

THE BETTERBIRTH STUDY

November 2014-December 2017

GLOBAL STRATEGIES TO END THE PREVENTABLE
DEATHS OF WOMEN & NEWBORNS IN CHILDBIRTH




ARIADNE LABS

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ACKNOWLEDGMENTS

This report presents six years of learnings, data, and insights from the BetterBirth Study implementing the World Health Organization's Safe Childbirth Checklist in India (2011-2017). It draws heavily on 10 years of global implementation of the Checklist, as well. Ariadne Labs gratefully acknowledges its partners in the BetterBirth Study, and all those who have supported the development and testing of the World Health Organization (WHO) Safe Childbirth Checklist and the BetterBirth team.

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EXECUTIVE SUMMARY

BETTERBIRTH: LEARNINGS FROM THE LARGEST STUDY OF THE

Over the past two decades, we have succeeded in increasing access to facility-based childbirth with skilled birth attendants around the world. Yet, we have not seen the expected reductions in maternal and newborn mortality with improved access alone. A failure to focus on improving the quality of care, along with affordable access to care, is widely acknowledged as the reason. Currently, many interventions target one or two of the major causes of death, but these strategies have not integrated a broader package of scalable improvements in quality of care.

The biggest opportunity to save lives in childbirth now lies in improving the quality of care, both the provision and experience of care for women, newborns, and frontline health care providers.

This report synthesizes lessons learned and offers global recommendations from the BetterBirth Study for policy makers, program designers, implementers, and health system leaders. BetterBirth, one of the largest studies ever conducted in maternal and newborn health, used a scalable intervention targeting the seven leading causes of maternal and

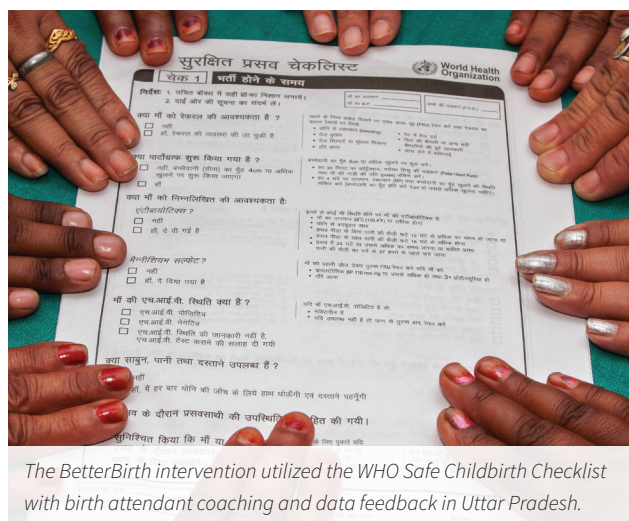
WHO SAFE CHILDBIRTH CHECKLIST, 2014-2017

newborn mortality during facility-based childbirth. The study, which took place from 2014 to 2017 in 120 frontline facilities in Uttar Pradesh, India, focused on an eight-month peer-coaching-based program to implement the World Health Organization (WHO) Safe Childbirth Checklist. We found that the BetterBirth implementation of the Checklist, coupled with coaching and data feedback, improved adherence to essential birth practices. Yet, these improvements did not reduce overall maternal and perinatal mortality in primary-level facilities.¹

During 2018, we analyzed more than 200 million data points from more than 157,000 women study participants and their newborns. Our goal was to discover ways to improve facility-based childbirth care to lower morbidity and mortality. We found there is no magic bullet—no individual clinical practice correlated with better outcomes. Rather, lower mortality correlated with an increased number of completed essential birth practices, regardless of which practices were done.

However, we found even this was insufficient to drive the change required to save lives at scale. Improving individual birth attendant performance was not enough. To deliver the comprehensive bundle of essential birth practices and achieve sustained outcomes, birth attendants should be supported by a health system that is integrated, cohesive, and seamless.

The BetterBirth data provide an evidence base for key strategies needed at all levels of the facility-based childbirth ecosystem: birth attendants, facilities, health systems, and women and their communities. The following recommendations from the BetterBirth experience offer a path to high-quality, person-centered childbirth care around the world.



The BetterBirth intervention utilized the WHO Safe Childbirth Checklist with birth attendant coaching and data feedback in Uttar Pradesh.

THE INTERVENTION: QUALITY MATTERS

The BetterBirth intervention (WHO Safe Childbirth Checklist + coaching + data feedback) demonstrated it is possible to improve multiple components of quality of care, including uptake of essential birth practices among birth attendants. Achieving this improvement in quality is critical to reducing maternal and perinatal disease, complications, and death.

To achieve wider-scale impact on outcomes, program leaders, funders, and global health agencies should consider

- » adapting the WHO Safe Childbirth Checklist to the local setting and integrating the Checklist into the workflow;
- » tailoring the implementation strategy to the facility's readiness level; and
- » nurturing leadership commitment to quality improvement.

BIRTH ATTENDANTS: COMPETENCY & WORKPLACE MATTER

Birth attendants around the globe encompass a diverse group of providers, from traditional birth attendants to nurse midwives to physicians. Ideally, these caregivers have the skills and authority to provide quality care while making childbirth a positive experience.

However, the BetterBirth Study found birth attendants often lacked individual competency and faced competing priorities and pressures in the workplace—including intertwined clinical, administrative, and financial pressures.

To remedy these challenges, birth attendants should have appropriate skills, continuous training, and advanced professional development to sustain their competency. They should also be supported by the workplace environment to accomplish their day-to-day responsibility for providing high-quality care. Such an enabling environment includes physical and psychological safety and security, a manageable clinical and administrative workload, and appreciation for a job well done. Incentives from inside and outside the facility need to align with best clinical practices. Simply, support structures within facilities should remove barriers to doing the right thing.

THE HEALTH FACILITY: READINESS MATTERS

We found substantial variation in mortality across facilities and searched for reasons why such vast differences existed. Historically, facility needs assessments focus on easily measured inputs, such as the number of staff or number of delivery rooms.

Instead, we found it is often the overlooked, difficult-to-quantify factors about a facility's readiness to take on quality improvement initiatives—leadership commitment, facility capability and capacity, organizational culture, and social context—that powerfully promote or hinder quality care.

With the critical information on all domains of facility readiness for quality improvement, interventions and implementation pathways can be tailored and strengthened to support early adopters and to work with resisters until they are ready to implement quality improvement programs. Program implementers should consider using qualitative methods, such as staff interviews and observation, to more fully understand facility-level culture, teamwork, and problem-solving as they design, adapt, and implement quality improvement interventions.

THE HEALTH SYSTEM: “SYSTEMNESS” MATTERS

Often, the building blocks of a health system are in place; however, they are rarely integrated or cohesive across the continuum of care. No one facility, birth attendant, or other component of the health-care system is responsible for all the gaps in care.

The BetterBirth Study uncovered worrisome fault lines in the critical connections within the health system, particularly in the referral system that manages the most vulnerable women and newborns in childbirth. With the concept of “systemness,” we focus less on the building blocks, such as supply systems, health care workforce, financing, or the individual health facilities, and more on the connections among them, such as communication and teamwork.

Systemness is the glue that holds all the pieces together; it is the vertical, horizontal, and diagonal integration across the system that matters. Key recommendations for solving these problems include

- » developing continuity of care from the antenatal to intrapartum to postpartum periods;
- » bolstering communication between frontline and higher-level health care facilities; and
- » strengthening transportation between facilities and supply line integration.

WOMEN & COMMUNITY: POWER MATTERS

Women and newborns must be at the heart of person-centered care if we want to improve their health outcomes. To achieve this, strategies must account for their social and economic context and prioritize what matters to them.

In the BetterBirth Study, we found the power dynamics among women, their communities, birth attendants, and the health system can promote or impede quality care. For example, women consistently received substandard and sometimes disrespectful care. Yet, most women reported high satisfaction with their care, which underscores low expectations and normalization of poor care. These contradictory findings suggest all individuals within the childbirth ecosystem should be sensitized to appropriate expectations for high-quality, dignified person-centered care.

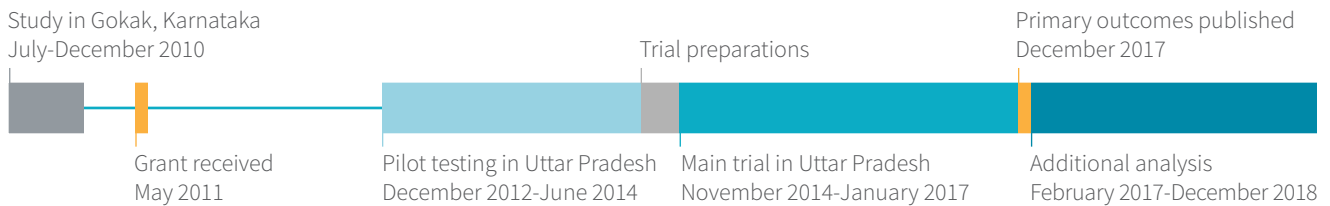
To put women at the center of childbirth care, we call for validated metrics of respectful care and patient satisfaction, birth attendant training and support in delivering person-centered care, and advances in women’s empowerment. ■

INTRODUCTION

In the past decade, we have made tremendous progress in decreasing maternal and newborn mortality around the world: the maternal mortality ratio has fallen 44% from 385 per 100,000 in 1990 to 216 per 100,000 in 2015.²

Likewise neonatal mortality has dropped from 37 per 1,000 live births in 1990 to 19 per 1,000 live births in 2015.³ Innovative strategies, such as conditional cash transfers and maternal waiting homes, have succeeded in shifting births from the home into facilities with skilled birth attendants. However, women and newborns continue to die from preventable causes, particularly in low-income countries. Of maternal deaths, 99% occur in low- and middle-income countries. More than half of maternal deaths occur in sub-Saharan Africa and almost one-third occur in South Asia. Moreover, nearly 5 million stillbirths and neonatal deaths occur each year; with the majority in low- and middle-income countries. We now know that poor quality of facility-based care is contributing to persistent rates of complications and death.

BetterBirth Study Timeline



To address the gaps in quality of care, the World Health Organization and a team of experts created the Safe Childbirth Checklist, a bundle of 28 essential birth practices proven to save lives during the hours around childbirth when women and newborns are at greatest risk. The essential birth practices target the leading killers of women and newborns:

- » hemorrhage,
- » infection,
- » obstructed labor,
- » hypertensive disorders,
- » birth asphyxia, and
- » complications from prematurity.

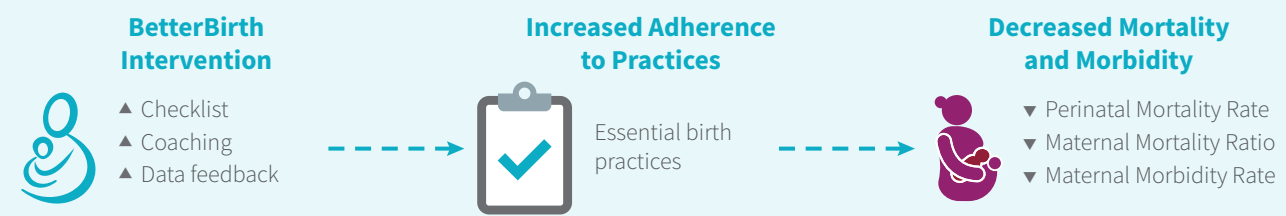
Ariadne Labs, a joint center of the Harvard T.H. Chan School of Public Health and Brigham and Women's Hospital, then designed the BetterBirth intervention for frontline primary-level facilities with the Checklist as the centerpiece. We paired the Checklist with an implementation strategy of peer-to-peer coaching of managers and birth attendants, along with data feedback for continual improvement.

In 2011, Ariadne Labs and global partners launched an ambitious randomized controlled trial to test our theory of change: whether the BetterBirth intervention could improve the quality of childbirth care through adherence to essential birth practices and reduce mortality and complication rates. The BetterBirth Study is among the largest ever conducted in maternal-newborn health, and offers a deep understanding of what is happening at the frontline of childbirth care.

With a population of 204 million, Uttar Pradesh has five million deliveries a year. Mortality among women and newborns in this setting is particularly high. Based on national data in 2012, the maternal mortality ratio in Uttar Pradesh was 258 deaths per 100,000 live births, significantly higher than the country mortality ratio of 174 per 100,000.⁴

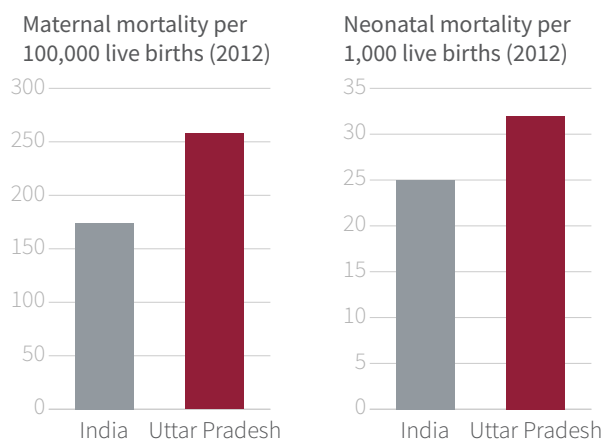
Recently released data [2014-2016] highlights progress in reducing maternal mortality in Uttar Pradesh to 201 deaths per 100,000 live births.⁵ Similarly, the newborn mortality rate was 32 deaths per 1,000 live births in Uttar Pradesh and 25 per 1,000 in India.

BetterBirth Theory of Change



CHILDBIRTH-RELATED DEATHS AROUND THE GLOBE EACH YEAR

303,000 maternal deaths² **1.3 million** intrapartum stillbirths **2.6 million** neonatal deaths

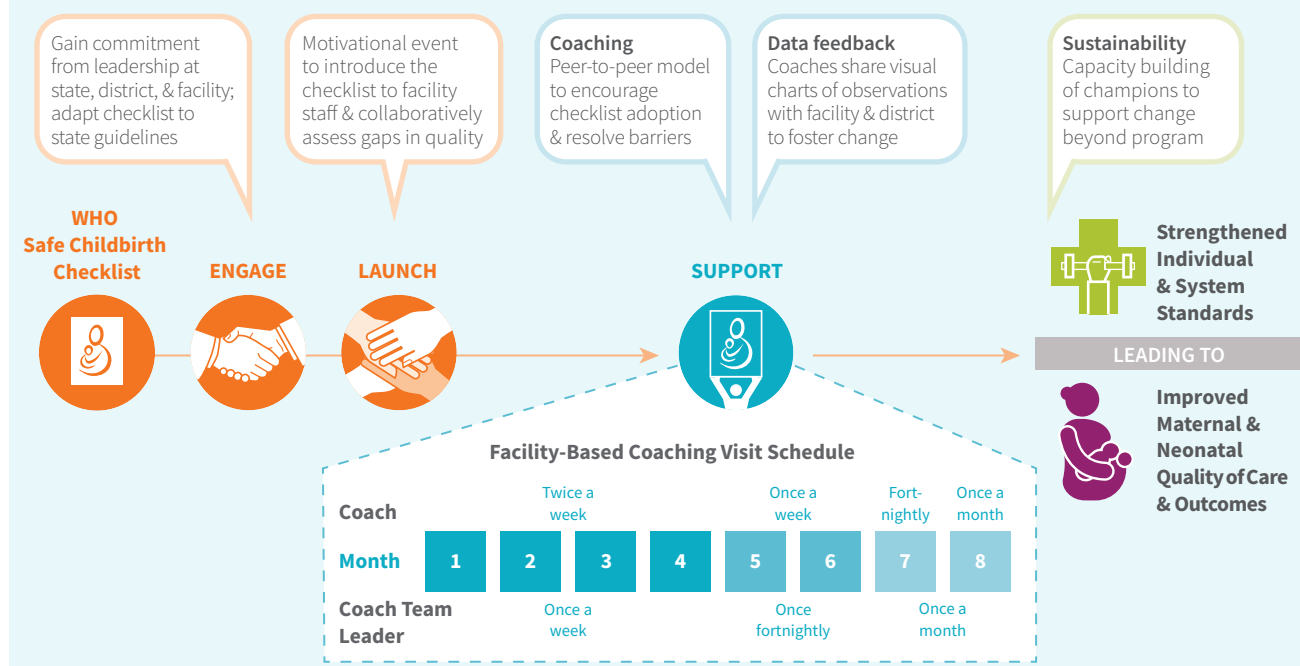


The BetterBirth intervention involved coaching visits over eight months, with intensive coaching in the beginning, tapering to one coaching visit per month. Using a variety of data collection methods, we

- » enrolled and followed up more than 157,000 women and newborn pairs across 120 facilities;
- » observed more than 5,000 deliveries across 30 facilities; and
- » interviewed a subset of birth attendants and medical officers in charge. Additional qualitative and quantitative data were gathered. (Appendix B)

The intervention was completed with a high degree of fidelity to the expected number of coaching visits. The data accuracy was 98% and we successfully followed up 99.7% of women enrolled.

The BetterBirth Implementation Strategy

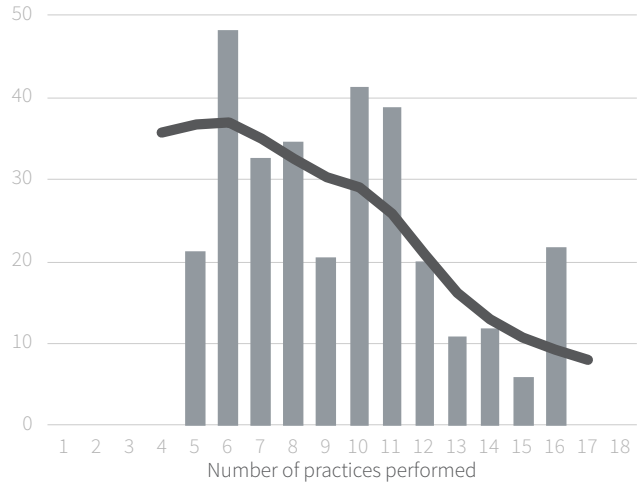


In the observation of 2,563 births after two months of the intervention, we found that intervention sites performed an average of 13.1 of the 18 observed practices in comparison with an average of 7.5 of 18 in the control sites. Four months after the intervention concluded in facilities, use of these essential practices remained higher than in control facilities (11.1 intervention, 7.5 control; 2,325 births observed).

Across intervention and control sites, there was no one Checklist practice that proved more important than others in predicting early newborn death. Instead, the more Checklist practices that were done, the lower mortality. One key finding was mortality rates were lowest when adherence to practices was more than 85%.

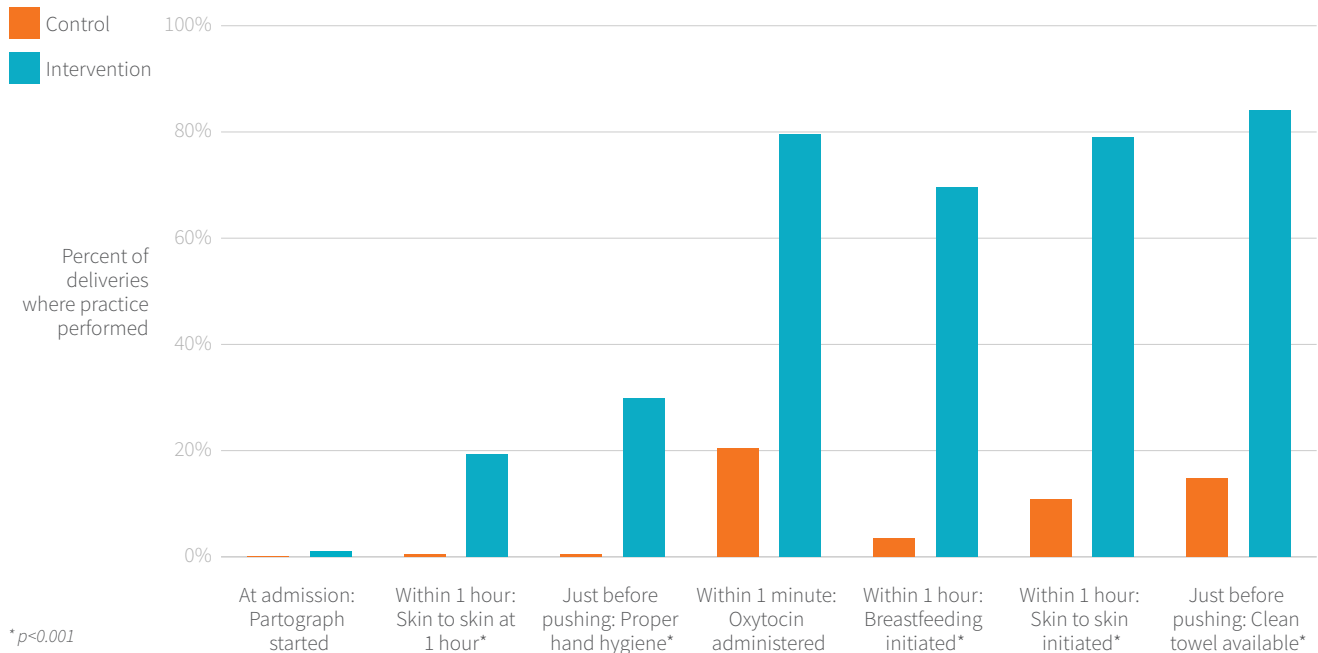
Neonatal mortality and essential birth practices

Early neonatal mortality per 1,000 live births $N = 2,248$ births observed*



* Cases where stillbirth occurred were excluded, as some behaviors, such as breastfeeding and initiating skin-to-skin, were not applicable

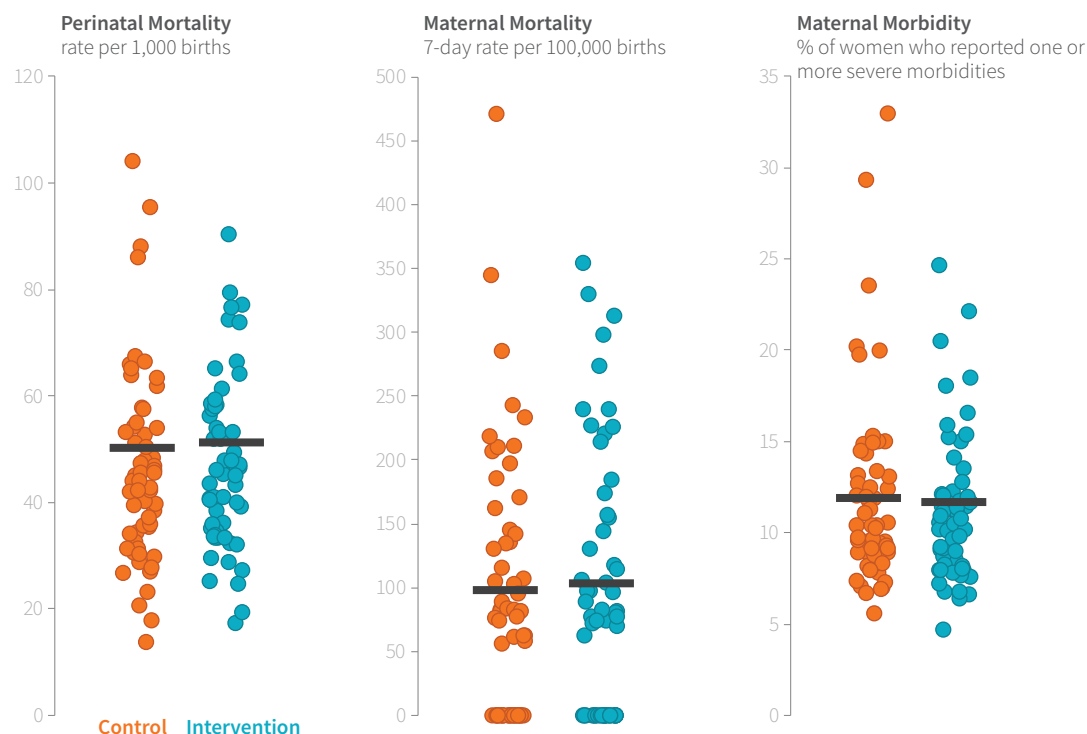
Intervention sites had a significantly higher adherence rate to practices after two months of coaching



* $p < 0.001$

**At scale,
7-day health
outcomes were
not different
across arms**

● Each bubble
denotes a
facility rate



While these findings were encouraging, overall, we found no difference in the death rates for women or newborns, or in women experiencing complications between intervention and control sites (more than 157,000 women at 120 facilities). In total, within seven days of childbirth, 149 women died and there were 7,445 perinatal deaths—of which 4,528 were early neonatal deaths.

