0.114)	(0.607)
Constant	0.00129	0.157+	4.690***	4.674***	2.223**	1.741***	1.829**
	(0.000832)	(0.0781)	(0.0905)	(0.0821)	(0.616)	(0.0841)	(0.414)
Observations	4025	4462	3688	3634	4025	1225	3266
r2	0.233	0.206	0.140	0.139	0.0793	0.112	0.152
df_m	2	3	3	3	3	3	3

Table 9: Effect of Pilot Quality Standards Program on Whether Any Measurement was Recorded in the Case Sheet

	Blood Pressure	Pulse	Blood Loss	Pallor	Uterus
Time	-0.000250	-0.0336	0.00233	0.146	0.0931
	(0.0283)	(0.0246)	(0.0234)	(0.110)	(0.0569)
Treatment	0.0995	0.0756	0.105	0.214	0.153
	(0.183)	(0.0926)	(0.189)	(0.187)	(0.196)
Time*Treatment	0.0768	0.0420	0.0843	-0.147	0.0293
	(0.0616)	(0.0315)	(0.0646)	(0.110)	(0.0913)
Constant	0.749**	0.866***	0.730**	0.121+	0.588**
	(0.145)	(0.0821)	(0.150)	(0.0577)	(0.115)
Observations	4462	4462	4462	4462	4462
r2	0.0397	0.0287	0.0439	0.0338	0.0506
df_m	3	3	3	3	3

Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

7.1b Rollout Results

Overall, 4.7 percent of the patients in the sample had evidence of postpartum hemorrhage in their patient record prior to treatment. This increased, by a non-significant amount, to 5.2 percent in the post-intervention period. Among the treatment group, 4.6 percent of patients had evidence of postpartum hemorrhage in their medical record and 5 percent of patients in the comparison group had evidence of postpartum hemorrhage in their medical record prior to treatment. These rates were not significantly different between the treatment and comparison group before treatment. The difference in difference analysis showed no impact of the MMR Quality Standards training program on postpartum hemorrhage rates. Rates for PPH, PIH and eclampsia are shown in Table 10.

The sample showed 16.6 percent of patients had evidence of pregnancy induced hypertension in their patient record during the baseline period. PIH rates increased significantly between the from baseline to 19.7 percent in the post-intervention period. Prior to treatment, 20.2 percent of patients in the comparison group had evidence of PIH, while 15.1 percent of patients in the treatment group had evidence of PIH in their medical record. Patients in the treatment group were significantly less likely to have evidence of pregnancy induced hypertension in their medical records before treatment. The difference in difference analysis showed no impact of the MMR Quality Standards training program on rates of pregnancy induced hypertension.

Fewer than 1 percent of the sample had evidence of eclampsia or preeclampsia during the baseline period. The number remained consistent across time, at 0.65 percent during baseline period and 0.64 during the post-intervention period. Baseline rates of preeclampsia or preeclampsia were equivalent across treatment status: treated records showed of 0.65 percent while comparison records showed a rate of 0.66 percent. The difference in difference analysis showed no impact of the MMR Quality Standards training program on rates of eclampsia or preeclampsia.

Zero records showed a diagnosis of HELLP syndrome in the patient record, in either time-period for the comparison and treatment groups. The vast majority, 99.3 percent, of patient records showed no recording of any symptoms related to HELLP in the medical record. No record showed 3 or more HELLP symptoms or seizure plus another symptom. Nine records showed evidence of seizure; 7 of these were treatment and 2 of these were comparison. There were no differences over time. Given the extremely low numbers and no true documentation of HELLP syndrome, this was not included in the analysis.

Table 10: Effect of MMR Quality Standards Program on PPH, PIH or Eclampsia rates

	PPH	PIH	Pre-eclampsia/Eclampsia
time	0.00499	0.0284	0.00360
	(0.0111)	(0.0454)	(0.00467)
treatment	-0.00392	-0.0505	-0.0000912
	(0.0203)	(0.0457)	(0.00571)
time=1 # treatment=1	-0.000309	0.00562	-0.00494
	(0.0170)	(0.0497)	(0.00617)
Constant	0.0499**	0.202***	0.00658+
	(0.0168)	(0.0376)	(0.00388)
Observations	7291	8650	8650
r2	0.000180	0.00470	0.000334
df_m	3	3	3

Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

7.1ba Quality Standards Related to Postpartum Hemorrhage

The MMR Quality Standards program had no impact on any of the measures of preventive care related to postpartum hemorrage included in this study. Results for PPH preventive care are shown in Table 11. There was no difference over time between treatment and control groups in the likelihood of recording blood loss as a quantity, in administering oxytocin at the time of birth, nor in the number of postpartum checks performed for any of the recommended vitals: blood pressure, pulse, blood loss, pallor and uterus contractions. There was no effect of the MMR Quality Standards program on the likelihood of conducting any postpartum monitoring check on any of the recommended vitals: blood pressure, pulse, blood loss, pallor and uterus contractions (Table 12).

Table 11: Impact of Rollout on Postpartum Hemorrhage Prevention Care
Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

	Blood loss as quantity	Oxytocin at birth	No. BP checks	No. Pulse checks	No. Blood Loss checks	No. Pallor checks	No. Uterus checks
time	0.00171	-0.00342	0.0384	0.0197	0.0853	-0.367	0.205
	(0.00208)	(0.0318)	(0.128)	(0.0905)	(0.122)	(0.265)	(0.133)
treatment	-0.000553	0.0160	0.522+	0.451	-0.358	0.580	-0.227
	(0.000930)	(0.0866)	(0.293)	(0.319)	(0.351)	(0.655)	(0.359)
time* treatment	-0.000899	0.0429	-0.114	-0.185	0.129	0.981*	-0.0520
	(0.00227)	(0.0454)	(0.161)	(0.156)	(0.159)	(0.407)	(0.149)
Constant	0.000894	0.338***	3.567***	3.792***	1.916***	1.802***	1.670***
	(0.000871)	(0.0644)	(0.193)	(0.242)	(0.296)	(0.419)	(0.253)
Observations	7434	8650	5586	5002	7236	760	4151
r2	0.000470	0.00231	0.0176	0.0128	0.0173	0.125	0.0140
df_m	3	3	3	3	3	3	3

Table 12: Effect of MMR Quality Standards Rollout of Likelihood of Conducting Any Postpartum Check

	Any BP check	Any Blood Loss check	Any Pulse check	Any Pallor check	Any Uterus check
time	-0.00340	-0.0474	0.0147	0.0164	0.0699+
	(0.0349)	(0.0359)	(0.0339)	(0.0220)	(0.0371)
treatment	0.00125	0.0713	0.0865	0.0148	0.0235
	(0.0603)	(0.0626)	(0.0640)	(0.0538)	(0.0768)
time*treatment	0.0528	0.0663	0.0300	-0.00128	-0.00847
	(0.0454)	(0.0404)	(0.0431)	(0.0400)	(0.0559)
Constant	0.629***	0.784***	0.499***	0.0702*	0.434***
	(0.0364)	(0.0485)	(0.0476)	(0.0305)	(0.0602)
Observations	8650	8650	8650	8650	8650
r2	0.00249	0.0160	0.00982	0.00128	0.00443
df_m	3	3	3	3	3

Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

If a woman had excessive blood loss (postpartum haemorrhage), she was no more likely to receive optimum care if she gave birth in a hospital that received the MMR Quality Standards program than if she gave birth in a comparison hospital. There was a marginally significantly negative impact of the MMR Quality Standards program on the likelihood of a woman with PPH being administered blood products (Table 13). There was no impact of the MMR Quality Standards program on the likelihood of a woman with PPH being referred to an ICU or higher level facility (Table 13). No medical record mentioned a history of placenta previa.

Table 13: Effect of MMR Quality Standards on Treatment for PPH

	Given Blood Products	Referred to ICU
time	0.202+	-0.0357
	(0.104)	(0.0564)
treatment	0.184	0.00315
	(0.138)	(0.0551)
time=1 # treatment=1	-0.241+	-0.0181
	(0.126)	(0.0724)
Constant	0.250*	0.107**
	(0.112)	(0.0386)
Observations	358	358
r2	0.0178	0.00785
df_m	3	3

Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

7.1bb Quality Standards Related to Pregnancy Induced Hypertension

Results for care related to pregnancy induced hypertension are shown in Table 14. The MMR Quality Standards program had a negative effect on prenatal urine testing. Hospitals that participated in the training program were less likely to have patients that received a urine test during pregnancy. The MMR Quality standards program had no impact on preventive measures to reduce complications associated with pregnancy induced hypertension. Pregnant patients with high blood pressure seen at treated hospitals were not more likely to be prescribed or receive anti-hypertensive medication after MMR Quality standards training. Postpartum patients with high blood pressure seen at treatment hospitals were not more likely to be prescribed or receive anti-hypertensive medication after MMR Quality standards training. The MMR Quality Standards training program had no effect on likelihood of preeclampsia and eclampsia patients being prescribed or receiving magnesium sulfate.

