East Africa

Preterm Birth Initiative



University of California San Francisco

Transforming the Culture of Care Improves Preterm Survival

The Intrapartum and Immediate Newborn Care Package in Kenya and Uganda Study Report







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Preterm baby wearing a tiny hat to keep warm Photo by Lubowa Abubaker

Overview

The East Africa Preterm Birth Initiative (PTBi EA) focuses on the most promising strategies to reduce the burden of preterm birth, the leading cause of newborn and under-five mortality. Established in 2014 with funding from the Bill & Melinda Gates Foundation, the initiative brings together researchers and clinicians from the University of California San Francisco (UCSF), Kenya Medical Research Institute (KEMRI), Uganda's Makerere University, the University of Rwanda, the Rwanda Biomedical Center and collaborators and partners from around the world. Motivated by a shared vision to improve outcomes for mothers, newborns and their families, this partnership has identified local maternal and newborn health priorities, generated a robust evidence base for promising interventions and developed implementation strategies to tackle prematurity. Together, we seek to reduce the burden of prematurity in our target geographies by (1) increasing survival among babies born preterm, (2) reducing the incidence of preterm birth, and (3) helping strengthen research capacity in the prematurity field.

This report presents PTBi EA's findings and lessons learned from an implementation trial in Kenya and Uganda that tested a quality improvement intervention package aimed at enhancing care during labor and delivery.

The trial's primary results were <u>published</u> in the *Lancet Global Health* in July 2020. Drs. Phelgona Otieno (KEMRI), Peter Waiswa (Makerere University) and Dilys Walker (UCSF) also discussed these findings in a recent <u>webinar</u>.

Mother and her preterm twins in Migori County Referral Hospital in Kenya Photo by Matthew Gillooley

Background

Preterm birth, or birth before 37 weeks of gestation, is the leading cause of death in children under five years old and is the strongest risk factor for early neonatal death. Approximately 35% of deaths among newborn babies are due to complications of preterm birth (UN Inter-agency Group for Child Mortality Estimation 2017). Those who survive are at risk for long-term disability and chronic health issues, often leaving families and communities wrestling with ongoing health, social and financial burdens. To decrease neonatal and child mortality and morbidity, it is of highest priority to avert prematurity and to help preterm infants survive and thrive.

The high burden of neonatal mortality in low- and middle-income countries (LMICs) disproportionately impacts those born small and too soon. Of the almost 15 million babies born preterm in 2014, more than 80% were in South Asia and sub-Saharan Africa (Chawanpaiboon 2019). In Kenya and Uganda, specifically, while annual neonatal mortality rates have ticked down over the last decade, they remain high at 20-26 per 1,000 live births (World Bank 2015). Estimates of preterm birth rates in these countries have ranged between 6.6% (Chawanpaiboon 2019) to 13.1% (Blencowe 2012). Of the estimated 2.6 million stillborn babies born in 2015, 77% were in South Asia and sub-Saharan Africa (Blencowe 2016). Because stillbirth is often not measured accurately, this may disguise even higher rates of prematurity and/or neonatal mortality (Lancet Series on Stillbirth 2011).

The largest burden of neonatal and preterm mortality occurs within the first 24 hours of life, and a large proportion of stillbirths occur within 12 hours of delivery. Thus, the intrapartum and immediate postnatal periods represent critical windows of opportunity to improve neonatal outcomes. While many perinatal evidence-based interventions exist, and may even be formally adopted into policy guidelines, they must be reinforced and fully implemented at scale in order to achieve their desired impact. Estimates suggest that up to two-thirds of neonatal deaths in high-burden countries could be averted with improved care during and immediately after birth, such as ensuring skilled birth attendance, appropriate use of antenatal corticosteroids, stimulation and resuscitation, and immediate newborn care including kangaroo mother care (Bhutta 2014). These estimates reflect how interventions, when implemented together rather than singularly, can significantly improve outcomes.

However, many proven interventions are not widely used in many low- and middle-income settings. Health system bottlenecks such as financial resource and workforce capacity limitations have constrained their ability to deliver interventions at scale (Dickson 2014). Cultural and other social barriers have also impeded progress in achieving high coverage levels of high-impact interventions.



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The Intervention

The limited uptake of evidence-based interventions during labor and the immediate postnatal period underscore the need for novel strategies to improve quality of care with a focus on both mother and baby. Low-cost interventions, while often perceived as basic, can be more practical solutions to real-world problems. Thus, PTBi EA invested in reinforcing what a health system already has and focused on quality of care and promotion of evidence-based practices that are known, but not routinely used.

Our intervention package comprised four core components (Table 1):

- 1. **Data strengthening:** Improvements in measurement and data use across study sites were critical to establishing reliable baseline measures and documenting reductions in the burden of preterm birth. We reinforced key indicator definitions, reviewed gestational age assignment and provided a platform for ongoing data feedback and mentoring.
- 2. Modified WHO Safe Childbirth Checklist (mSCC): We modified the WHO Safe Childbirth Checklist to align with each country's national

guidelines and adapted our implementation strategies to local settings. Additional clinical prompts were added to remind health care providers of key evidence-based practices around identification of preterm labor and care of the preterm infant.

- 3. **PRONTO simulation and team training:** This emergency obstetric and neonatal care simulation-based training emphasized the identification, triage and management of preterm labor and birth with a focus on preeclampsia, chorioamnionitis and other related conditions. With curricula tailored to each country, this training aimed to increase uptake of evidence-based practices and strengthen communication and teamwork among facility teams.
- 4. **Quality Improvement (QI) Collaboratives:** Facility-based QI teams implemented Plan-Do-Study-Act cycles to overcome system bottlenecks and to track core QI indicators related to preterm birth. QI learning sessions enabled cross-facility sharing of QI experiences and ideas for change.