We had many theories about why we did not see an impact on complications or death. Using data from the study, we were able to investigate some of them, including:

- » Coaching and Checklist use at the birth attendant level alone cannot overcome major health system challenges, such as broken referral systems, insufficient access to cesarean deliveries, and supply gaps for key medications and equipment.

- » There was limited birth attendant competency in managing childbirth, particularly for women with complications. Overall, there was insufficient and/or unsustained adherence to essential birth practices.
- » Adherence to essential birth practices is just one component of quality of care; the other components also need to be addressed across the continuum of pregnancy, childbirth, and postpartum care.



A BetterBirth coach reviews roles and responsibilities of labor and delivery staff focused on key practices for the care of women and their newborns.

In addition, we developed hypotheses for further research, including:

- » Facility-level readiness for quality improvement varies. These factors were unaccounted for because the traditional needs assessment did not fully capture the commitment, capability, capacity, culture, and context at the facility prior to implementation.
- » Access to high-quality antenatal and postnatal care is limited. In particular, there is inadequate risk stratification for childbirth at the appropriate facility level prior to onset of labor, and there is inadequate follow-up of complications that occur around delivery and after discharge.

- » Behaviors on the Safe Childbirth Checklist address prevention and early identification of common complications that could lead to mortality, but do not fully address comprehensive complication management.
- » The Safe Childbirth Checklist does not incorporate intra- or inter-facility communication structures, which are crucial to implement a quality improvement portfolio.

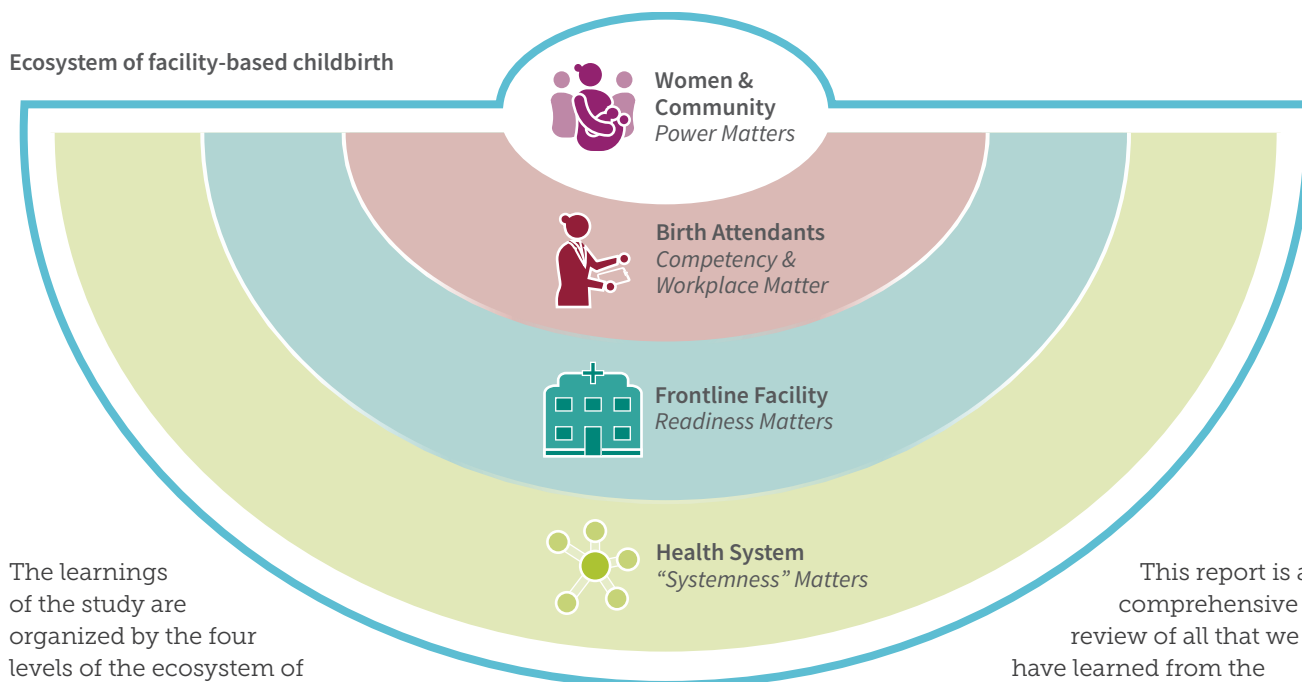
None of these theories alone explained the lack of anticipated reduction in mortality, so we shifted our focus to quality of care and widened our lens to the health system.

As highlighted by the Lancet Global Health Commission on High Quality Health Systems, the majority of deaths globally are not due to lack of access to health care, rather to poor quality of care.⁶

As defined in the WHO framework, quality of care consists of safe, effective, timely, efficient, equitable and person-centered care.⁷

We returned to the BetterBirth Study data to learn as much as possible about the quality, functionality, and effectiveness of the health system, the people who operate it, and the women who are served by it.

Ecosystem of facility-based childbirth



The learnings of the study are organized by the four levels of the ecosystem of facility-based childbirth:

1. The birth attendant, her perspective, training, and experience.
2. The facility, its resources, staff, leadership, and culture.
3. The health system, its resources, and connections.
4. The woman and her community.

Our single most important finding is that no one facility, birth attendant, or other component of the health-care system is responsible for the gaps in care. It is the connections between the health system components and levels that must be strengthened. Indeed, even when birth attendants are doing their best, they face systemic failures that impede the delivery of quality care. We call this “systemness,” a term already in circulation across industries, that points to the critical importance of under-measured, unrecognized factors like teamwork, communication, personnel, and supply coordination.

This report is a comprehensive review of all that we have learned from the BetterBirth Study, written for a global audience. Key recommendations are presented in each chapter, with a clear focus on actionable and measurable approaches going forward.

The challenges faced within the health system of Uttar Pradesh are not unique to India. Many regions around the world face similar challenges. We believe the learnings from BetterBirth are widely applicable across low- and middle-income countries and will be of interest to policy makers, program designers, implementers and health system leaders.

One final point: National and regional health leaders in India are to be commended for prioritizing quality improvement innovations like the WHO Safe Childbirth Checklist and several new maternal-newborn health programs. The work of health system strengthening is difficult and demands buy-in at the highest levels and long-term strategies for change. The world can learn from India's commitment and we hope this study supports their efforts and others globally. ■

We believe the learnings from BetterBirth are widely applicable across low- and middle-income countries and will be of interest to policy makers, program designers, implementers and health system leaders.



THE BETTERBIRTH INTERVENTION —

As part of the global shift to facility-based childbirth with skilled birth attendants, the BetterBirth intervention centers on the implementation of the World Health Organization Safe Childbirth Checklist to improve quality of care in facilities.

The Checklist was created in 2009 to ensure key evidence-based practices during labor and delivery were provided to every woman and newborn, every time. The WHO Checklist was developed through a rigorous process in which experts identified 28 essential birth practices that prevent the major causes of maternal and neonatal morbidity and mortality.

The Checklist divides these practices into four “pause points,” or moments to remind birth attendants to follow the practices: on admission, just prior to delivery, within one hour of birth, and before discharge.

QUALITY MATTERS

The Checklist was designed as a clinical reminder and as an accountability tool to identify gaps in care delivery and essential supplies. Its primary purpose is to hold birth attendants accountable for adhering to key practices, but it also holds leaders accountable for restocking supplies and addressing other barriers.

The BetterBirth Study was a randomized controlled trial of an intervention package that supported the WHO Safe Childbirth Checklist implementation. Control sites participating in the study received standard care. For the intervention sites, the BetterBirth partners recognized that a checklist alone would not reduce childbirth-related deaths or complications. Therefore, the intervention was paired with an implementation strategy of engage-launch-support.

The WHO Safe Childbirth Checklist

Upon admission to the facility

Just before pushing or C-section

Soon after birth (within 1 hour)

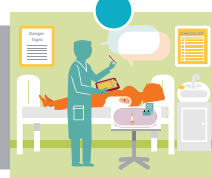
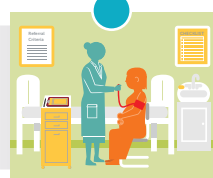
Before discharge from the facility

BEFORE BIRTH WHO Safe Childbirth Checklist	
1 On Admission	
Does mother need referral? <input type="checkbox"/> Yes, urgent <input type="checkbox"/> No, non-urgent	Check your facility's status • Is there a referral system in place? • Are there any barriers to referral?
Partograph started? <input type="checkbox"/> Yes, with start other notes <input type="checkbox"/> No	Start partograph every 4 hours. If not started, start now. • Is there a partograph in place? • Are there any barriers to partograph?
Does mother need to start: Analgesia? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given Magnesium sulfate and antiepileptic treatment? <input type="checkbox"/> Yes, magnesium sulfate given <input type="checkbox"/> No, magnesium sulfate not given	Ask for analgesia before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Confirm supplies are available to start birth and are given for each vaginal exam. <input type="checkbox"/> Yes, supplies available <input type="checkbox"/> No, supplies not available	Check for supplies before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Reassure birth companion to be present at birth. <input type="checkbox"/> Yes, birth companion present <input type="checkbox"/> No, birth companion not present	Reassure birth companion to be present at birth. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.

BEFORE BIRTH WHO Safe Childbirth Checklist	
2 Just Before Pushing (Or Before Caesarean)	
Does mother need to start: Analgesia? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given Magnesium sulfate and antiepileptic treatment? <input type="checkbox"/> Yes, magnesium sulfate given <input type="checkbox"/> No, magnesium sulfate not given	Ask for analgesia before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Confirm essential supplies are at bedside and proper for delivery. <input type="checkbox"/> Yes, supplies available <input type="checkbox"/> No, supplies not available	Check for supplies before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
For baby: <input type="checkbox"/> Clean hands <input type="checkbox"/> Dry or clean skin <input type="checkbox"/> Sterile drapes for C-section <input type="checkbox"/> Sterile gloves <input type="checkbox"/> Sterile drapes <input type="checkbox"/> Sterile drapes	Prepare to start for baby immediately after birth. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
<input type="checkbox"/> Assistant identified and ready to help at birth if needed.	

AFTER BIRTH WHO Safe Childbirth Checklist	
3 Soon After Birth (Within 1 Hour)	
Is mother bleeding abnormally? <input type="checkbox"/> No <input type="checkbox"/> Yes, bleed for help	Check for bleeding abnormally. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Does mother need to start: Analgesia? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given Magnesium sulfate and antiepileptic treatment? <input type="checkbox"/> Yes, magnesium sulfate given <input type="checkbox"/> No, magnesium sulfate not given	Ask for analgesia before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Does baby need: Analgesia? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given	Check your facility's status. • Is there a referral system in place? • Are there any barriers to referral?
Check your facility's status: <input type="checkbox"/> Yes, supplies available <input type="checkbox"/> No, supplies not available	Check for supplies before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Start breastfeeding and skin-to-skin contact (If mother and baby are well). <input type="checkbox"/> Yes, breastfeeding and skin-to-skin contact started <input type="checkbox"/> No, breastfeeding and skin-to-skin contact not started	Start breastfeeding and skin-to-skin contact if mother and baby are well. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.

AFTER BIRTH WHO Safe Childbirth Checklist	
4 Before Discharge	
Confirm stay at facility for 24 hours after delivery. <input type="checkbox"/> Yes, stay at facility <input type="checkbox"/> No, leave facility	Check for bleeding abnormally. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Does mother need to start antibiotics? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given	Ask for analgesia before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Is mother's blood pressure normal? <input type="checkbox"/> Yes, blood pressure normal <input type="checkbox"/> No, blood pressure not normal	Give analgesia before administration of any medication. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Is mother bleeding abnormally? <input type="checkbox"/> No <input type="checkbox"/> Yes, bleed for help	Check for bleeding abnormally. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Does baby need to start antibiotics? <input type="checkbox"/> Yes, given <input type="checkbox"/> No, not given	Check your facility's status. • Is there a referral system in place? • Are there any barriers to referral?
Is baby feeding well? <input type="checkbox"/> Yes, baby feeding well <input type="checkbox"/> No, baby not feeding well	Check for bleeding abnormally. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.
Discuss and offer family planning options to mother. <input type="checkbox"/> Yes, family planning options discussed <input type="checkbox"/> No, family planning options not discussed	Discuss and offer family planning options to mother. • Give analgesia if needed. • Give magnesium sulfate if needed. • Give antiepileptic treatment if needed.



THE CHECKLIST IN ITALY

A teaching hospital in Florence, Italy, implemented the WHO Safe Childbirth Checklist as a tool to support health-care workers managing critical activities during delivery. Results demonstrated improved interdisciplinary teamwork and communication.⁸



As part of the study's **engagement** campaign, leaders at the facility, district, and state levels were solicited for their views on and commitment to the Checklist, which had been adapted to India's Ministry of Health and Family Welfare guidelines.



An inspirational **launch** event formally introduced the Checklist to each facility, motivated birth attendants, and assessed existing gaps that could hinder its adoption.



The **support** strategy used peer-to-peer coaching to build trust between birth attendants and coaches. These coaches—trained nurses employed by an independent, external organization—worked directly with birth attendants. The coaching had three primary goals:

1. to motivate birth attendants to change their practices,
2. to observe, record, and share information about birth attendants' behaviors to facility and district leaders in order to increase system-level support for improved quality of care, and
3. to support birth attendants in their efforts to problem-solve and overcome barriers to essential practices.

Coaches visited each facility twice weekly during the early stages of the intervention, with the frequency of visits decreasing to once monthly by the end of the intervention, for a total of 43 visits over an eight-month period. Due to the study design and requirements, the support strategy could not be adapted from facility to facility.

Coaches did not provide clinical care, specific training in birth attendant competency, or medical supplies; rather, they supported the birth attendants and leaders to activate resources within their own facility. Although coaches did not intervene in emergencies, they did have the authority to communicate any concerns to the medical officer in charge, if needed. Coaches also had the discretion to encourage appropriate referral of a woman or newborn before, during, or after observation, since such measures are explicitly spelled out in the Safe Childbirth Checklist.

Facility-Based Coaching Visit Schedule

Coach	Twice a week		Once a week		Fort-nightly	Once a month	43 visits		
Month	1	2	3	4	5	6	7	8	Total
Coach Team Leader		Once a week			Once fortnightly			Once a month	23 visits

Coach team leaders focused on supporting the facility leadership and ensuring strong communication between frontline birth attendants, facility leaders, and district-level leaders. By enhancing communication, team leaders were able to more quickly identify deficiencies in supplies, staffing, and skills, while encouraging facility leadership to problem-solve these gaps.

Data-feedback strategies at the facility and district levels included sharing heat maps, a data visualization tool, of adherence to essential birth practices. This feedback process was carried out in a collaborative and nonpunitive manner through sharing data results

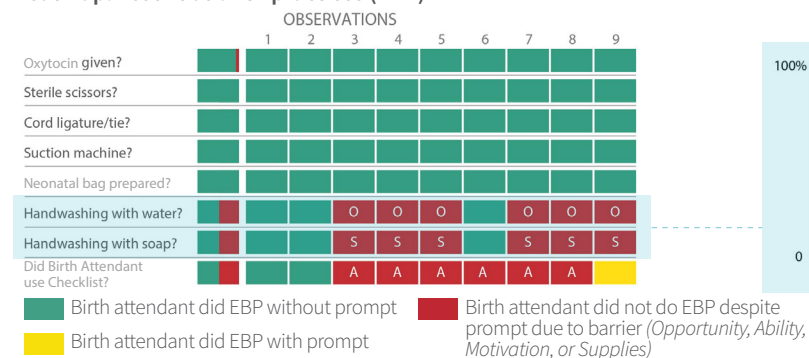


A team leader and coach support birth attendants in completing the essential birth practices on the Safe Childbirth Checklist.

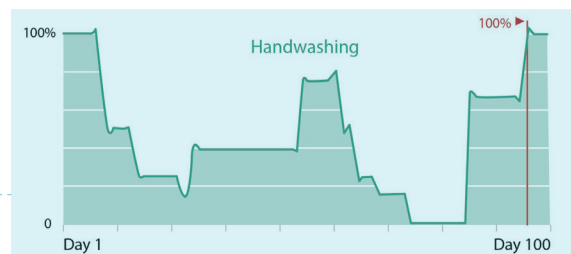
in aggregate rather than at the individual level. The purpose was to hold birth attendants, coaches, and leaders accountable for improving adherence by addressing opportunity, ability, and motivation barriers. District health personnel benchmarked facility-level behavior change to track improvement over time.

At each facility, a motivated and respected staff member was selected by facility leadership to be a childbirth quality champion. The champion worked closely with team leaders to improve quality of care and support the Safe Childbirth Checklist beyond the BetterBirth Study.

Heatmap: Essential birth practices (EBP)



BEHAVIOR CHANGE OVER TIME



KEY FINDINGS FROM THE BETTERBIRTH STUDY

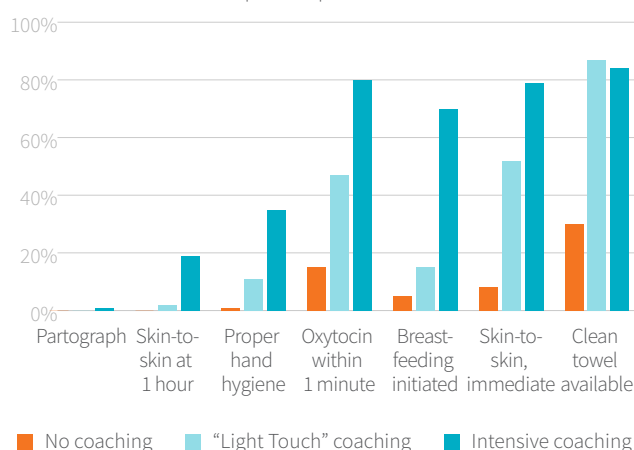
Implementation of the WHO Safe Childbirth Checklist in primary facilities improved overall uptake of and adherence to essential birth practices. Among the study's findings:

- » After two months of coaching, **birth attendants who received coaching and the Checklist had higher adherence to practices** than birth attendants in control facilities (2,563 births observed). After the intervention was completed, birth attendants who received the intervention maintained higher adherence to practices compared to birth attendants in control sites (2,325 additional births observed).
- » **In the presence of a coach, birth attendants were often able to overcome pressures** such as misaligned clinical and financial incentives.
- » **Adherence was lower when the coach was not present** and the birth attendant was observed instead by an independent data collector.
- » After study completion, a shorter, "light touch" intervention was implemented in control facilities. In this intervention, coaching occurred through 10 visits over eight weeks and used a prescriptive training program. We found that **adherence to essential birth practices was lower in the "light touch" group** compared to the birth attendants who received the full intervention (1,210 births observed during "light touch").