Table 14: MMR Quality Standards Impact on Health Care Practices Related to PIH and Eclampsia

	Prenatal Urine Test	Anti-hypertensives for High BP in Pregnancy	Abti-hypertensives for High BP Postpartum	Abti-hypertensives Prescribed for High BP Postpartum	Magnesium Sulfate for Eclampsia	Magnesium Sulfate Prescribed for Eclampsia
time	0.143*	0.0338+	0.0401	0.135+	-0.189	-0.189
	(0.0622)	(0.0182)	(0.0677)	(0.0721)	(0.204)	(0.204)
treatment	0.0726	-0.0184	-0.00794	0.0720	0.0202	-0.0253
	(0.130)	(0.0292)	(0.0852)	(0.0948)	(0.133)	(0.138)
time=1 # treatment=1	-0.158*	-0.00631	0.0594	-0.0276	0.146	0.259
	(0.0725)	(0.0332)	(0.0962)	(0.0941)	(0.221)	(0.221)
Constant	0.604***	0.900***	0.839***	0.774***	0.889***	0.889***
	(0.105)	(0.0145)	(0.0533)	(0.0661)	(0.129)	(0.129)
Observations	5121	908	172	172	56	56
r2	0.00603	0.00350	0.0144	0.0350	0.0462	0.0502
df_m	3	3	3	3	3	3

Standard errors in parentheses
+ p<.10, * p<.05, ** p<.01, *** p<.001

8. Discussion

Overall, the results of the impact analysis suggest that the pilot MMR Quality Standards program was moderately associated with improvement in care delivery. This provides evidence that training may be helpful in promoting uptake of evidence-based guidelines. However, when the program was expanded to the rollout phase, several changes were made to how it was delivered. The program reduced from a comprehensive program that included monitoring and support with visual aids to a shortened, single training session and little to no hospital administration involvement. The results from the impact analysis showed no significant effect of the single, shorted training program on likelihood of physicians and nurses using evidence-based guidelines. Together, these results suggest that training alone, particularly a short primarily lecture based training, is not an effective means of changing provider behavior. The MMR Quality Standards program was effective as a comprehensive package, but not as a standalone training. Future efforts to improve health care quality should take note of this.

Hospitals were marginally significantly less likely to administer blood and blood products after receiving the MMR Quality Standards training. We can hypothesize two potential explanations for this. First, it is possible that the training confused physicians and left them feeling less confident about the administration of blood and blood products. Prior to the training, many physicians reported that they had not known that specific blood products were required, rather than just whole blood, to treat PPH. Some nurses reported that they did not understand the lecture on blood products. Given that the blood products training covered a lot of complicated material in a short time, it is possible that the training left nurses and physicians confused. The main takeaway – do not give blood products – was consistently reported as understood by nurses and physicians, but they may have felt less sure about which blood products to given. This may have been exacerbated by the lack of facilities to administer blood products at hospitals. For example, nurses and physicians may now understand that whole blood can cause problems, and may not be ideal treatment, but did not have access to blood products. Therefore, they may have avoided administration of any blood with the hope of avoiding complications associated with using whole blood.

Another alternative explanation is that nurses and physicians at treated hospitals used fewer blood products to treat PPH and relied instead on uterotonic treatment. There is a marginally significant evidence that treatment hospitals increased use of Prostaglandin F2 Alfa over after training. Prostaglandin F2 Alfa is an emerging therapy for severe PPH. In other words, it does seem plausible that attending the training program caused nurses and physicians to treat postpartum hemorrhage with uterotonics in place of blood products. However, use of uterotonics to treat severe PPH was not a quality

standard; so, we can only speculate that this was in direct response to a protocol taught during the training program. This is possible, as we mentioned the training added components in addition to the MMR quality standards, but we do not have evidence that trainers instructed hospitals to use uterotonics instead of blood products or to prevent the need for blood products.