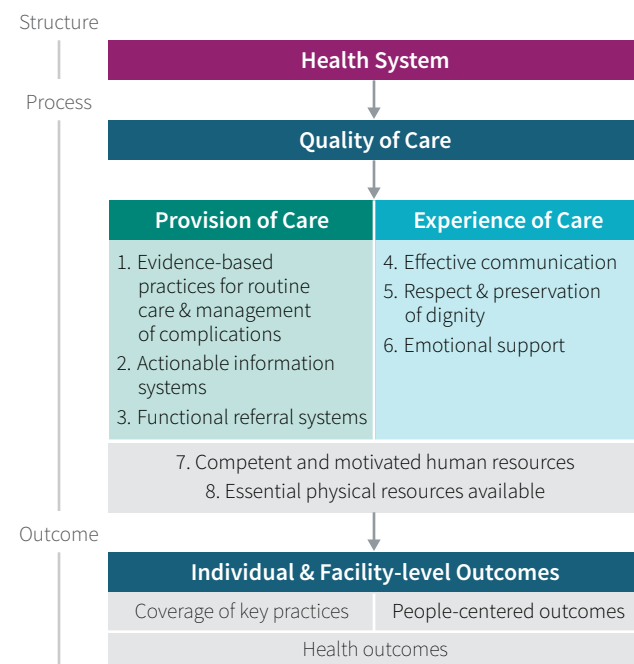
The BetterBirth Study showed behavior change is possible. It also demonstrated that more is required to enhance quality and actually improve maternal and newborn health outcomes. The WHO Quality of Care Framework,⁷ published in 2016, defines the two most important domains of quality as 1) the provision of care and 2) the experience of care among women,

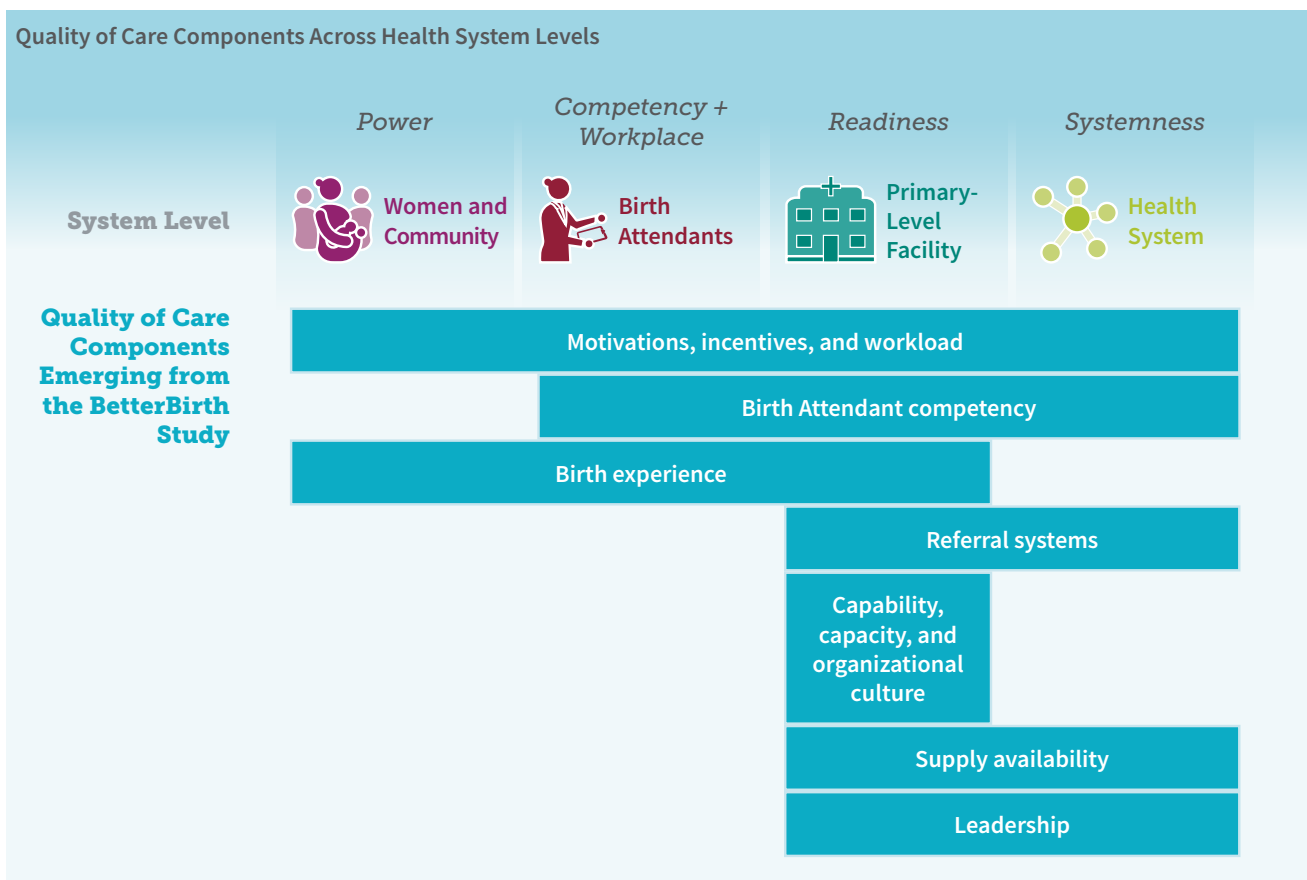
Customized, frequent coaching is more effective than didactic, less frequent coaching

Percent of deliveries where practice performed



WHO framework for quality of maternal and newborn health care⁷





newborns, and their families. In the BetterBirth intervention, the provision of care was defined narrowly as adherence to 28 essential practices. While this specific goal was a prerequisite for improvement, it did not suffice to reduce morbidity and mortality.

This unexpected result may stem from the fact that the BetterBirth intervention was not designed

to improve other quality-of-care components, including

- » birth attendant competency;
- » motivations, incentives, and workload;
- » emotional support, respect, and dignity for women and their families; and
- » referral systems.

Such insights from the study highlight the need to widen the focus beyond one single component of health-care quality, and instead to acknowledge and leverage the interdependence and connectedness of all components.

ADDITIONAL INSIGHTS FROM AROUND THE GLOBE

After initial pilot testing of the Safe Childbirth Checklist, the WHO created a global collaborative in 2012 to understand how the Checklist could be adapted to different contexts. The WHO and Ariadne Labs drafted an implementation guide to accompany the Checklist, following a survey that had been administered among its collaboration sites to assess the factors that promoted or hindered Checklist use. Findings from both global sites and the BetterBirth Study were incorporated into the guide. More than 30 sites participated in this collaborative to share how they adapted strategies and coaching models to fit their unique needs, constraints, and local customs.

Many sites that employed a coaching model used coaches who were based within their facilities and had strong, established relationships with peers and leaders. These coaches identified knowledge and skills gaps, and addressed the gaps through a variety of strategies, including clinical trainings, simulations, and real-time skills-building workshops. Coaches were either leaders within the facility or were otherwise institutionally connected to facility leaders—positions that gave them the authority to take action when needed to overcome hurdles to Checklist use, such as stock outs or staffing problems. These interpersonal and organizational relationships within the health facilities ensured that participants were accountable to each other, which in turn eased adoption of the essential birth practices and encouraged other positive behavior changes over time.

Now that the WHO Safe Childbirth Checklist has been disseminated globally, new insights have emerged from implementers. The main learnings from the Collaborative are captured in a new report, *WHO Safe Childbirth Checklist: Lessons from the Field*, and offer further strategies for implementation success.

An overarching theme is that the Checklist must be locally owned, adapted, and implemented to ensure its relevance, acceptability, and successful uptake. At the same time, stakeholder engagement across the health care system—from frontline users to facility managers to state leaders—boosts Checklist adherence. The WHO Safe Childbirth Checklist was most often successful as part of a larger quality improvement initiative, including skills labs, maternal death audits, and quality improvement cycles.

The WHO global collaborative enabled implementers to share successes and challenges, and to discuss further strategies to improve quality of care in childbirth. Topics discussed included how to counter staff resistance to using the Checklist; how to enhance understanding of Checklist tasks; and how to improve clinical skills. Additionally, implementers from around the world shared how they used the Safe Childbirth Checklist to encourage accountability in clinical decisions and to improve supply chains.

ADAPTING THE CHECKLIST IN SRI LANKA

The WHO Safe Childbirth Checklist was implemented in the University Obstetrics Unit at De Soysa Hospital for Women, Colombo, and two obstetric units at Teaching Hospital, Mahamodara, Galle, Sri Lanka.

The implementation team adapted the original Checklist to fit into their local context by adding the use of antenatal corticosteroids to the Checklist and encouraging the presence of a labor companion. They also modified the first two pause points—the first point was advanced to admission to the antenatal ward; the second point became admission to the labor ward.⁹

ADAPTING THE CHECKLIST IN MEXICO

A working group was established with the participation of the obstetrical, perinatology, and quality management staff from four hospitals in the state of Hidalgo, the state of Mexico, and Mexico City, supported by a research team from the National Institute of Public Health.

This group spent time adapting the Safe Childbirth Checklist to the local context prior to implementing it. For example, the original WHO Checklist is a single document including practices for women during labor and delivery, and for newborns after birth. This group separated the Checklists (one for women and another for newborns) to better incorporate additional childbirth care responsibilities into the Checklist.

Additionally, the original Checklist asks if there was a cesarean section. In Mexico, they added a check on the reason for the cesarean section, according to a list proposed by the working group based on accepted practice guidelines.¹⁰

States in Mexico with hospitals using the Checklist



KEY RECOMMENDATIONS

In future implementation of the BetterBirth intervention and similar quality improvement initiatives, the tool and implementation strategy should be adapted to the local context. Below are recommendations to facilitate adaptation of each component of the BetterBirth intervention.

SAFE CHILDBIRTH CHECKLIST

- Clarify the purpose of the Checklist (i.e., decision support, memory aid, accountability tool) and the intended users (i.e., individual birth attendants, teams of birth attendants).
- Ensure that the Checklist is supported internally and that it meets an identified gap at the facility.
- Support real-time use, not just retrospective documentation, through identifying and supporting champions.
- Consider adapting and/or editing the Checklist and its pause points, or introduce the Checklist through a step-wise process, according to the facility's workflow constraints.
- Ensure an adequate supply of paper Checklists or use electronic Checklists.
- Consider linking the Safe Childbirth Checklist with other safety bundles, crisis checklists, or cesarean checklists, to better manage complications.



A coach reviews the Checklist practices with a birth attendant and assists with identifying and addressing barriers to adherence.

COACHING

Coaches should be appropriately trained and empowered to develop strong relationships, provide effective and nonjudgmental feedback, and define a clear process for problem solving.

Ongoing supportive supervision for coaches themselves is needed to continually build skills and share problem-solving strategies.

Consider intensive and/or ongoing coaching to achieve and sustain adherence to essential birth practices.

Coaches should be able to support and empower birth attendants to identify and address barriers to behavior change in real time.

Provide coaching to all birth attendants and across all pause points, including during night shifts.

Ensure that coaching for quality improvement initiatives includes mechanisms for accountability and reaches facility-, district-, and state-level managers in addition to birth attendants.

Facility leaders should strive to create a synergistic relationship with coaches to uphold the quality improvement intervention.

Coaches should recognize and address existing incentives (e.g., financial and social expectations of childbirth care) that influence birth attendant behavior as part of their coaching approach.



A coach shares a heat map reflecting adherence to practices with birth attendants and points out areas for improvement.

Coaches should be flexible in adapting their strategy based on birth attendant needs, rather than strictly following a rigid coaching curriculum or protocol.

Coaches may benefit from a government title or other form of institutional empowerment, rather than operating as external project personnel separate from the local health facility.

While implementation partners around the globe reported success with coaches who came from within facilities, further research is needed to evaluate the impact of internal versus external coaches.

DATA FEEDBACK

Incorporate human-centered design in developing data feedback platforms, including user-friendly data visualization and integration with systems that routinely collect information.

Ensure that data-feedback mechanisms are not used to punish staff, but rather to constructively address gaps in care and hold systems accountable for improvement. ■

BIRTH ATTENDANTS —

Birth attendants are vital to improving quality of care and maternal and neonatal health outcomes.

According to the World Health Organization (WHO), most obstetric complications could be prevented or managed if women had access to skilled birth attendants—usually nurses, midwives, and physicians—during childbirth. In line with this guidance, the BetterBirth Study underscored the idea that a competent birth attendant is essential to high-quality care.

In 2018, a joint statement by WHO and other global health agencies updated the definition of a skilled birth attendant.¹¹ The new definition goes beyond counting how many of these specialized health professionals are present during childbirth—a traditional public health proxy for quality—to addressing birth attendant competency. The revised definition emphasizes the required knowledge, skills, and behaviors to deliver evidence-based, high-quality, dignified care to women and newborns.

Yet, individual competency alone does not ensure optimal outcomes. Even the most competent birth attendants in any setting do not work in a vacuum. The BetterBirth Study showed that the workplace itself can either support or hinder highly skilled birth attendants in providing the care they know how and want to provide. And workplace structure and culture shape how birth attendants interact with women and their families.

COMPETENCY & WORKPLACE MATTER

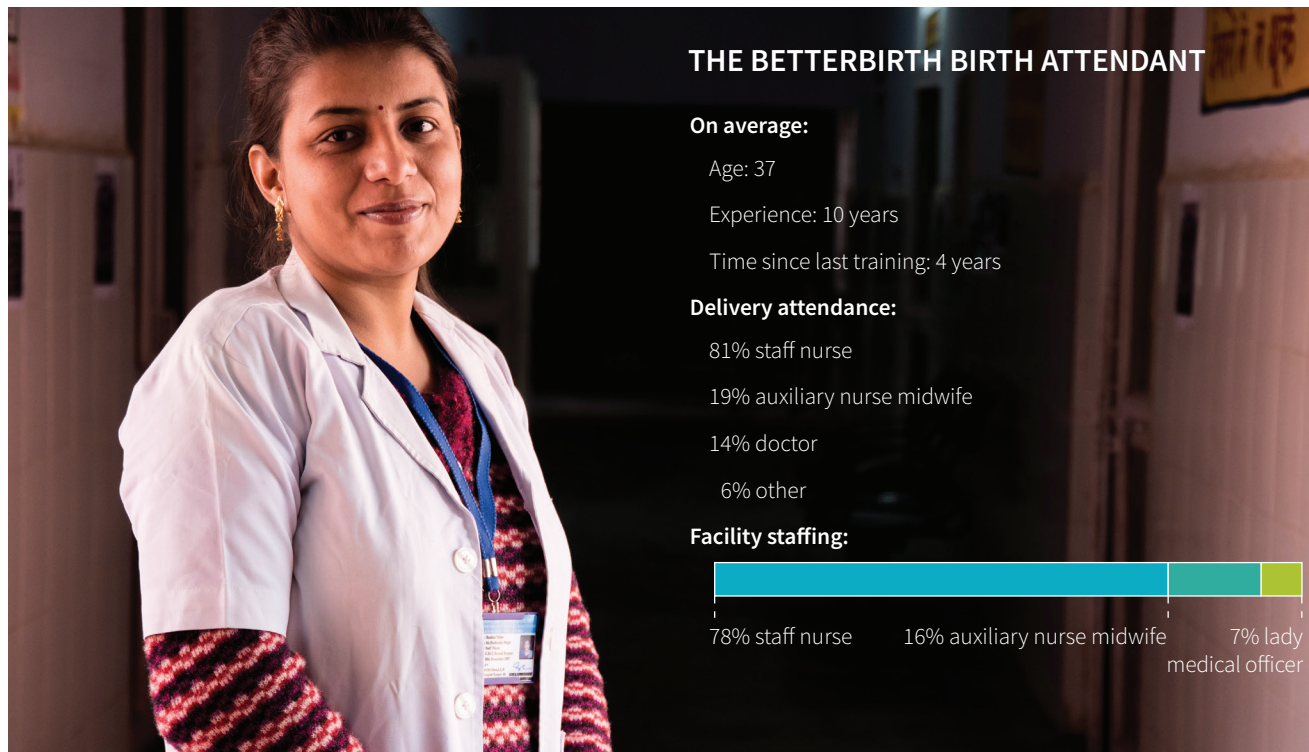
Supportive workplace environments encourage more positive birth attendant attitudes and motivation by boosting communication among staff; empowering birth attendants to carry out assigned tasks; clarifying the chain of command; ensuring physical security and safety of facility staff; halting financial transactions between staff and families that undermine patient care; and easing workloads.

BIRTH ATTENDANTS: GAPS IN COMPETENCY

In the BetterBirth Study, nurses attended the majority of births in primary health centers (81%). Auxiliary nurse midwives attended 19% of births; general physicians

attended 14% of deliveries. Women may have had multiple clinicians providing care. On average, birth attendants were 37 years old; had 10 years of experience; and had received their last in-service training four years previously (from interviews of 610 nurses). Each facility employed an average of 4.4 skilled birth attendants. For birth attendants at BetterBirth facilities, the general training for an auxiliary nurse midwife was a two-year course, and for nurses, a three-year course, with minimal clinical experience during training.

Strikingly, many of the birth attendants in the study did not meet competency requirements, as defined by the 2018 joint statement from global health agencies. For example, more than half of birth attendants (55%) reported that they had not attended the “Skilled Birth Attendant” training.



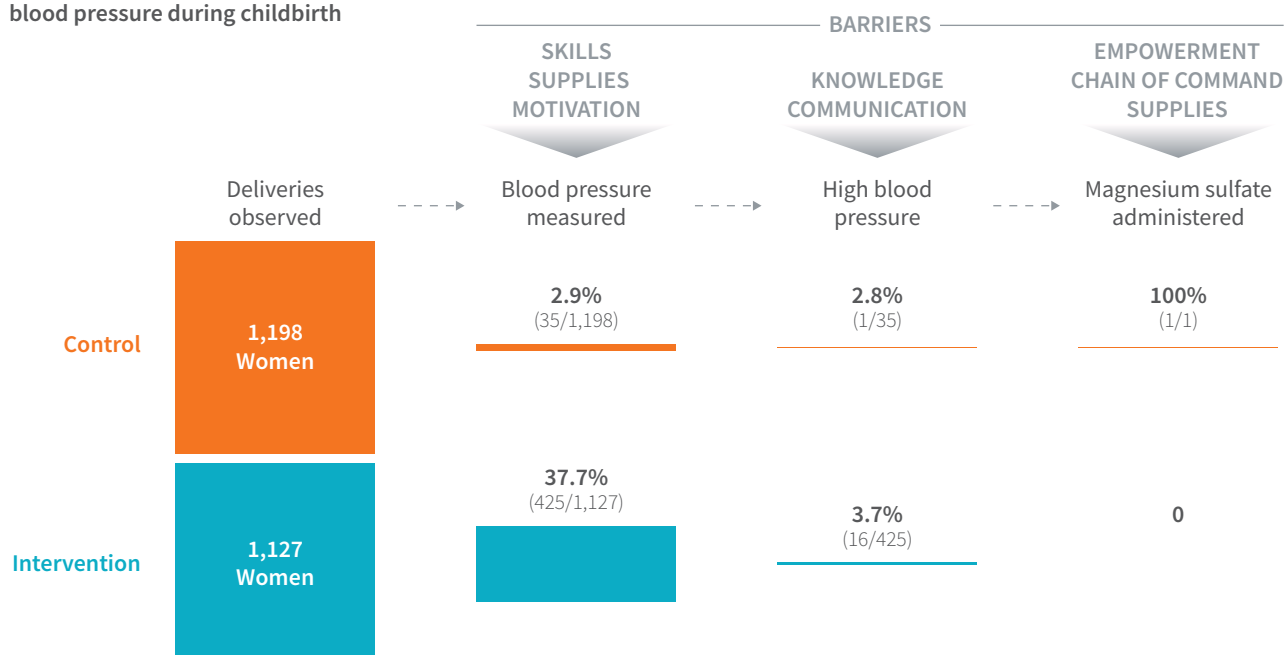
Many nurses had little or no practical clinical experience in managing labor or attending deliveries prior to working in the facility. As one staff nurse explained: "I did a six-month general nursing and midwifery internship, but never saw a delivery. The first time I observed a delivery was at this facility." Another staff nurse echoed that experience: "In school, from 8 a.m. - 10 a.m., we only learned about cleaning in the hospital, but not practical work...Midwife work was only one year, and it wasn't required that any delivery or baby resuscitation happen in front of me."

In general, birth attendants demonstrated minimal adherence to the most basic practices of quality childbirth care consolidated in the Safe Childbirth Checklist—practices such as handwashing, administering antibiotics if there are signs of

infection, preparing clean delivery supplies, and warming the newborns. In the control sites, birth attendants on average performed fewer than eight of the 18 required behaviors on the Checklist (1,304 births observed), an indicator of the poor quality care that is being documented globally as more and more women give birth in facilities.

"I did a six-month general nursing and midwifery internship, but never saw a delivery. The first time I observed a delivery was at this facility." – Birth Attendant

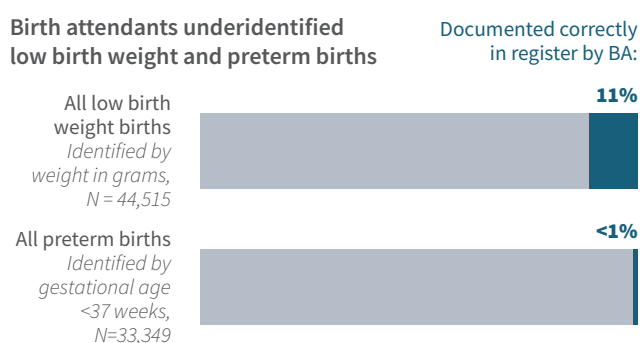
Observed management of blood pressure during childbirth



Even after two months of coaching at the intervention sites (1,259 births observed), in only 30% of births did birth attendants properly wash their hands prior to a vaginal exam. Likewise, a newborn's temperature was measured in only 43% of births, potentially preventing birth attendants from recognizing and treating early signs of newborn distress.

Birth attendants also struggled with taking blood pressure accurately, discerning abnormal clinical findings, responding appropriately to abnormal readings, and managing other medical complications—deficiencies that reflect their limited clinical training and empowerment.

Indeed, although preterm and low birthweight babies contribute to most early neonatal mortality, among 44,515 low-birth weight newborns, only 11% were correctly documented as such in the birth register by birth attendants. Fewer than 1% of the preterm births were correctly recorded.



Overall in the BetterBirth Study, care provided in many deliveries failed to meet WHO safety standards. Because women often arrived shortly before delivery, there was limited time to adhere to all essential practices during labor. And while women were assessed by a birth attendant during admission, they did not always receive subsequent monitoring, and in some cases were not assessed at all after admission.

QUALITY IMPROVEMENT IN NAMIBIA



Birth attendants and facility staff review and discuss the WHO Safe Childbirth Checklist.

A study examining the implementation of the WHO Safe Childbirth Checklist in the Gobabis District of Namibia revealed that on average, midwives completed 68% of essential birth practices.



A birth attendant prepares for a newborn resuscitation training.

After six months of intensive coaching and supportive feedback, the average rate of essential birth practice completion rose to 93%.¹²

Among the 4,888 observed deliveries, fewer than 1% had a partograph. Only two of the 18 facilities designated to offer cesarean deliveries actually conducted cesareans on a regular basis.

Encouragingly, the BetterBirth Study did demonstrate that dramatic improvement is possible in frontline facilities, even when training and resources are constrained. With two months of intensive coaching and supportive feedback, birth attendants in intervention facilities performed on average 13.1 of 18 essential birth practices, as compared to 7.5 in control sites (2,563 births observed). After 12 months, 11.1 practices were still performed on average at intervention sites, compared with 7.9 in control sites (2,325 births observed), highlighting the potential for improvement.

A key insight from the study was that health system leaders need to better position birth attendants to succeed by making long-term investments in birth attendant competency. This must be an ongoing process—one that starts in professional, pre-service training and lasts over the course of birth attendants' work lives. This continual coaching and support is critical, as some complications that arise during pregnancy and delivery are infrequent at the facility level. Practice in managing rare but untoward events—through up-to-date knowledge, technical skills, obstetric emergency simulation, clear communication, teamwork, and positive workplace attitudes and behaviors—is essential to consistently deliver high-quality care.



A birth attendant refers to the WHO Safe Childbirth Checklist as she prepares for a delivery.



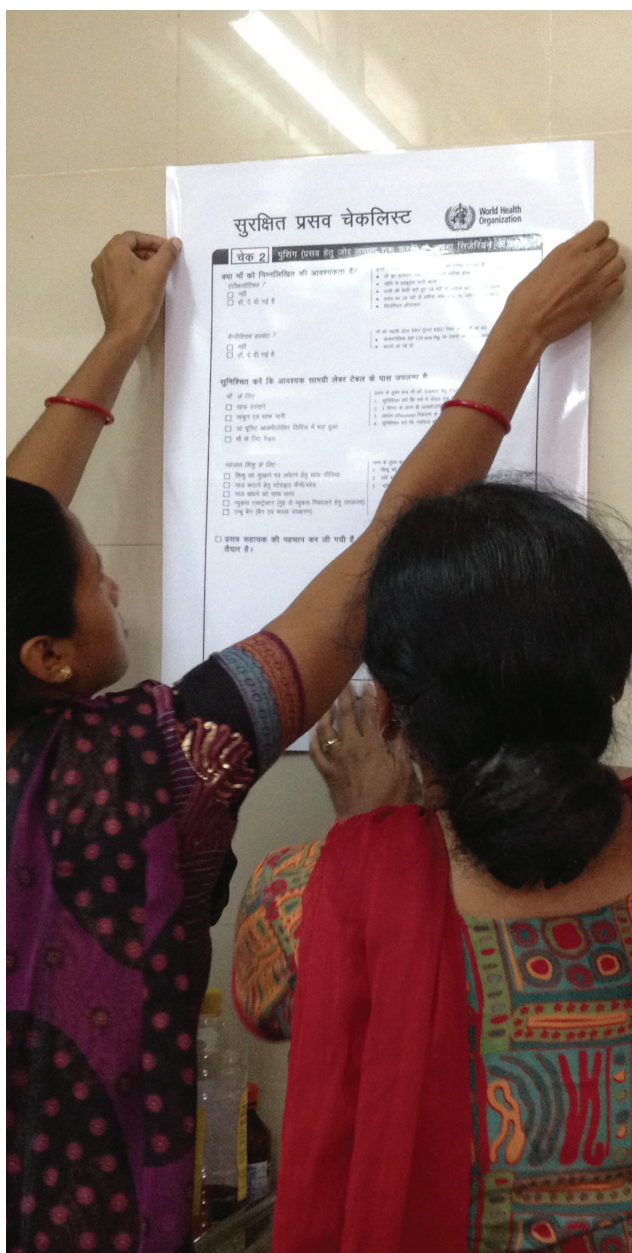
A birth attendant stands ready to care for women and their newborns during childbirth.

EXAMINING THE WORKPLACE: MOTIVATIONS, INCENTIVES, PERCEIVED WORKLOAD

Just as important as ensuring individual birth attendant competency is creating safe, supportive, and empowering workplace conditions that enable birth attendants to do their jobs well. The BetterBirth Study found that birth attendants supported the Safe Childbirth Checklist in general, but felt they frequently were not able to adhere to it.

The study uncovered a variety of workplace factors that hampered birth attendants and potentially undermined quality of care. One hurdle common here and in facilities worldwide is a workplace environment that makes birth attendants feel less empowered to follow essential birth practices, which in turn makes them less motivated to participate in quality improvement initiatives. For example, among the 33 birth attendants interviewed at both high- and low-mortality intervention facilities, only 11% reported ever receiving verbal appreciation from their supervisors. As one birth attendant explained, "If someone took up extra work, then the person was given more work, and if there was a mistake, then they would be scolded for that work."

One hurdle common here and in facilities worldwide is a workplace environment that makes birth attendants feel less empowered to follow essential birth practices, which in turn makes them less motivated to participate in quality improvement initiatives.



A birth attendant posts the Safe Childbirth Checklist on the wall as a reminder of the essential birth practices during childbirth.

"If someone took up extra work, then the person was given more work, and if there was a mistake, then they would be scolded for that work." – Birth Attendant

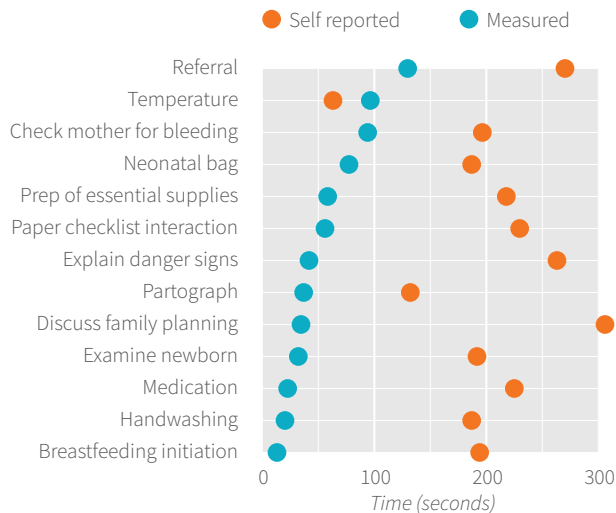
The inability of nurses to make timely and independent clinical decisions, coupled with lack of access to senior medical staff, delayed management of complications and created a major gap in quality of care. Birth attendants interviewed at high-mortality sites further stated that they lacked autonomy to make decisions, while those in medium- and low-mortality sites said they could make decisions independently. Birth attendants at low-mortality sites reported higher satisfaction in their working relationships among peers and physician leaders.

Concerns about physical safety also weighed on the staff. This problem is seen globally, with rising numbers of reports of violence against health-care providers. Many birth attendants felt threatened by family members and drunken visitors, especially at night. As one birth attendant said, "There is no guard here. We worry. People come drunk and create chaos. The patients' family members also bother us."

Birth attendants also experienced high cognitive load during work, with minimal support in stressful, busy facilities. They significantly overestimated the amount of time required to carry out key tasks, a miscalculation that likely reflected the task's cognitive load, rather than the amount of time objectively required for the tasks. The study's time-motion and time-use data confirmed that birth attendants' estimates about how long it took them to complete many Safe Childbirth Checklist tasks were often much longer than the observed time.

In a survey of 61 birth attendants, they estimated it takes 195 seconds (~3 minutes) to help a woman initiate breastfeeding; however, through direct observation, data collectors found that birth attendants took an average of 24 seconds (average across 43 observations of breastfeeding initiation). Similarly, while birth attendants estimated it takes 256 seconds (~4 minutes) to explain postdelivery danger signs, direct observers noted that birth attendants spent only 28 seconds providing the counseling (average across 41 observations).

Misalignment between perception and reality of time to execute essential birth practices



The discrepancy between what birth attendants perceived and what independent observers recorded as the amount of time required to complete Checklist tasks point to the cognitive burden of the Checklist and potential poor quality of completing individual tasks. We measured how long it took birth attendants to perform each item on the Checklist, then totaled the times.

On average, they completed the entire Checklist—everything from measuring vital signs during labor to having a family planning discussion after delivery—in less than 10 minutes. But these practices require a greater investment of time and attention to be performed competently.

In general, we found that birth attendants had competing priorities that sometimes made it difficult for them to follow the Checklist. To better understand this, we followed birth attendants at 20 facilities and recorded what activities they did every two minutes. From over 1,300 hours of observation, we found birth attendants spent a considerable portion of their time on tasks such as nonchecklist clinical care (17%), administrative tasks (25%), or taking breaks (51%). Indeed, the birth attendants spent only 5% of their time on Checklist tasks.

In addition, many kinds of private and customary financial transactions undermined quality care. Women and families made payments to birth attendants throughout the course of childbirth care, and these payments may have colored birth attendants' motivations for providing care. Through face-to-face interviews with 158 women who had experienced a stillbirth or early newborn death, 82% paid for childbirth care meant to be free, and roughly half were forced to provide payment, as opposed to voluntary payment. On average, the payments equaled roughly a family's total monthly income, and families with lower education appeared more likely to pay for services.

These payments often influenced whether birth attendants would make referrals to private versus public facilities. In a minority of cases, the payments partially determined clinical decisions and care.

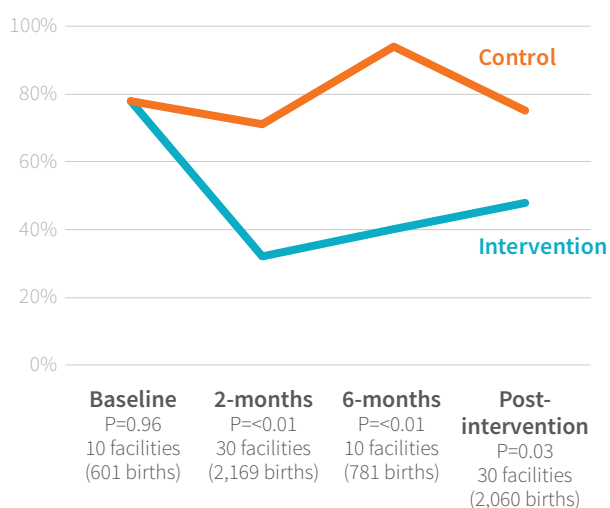
MISUSE OF OXYTOCIN

The WHO Safe Childbirth Checklist includes a checkpoint about administering oxytocin within one minute after birth to reduce the risk of postpartum hemorrhage. However, observers noted that oxytocin was commonly given to women in labor prior to birth. While oxytocin can be an appropriate medication for augmenting labor, WHO guidelines require that safety measures be taken when administering the drug because of the heightened risk of excessively long contractions, subsequent fetal distress, and possibly death.¹³ WHO guidelines also advise confirming a delay in labor before administering the drug; closely monitoring the fetal heart rate and uterine contraction pattern using a partograph to monitor labor progress; and having the capacity to manage adverse effects and perform a cesarean delivery, if needed.

Despite these guidelines, financial incentives and demands to inappropriately administer oxytocin to speed up labor prevailed. Many of these drivers were extraneous to clinical considerations. “Birth attendants continue to induce labor in order to conduct as many deliveries as possible and earn more money,” a study observer explained. As a coach observed at one site, even a community health worker “encouraged provision of oxytocin antepartum.”

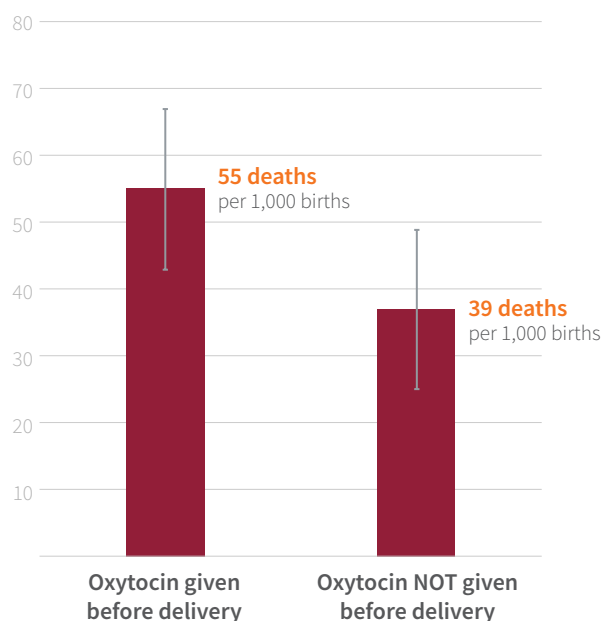
In India and around the world, this practice is an open secret. In our study, birth attendants tried to hide the inappropriate administration of oxytocin from observers. As a study observer explained: “Sometimes, the birth attendants know that if they use oxytocin, the delivery will happen in 30 minutes. So they will close the door so that oxytocin is not administered in front of us. I can keep knocking and saying, ‘Sister, open the door.’ She is not going to open the door. What happened? She makes excuses like, ‘I went to the washroom,’ or this happened. Yet in this little time until the door is opened, the delivery has already happened.”

Behavior change: inappropriate intrapartum use of oxytocin during labor



Perinatal mortality: intrapartum oxytocin use during labor

Perinatal mortality (per 1,000 births)



In the BetterBirth Study, as in previous studies, intrapartum use of oxytocin increased the risk of harm to the newborn. In more than 2,900 observed births where health outcomes were also obtained, the perinatal mortality ratio was much higher (55 deaths per 1,000 births) for women who received oxytocin before delivery than for those who did not (39 deaths per 1,000 births). One positive result of the BetterBirth Study was that the intervention reduced the unmonitored administration of oxytocin during labor to less than 35% of deliveries—clearly demonstrating that demands from women and their families on birth attendants to administer oxytocin can be overcome with coaching. Impressively, at the one-year mark, which was four months after the end of coaching, the study's intervention sites continued to administer oxytocin before delivery at lower rates than in control sites.

SUPPORTING BIRTH ATTENDANTS: KEY RECOMMENDATIONS

The vast majority of frontline birth attendants in facilities around the world are proud of doing their jobs well and want to provide the best quality care possible. However, limited competency training and support, challenging workplace conditions, and financial and social pressures all affect how birth attendants interact with women and the quality of care they provide. As this study demonstrated, these factors frequently stymie birth attendants' efforts to provide person-centered care before, during, and after childbirth.

Because the WHO Safe Childbirth Checklist is not a replacement for clinical training, ongoing training is needed to ensure birth attendant competency. This training should also include skills refreshers, simulations, ongoing coaching, and accountability structures to support routine obstetric and newborn care, identification and management of life-threatening emergencies, teamwork and communication, and respectful person-centered care.

To build a culture of patient safety (doing no harm) and quality (doing all the right things), facility leaders must support an agenda of quality improvement. Without such commitment, it is difficult to inspire and sustain change. Improving workplace culture will require identifying and supporting a safety-and-quality champion at each facility.

Ensure the physical and psychological safety of all health facility staff.

To manage the cognitive load ("busyness" effect) on birth attendants of a quality-improvement intervention, facility leaders should consider introducing the Checklist in a step-wise process or in distinct phases. This may entail task-shifting or task-sharing to appropriately assign duties based on needed skills and on the scope of practice. This could also include review of administrative requirements to reduce documentation burden.

To discourage private financial transactions that undermine quality care, incentive structures should directly address and overcome perverse financial incentives that lead to harmful practices, such as inappropriate oxytocin use or unlawful payments for care. ■

FRONTLINE CHILDBIRTH FACILITY —

The physical and organizational environment in which women and birth attendants interact profoundly affects the provision and experience of care.

The BetterBirth Study yielded important clues about how quality care breaks down and what questions need to be answered at the health facility level to improve health outcomes.

Above all, the study revealed that a facility's readiness for quality improvement goes beyond traditional measures, such as supply availability and birth attendant staffing. Readiness refers to a site's ability to implement a quality improvement intervention with respect to a multitude of factors that impact implementation success.

These factors include leadership commitment to quality improvement, positive organizational culture including teamwork and motivated staff, quality-improvement experience and implementation expertise, and other contextual factors that together nurture or thwart a supportive environment for delivering high-caliber care. Sites can vary in their degree of readiness across the factors; they can be highly ready for quality improvement on some dimensions and less ready on others.

— READINESS MATTERS

Readiness is not just about being ready to implement a new program; rather, it's about readiness for each stage of the implementation. For example, it is critical to understand there is a learning curve and additional cognitive load for staff participating in a new quality improvement project. Managers should recognize and account for this added cognitive load along with the regular workload when preparing for implementation.

BETTERBIRTH FACILITIES

In Uttar Pradesh, government-run facilities are the most common location for childbirth, accounting for 45% of births. By comparison, 32% of births take place in homes, and 23% in private facilities.¹⁴

The BetterBirth Study was conducted in 120 primary health centers, community health centers, and first-referral units. Each facility delivered about 1,600 newborns per year (~4 to 5 births per day). An average of four skilled birth attendants were assigned to each facility, one to two of whom were present during each shift.

Outwardly, frontline facilities shared key characteristics—delivery load, staffing, supply availability—and offered very similar childbirth services. All were open 24/7. Among all women in the study, only 2% had a cesarean delivery—the vast majority of which were conducted outside study facilities and in hospitals. This low cesarean delivery rate points to the capacity limitations in providing comprehensive emergency obstetric care.



Among our study facilities, the average distance to a district hospital was 30 kilometers. The median time between admission and delivery was 105 minutes, which limited the opportunities for birth attendants to intervene during labor.

While the interval before discharge was not recorded, qualitative interviews suggest that women often left two to six hours after delivery. And although the study's 18 first-referral facilities were designated to provide comprehensive emergency obstetric and neonatal care, including cesareans, these sites generally did not operate at that level.

WHAT DRIVES DIFFERENCES IN INTERVENTION UPTAKE IN FACILITIES?

Despite their apparent similarities, facilities showed dramatic variation in how and whether they integrated and carried out the BetterBirth intervention. In taking on the BetterBirth intervention, the sites clearly operated under differing contexts and degrees of readiness. Moreover, sites were asked to participate in the study and leadership commitment varied.

	PRIMARY HEALTH CENTER* (46 IN STUDY)	COMMUNITY HEALTH CENTER** (56 IN STUDY)	FIRST REFERRAL UNIT (18 IN STUDY)
<i>India Public Health Standards Guidelines</i>			
Population served	20,000-30,000	80,000-120,000	80,000-120,000
Number of beds	4-6	30	30
Childbirth staff	At least 1 medical officer 4 midwives	1 obstetrician/gynecologist 1 pediatrician 10 nurses	1 obstetrician/gynecologist 1 pediatrician 10 nurses
<i>Childbirth services offered</i>			
Management of normal deliveries	X	X	X
Forceps/vacuum-assisted deliveries	X	X	X
Manual removal of placenta	X	X	X
Identification and pre-referral management of emergencies for postpartum hemorrhage (PPH), eclampsia, sepsis	X		
Identification and management of complications including PPH, eclampsia, sepsis		X	X
Essential newborn care	X	X	X
Newborn stabilization unit		X	X
Basic and emergency obstetric care, including cesarean delivery		X	X
Comprehensive obstetric care, including family planning, safe abortion, blood storage unit, referral services			X

* India Public Health Standards (IPHS) Guidelines for Primary Health Centres, Revised 2012

** India Public Health Standards (IPHS) Guidelines for Community Health Centres, Revised 2012

A subset analysis of 15 intervention facilities, where independent observers recorded how closely the staff adhered to intervention behaviors after two months of coaching, showed how thoroughly the intervention was adopted at the facility level (1,259 births observed).

This analysis found that seven facilities were strong adopters, while two largely resisted the intervention. The conventional and easily measured indicators of a facility’s capability for quality improvement—such as supply availability and birth attendant staffing—did not explain the variation in intervention uptake.

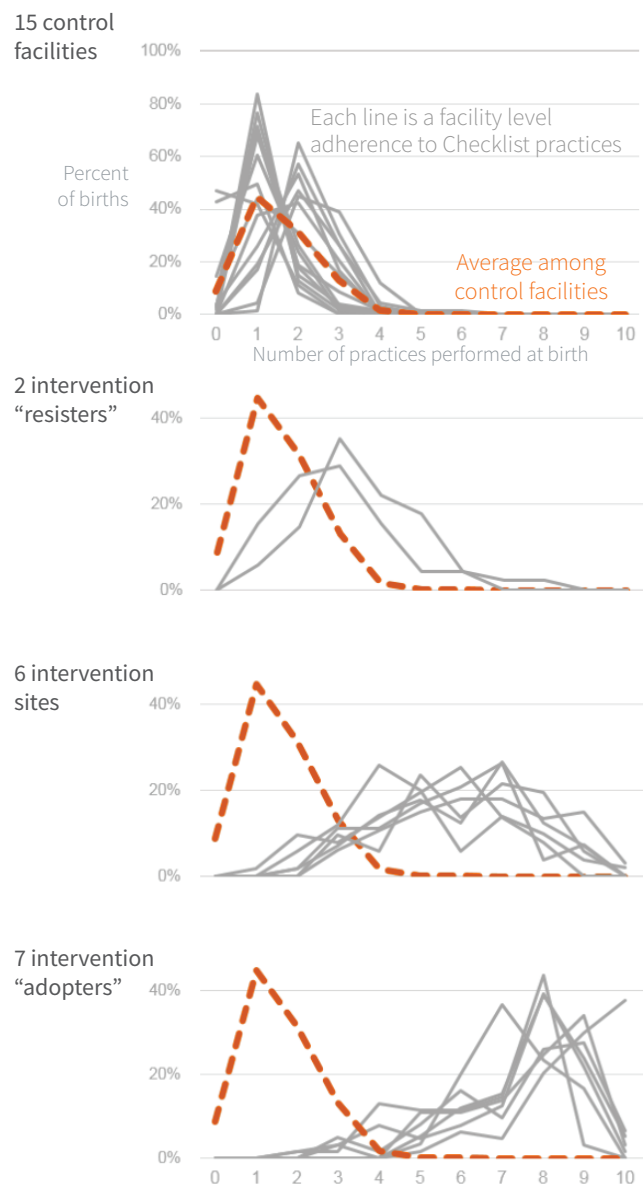
One plausible influence on intervention uptake was the support of the facility-level childbirth quality champion in promoting or encouraging quality improvement initiatives. Although it is challenging to measure readiness for quality improvement or leadership effectiveness at these facilities, the study did uncover several telling patterns with regard to turnover.

Leadership turnover was common in the intervention facilities. For example, among the 60 intervention facilities, 18 (30%) experienced a change in head of facility, and five (8%) experienced a change in childbirth quality champion for the BetterBirth intervention.

While turnover among heads of facility was not significantly associated with Checklist behavior adherence or with maternal and neonatal outcomes, facilities with childbirth quality champion turnover tended to have lower mean adherence with essential birth practices. This suggests the consistent presence of a quality improvement champion in a given facility is likely to boost adherence to positive behaviors.

Uptake of Checklist intervention varied by site

Of 10 practices observed, some sites resisted change and others strongly adopted the intervention



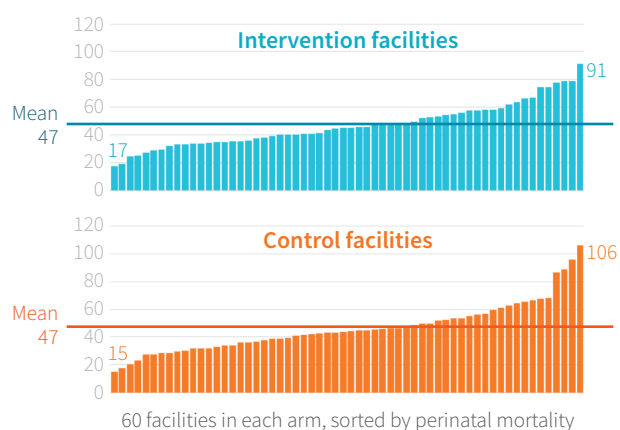
This analysis included 10 essential birth practices, such as taking temperature or blood pressure, in the intensive coaching phase only. Referrals, multiples, and macerated stillbirths were excluded.