Hospitals in the treatment group seemed to have fewer patients with prenatal urine testing after they participated in the MMR Quality Standards Training program. It is difficult to construct a plausible explanation for this, but we can imagine one possibility. Patients do not always obtain prenatal care at the same facility in which they give birth. In fact, the mother interviews suggest it is fairly common for government hospitals in particular to refer patients to a higher-level facility for labor and delivery. It is possible that referrals to hospitals that participated in the MMR Quality Standards training program increased after the training. Perhaps other hospitals were aware that these facilities had been trained and felt their patients would be safer giving birth in a trained hospital. Urine tests in the medical record might be reduced in these cases, either because the referring facility did not do the test or because the test was not transferred along with the patient.

Overall, nurses and doctors said they found the training to be helpful and indicated appreciation for the opportunity to learn about advances in their field. Willingness and ability to translate their education into practice; however, seemed to hinge on several factors. Some of these were internal to the health care provider. For example, several providers were not convinced of the importance of new techniques, while others were motivated to take on substantial personal burden to enact what they had learned. Future efforts that incorporate training as a primary strategy to change provider behavior might consider strategies that address these individual differences.

Even motivated individuals may face barriers related to confidence in applying new techniques. Lecture-based learning imparts knowledge, but health care providers must also be given adequate time to practice new techniques to establish confidence and proficiency. Given that obstetric emergencies are rare and arise suddenly, often unexpectedly, continuing education programs must consider the optimum amount and mode of practice to develop proficiency.

External factors that affected provider implementation of training material included barriers related to infrastructure, material supply, staffing and support of hospital leadership. The Kerala government is aware of the constraints hospitals face regarding infrastructure and material supply. At the time of this writing, they are in the process of a major initiative to equip government hospitals with the necessary buildings, supplies and machinery to provide the care recommended within the Quality Standards Program[4]. Nonetheless, resource constraints are a common occurrence in low and middle-income countries. That some providers found ways to work around the infrastructure and supply limitations suggests that motivation is a powerful contributing factor to overcome these types of external limitations. Many of the evidence-based practices to reduce maternal mortality, like fourth stage management and active management of third stage labor, are possible in resource-constrained environments, but may require a high level of commitment to accomplish.

Overall, to promote uptake of evidence-based guidelines, training programs should focus only on the guidelines to be used. The trainings need to include opportunities for physicians to practice and master skills. Some physicians and nurses may be more resistant to receiving new information. Increased effort must be dedicated to motivating and convincing hospital staff of the benefits of using evidence-based medicine. Moreover, to increase the chances of successful uptake, training programs should be complemented with additional components like those included in the MMR Quality Standards pilot program. This includes ongoing monitoring, visual reminders, extended training and inclusion of hospital administration throughout the process.

8.1 Limitations

Although a strong quasi-experimental approach for reducing confounding variables that muddle the ability to attribute causality to interventions, the difference in difference model relies on one assumption – parallel paths. This idea, that causality can be established in the absence of statistically equivalent baseline groups, if the time trends for both groups are equivalent, is powerful so long as we can review

[4] Sri. Keshvendra Kumar I A S, Kerala State Mission Director, National Health Mission, Oral Communication November 3, 2017.

those time trends and identify parallel trends. To test this assumption, we compared the 12 month pre-intervention trends to the 12 month post-intervention trends. We did this in two ways. First, we calculated the slope of outcome verses time for each group, intervention and comparison, then ran a t-test for equivalence between the two slopes. We also plotted the pre- and post- intervention time trends for each group, intervention and comparison, to observe differences in trends and trajectories for these groups during each time period. Graphs and results of the statistical tests for each outcome are available upon request.

Unfortunately, in this study, we did not observe parallel trends for most of our measured outcomes. As well, the slopes are statistically significantly different ($p<.001$). Overall, we find evidence in the observation of the graphs that our primary conclusions are still supported. The trajectories of intervention hospitals appear unaffected or negatively affected in the rollout phase. In the case of urine testing, our significant result can be observed as such: both comparison and treatment hospitals increased in the post-intervention period, but the comparison group increased at a greater rate than treatment hospitals. This suggests that our finding, that the rollout intervention was not successful at improving utilization of evidence-based guidelines, holds.

For the pilot results, our observations of the time trends also support our findings. We found a significant, positive effect of the pilot intervention on the proportion of providers measuring blood loss in a quantifiable way. In our time trends analysis, we observe a strong and sudden positive upward trend in the treatment group just after the intervention and no change in the comparison group during this period. Although the difference in slopes in the pre-treatment period was significant, the magnitude was small and is not observable by graph. We found a significant, positive effect of the pilot intervention for increasing the number of fourth stage pulse measurements. Our time trends analysis suggests that the treatment group continued a positive trajectory during this period, while the comparison group faced a sudden drop. This is suggestive that the intervention may have helped sustain momentum against a negative external pressure. The same phenomenon was observed for fourth stage blood pressure readings, for which we also found a significant positive effect. Finally, our results found a significant negative effect of the intervention on the number of pallor readings during the fourth stage. Our time trends analysis shows the slope reverses from positive to negative for the treatment group after intervention. In contrast, the comparison group continues an upward trajectory of fourth stage pallor measurements. Overall, our time trends analysis supports the findings from the pilot difference in difference analysis.

9. Specific Findings for Policy and Practice

The findings from this report suggest that a half day training, without additional supports, is an insufficient intervention to change provider behavior and improve the quality of care mothers receive during labor and delivery. When implemented alongside improvements in infrastructure, adequate supply of materials and ongoing monitoring, the MMR Quality Standards Program showed evidence of having a positive effect on physician and nurses' care practices. Training may be a helpful component of a comprehensive strategy to change the way hospitals deliver care to pregnant women. In consideration of the impact and qualitative findings, we propose the following recommendations.

1. Involve leadership to ensure buy-in

One consistent message that arose across focus group discussions with nurses and doctors was that administrators who were unaware or unsupportive of the MMR Quality Standards program served as a strong barrier to program uptake. Conversely, staff reported that hospital leaders who understood and supported the program provided a strong expectation and vision for how the standards could be used in the hospital. The pilot study, which brought hospital administrators in from the beginning and included them as program monitors throughout the program, found positive results. The rollout study, which did not include hospital administrators in any part of the program, found no results. Collectively, these findings support the strong positive role hospital administrators can play when they are included in the program and used to help engage and promote the standards in the hospital. When hospital administrators are not included in the program, they can hinder efforts to change. Future efforts to promote evidence-based guidelines in a hospital setting need to include hospital administrators and other leadership as key stakeholders and program implementers. Ultimately, they are responsible for setting hospital policy, establishing the tone and direction of the organization and are the ones who can take active steps to ensure compliance from hospital staff.

2. Look for ways to engage nurses and physicians with learning and test competency

One strong theme that arose during the focus group discussion was that physicians served as a second barrier or facilitator to using evidence-based guidelines. Physicians mistrusted the material taught in the training program or who felt uncertain in their ability to execute techniques reported these as barriers to implementing the program. In the transition from pilot phase to rollout, the training was shortened and more material added. Our team's observation of those trainings reported that much of the time was devoted to lecture and the other portion was demonstration by the trainer. Physicians received no hands-on practice and often were not given the rationale for using evidence-based guidelines. Many physicians walked away from the training feeling unsure. Some felt unsure that the new care practices were truly better for the patient. Others may have believed that the new care practices were beneficial but didn't feel confident in their own ability to use the technique. Future efforts to train physicians must include practical application – physicians must be able to practice the techniques regularly to gain competence and master the approach under emergency conditions. A one-time training is not enough. Repeated messaging coupled with patient stories and evidence of the consequences of failing to use evidence-based guidelines will promote physician adherence to the guidelines.