A typical delivery room in a facility with the WHO Safe Childbirth Checklist posted on the wall.

Large variation in facility-level outcomes in both arms

Perinatal mortality (deaths per 1,000 births) including referred cases



HEALTH OUTCOMES ALSO VARY

Not only did facilities range widely in how well they adopted the BetterBirth intervention, they also showed remarkable variation in health outcomes. Among the 120 facilities and more than 157,000 births, the study found a seven-fold difference in the perinatal mortality rate across facilities; the lowest-mortality site had 15 deaths per 1,000 births, and the highest-mortality site had 106 deaths per 1,000 births. The maternal mortality ratio ranged from 0 deaths to 471 per 100,000 live births. Severe maternal morbidity ranged from 5% to 33% of women. Referral rates ranged from <1% to 33%, and did not vary across different types of facility (primary health center, community health center, first-referral unit).

What drove this variation in outcomes? Results of the main study showed the intervention did not affect these outcomes generally. However, we found that regardless of study arm, perinatal mortality tended to be lower in births where more birth practices were performed, as opposed to fewer practices. Yet it is unclear if each additional practice contributed independently to lower mortality, or if facilities had some other positive attributes that led to both high adherence to behaviors and low mortality.

Surprisingly, across all 120 study facilities, traditional care-related factors, such as staffing ratios, facility type, or supply availability, were not consistently associated with health outcomes. Rather, health outcomes were most strongly associated with socioeconomic characteristics.

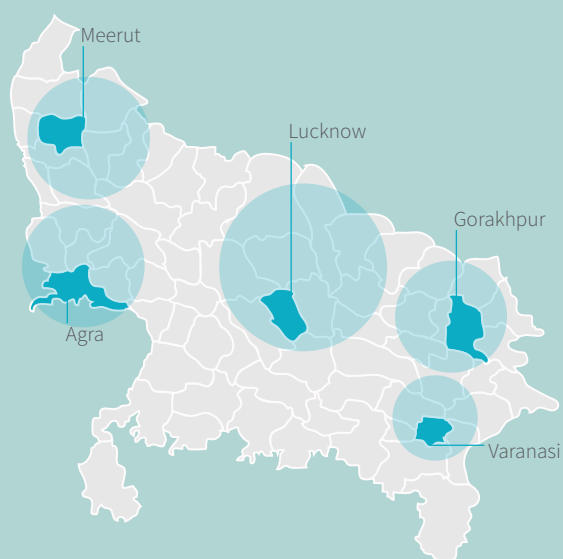
For example, higher perinatal mortality correlated with lower district-level female literacy, location in the central geographic region of Uttar Pradesh, and a higher previous neonatal mortality rate (as measured with a different method than the study used). Severe maternal morbidity also correlated with central geography, and paradoxically, more supplies of four key birth-related drugs. It is difficult to interpret this finding. It could indicate the medications were sitting untouched on a shelf and not being used to treat patients; or that the medications were being ordered more frequently, used inappropriately, and causing harm; or that facilities with more supplies dealt with a higher volume of patients with complications (whether due to location or because of reputation).

Even among facilities with at least one maternal death, we found no measured facility-level attribute that predicted maternal mortality.

Maternal mortality was rare; 47 of the 120 facilities did not have any maternal deaths during the 12 months of data collection. Even among facilities with at least one maternal death, we found no measured facility-level attribute that predicted maternal mortality.

REGIONAL HUBS

For administrative purposes of the study, we delineated five regional “hubs” throughout Uttar Pradesh: Lucknow, Agra, Varanasi, Gorakhpur, and Meerut. These hubs were created for convenience and included both rural and urban sites. We included “hub” in our statistical model to understand if there were differences in how the program was deployed across regions. While we did find hub (labeled “Central Geography”) to be significant, it is unclear what is driving that difference. It may be due to fundamental differences in the regions we delineated for each hub, or to differences in how the program was implemented.



Referral rates strongly correlated with women reported to have anemia and with women requiring a cesarean delivery; these patterns were not unexpected, given the study's frontline facilities lacked blood transfusion and surgical capacity.

Aside from these significant relationships, note the characteristics that were not related: a host of typical measures such as staffing levels and staff training, facility type and distance to hospital, age and gravidity of the patient population, and so forth had no relationship to outcomes. This suggests that whatever attribute of facilities is driving the wide difference in outcomes, we did not measure it, or measured it improperly.

OUTCOME VARIATION: UNDER A MAGNIFYING GLASS

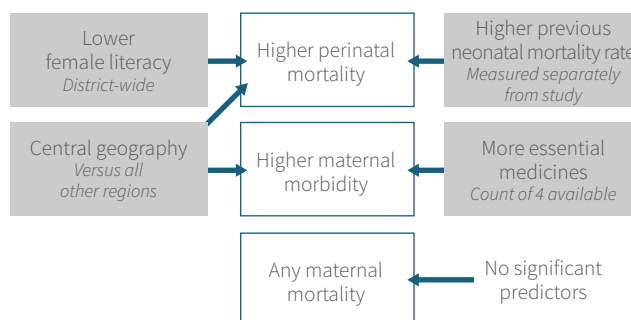
We wanted to look further into this question. Although the intervention did not change health outcomes in the aggregate, were there certain types of facilities where the intervention did improve outcomes? Although we may not have directly measured what it is about facilities that determines their health outcomes, perhaps we could learn more by examining facilities where the intervention had impact.

We discovered that during the most intensive phase of the intervention, when coaching occurred twice per week, the intervention was associated with lower perinatal mortality in smaller-volume facilities (those that had about 90 births per month), after adjusting for other possible measured characteristics.

These encouraging trends in lower volume sites may stem from the fact they had more time and space to implement the Safe Childbirth Checklist and other parts of the intervention. Considering the additional cognitive load the 28-item Checklist places upon a birth attendant responsible for multiple clinical and

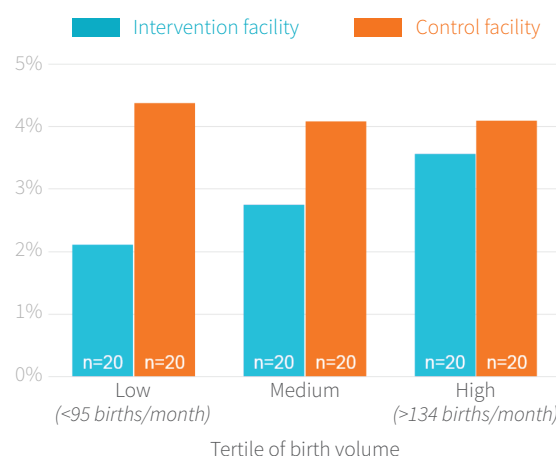
What correlates with facility-level outcomes?

Statistically significant predictors from multivariable models, n=120



Birth volume and perinatal mortality

Site level



administrative tasks, it is plausible that birth attendants at busier facilities do not have the bandwidth to meaningfully integrate new behaviors into their day-to-day practice.

The superior performance of lower-volume facilities points to the need to better understand how facility work environments and readiness enable them to take on an ambitious quality-improvement intervention.

STRENGTHENING FRONTLINE FACILITIES: KEY RECOMMENDATIONS

Preparing frontline facilities for their many tasks and roles in delivering high-quality childbirth care will require bolstering readiness and leadership. By conducting systematic readiness assessments of capability, capacity, commitment, culture, and context, facilities can identify and fill gaps in carrying out quality-improvement efforts such as the Safe Childbirth Checklist.

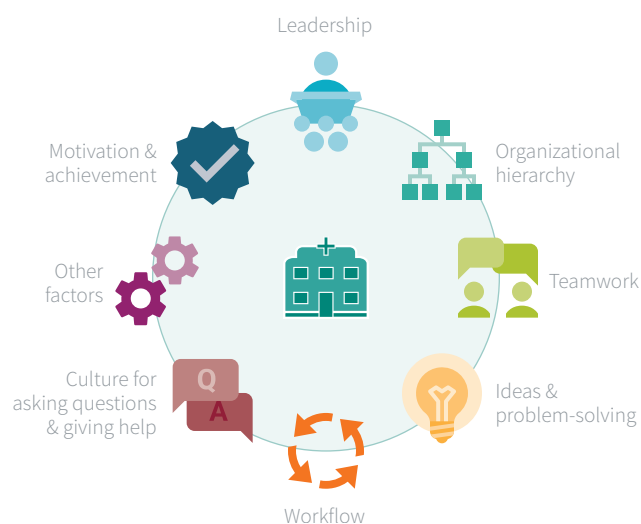
Most current readiness assessments do not shed light on the internal and external contexts in which a facility operates. To remedy this problem, reliable assessment instruments for facility readiness should:

- Assess birth attendants' competency, work roles, and scope of practice.
- Assess the cognitive load for facility staff, including patient volume, and integrate that information into new strategies to smooth the workflow.
- Assess the capacity of facility leaders and staff to carry out quality improvement initiatives. This assessment should consider such factors as staff turnover, staff empowerment, and accountability mechanisms.
- Assess the facility's physical conditions, such as cleanliness, functional supply chains, and safety.
- Assess the facility's organizational culture around teamwork and quality improvement.
- Tailor implementation packages to the needs of facility adopters and resisters, and align these packages with the facility's readiness level.

To optimize facility leadership:

- Draw up plans that ensure smooth operation during leadership turnover, even for a relatively short time span.
- Develop clear processes by which new leaders can quickly grasp ongoing quality initiatives.
- Ensure accountability and oversight to sustain high-quality childbirth care when turnover occurs.
- Provide ongoing support for facility leaders, and safety and quality champions.
- Adopt incentives (financial, status/prestige, training opportunities, recognition, awards) and nurture supportive environments that will help facility leaders and champions thrive.
- Train facility directors in management best practices and leadership competencies. ■

Components of facility readiness for quality improvement



HEALTH SYSTEM —

**Strong connections
are essential
between frontline
and higher-level
facilities across
antenatal,
intrapartum, and
postnatal care.**

When complications arise in childbirth, an effective referral system can save the lives of women and their newborns by bringing them to the right care at the right time.

The WHO Safe Childbirth Checklist focused on early identification of complications and encouraged facilities to identify referral criteria based on their available services. An effective referral system is a myriad of complex components, ranging from physical transportation to communication lines to supply chains. "Systemness" is achieved when all interactions between the system and its infrastructure, facilities, and staff members are planned, streamlined, optimized, and harmonized, yielding more than the sum of their parts.¹⁵ The intentional vertical, horizontal, and diagonal integration of care delivery across the health system results in "systemness."

“SYSTEMNESS” MATTERS

A universal example of “systemness” is the everyday traffic on our roadways. A well-coordinated transportation system runs smoothly. Traffic “systemness” is undergirded by rules of the road, a shared understanding of those rules, and expectations that the rules will be followed. Just as important is the infrastructure to support learning, such as driver’s education and licensing; physical infrastructure to enforce the rules, such as seatbelts, traffic lights, and stop signs; and enforcement through policing, insurance, and licensing. In the same way, the provision of health care and the experience of receiving care rely on well-integrated “systemness.”

Data from the BetterBirth Study illuminated not only the challenges that arise in referral systems and supply chains, but also the opportunities to improve “systemness” to drive better outcomes for women and newborns.

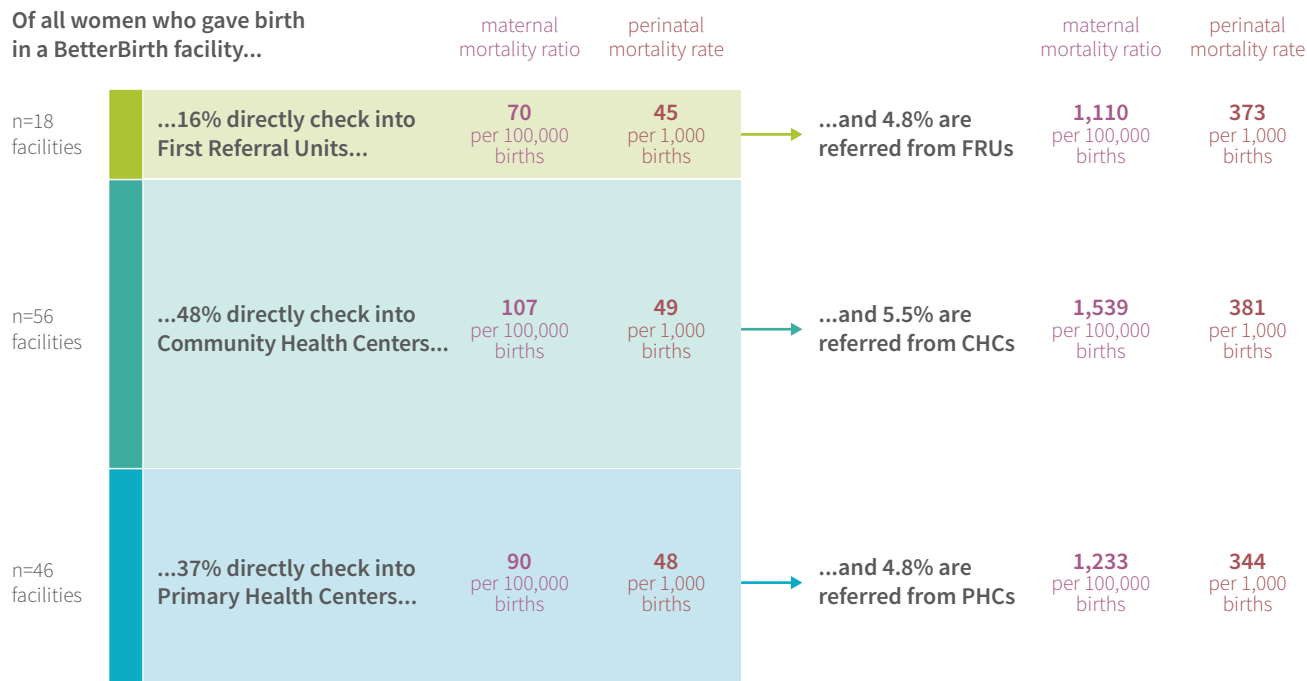
WHAT HAPPENS IN REFERRAL?

OVERALL

Across the entire study of more than 157,000 women, the referral rate for all women was 6% and a startlingly low 1.6% of newborns. Not surprisingly, mortality rates among referred women and newborns were high.

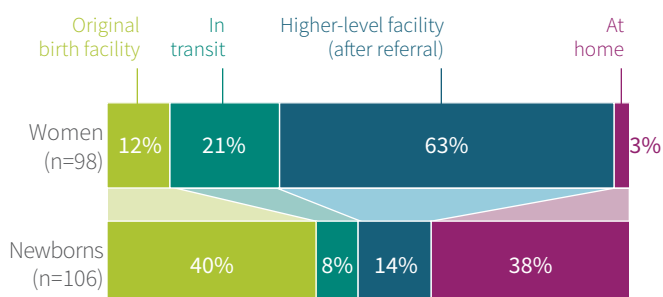
A subanalysis of maternal deaths and early neonatal deaths shines a light on how referral mechanisms linking lower- and higher-level facilities in any setting can fail, leading to mortality. We found referral systems were poorly organized and resourced, impeding delivery of the right care at the right time for women with life-threatening complications.

Of all women who gave birth in a BetterBirth facility...



Of the 149 cases of maternal deaths, we have complete referral data for 98. Most of these women (84%) died after receiving at least one referral to a higher level of care. Although the health system correctly referred these women to higher-level facilities, the women did not receive the care they needed in time. Among women who died, 12% did so at the original facility where they sought care, 21% died in transit (mostly in ambulances or private transport), and 63% died at a higher-level facility; 3% died at home. Some women's families reported being turned away from the referral facility and sent elsewhere because the women were too sick.

Maternal and Neonatal Death Locations



stabilization prior to transfer, or multiple transfers across the health system led to these delays in appropriate care and, ultimately, women's deaths.

The diagram illustrates the flow of women through four facilities and the outcomes of their care. The flow starts with 98 women at Facility 1, where 12 died. 82 women were referred out to Facility 2, where 3 were turned away and 15 died in transit. 64 women were admitted to Facility 2, where 44 died. 20 women were referred again to Facility 3, where 1 died and 15 died. 2 women were referred again to Facility 4, where 1 died in transit. 4 women were discharged from Facility 2, where 3 died at home and 1 died in transit returning to the facility.

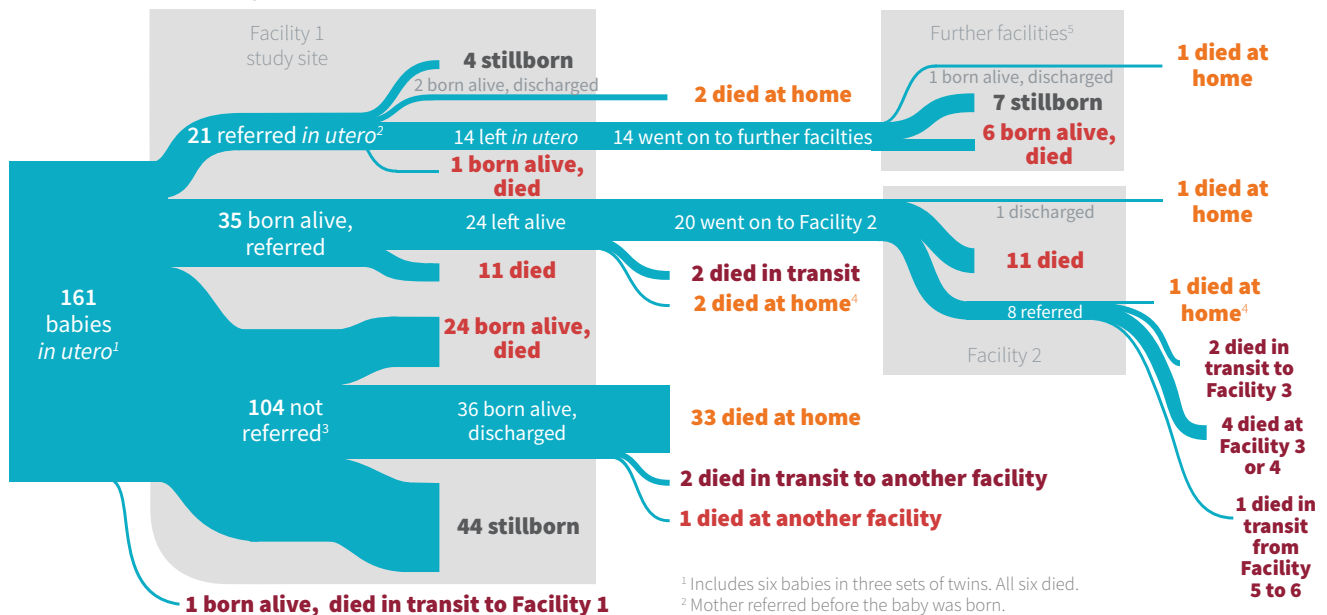
Facility	Flow Description	Count
Facility 1	Initial population	98 women
Facility 1	Died	12 died
Facility 2	Referred out from Facility 1	82 referred out, left facility
Facility 2	Turned away	3 turned away
Facility 2	Died in transit	15 died in transit
Facility 2	Admitted	64 admitted to next facility
Facility 2	Died	44 died
Facility 3	Referred again from Facility 2	20 referred again
Facility 3	Died	1 died
Facility 3	Died	15 died
Facility 4	Referred again from Facility 3	2 referred again
Facility 4	Died in transit	1 died in transit
Facility 4	Died	2 died
Facility 2	Discharged	4 discharged
Facility 2	Died at home	3 died at home
Facility 2	Died in transit returning to facility	1 died in transit returning to facility

NEWBORN REFERRAL

Quite a different referral process emerged from the BetterBirth data for newborns. Sick newborns were often not appropriately identified or referred by birth attendants. Families of nonreferred sick newborns struggled to find the right care once the baby came home. In a subset of 106 cases where a newborn death occurred (excluding stillbirths), we followed up with families to understand what happened. Among the newborns who died, 40% died at the original facility where they were born, 8% died in transit, 14% died at a higher-level facility, and 38% died at home. In some cases, newborns were taken to multiple facilities prior to their death. These newborns often did not survive transport to the referral facility, and if they did, their condition had seriously deteriorated by the time they arrived. This suggests they were not referred often enough, quickly enough, or appropriately stabilized.

Other newborns went home and died within seven days. We found in the period between discharge and death, their families often tried to seek care for the newborns, typically from multiple sources. For newborns discharged without a referral (n=36), 45% of families sought care at some point before the newborn's death. Most of these families consulted several care sources (i.e., at least one government or private health facility, and a traditional healer). Although five of the 36 non-referred newborns were seen by traditional healers, very few families limited their care-seeking to only a traditional healer; most also sought allopathic care. In cases where families sought care, facilities either tried to help the newborns but were unsuccessful, or informed the families the newborns were too ill and would not respond to further treatment. In those instances, most newborns returned home, where they eventually died.

Perinatal Death Mapping: Referrals and place of death



¹ Includes six babies in three sets of twins. All six died.

² Mother referred before the baby was born.

³ Neither mother nor baby referred at any point.

⁴ Went home against medical advice.

⁵ Includes up to 4 ensuing referrals for the mother before the birth.



Women register at a facility.

COMPARISON OF MATERNAL AND NEWBORN REFERRAL

Some potential explanations for the difference in referral patterns between women and newborns are:

- » the most common cause of neonatal deaths was asphyxia shortly after birth, which precluded timely referral;
- » newborn complications were underidentified and not managed appropriately; and
- » in a setting where one in 20 newborns die, a number of newborn deaths were expected by both families and birth attendants. That may have translated into unwillingness of birth attendants to refer sick babies, and reluctance of families to bring sick babies to higher-level facilities for care because of the perceived futility and potential cost.

HOW DID THE SYSTEM FAIL WOMEN AND NEWBORNS?

BetterBirth Study data from maternal death reporting, verbal and social autopsies of perinatal deaths, records of complications and referrals, and birth attendant interviews shed light on what happened. Among the study's findings:

POOR RISK STRATIFICATION

Lack of coordination between antenatal care and intrapartum care resulted in women with high-risk pregnancies giving birth at lower-level facilities that were not well equipped to manage complications.

UNDER-IDENTIFICATION OF COMPLICATIONS

That complication rates in the main study were lower than expected suggests birth attendants may have failed to identify complications. For the more than 157,000 women, we would have expected 15% of women to have a complication, but only 10% had a

complication documented by the facility. For example, fewer than 1% of women were identified with pre-eclampsia or eclampsia, compared to an expected 2-8%.¹⁶

UNDER-REFERRAL OF COMPLICATIONS

In cases where birth attendants did identify complications, referral rates were lower than expected for both women and newborns. Among the women identified with a complication warranting referral, 22% were not referred. These included women with placenta previa, obstructed labor, and hemorrhage. Furthermore, 77% of newborns identified with a complication warranting referral were not referred. These included newborns with hypothermia, low birth weight, and asphyxia.

SOCIAL PRESSURES SURROUNDING REFERRAL

In some cases, families refused referral for women because of fear of the unknown, or because they could not provide informal payment to workers at referral facilities. Birth attendants expressed frustration with families refusing referral. On the other hand, women themselves reported feeling threatened with referral if they complained or were unwilling to pay extra fees at the frontline facility.

TRANSPORTATION PROBLEMS

Ambulances were not equipped with basic supplies such as oxygen (from birth attendant and patient interviews).

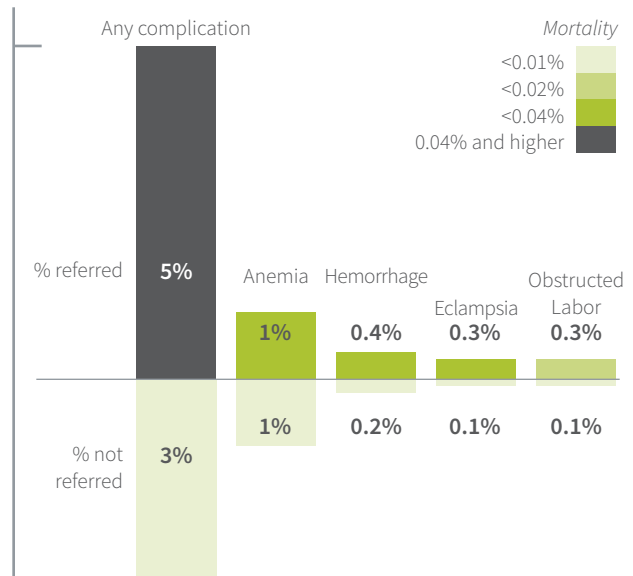
EMERGENCY PERSONNEL STAFFING

Ambulance staff were not trained or were unavailable to support critical care during transport (from birth attendant and patient interviews).

POOR COMMUNICATION BETWEEN FACILITIES

Although referral protocols exist, referral facilities often received scant information about incoming women with complications (from birth attendant interviews). In addition, lower-level facilities were not informed how the women fared once they were referred.

Maternal mortality rates by referral status, among women with identified complications



PRESSURE TO MAINTAIN DELIVERY LOAD

Coaches reported that birth attendants applied WHO Safe Childbirth Checklist referral criteria, but received pushback from the medical officers in charge if additional referrals reduced the number of deliveries performed at their facility. We found that, overall, the health system wanted to maximize use of lower-level facilities, given the high patient loads at district hospitals. However, lower-level facilities were often not properly staffed and resourced to provide the designated level of care.

These findings suggest a broken referral system between frontline facilities and higher levels of care may have contributed to maternal and newborn deaths. Connections failed at critical points when lives might have been saved. An intact, functional referral system is a microcosm of "systemness," and reveals the need to connect all parts of the health system to better serve women and newborns.

SUPPLY SYSTEM GAPS

"Systemness" also requires maintaining a responsive supply chain across all facility levels. A reliable supply of essential medications and equipment—one continually monitored, supported, and integrated into all levels of the health system—is one of the six WHO-recognized building blocks for providing high-quality care.¹⁷ Globally, fractured supply chains and inadequate supply availability remain a persistent problem in maternal and newborn health.

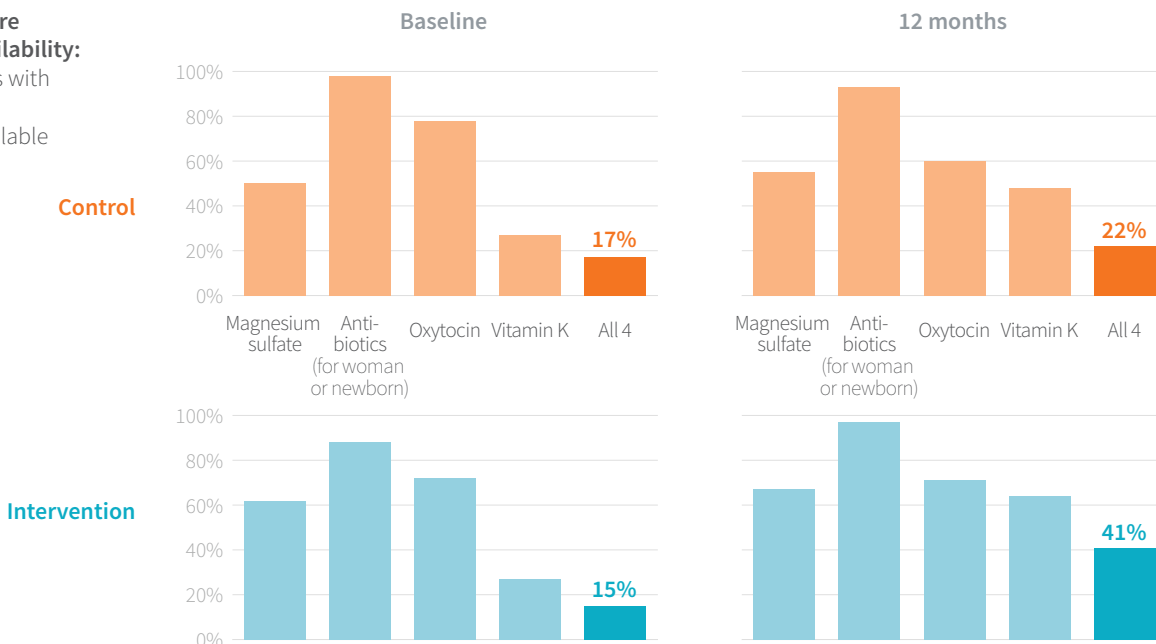
In the BetterBirth facilities, we found significant gaps in supply availability. The sites carried about two-thirds of the supplies 80 percent of the time (as measured by quarterly supplies audits at every facility over 12 months). The other third of supplies were available only sometimes or rarely. Some of the missing items included critical supplies such as a fetoscope or Doppler device, vitamin K, antibiotics, and oxytocin.

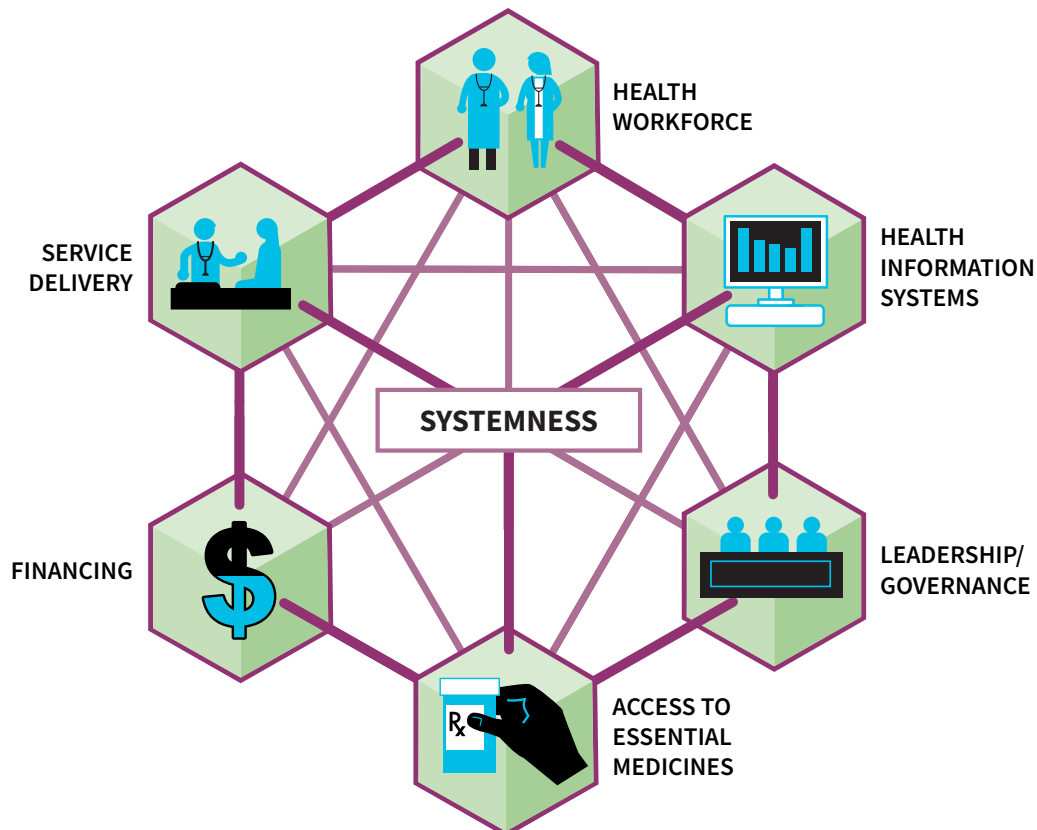
Encouragingly, the BetterBirth strategy of using the Safe Childbirth Checklist as a supply organization tool increased the availability of some supplies and medications—including those that were often missing like the fetoscope or Doppler device—but not the majority of supplies. While the availability of four key drugs (magnesium sulfate, vitamin K, antibiotics, and oxytocin) improved, it was still insufficient; fewer than 50% of facilities had all four drugs stocked. Furthermore, availability did not guarantee the medications were used appropriately.

Among sites that started out with lower baseline supply availability (<70%), the BetterBirth intervention resulted in greater improvement in supply availability, compared to control sites (n=30 facilities). Yet as these findings illustrate, gaps in the supply chain of essential medications and equipment generally persisted, even after improvement in some facilities.

Medications are limited in availability:

Percent of sites with four essential medicines available





Systemness: the connectedness among the WHO building blocks for health system strengthening

“SYSTEMNESS” IMAGINED

In an ideal health-care environment, women and newborns receive care that is respectful, timely, consistent, seamless, integrated, comprehensive, appropriate, and person-centered. Within such a system, health-care providers and administrators work collectively and collaboratively at all levels of the system to meet the needs of women and newborns.

“Systemness” is the glue that binds all levels and types of care, transcending inputs such as health services and the workforce. Indeed, it is the essential ingredient

that connects the building blocks of reliable, high-quality health systems. Our study showed that ultimately, “systemness” is the critical, yet often invisible, component needed to enhance quality and improve health outcomes for women and newborns across the continuum of care, from the antenatal to intrapartum to postpartum periods.

Systemness removes systemic barriers to high-quality care, and prevents fragmentation, gaps, delays, or redundancy. When birth attendants are supported in a functional and integrated health system, it is easier for them to do the right thing.

In a high-quality childbirth experience within a health system with "systemness":

- » Women with risk factors receive proper antenatal care and are stratified to appropriate levels of childbirth care according to their pregnancy and delivery risks.
- » Women have timely access to appropriate health facilities for childbirth.
- » Skilled birth attendants maintain competency in identifying, managing, and correctly referring women with pregnancy-related complications.
- » Skilled birth attendants treat women and their families with dignity and respect.
- » Facility leadership enables and supports skilled birth attendants to do their jobs effectively, and feel satisfaction in doing so.
- » Supply lines of essential medications, blood banks, and equipment are intact, with no items out of stock.
- » Referral transportation systems—including drivers, properly trained medical personnel, and properly equipped ambulances—are functional 24/7.
- » Communication systems connect health workers at referring and receiving facilities 24/7, with established protocols for capturing and sharing critical patient information.
- » Higher-level referral facilities have the human and resource capacity to manage women who arrive with complications.
- » Women and newborns return home with the postpartum support needed to ensure their healthy recovery and transition.

ENHANCING “SYSTEMNESS”: KEY RECOMMENDATIONS

To make significant impact on health outcomes at scale, coordinated, and intersectoral efforts are required across the health system. Mapping the building blocks of a system and understanding where connections fail is critical to strengthening health systems and achieving “systemness.” Stakeholders must align on a shared vision of how the elements of a health system should work together, recognizing no one stakeholder can fix an entire system.

To this end, leaders and administrators should strive to conduct a needs assessment of the health system, measure gaps, and track progress against those gaps regularly. Key areas should include the following:

Develop continuity of care from antenatal to intrapartum to postpartum periods through seamless management of health conditions. This effort should be led by a care team, organized through synchronization of medical records, and carried out with communication among health workers, and between patients and health workers.

Improve risk stratification during antenatal care, to ensure that women—especially those with risk factors—deliver in facilities that have the capacity to care for them.

Define levels of maternal care (a classification system of facility capacity to manage childbirth and possible complications, based on staffing levels, resources, space, and technology) and support appropriate risk stratification for women.

Create standardized protocols and two-way communication lines to identify, document, and refer women and newborns to higher levels of care when complications occur.

WOMEN & COMMUNITY —

In the nearly two decades since the United Nations adopted its ambitious Millennium Development Goal 5—to improve maternal health—the death rate among childbearing women has fallen dramatically.

A larger proportion of women are giving birth in health facilities and with the assistance of skilled birth attendants, rather than at home with an untrained family member or community member. In India, the Janani Suraksha Yojana program—a safe motherhood intervention run by the country's National Rural Health Mission—successfully increased the rates of facility-based childbirth since 2005 by offering financial incentives to women through conditional cash transfers.

However, this progress was not seen in other services across the continuum of care. For example, most recent national surveys showed that only 51% of women had at least four antenatal care visits.¹⁴

POWER MATTERS

Despite the dramatic scale-up of facility-based deliveries globally, reductions in maternal deaths have not been as large as public health experts had hoped. In recent years, progress has plateaued.

One reason for this disappointing trend concerns quality of care, which is addressed through innovations like the Safe Childbirth Checklist. Another is that too little attention has been paid to the women themselves and to their expectations and experience of their health care encounters. The 2016 World Health Organization quality of care framework for women and newborns underscores this disconnect; the experience of care for pregnant women during childbirth is just as important as the provision of care in achieving person-centered results.⁷

In the ecosystem of facility-based childbirth care, women and their communities are deliberately placed at the center so they are seen, heard, and prioritized. That should be done with consideration for the broader context of women's communities.

Women face a multitude of power dynamics and cultural practices—both in their communities and in the health system—that can hasten or delay when they seek care, amplify or stifle their voiced preferences, raise or lower their expectations for quality care, and normalize or sanction disrespectful treatment. These ubiquitous but often hidden power dynamics must be taken into account in the design of any intervention that aims to raise demand for quality care.



THE BETTERBIRTH MOTHER

On average:

Age: 26

Number of previous childbirths: 1-2

Median time between admission and delivery: 105 minutes

Delivery time evenly spread throughout 24 hours

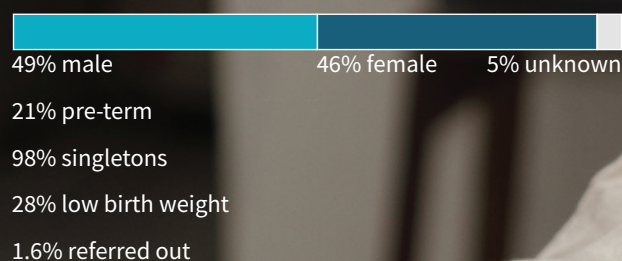
Delivery type:



Referrals:



THE BETTERBIRTH BABY



THE CHILDBIRTH EXPERIENCE

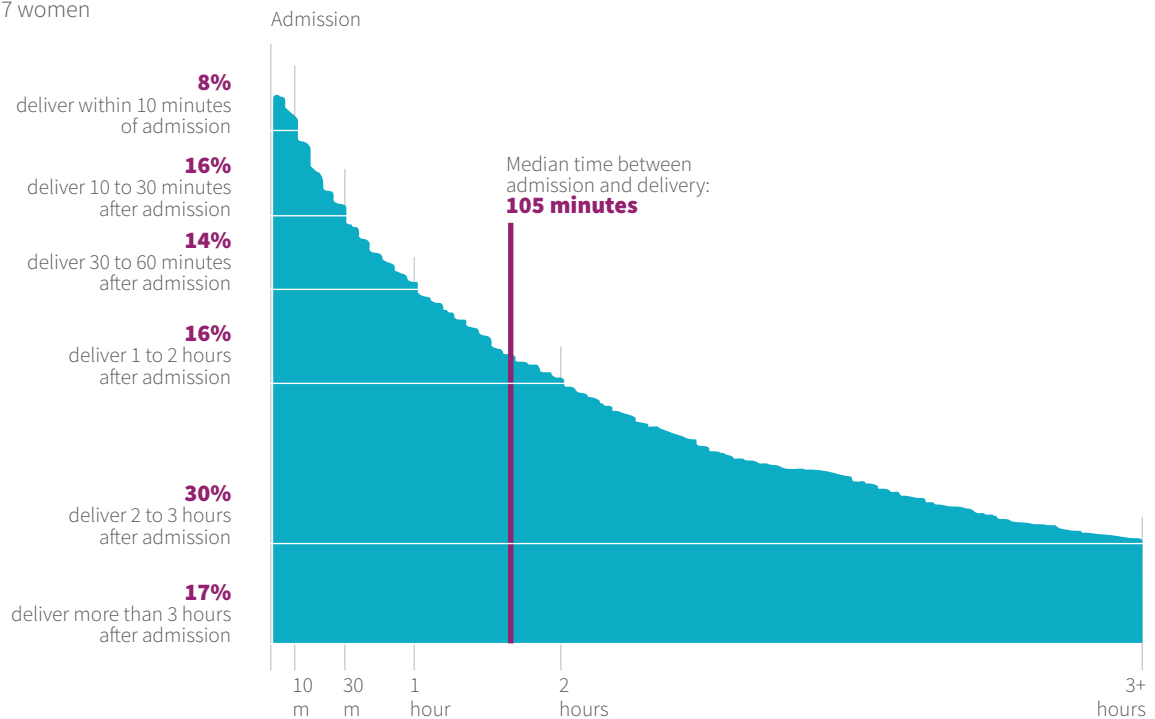
The well-documented link between women's social and economic advancement and their health outcomes during childbirth does not tell the whole story. Just as important as these sociodemographic drivers are women's expectations about health care and childbirth. In the BetterBirth Study, coaches often noted poor conditions at health facilities, which sometimes lacked adequate food and bathrooms for patients, and did not have the space or resources to allow for privacy or accommodate family members (from coaching observations and notes). Because of space constraints, single beds had to hold two women and two newborns at times. These conditions were often viewed as inconvenient, but normal.

It's no wonder, given the uncomfortable conditions, that women spent minimal time at health-care facilities. In the study, the median amount of time a woman spent at a facility from admission to delivery was only 105 minutes. Based on interviews, we estimate the women left or were discharged approximately two to six hours after giving birth. While women ostensibly received skilled attendance at birth, many actually spent very little time at the health facility.

This brief time in the facility created challenges for care around childbirth. When a woman arrived late in labor, it hindered birth attendants' ability to identify complications before delivery, and left precious few minutes to refer the woman to a higher-level facility before delivery, if needed. Likewise, time constraints

Time between admission and delivery

Data from 144,237 women



after delivery limited birth attendants' ability to identify maternal or newborn complications, such as hemorrhage or respiratory distress, respectively, which can occur after a woman and newborn return home. Indeed, the WHO recommends both the woman and newborn stay at a facility for the first 24 hours after birth to monitor their recovery and address complications immediately.

Moreover, when women leave a facility too soon—either by choice or because of space constraints—they have less access to counseling and support on important topics such as breastfeeding, infant care, immunizations, and danger signs. In the BetterBirth Study, birth attendants spent very little time on counseling (see Chapter 2: Birth Attendants); on

average, the discussion about danger signs lasted a mere 28 seconds (41 observations). One week after delivery, only 6% of the more than 157,000 women surveyed could name any danger sign that would prompt them to seek medical care.

The overuse of medications such as oxytocin to speed up deliveries may be another factor contributing to women's abbreviated facility stays. The study's qualitative interviews revealed many women had received oxytocin in the community or at home before reaching the facility. Birth attendants reported feeling pressured by families to administer additional oxytocin, perhaps to conform to social norms because conditions at the facility were unpleasant for women and their families (i.e., there was no place for families to sit, no

ONLY 6% OF WOMEN COULD REMEMBER ANY MATERNAL OR NEWBORN DANGER SIGN

Maternal Danger Signs

- » Bleeding
- » Severe abdominal pain
- » Fits or seizures
- » Severe headache or visual disturbance
- » Breathing difficulty
- » Fever or chills
- » Difficulty emptying bladder
- » Dribbling of urine
- » Severe vaginal pain
- » Pus or foul-smelling discharge from vaginal area
- » Swollen, red, or tender breasts

Neonatal Danger Signs

- » Fast / difficulty breathing
- » Fever
- » Unusually cold
- » Stops feeding well
- » Less activity than normal
- » Whole body becomes yellow
- » Looks sick (lethargic or irritable)
- » Looks yellow, pale, or bluish
- » Body is arched forward
- » Irregular movements of the body, limbs, or face

pain control, and no food to eat). These same stresses prompted community health workers to persuade birth attendants to give oxytocin. Indeed, prior to the intervention, independent observers documented that 80% of women whose birth was observed (603 births observed) received oxytocin to augment labor upon arrival at the facility. While it is difficult to ascertain the true incidence of labor delays that would warrant labor augmentation in this environment, these rates are exceptionally high, given the lack of maternal and fetal monitoring and lack of cesarean delivery capability at these facilities in the event one is indicated.



A birth attendant draws up oxytocin.

Globally, numerous studies have shown advances in women's education, income, and empowerment are associated with lower maternal and perinatal mortality. Findings from the BetterBirth Study confirm this trend. The most powerful predictor of perinatal death in any facility was the level of women's literacy in the district where the facility was located. Globally, we should continue to strengthen education and empower women's voices in the effort to improve health outcomes.