3. Adapt a culture of patient-centeredness and accountability

In most cases, mothers believed government hospital nurses and physicians to be as competent, and in some cases more competent, than the private sector equivalents. The majority of negative perceptions mothers expressed related to government hospitals were centered around cleanliness, uncaring attitudes of staff, and mistrust. Mothers feared that government doctors or other staff would demand the patient attend private facility appointments, so the doctor could take extra payment. They also expressed an uncertainty about whether government doctors were always acting in the patient's best interest or the best interest of the doctor. Nurses and other hospital staff have a strong reputation of behaving cruelly or uncaring toward mothers and their families. While the MMR Quality Standards program aims to improve the technical care patients receive, little to no attention is paid to training staff on caring for patients' emotional needs. Labor and delivery are an intensely personal experience, with mothers facing a cacophony of emotions and physical sensations. Yet, every woman interviewed could recall and clearly describe the sequence of events from the start of her labor to the birth of her baby. One cannot neglect the miraculous nature of birth, the fundamental wonder of bringing life into the world, and the reality that – for most mothers – giving birth, even for the 7th time, is a major life event. Hospitals should adopt a culture of patient-centeredness and develop a system of accountability to ensure the ethical and humane treatment of mothers during the birthing process.

4. Invest in supply and infrastructure

Another consistent theme, across data sources – mother interviews, hospital survey, and labor ward focus groups – is the lack of infrastructure in government hospitals. Mothers express it as a fear that they will be told to go to another hospitals, or be forced to delivery in a private hospital, if any complication arises during labor or late stage pregnancy. The hospital survey shows insufficient bed capacity, inadequate access to ICU facilities, and lack of supplies and equipment – such as reagent strips to test for PIH and blood products to treat PPH – to properly implement the quality standards. Nurses and doctors complain that they do not have time or materials to properly sanitize equipment, perform fourth stage monitoring and they also mention a lack of blood products to treat PPH. This has a direct impact on the ability of labor ward staff to implement quality standards. Hospital staff cannot implement evidence-based guidelines without the associated materials, equipment and administrative support required to do so. The government must make it a priority to invest in ongoing supply and maintenance of materials to support the health of its patients. The safety of mothers and babies must be protected. As the stewards of the next generation, mothers' health and wellbeing must be prioritized.

5. Implement ongoing monitoring

As part of developing a culture of accountability, labor wards must undergo ongoing quality assurance and monitoring. The government is currently collecting information inconsistently and does not use the information to inform or implement change across hospitals. Hospitals should be given a monthly or quarterly report – ideally, in the form of a score card that rates their performance on health care delivery, patient care, cleanliness, safety and health outcomes. Hospitals should be given expectations with incentives or penalties attached. Monitoring can also help the government learn what steps are needed to promote ongoing program implementation and successful uptake of evidence-based guidelines.

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Appendix A – Sample Design

Table Appendix A1: Pilot Phase Hospitals

District	Type	Match District	Match Type
Eranakulam	general	Alappuzha	womenandchildren
Thiruvananthapuram	community	Thiruvananthapuram	taluk
Thiruvananthapuram	district	Eranakulam	district
Thiruvananthapuram	taluk	Thiruvananthapuram	taluk
Thiruvananthapuram	womenandchildren	Kannur	general

Table Appendix A2: Pilot Phase – 10 % days of the month over 24 months
*Day of the month randomly generated using random generator; days of month within a month held consistent across years

Year	Month	Day1	Day2	Day3
2012	April	1	15	18
2012	May	4	5	20
2012	June	7	16	30
2012	July	4	16	31
2012	August	2	6	30
2012	September	7	25	28
2012	October	19	24	30
2012	November	16	19	22
2012	December	15	27	28
2013	January	5	13	27
2013	February	5	14	26
2013	March	6	7	16
2013	April	1	15	18
2013	May	4	5	20
2013	June	7	16	30
2013	July	4	16	31
2013	August	2	6	30
2013	September	7	25	28
2013	October	19	24	30
2013	November	16	19	22
2013	December	15	27	28
2014	January	5	13	27
2014	February	5	14	26
2014	March	6	7	16

Table Appendix A3: Rollout Phase Hospitals

Treatment			Matched Comparison		
District	**Type**	**2014-2015 Deliveries**	**District**	**Type**	**2014-2015 Deliveries**
Alappuzha	womenandchildren	2128			
Eranakulam	District	1509	Thrissur	district	518
Eranakulam	general	1003	Eranakulam	womenandchildren	419
Idukki	taluk	1686	Palakkad	taluk	759
Kannur	district	3458	Malappuram	taluk	1636
Kannur	general	4220	Malappuram	taluk	1234
Kannur	taluk	2024	Malappuram	taluk	363
Kasargode	district	1710	Eranakulam	taluk	562
Kasargode	general	2732	Eranakulam	taluk	433
Kollam	taluk	1517	Kollam	taluk	1325
Kollam	taluk	1205	Kollam	taluk	462
Kottayam	general	1492	Thrissur	taluk	631
Malappuram	district	2721	Malappuram	district	2457
Malappuram	district	2324	Eranakulam	taluk	333
Palakkad	taluk	1701	Palakkad	taluk	1004
Pathanamthitta	general	1410	Eranakulam	taluk	197
Pathanamthitta	general	1332	Eranakulam	taluk	120
Thiruvananthapuram	district	2040	Thiruvananthapuram	community	303
Thiruvananthapuram	general	1279			
Thiruvananthapuram	taluk	841	Thiruvananthapuram	taluk	626
Thrissur	general	2892	Kannur	taluk	172
Wayanad	taluk	801	Wayanad	taluk	623

Table Appendix A4: Rollout Phase – 10 % of days of the month over 24 months
*Same day of month used as pilot for consistency. Training dates and therefore 24 month period varied across hospitals

month	Day1	Day2	Day3
January	5	13	27
February	5	14	26
March	6	7	16
April	1	15	18
May	4	5	20
June	7	16	30
July	4	16	31
August	2	6	30
September	7	25	28
October	19	24	30
November	16	19	22
December	15	27	28

Appendix B – Sample Size and Calculations

We identified five government hospitals that participated in the pilot phase which met the study criteria: 1) was not a university or teaching hospital; 2) fully participated in the pilot phase of the MMR Quality Standards Program; 3) the hospital is at least a taluk level, non-Aryuvedic facility; and 4) the facility had at least 20 deliveries per year.

Table Appendix B1: Number of Medical Records captured for each Pilot Phase hospital and Matched Comparison hospital

Hospital	No. of Hospitals	No. of Medical Records in the Pre-Treatment Period	No. of Medical Records in the Post-Treatment Period	Total
Pilot – Taluk	1	214	206	2,468
Pilot – District	1	108	133	
Pilot – General	1	181	248	
Pilot – Women and Children	1	645	733	
Comparison – District	1	101	145	1,994
Comparison – District	1	96	145	
Comparison – General	1	310	408	
Comparison – Women and Children	1	389	400	
Total	8	2044	2418	4,462

The government provided our research team with a list of 22 hospitals for which it planned to deliver the rollout phase, which met the study criteria: 1) was not a university or teaching hospital; 2) fully participated in the pilot phase of the MMR Quality Standards Program; 3) the hospital is at least a taluk level, non-Ayurvedic facility; and 4) the facility had at least 20 deliveries per year. We followed the same matching strategy as employed during the pilot phase. Matching hospitals were also chosen from a set of hospitals that met the study criteria.