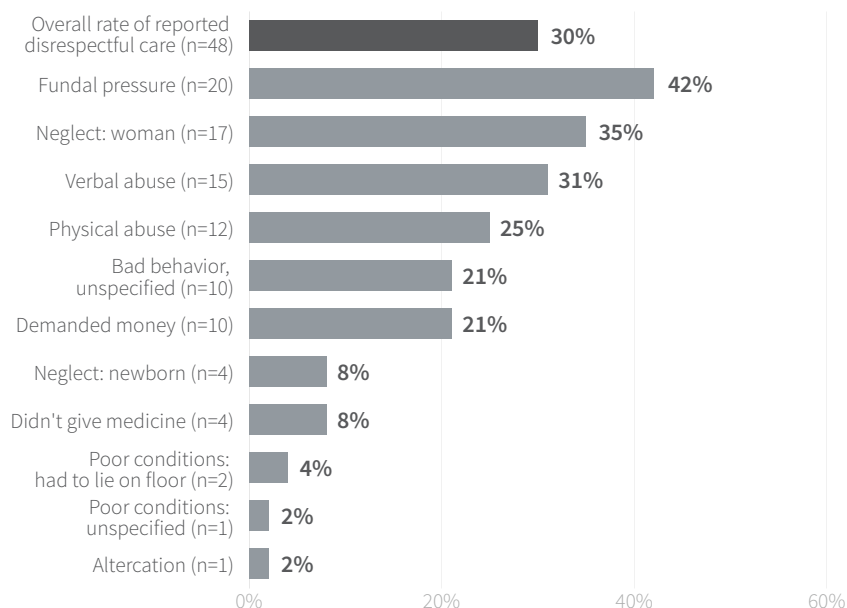
THE QUEST FOR DIGNIFIED MATERNITY CARE

The imperative for respectful maternity care has gained global attention, and was underscored in the WHO quality of care framework. Yet, in a subsample of women whose newborns died (n=158 verbal autopsy narratives), 30% reported some form of disrespect or abuse. Among the examples of mistreatment were overall disrespectful care, neglect, verbal abuse, physical abuse, demands for money, neglect of the newborn, and such poor facility conditions that women in labor were forced to lie on the floor.

In this subsample of women whose newborns died, neglect was common (35%) among those who reported disrespect or mistreatment. Women reported being examined upon arrival, then left alone for hours until delivery. They told of receiving no care or attention during nighttime hours.

Verbal abuse (31%) and physical abuse (25%) were also prevalent. And such incidents of abuse were not isolated—many forms of mistreatment could occur during a single stay at the facility. Indeed, 17% reported three types of abuse; 38% reported two types of abuse; and 38% reported one type of abuse. Overall, 63%

Women are being mistreated: a subsample of women whose newborns died
(n=158 verbal autopsy narratives)



reported experiencing two or more types of disrespectful care. Such discourteous and even contemptuous treatment naturally drives women and family members to minimize the time spent at a health care facility.

Paradoxically, these negative experiences are not reflected in women's reported overall perception of the care they received. For example, 95% of the almost 150,000 women surveyed reported high satisfaction with their care during childbirth, and most said they would recommend the facility to a friend or family member (of note, women and families who

experienced a death were not asked satisfaction questions).

BetterBirth call center staff responsible for the majority of all patient follow-up reported that women would spontaneously recount instances of neglect, poor care, and abuse during childbirth, yet insist they were satisfied with care when asked directly. The disconnect between some experiences of disrespectful care and the overall positive accounting of care may point to women's low expectations and their disempowerment within the system, as well as a lack of psychological safety in reporting poor care.

A CLOSER LOOK AT DISRESPECTFUL CARE

One woman in the BetterBirth Study recounted her experience of disrespectful care and physical abuse during labor and delivery. The woman described receiving multiple injections to increase pain (contractions) before the baby started to deliver. At some point, the baby became stuck; the woman said the nurse told her to exert force, and scolded and slapped her. According to the woman, a facility cleaner began pressing on her abdomen to hasten delivery. Eventually the baby boy was born.

this subset of women, 82% said they paid for childbirth care. Sometimes, these payments were voluntary; more often, they were forced or coerced. Frequently, women or their families had to pay additional fees for medications, in-facility stays, and other aspects of care. Women reported paying slightly more for care in intervention facilities than in control sites, which could be due, in part, to the additional care given to the women, such as blood pressure measurement, fetal monitoring, and follow-up.

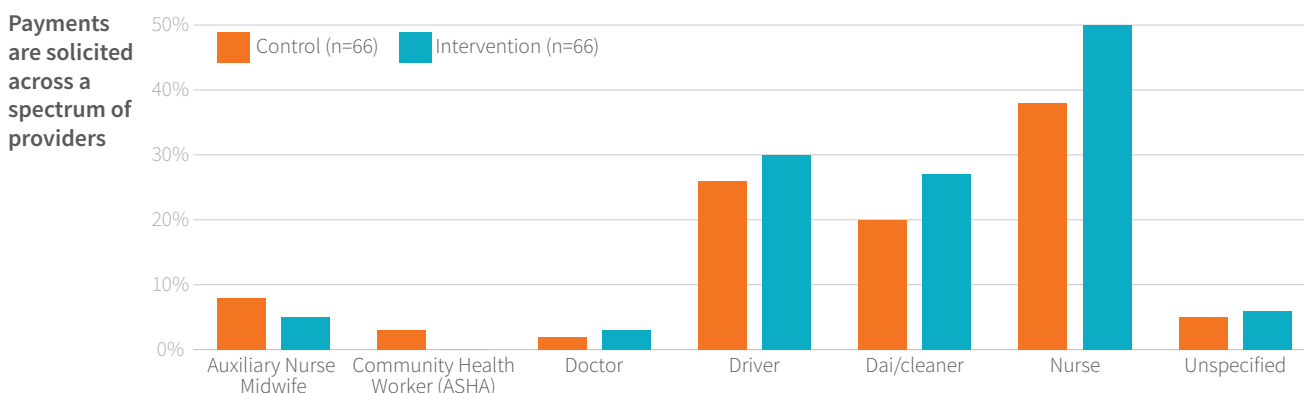
In fact, the BetterBirth Study found multiple people within the health system received payments. Among women reporting making informal payments, nurses were the most commonly remunerated, followed by ambulance drivers and facility cleaners. In the most extreme cases of financial pressure, nine out of 158 interviewed participants reported care was withheld until they paid.

FINANCIAL TRANSACTIONS

Around the globe, financial barriers often impede access to proper childbirth care, and this proved true as well in the BetterBirth Study. While Uttar Pradesh mandates free childbirth care in public facilities, women and their families are often involved in financial transactions during labor and delivery.

While we did not interview all women about financial transactions, the women interviewed during verbal autopsy for their newborns (158 interviews) did mention payments and other transactions. Among

The average payment for childbirth was equivalent to a family's monthly income. If a complication occurred, women and families were often reluctant to be referred to a higher-level facility, because they were concerned about paying the customary expenses of additional care providers, ambulance drivers, and others. They were also leery about the unknown quality of care they would receive at the referral facility.



WOMEN AND COMMUNITY: KEY RECOMMENDATIONS

Improving the quality of care—both the provision and experience—requires focusing on women and their voices. Raising women’s expectations for care and preserving their dignity during childbirth are essential to high-quality, person-centered care. More broadly, women’s empowerment, including education, needs to be a priority. Women need to be heard and involved in designing initiatives that affect their health.

Assess and improve financial systems that appropriately incentivize care through formal payments (i.e. timely and appropriate salary) and penalize informal payments across the continuum of care and levels of care.

Develop metrics and methods for analyzing the drivers of disrespectful care and abuse, respectful care, and patient satisfaction and experience.

Integrate respectful, person-centered care in birth attendant training. Such an approach should include strategies to communicate health-related information in ways women can understand and remember. Equipped with the appropriate knowledge (such as danger signs, advantages of exclusive breastfeeding, importance of immunizations, and family planning options), women are best positioned to care for themselves and their newborns once they return home after birth.

Build programs to strengthen women’s agency in forming expectations and increase their power in demanding respectful, dignified maternal and newborn care. ■



CONCLUSION —

The BetterBirth Study, along with other programs around the globe that have implemented the WHO Safe Childbirth Checklist, has shown change is possible in improving quality of care during the moment of childbirth. But sustained transformation in the way women and newborns are cared for before, during, and after birth will require an ambitious, dedicated, multifaceted effort.

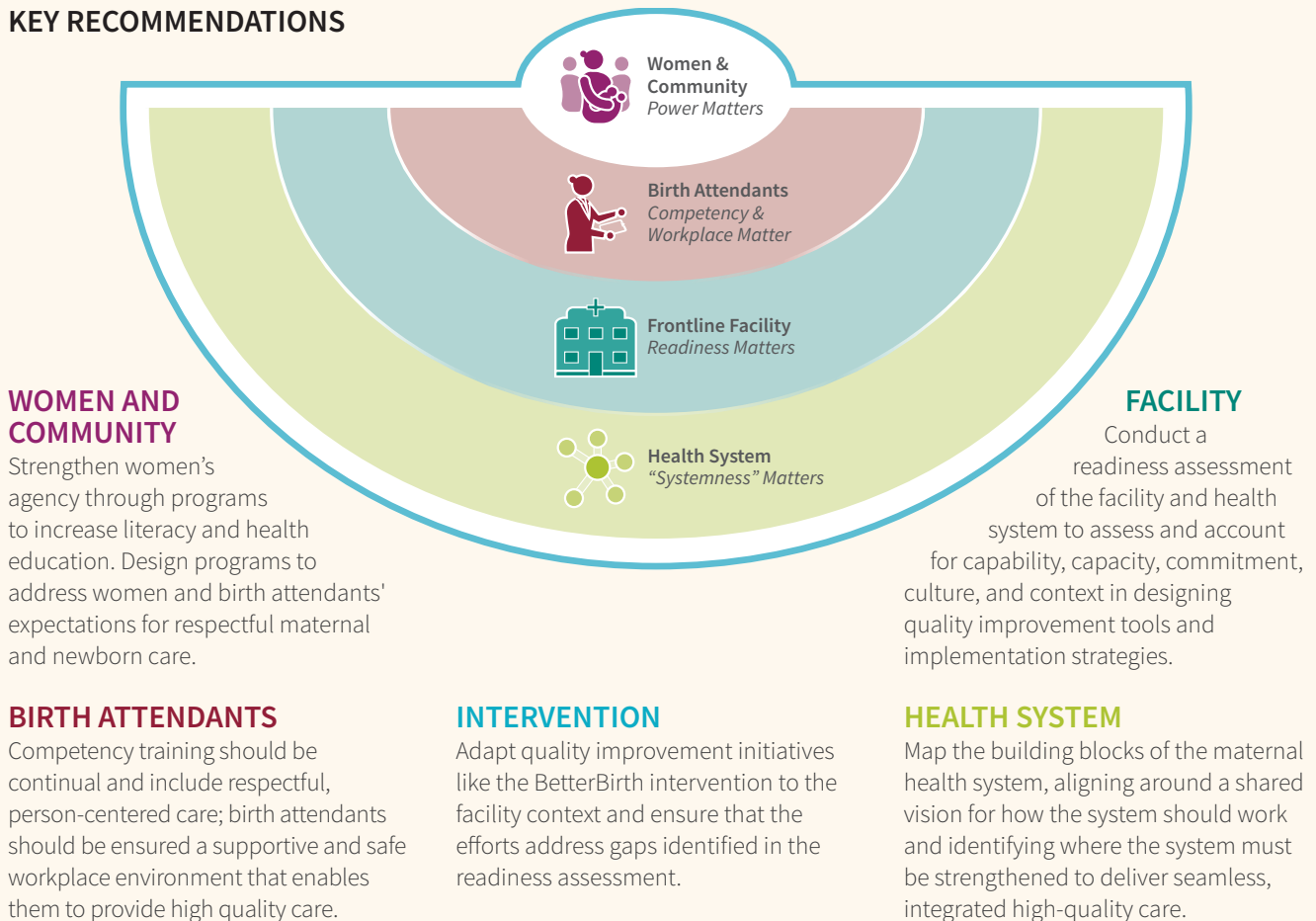
CHANGE IS POSSIBLE

Incremental improvements in the building blocks of a health-care system—workforce, service delivery, medical information databases, access to essential medications, leadership and governance, and financing—are critical. But they are not enough.

Reducing maternal and neonatal deaths will require a comprehensive approach that addresses system complexity around childbirth. Successful solutions will align goals from women and their communities, birth attendants, facility operations, and the overarching

health-care system in which women seek and birth attendants deliver care. To develop these solutions, the social and structural forces that shape interactions between women and their caregivers must be examined. The solutions will also address facility leadership and management around implementing and sustaining quality improvement initiatives. And these solutions will demand enhancing the “systemness” of the health-care continuum, so every woman and every newborn has the best possible chance of living a healthy life.

KEY RECOMMENDATIONS



TRANSLATING BETTERBIRTH LESSONS INTO ACTION

1. INTEGRATE PERSON-CENTERED CARE FOR WOMEN AND NEWBORNS

The maternal-newborn health community should envision solutions that value the experiences of women and newborns as ends in themselves. Successful solutions incorporate women and newborns as intimate dyads, not separate clinical caseloads. While this may appear obvious, it is common to see individual interventions that only account for one or the other, not both. Therefore, interdisciplinary care teams are needed at every level of the health system to bridge the divide that occurs at the time of birth and ensure each woman and newborn is treated with dignity and respect.

2. PRIORITIZE QUALITY OF CARE

In the Sustainable Development Goal era, there is a growing movement around universal health coverage and meaningful access to high-quality care. We must integrate childbirth quality-of-care initiatives into the continuum of health care across the life course for both women and newborns. Pregnancy and childbirth are opportunities to engage women and their families in their health care, especially in locales where they may not otherwise interact with the health system. Complications in pregnancy have long-term health implications for women and newborns; connecting them to the right care during pregnancy and birth will set them on a lifelong path toward better health.

3. HARNESS DATA

Policy makers and program leaders should harness the power of data in designing systems-based solutions. When we use data effectively, we can highlight challenges, demonstrate impact, and advocate for investment in the solutions that work. This requires novel measures and methods to capture information on quality of care (both provision and experience of care) and readiness. Further, we should collect relevant information to measure impact, analyze the findings, and generate evidence-based recommendations for action. Importantly, these findings and recommendations should be communicated back to the district and facility leadership to monitor progress.



A BetterBirth Coach Team Leader and Coach review clinic data prior to a facility coaching session

4. DEVELOP TAILORED IMPLEMENTATION

Quality improvement initiatives in maternal and newborn health require a step-wise approach, starting with leadership commitment to reducing harm and optimizing outcomes for women and newborns. Leaders at every level—from the frontline facility to the district to the state and national levels—should identify health system gaps and determine priorities for action based on feasibility and impact. Quality improvement initiatives should be customized to address specific gaps and incorporated into workflows at the facility level.



5. APPLY SYSTEMS THINKING

To achieve true and sustained impact on childbirth care and outcomes, program designers, funders, and policymakers need to move away from a narrow focus on individual health systems building blocks, birth attendants, or facilities to a broader systems-thinking approach. Systems thinking recognizes and seeks solutions for complexity; it understands the connections among all interdependent parts of the health system that yield a whole greater than the sum of its parts. Developing the right systems-based solutions will require interdisciplinary and cross-sectoral partnerships. It will also require long-term investment, not short-term quick fixes. One instructive precedent is the HIV/AIDS pandemic, which was contained through a progressive, systems-thinking approach that included intersectoral collaborations grounded in advocacy, community empowerment, clinical medicine, and population health. While we should think about the gaps in childbirth care through the wider lens of health systems, we must focus on who the solutions are designed for, remembering that women and newborns are central to our efforts.

Finally, improving the health and well-being of women and their newborns starts with what matters in facility-based childbirth: women's experience of care, birth attendant competency and an enabling workplace, facility quality improvement tools and implementation strategies adapted to the local context, and systemness that ties all the parts together so everyone receives high-quality, dignified care, every time. ■

APPENDICES

A: STUDY DESIGN & MEASUREMENT

To understand strengths and challenges in the quality of childbirth care, it is important to have reliable methods to measure progress. The BetterBirth Study implemented a variety of rigorous, customized approaches to ensure the collection of high-quality data in a setting of scarce resources, and uneven documentation of care at the facility level. We provide our measurement strategies and recommendations for researchers below.

PILOTING AND ADAPTATION

The BetterBirth intervention and implementation strategy resulted from an adaptive design process with implementation, evaluation, and feedback that demonstrated improved adherence to essential birth practices after iterative changes in multiple pilot sites.

Adaptation to create the BetterBirth intervention package used in the randomized controlled trial

	KARNATAKA PILOT	FIRST ADAPTATION	SECOND ADAPTATION	RCT
Leadership engagement	Study lead introduced to district and facility leadership	Nonstandardized introduction to district and facility leaders	Formalized introduction at district and facility including strong focus on motivation to drive adoption	Same as in second adaptation
Education of facility staff	One-day training on the Checklist supported by instructional video and hands-on simulation	3-day training for staff (2 days didactic, one day coached practice using the Checklist)	Semi-structured launch including 1-2 day workshop introducing Checklist, problem solving and strong focus on motivation	Structured 2-day launch with increased focus on implementation of the Checklist with day 2 on-site for official start
Coaching support	Core team of head of facility, senior physician and labor nurse supplemented by physician from the study team. Coaching provided during normal clinical routines supplemented every 2 weeks by study physician Coach training through review of Checklist	Physician-led team of physicians and nurses coaching birth attendants Coaching provided every 1-2 weeks for 4-6 weeks Coach training through 2-day, on-site workshops focusing on clinical skills	Peer-to-peer model: nurse coaches for birth attendants (behavior change), physician coach for facility leader and childbirth quality coordinator (systems change and Checklist leadership) Coach training focused more on quality improvement approaches and behavior change	Same as in second adaptation with additional focus on district lead to build support for Checklist Coach training using standardized curriculum focused on coaching skills to drive behavior change and barriers framework (opportunity, ability, motivation) with strong focus on motivation
Data feedback loop	Subset of baseline observation data feedback to staff to identify quality gaps	None	Paper-based system used to capture and review observation data by team to identify persisting gaps and behavior change	Robust app-based system to provide real time data feedback on coach observations and essential birth supplies to Study team, facility and district
Safe Birth Supplies (SBS)	Largely available	Supply chain gaps identified	Increased focus of coach team leader to help head of facility, and district leaders leverage existing resources to address gaps	Strengthened focus for coaching and advocacy at facility and district levels to improve supply availability

One important lesson learned in the pilot phase was the importance of peer-to-peer coaching (instead of physician-led coaching of birth attendants) and skills needed to effect behavior change in birth attendants.

The randomized controlled trial design ensured rigor but also limited the ability to adapt the intervention along the way. This constraint meant that refining the intervention and implementation approach during the piloting phases was crucial.

BASELINE MORTALITY MEASUREMENT

We used existing facility register data from the year prior to the study to calculate baseline mortality rates in study facilities. Because of challenges with facility record-keeping and reporting prior to study initiation, it would have been preferable to do rigorous baseline measurement of mortality as part of the study.

We found that the BetterBirth intervention did not reduce perinatal mortality rates compared to change from baseline; perinatal mortality rates increased overall in both intervention and control arms, likely because of improved record-keeping and reporting.

DATA COLLECTION FOR HEALTH OUTCOMES

FACILITY-RECORDED OUTCOMES

Across the 120 facilities, data collectors obtained birth event registration and follow-up data (demographic information relating to the woman and newborn; contact information for the family and the family's community health worker/accredited social health activist; and data for in-facility survival outcomes for each woman-newborn dyad) from facility registers.

At the beginning of the trial, facility registers were at times incomplete and at some facilities did not exist at all. Leadership support and birth attendant buy-in was needed to address this gap. BetterBirth data collectors recorded information from registers twice per week during enrollment; this frequent oversight quickly improved the use and completeness of facility registers in both intervention and control sites.

BetterBirth data collectors recorded information on maternal or perinatal complications noted by the birth attendants in the facility registers. Unfortunately, named complications were not verified through a secondary means (physical exam, lab test, etc.), making interpretation more difficult. Additionally, we suspect that complications were significantly underreported. For example, among the 44,515 infants with documented weight less than 2,500 grams, only 11% were noted to be low birth weight.

PRIMARY OUTCOMES

Primary outcome for the trial was the rate of a composite measure of maternal, fetal, and newborn outcomes that occurred from birth to 7 days after birth. Specific outcomes comprising the composite measure included:

Maternal outcomes:

- » Maternal death within 7 days: death of a woman at any time from admission to the facility for childbirth, through delivery, until 7 days following delivery;
- » Severe maternal complications within 7 days: Defined by the following clinical criteria: fits (in absence of history of epilepsy,) loss of consciousness retained at >1 hour, high fever and foul smelling vaginal discharge, postpartum hemorrhage, or stroke.

Fetal and Neonatal outcomes:

- » Stillbirth: fetal death occurring at ≥ 28 weeks of gestation OR with a birth weight of ≥ 1000 gm at birth, including both fresh and macerated stillbirths;
- » Early neonatal mortality: newborn death that occurred in the first week of life.

SECONDARY OUTCOMES

Secondary outcomes for the trial included:

Combined maternal, fetal and newborn outcomes:

- » composite rate of maternal death within 7 days,
- » fresh or macerated stillbirth, and
- » neonatal death at 7 days.

Maternal outcomes:

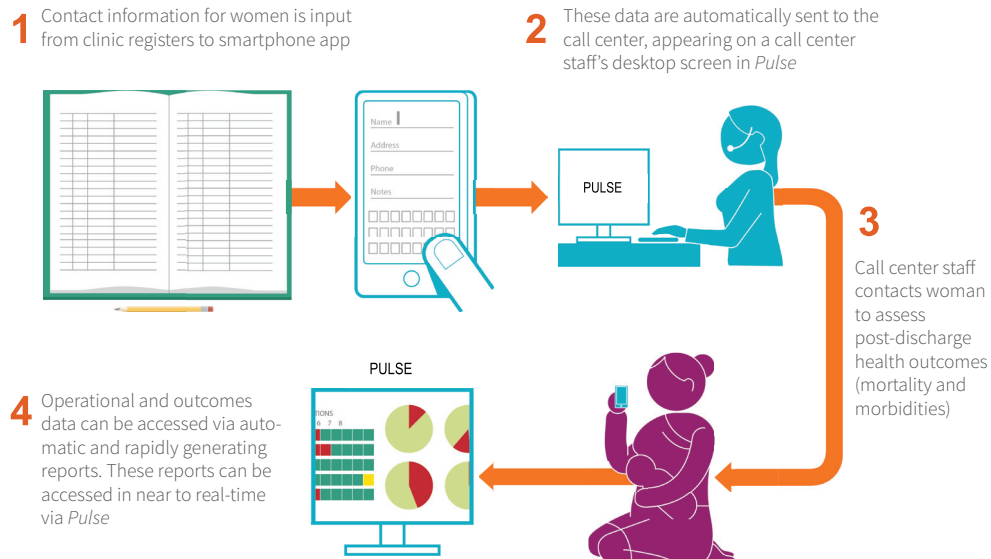
- » Rate of maternal death (measured through 7 days after delivery),
- » rate of severe maternal complication described above (measured through 7 days after delivery),
- » rate of inter-facility transfer, and
- » the rates of the following maternal procedures: blood transfusion, hysterectomy, need to revisit facility due to a problem, C-section.