Table Appendix B2: Distribution of hospitals by type and treatment status

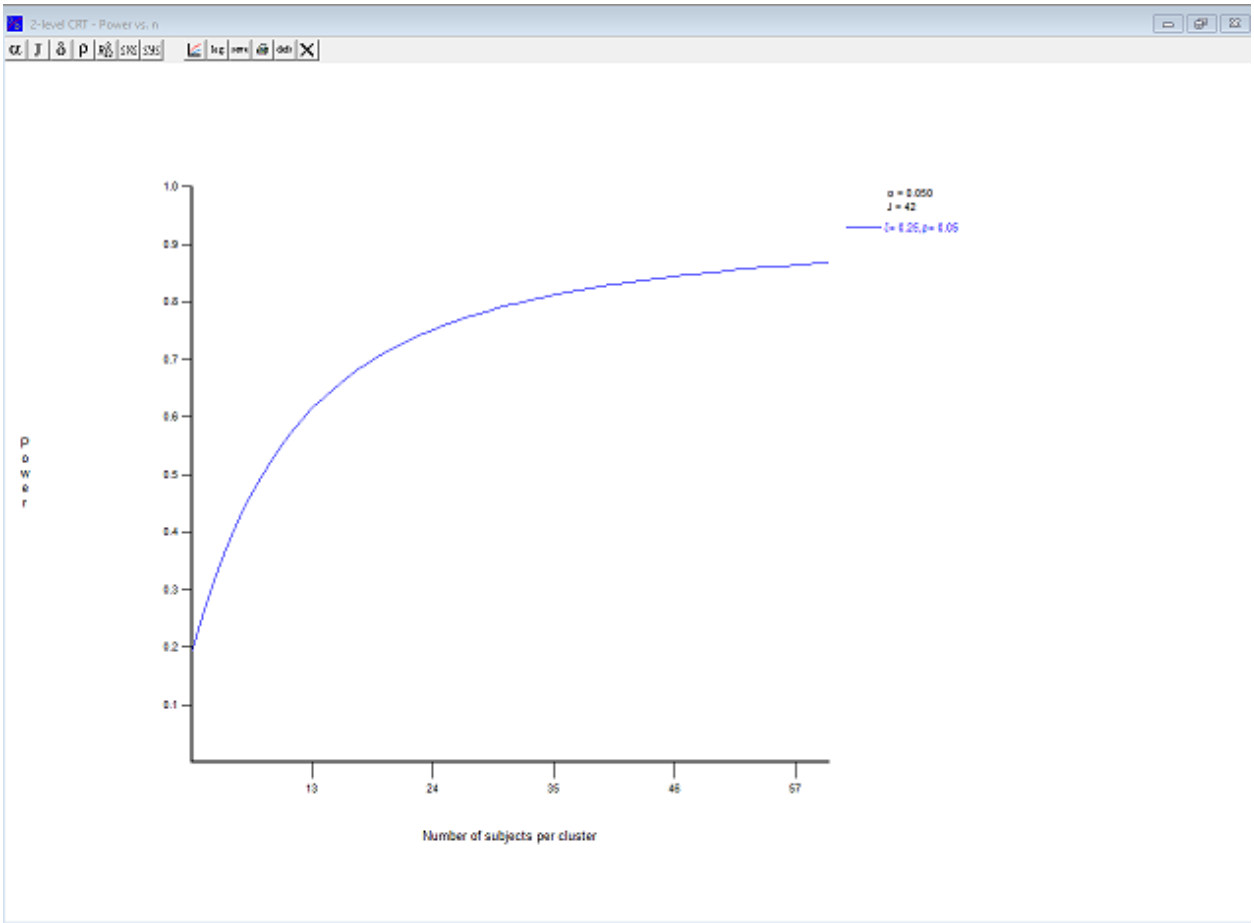
	No. of Treatment Hospitals	No. of Comparison Hospitals	Total
District	6	2	8
Taluk	7	15	22
Women and Children	1	1	2
General	8	0	8
Total	22	18	40

Table Appendix B3: Number of Medical Records captured for each Rollout Phase Treatment hospital and Matched Comparison hospital

Hospital	No. of Medical Records in the Pre-Treatment Period	No. of Medical Records in the Post-Treatment Period	Total
Rollout - Taluk	892	795	6300
Rollout - District	1,307	1,007	
Rollout – General	1,043	889	
Rollout – Women and Children	149	218	
Comparison – District	1058	685	2350
Comparison – District	266	270	
Comparison – Women and Children	44	27	
Total	4759	3891	8,650

Power Calculations

All power calculations were conducted using Optimal Design Software, which allows for real-time adjustment of number of clusters and cluster size. Holding our ability to correctly identify a true effect at 0.8, (Type II Error), and the likelihood of falsely rejecting the null hypothesis at 0.05, we estimated the number of units (patient records) within hospitals required to adequately detect an effect size of 0.25, under a scenarios of intraclass correlation coefficients equal to 0.05 and 0.1. The number of clusters was fixed (not adjustable by the research team.) With an intraclass correlated of 0.05, we could safely detect an effect size of 0.25 given 38 observations per cluster.



Appendix C – Structural Equation

The empirical specification of the difference in difference model employed is:

$$Y_{ijt} = \gamma_0 + \gamma_1 Treat_j + \gamma_2 Post_t + \gamma_3 Treat_j \text{ x } Post_t + \epsilon_{ijt}$$

Y denotes the individual-level average for a given outcome at hospital *j* in time *t*. *Treat* is a dummy indicator for treatment. *Post* is a dummy indicator for the post-intervention period. γ_3 is the DinD estimate. It is interpreted as the change in the outcome affected by the intervention relative to the changes for outcomes not affected by the intervention. Standard errors were adjusted for clustering at the hospital level.

Appendix D – MMR Theory of Change – Pictorial Representation