Newborn outcomes:

- » Fresh or macerated stillbirth,
- » rate of early neonatal death (within 7 days),
- » rate of inter-facility transfer,
- » need to revisit facility due to a problem.

Rates of adherence by health workers to essential childbirth practices (“process measures”):

- » maternal temperature obtained on admission,
- » maternal blood pressure obtained on admission,
- » partograph use,
- » inappropriate initiation of oxytocin before delivery of the baby,
- » appropriate hand hygiene (use of soap and water, and wearing clean gloves) by health workers at the time of delivery,
- » skin-to-skin care, oxytocin administration within 1 minute after birth,
- » newborn weight and temperature obtained within 1 hour after birth, and
- » initiation of breastfeeding within 1 hour after birth.



PATIENT SELF-REPORTED OUTCOMES

- » Total sample: 157,689 births across intervention and comparison facilities.
- » Inclusion criteria: all women admitted to a study site for childbirth. Exclusion criteria: women referred into the study facility from a subcenter, those being managed for abortion, and those who did not provide consent.
- » Female call center personnel followed up with woman-newborn dyads via phone call (or through a home visit when needed) between eight to 21 days post-childbirth to ascertain patient-reported outcomes, including maternal severe morbidity, maternal mortality, and perinatal mortality.
- » Loss to follow up: 0.3% of women eligible for follow-up.
- » The call center was also used to collect additional information on patient satisfaction, family planning practices, and women's understanding of postpartum danger signs.
 - › At the end of follow-up calls or visits with women and/or their families to collect health outcomes, two additional questions were used to assess patient satisfaction:
 - › "How satisfied are you with the care you received at this facility?" (Very satisfied, Somewhat satisfied, Somewhat unsatisfied, Very unsatisfied)
 - › "How likely are you to recommend this facility to your friends or family for their delivery?" (Very likely, Somewhat likely, Somewhat unlikely, Not likely at all) The BetterBirth call center was effective, with high accuracy and validity, in ascertaining health outcomes. In an under-resourced and geographically vast setting with high cell phone coverage, the call center successfully followed up with the large majority of women.
 - › These questions were only asked to women or their husbands, not to more distal family members. Satisfaction-related questions were not asked in any cases where a maternal or perinatal death occurred.
- » The call center was very acceptable to women and less costly than home visits for follow-up.

DIRECT OBSERVATION OF CARE

INDEPENDENT OBSERVERS

Trained data collectors (all nurses) directly observed health workers that attended to women and their newborns around the time of birth, and at the first three of the four Checklist pause points in a subset of 30 facilities (15 intervention, 15 comparison matched pairs). Observations were conducted at baseline (10 facilities), after two months of coaching (30 facilities), after six months of coaching (10 facilities) and four months after the end of coaching (30 facilities). Direct observation was intended to measure the impact of the Safe Childbirth Checklist intervention on delivery of essential birth practices, as a secondary outcome. A convenience sample of women and newborns cared for by the health workers around the time of childbirth during data collectors' daytime duty hours was included in this component of the study. The aim was to obtain approximately 60 observations at each observation point (on admission, before pushing, within one minute of delivery, within one hour of delivery) per facility per data collection period. Checklist pause point four was not observed because of the uncertain time and place of discharge in these facilities. Facility-based data associates observed and recorded activities in the admission, labor and delivery, and postpartum wards. Data was recorded on standardized (paper-based) data collection forms and then entered onto a mobile application.

COACH OBSERVERS

In the 60 intervention sites, coaches also collected data on Checklist practices conducted by birth attendants at each coaching visit over the eight-month intervention. While the coaches' main role was not data collection, but rather to help facility staff document gaps in care and work towards improvement, the study capitalized on their presence at facilities to obtain additional observation data. Behaviors as observed by coaches were documented across all four pause points of the Checklist.

OTHER DATA SOURCES

Additional quantitative and qualitative data were collected via multiple methodologies (see Appendix B for further details), including

- » Quarterly surveys of supply availability at all facilities and biweekly surveys of supply availability at intervention facilities during the eight months of coaching;
- » Self-administered surveys of birth attendants in intervention facilities to assess 1) Checklist use and acceptability, 2) safety culture, and 3) time use;
- » Systematic collection of birth attendant characteristics;
- » Tracking of facility-level leadership changes (medical officer in charge, medical superintendent, childbirth quality champion);
- » Time-motion and work-sampling observations of health care workers to assess time spent on Checklist-related activities and overall distribution of time at facilities.

- » Total administrative costs of the intervention;
- » Verbal autopsy interviews with families who had experienced a stillbirth or early neonatal death during the study;
- » Interviews with birth attendants across three categories of facilities: facilities with high uptake of the intervention, facilities with moderate uptake of the intervention, facilities with minimal uptake of the intervention;
- » Focus group discussions with coaches and BetterBirth research staff; and
- » Verbal surveys of women on satisfaction with care, knowledge of danger signs, and family planning practices.

DATA QUALITY ASSURANCE

The study included a robust, multi-component data quality monitoring and improvement system (DQMIS) that ensured high-quality data for health outcomes and directly observed care throughout the BetterBirth Study. Functional components of the system included

- » in-country monitoring and evaluation team to support data management and quality;
- » standard operating procedures and tools for data collection;
- » research staff training for data quality;
- » an electronic data collection and reporting system that allowed for real-time data feedback for use in coaching; and
- » DQMIS protocol including data collection audits, rapid data feedback, and supportive supervision.

DQMIS activities were carried out by data collectors and their supervisors across all data collection workflows, and focused on ensuring consistency and accuracy in data collectors' recording of information; proper transfer of data from paper-based to electronic formats; and ongoing supportive supervision of field workers regarding data collection.

To ensure high-quality implementation of the intervention package, implementation teams conducted progress reporting, and designated supervisors conducted in-person monitoring visits to observe the quality of implementation, validate data on implementation progress, and compare achievements against predefined benchmarks.

MESSAGE SYNTHESIS PROCESS

With the abundance of data produced by the BetterBirth Study, we underwent an iterative process to analyze and interpret primary and secondary outcomes and to integrate those findings with additional insights collected through qualitative interviews, surveys, and process measures. The goal of the process was to produce messages that are relevant, innovative, and actionable for implementers and policymakers, both globally and in Uttar Pradesh. During this eight-month process, messages were developed and distilled through a series of meetings with other global implementation experts, policy experts, researchers, representatives from professional organizations, and government officials.

RECOMMENDATIONS

Conduct rigorous baseline data collection to better understand impact of the intervention in complex health systems.

Consider adaptive trials or other implementation science strategies for complex interventions. Multiple adaptations of an intervention may be necessary to maximize the impact of a quality improvement initiative.

Use mixed methods to measure process indicators on how/why implementation is working or not working, where the barriers/gaps are, and how they are addressed, in order to contextualize the outcome measures.

Incorporate added measurement of behaviors for the cascade of actions following Checklist items (i.e., if measured blood pressure was high, was the patient given magnesium sulfate? If maternal temperature was high, was she given antibiotics?).

Cost-effectiveness, which is often left out of program evaluations, should be included.

Invest in mechanisms or systems to minimize loss to follow up and maximize accuracy of data, such as

- › Mobile/electronic data-capture systems;
- › Call centers for outcome measurement; and
- › Systems for data-quality assurance.

B: SUMMARY OF DATA SOURCES

The BetterBirth Study collected more than 204 million quantitative data points and a wealth of qualitative data over the course of the study, from November 2014 to August 2017. While many of our methods have been described in depth in multiple publications, this appendix serves as a brief reference on all data sources referred to in this report, both published and unpublished.

SEVEN-DAY MATERNAL MORTALITY, PERINATAL MORTALITY, AND SELF-REPORTED SEVERE MATERNAL MORBIDITY OUTCOMES

NUMBER OF PARTICIPANTS OR FACILITIES

Total sample of 157,689 enrolled women with births across 120 facilities (60 intervention and 60 comparison facilities). Of these, final seven-day outcomes were obtained for 157,145 cases.

DESCRIPTION

All women who were registered for childbirth at a BetterBirth facility were included in the sample, excluding those who were referred in, those who were managed for abortion, or those who did not consent to participate. Outcomes were obtained either through a follow-up call or in-home visit from the eighth day to the 43rd day after delivery.

DIRECT OBSERVATION OF CHILDBIRTH CARE

NUMBER OF PARTICIPANTS OR FACILITIES

- » Baseline: 10 facilities (five intervention, five control); 603 births observed at one or more pause points
- » After two months of coaching: 30 facilities (15 intervention, 15 control); 2,563 births observed at one or more pause points
- » After six months of coaching: 10 facilities (five intervention, five control); 897 births observed at one or more pause points
- » Four months after the end of the intervention: 30 facilities (15 intervention, 15 control); 2,325 births observed at one or more pause points

DESCRIPTION

Independent observers (trained nurses) recorded birth attendants' adherence to birth practices using a standardized data-collection form and included 60 observations at each of the following observation points: 1) on admission, 2) just before pushing, 3) one minute after delivery, 4) within one hour of delivery—for a total of 240 observations per facility for each round of data collection. Birth practices at the time of discharge were not observed, because of the uncertain nature of time and place of discharge in these facilities. Data were collected only during daytime hours because of security concerns.

MATERNAL DEATH QUALITATIVE REVIEW

NUMBER OF PARTICIPANTS OR FACILITIES

98 out of 149 maternal deaths in the study

DESCRIPTION

Of the 149 maternal deaths that occurred in the study, routine follow-up call recordings with families for 98 cases were located, analyzed, and had complete data related to circumstances surrounding the location of a woman's death. We performed qualitative coding of the recordings and created summary statistics for coded variables.

PERINATAL VERBAL AUTOPSY

NUMBER OF PARTICIPANTS OR FACILITIES

Of the 7,445 perinatal deaths, we identified 161 perinatal deaths (106 early neonatal deaths, 55 stillbirths) where the delivery was observed (i.e., we had data on adherence to Safe Childbirth Checklist practices). Due to twins, the total number of interviews with mothers was 158.

DESCRIPTION

We conducted in-person verbal and social autopsy interviews with these families to document the circumstances of the perinatal death. Descriptive statistics were generated for type and cause of death and referrals.

BIRTH ATTENDANT INTERVIEWS

NUMBER OF PARTICIPANTS OR FACILITIES

A total of 33 interviews were conducted in 12 intervention facilities (four low-mortality sites, four medium-mortality sites, four high-mortality sites).

DESCRIPTION

We conducted in-depth semi-structured interviews with birth attendants at selected facilities after the completion of the intervention to glean experiences with the Checklist.

MEDICAL OFFICER IN CHARGE/ CHILDBIRTH QUALITY CHAMPION INTERVIEWS

NUMBER OF PARTICIPANTS OR FACILITIES

A total of 47 interviews with the medical officer in charge and the childbirth quality champion(s) were conducted in 20 intervention facilities.

DESCRIPTION

Semi-structured interviews were completed at intervention facilities that had recently phased out of the study. Sites were chosen based on coach and coach team leader feedback, so interviews could be evenly distributed across high- and low-performing facilities. Interviews were conducted with both the head of facility (medical officer in charge or medical superintendent) and the nominated childbirth quality champion. If a facility had more than one childbirth quality champion, all were asked to participate.

BETTERBIRTH STAFF FOCUS GROUPS

NUMBER OF PARTICIPANTS OR FACILITIES

- » Direct observers' focus group: one focus group discussion, seven participants
- » Coach focus group: one focus group discussion, six participants

DESCRIPTION

Informal focus groups were held with BetterBirth Study staff. The discussions focused on study staff perceptions of successes, challenges, and other significant experiences regarding the BetterBirth intervention and study (both to understand quality improvement from an implementation perspective, and to understand the context of the intervention within the study facilities).

PATIENT SATISFACTION SURVEY

NUMBER OF PARTICIPANTS OR FACILITIES

149,268 patients (75,540 intervention and 73,728 control) answered the satisfaction questions.

DESCRIPTION

As part of the follow-up phone call or visit to assess seven-day outcomes, women were additionally asked two satisfaction-related questions concerning the care received during childbirth.

CHECKLIST UTILIZATION SURVEY

NUMBER OF PARTICIPANTS OR FACILITIES

969 healthcare workers were surveyed.

DESCRIPTION

Anonymous surveys were conducted to capture health care worker opinions about ease of usability of the Checklist and inclination of health care workers to adopt the Checklist as part of their practice. Each intervention facility administered the survey three times: eight weeks after the start of the intervention, and then six and 12 months after the initial survey.

COST EFFECTIVENESS ANALYSIS: TIME MOTION

NUMBER OF PARTICIPANTS OR FACILITIES

1,559 measurements from 10 intervention facilities were observed.

DESCRIPTION

Observations were done to obtain granular data on how much time it takes to complete Checklist-related activities.

COST EFFECTIVENESS ANALYSIS: TIME USE

NUMBER OF PARTICIPANTS OR FACILITIES

61 surveys of staff nurses from 15 intervention facilities were conducted.

DESCRIPTION

A survey was conducted to capture health-care worker perception of time spent with the WHO Safe Childbirth Checklist in relation to other clinical duties.

COST EFFECTIVENESS ANALYSIS: WORK SAMPLING

NUMBER OF PARTICIPANTS OR FACILITIES

More than 1,300 hours of observations from 20 intervention and control facilities were collected.

DESCRIPTION

Observations were done to obtain a snapshot of how health workers' time during their work shifts is divided among activities in which they are directly interacting with patients, engaging in direct patient care activities but not interacting with patients, and engaging in work activities that do not pertain to specific patients.

C: BETTERBIRTH PUBLICATIONS

Benefits of Advance Oxytocin Preparation Could Extend to the Newborn. *Global Health: Science and Practice*. 2015;3(2):149-149.

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BETTERBIRTH IMPLEMENTATION RESOURCES

WHO Safe Childbirth Checklist website

<https://www.who.int/patientsafety/topics/safe-childbirth/childbirth/en>

Ariadne Labs BetterBirth Community of Practice

<https://portal.ariadnelabs.org/groups/betterbirth-public-group>

D:THE WHO SAFE CHILDBIRTH CHECKLIST

BEFORE BIRTH

WHO Safe Childbirth Checklist



1 On Admission	
Does mother need referral? <input type="checkbox"/> No <input type="checkbox"/> Yes, organized	Check your facility's criteria
Partograph started? <input type="checkbox"/> No, will start when ≥ 4 cm <input type="checkbox"/> Yes	Start plotting when cervix ≥ 4 cm, then cervix should dilate ≥ 1 cm/hr • Every 30 min: plot HR, contractions, fetal HR • Every 2 hrs: plot temperature • Every 4 hrs: plot BP
Does mother need to start: <i>Antibiotics?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes, given <i>Magnesium sulfate and antihypertensive treatment?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes, magnesium sulfate given <input type="checkbox"/> Yes, antihypertensive medication given	Ask for allergies before administration of any medication Give antibiotics to mother if any of: • Mother's temperature $\geq 38^{\circ}\text{C}$ • History of foul-smelling vaginal discharge • Rupture of membranes > 18 hrs Give magnesium sulfate to mother if any of: • Diastolic BP ≥ 110 mmHg and 3+ proteinuria • Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain Give antihypertensive medication to mother if systolic BP > 160 mmHg • Goal: keep BP $< 150/100$ mmHg
<input type="checkbox"/> Confirm supplies are available to clean hands and wear gloves for each vaginal exam.	
<input type="checkbox"/> Encourage birth companion to be present at birth.	
<input type="checkbox"/> Confirm that mother or companion will call for help during labour if needed.	Call for help if any of: • Bleeding • Severe abdominal pain • Severe headache or visual disturbance • Unable to urinate • Urge to push

This checklist is not intended to be comprehensive and should not replace the case notes or partograph. Additions and modifications to fit local practice are encouraged. For more information on recommended use of the checklist, please refer to the "WHO Safe Childbirth Checklist Implementation Guide" at: www.who.int/patientsafety.

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BEFORE BIRTH

WHO Safe Childbirth Checklist



2

Just Before Pushing (Or Before Caesarean)

Does mother need to start:

Antibiotics?

- ☐ No
- ☐ Yes, given

Magnesium sulfate and antihypertensive treatment?

- ☐ No
- ☐ Yes, magnesium sulfate given
- ☐ Yes, antihypertensive medication given

Ask for allergies before administration of any medication

Give antibiotics to mother if any of:

- Mother's temperature $\geq 38^{\circ}\text{C}$
- History of foul-smelling vaginal discharge
- Rupture of membranes >18 hrs
- Caesarean section

Give magnesium sulfate to mother if any of:

- Diastolic BP ≥ 110 mmHg and 3+ proteinuria
- Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Give antihypertensive medication to mother if systolic BP >160 mmHg

- Goal: keep BP $<150/100$ mmHg

Confirm essential supplies are at bedside and prepare for delivery:

For mother

- ☐ Gloves
- ☐ Alcohol-based handrub or soap and clean water
- ☐ Oxytocin 10 units in syringe

For baby

- ☐ Clean towel
- ☐ Tie or cord clamp
- ☐ Sterile blade to cut cord
- ☐ Suction device
- ☐ Bag-and-mask

Prepare to care for mother immediately after birth:

Confirm single baby only (not multiple birth)

1. Give oxytocin within 1 minute after birth
2. Deliver placenta 1-3 minutes after birth
3. Massage uterus after placenta is delivered
4. Confirm uterus is contracted

Prepare to care for baby immediately after birth:

1. Dry baby, keep warm
2. If not breathing, stimulate and clear airway
3. If still not breathing:
 - clamp and cut cord
 - clean airway if necessary
 - ventilate with bag-and-mask
 - shout for help

- ☐ **Assistant identified and ready to help at birth if needed.**

This checklist is not intended to be comprehensive and should not replace the case notes or partograph. Additions and modifications to fit local practice are encouraged. For more information on recommended use of the checklist, please refer to the "WHO Safe Childbirth Checklist Implementation Guide" at: www.who.int/patientsafety.

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AFTER BIRTH

WHO Safe Childbirth Checklist



3

Soon After Birth (Within 1 Hour)

Is mother bleeding abnormally?

- ☐ No
☐ Yes, shout for help

If bleeding abnormally:

- Massage uterus
- Consider more uterotonic
- Start IV fluids and keep mother warm
- Treat cause: uterine atony, retained placenta/fragments, vaginal tear, uterine rupture

Does mother need to start:

Antibiotics?

- ☐ No
☐ Yes, given

Ask for allergies before administration of any medication

Give antibiotics to mother if placenta manually removed or if mother's temperature $\geq 38^{\circ}\text{C}$ and any of:

- Chills
- Foul-smelling vaginal discharge

If the mother has a third or fourth degree of perineal tear give antibiotics to prevent infection

Magnesium sulfate and antihypertensive treatment?

- ☐ No
☐ Yes, magnesium sulfate given
☐ Yes, antihypertensive medication given

Give magnesium sulfate to mother if any of:

- Diastolic BP ≥ 110 mmHg and 3+ proteinuria
- Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Give antihypertensive medication to mother if systolic BP > 160 mmHg
• Goal: keep BP $< 150/100$ mmHg

Does baby need:

Referral?

- ☐ No
☐ Yes, organized

Check your facility's criteria.

Antibiotics?

- ☐ No
☐ Yes, given

Give baby antibiotics if antibiotics given to mother for treatment of maternal infection during childbirth or if baby has any of:

- Respiratory rate $> 60/\text{min}$ or $< 30/\text{min}$
- Chest in-drawing, grunting, or convulsions
- Poor movement on stimulation
- Baby's temperature $< 35^{\circ}\text{C}$ (and not rising after warming) or baby's temperature $\geq 38^{\circ}\text{C}$

Special care and monitoring?

- ☐ No
☐ Yes, organized

Arrange special care/monitoring for baby if any:

- More than 1 month early
- Birth weight < 2500 grams
- Needs antibiotics
- Required resuscitation

☐ **Started breastfeeding and skin-to-skin contact (if mother and baby are well).**

☐ **Confirm mother / companion will call for help if danger signs present.**

Responsibility for the interpretation and use of the material in this checklist lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use. For more information visit www.who.int/patientsafety.

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AFTER BIRTH

WHO Safe Childbirth Checklist



4

Before Discharge

☐ Confirm stay at facility for 24 hours after delivery.

Does mother need to start antibiotics?

- ☐ No
☐ Yes, given and delay discharge

Ask for allergies before administration of any medication
 Give antibiotics to mother if any of:
 • Mother's temperature $\geq 38^{\circ}\text{C}$
 • Foul-smelling vaginal discharge

Is mother's blood pressure normal?

- ☐ No, treat and delay discharge
☐ Yes

Give magnesium sulfate to mother if any of:
 • Diastolic BP ≥ 110 mmHg and 3+ proteinuria
 • Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

 Give antihypertensive medication to mother if systolic BP >160 mmHg
 • Goal: keep BP $<150/100$ mmHg

Is mother bleeding abnormally?

- ☐ No
☐ Yes, treat and delay discharge

If pulse >110 beats per minute and blood pressure <90 mmHg
 • Start IV and keep mother warm
 • Treat cause (hypovolemic shock)

Does baby need to start antibiotics?

- ☐ No
☐ Yes, give antibiotics, delay discharge, give special care

Give antibiotics to baby if any of:
 • Respiratory rate >60 /min or <30 /min
 • Chest in-drawing, grunting, or convulsions
 • Poor movement on stimulation
 • Baby's temperature $<35^{\circ}\text{C}$ (and not rising after warming) or baby's temperature $\geq 38^{\circ}\text{C}$
 • Stopped breastfeeding well
 • Umbilicus redness extending to skin or draining pus

Is baby feeding well?

- ☐ No, establish good breastfeeding practices and delay discharge
☐ Yes

☐ Discuss and offer family planning options to mother.

☐ Arrange follow-up and confirm mother / companion will seek help if danger signs appear after discharge.

Danger Signs

Mother has any of:

- Bleeding
- Severe abdominal pain
- Severe headache or visual disturbance
- Breathing difficulty
- Fever or chills
- Difficulty emptying bladder
- Epigastric pain

Baby has any of:

- Fast/difficult breathing
- Fever
- Unusually cold
- Stops feeding well
- Less activity than normal
- Whole body becomes yellow

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