Table 1. Summary of interventions

Component	Target facilities	Core activities	Dosage per facility
Data Strengthening	Intervention + control sites	 Focused on maternity register data to strengthen existing data collection processes for standard indicators Promoted use of gestational age measurement tools Conducted data quality assessments to collect specific DHIS-related indicator data Provided ongoing training and mentorship to clinical leadership, health records offi- cers, nurses, midwives, doctors and staff 	 15 hours of data quality assessments 36 hours of data mentorship 108 hours of facility report-backs 15 hours of record re-organization
mSCC checklist	Intervention + control sites	 Focused on provider gestational age assessment and documentation, identification and management of preterm labor, postnatal care for preterm infants Piloted to optimize content and roll-out Monitored completeness and uptake by each of five pause points Reinforced with QI & PRONTO at intervention facilities 	 9 hours of initial training 36 hours of mentorship 36 hours of completion monitoring
PRONTO Simulation training	Intervention sites only	 Included standard BEmONC content and emphasized prematurity-related intrapartum and immediate postnatal care practices Provided bedside mentoring and conducted knowledge reviews through PRONTO mentors Conducted simulations and team training activities 	 40-60 hours of knowledge review 40 hours of skills stations 14–20 hours of teamwork activities 27–39 hours of simulations 50-56 hours of bedside mentorship
Quality Improvement Collaboratives	Intervention sites only	 Created facility QI teams to discuss QI projects and follow plan-do-study-act cycles Tracked 3 QI indicators: gestational age assessment, antenatal corticosteroid provision, uptake of Kangaroo Care Established country-specific QI Collaboratives/learning sessions to discuss QI indicators and ideas for change 	 80 hours of learning sessions 40–48 hours of QI training 70–74 hours of facility QI meetings 35 hours of facility QI mentorship

Figure 1. Theory of change



Our theory of change (Figure 1) was based on the belief that attention to measurement and QI processes can have a transformative effect on the quality of care delivered to women and their babies. Even in low-resource settings, with no grand changes in existing manpower, resources, or technology, a commitment to improved care for pregnant women and their newborns can yield dramatic improvements in health outcomes and reduce the burden of prematurity.



Health providers look at a pregnancy wheel during a PTBi EA training *Photo by Matthew Gillooley*

Study Results

The PTBi EA intervention package was intended to reinforce existing data systems to improve data use, strengthen provider skills and team communication and catalyze system improvement. We hypothesized that these interventions, implemented together as a package, could reduce the combined rate of fresh stillbirth and neonatal mortality among preterm and low birthweight infants by 30% in intervention facilities compared to control facilities.

To evaluate the effect of the full intervention package on preterm mortality, we conducted a cluster-randomized controlled trial among 20 public sector health facilities in the Busoga Region of Uganda and Migori County, Kenya (Figure 2). Ten control facilities received data strengthening and the mSCC, whereas ten intervention facilities received all four components of the package (i.e., data strengthening, mSCC, PRONTO simulation and team training, QI Collaboratives). Study clusters in Uganda were four district facilities (two public and two non-profit missionary) which together have approximately 9,000 annual deliveries. In Kenya, the 16 study sites included 14 public and two non-profit missionary facilities and together have approximately 11,000 deliveries per year. Three referral hospitals were exposed to the full intervention package, but were excluded from the trial as they could not be pair-matched.

Birth outcome data were captured for all deliveries listed in maternity registers from October 1, 2016, to May 31, 2018, in Uganda and to April 30, 2019, in Kenya (Figure 3). In Kenya, the study was extended to compensate for a five-month nurses' and a two-month doctors' strike that greatly reduced delivery volume. All facilities were first exposed to data strengthening and introduction of the mSCC, followed by PRONTO and QI Collaboratives at intervention facilities only.

Mothers with infants born alive weighing between 1,000g and 2,500g, or less than 3,000g with a recorded gestational age less than 37 weeks were approached to consent for follow-up to 28 days. Births identified as a fresh stillbirth meeting the same eligibility criteria were also included. A total of 1,491 control and 1,447 intervention group participants (total n=2,938) had complete primary outcome data.

KENYA UGANDA

Figure 2. Study regions | Kenya and Uganda Intrapartum Package

Figure 3. Study timeline and intervention roll-out



Figure 4. Intervention facilities had lower rates of fresh stillbirth and neonatal death among eligible infants than control facilities



For the primary outcome, 23.3% (347/1,491) of control group eligible infants were stillborn or died in the neonatal period compared with 15.3% (221/1,447) in the intervention group (Figure 4).

This means that study-eligible babies born in hospitals receiving the full intervention package had 34% greater odds of surviving to 28 days, compared to eligible babies born in hospitals that



Figure 5. Reduced mortality odds among eligible births was significant across all outcomes

did not receive the intervention package. These gains in survival were seen at birth and upon discharge, as demonstrated by the reduced odds of fresh stillbirth and pre-discharge mortality among eligible infants, respectively (Figure 5).

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The intervention package similarly showed a trend toward reductions in fresh stillbirths and pre-discharge mortality among all babies born in intervention hospitals (Figure 6), not just those born preterm or low birthweight. While our study was not designed to assess this specifically, these data suggest that all births may have benefited from exposure to the intervention package.

Figure 6. All births benefitted from the intervention package



The challenge with gestational age

Data on preterm birth rates are of limited value as the current gold standard for gestational age estimation, first trimester ultrasound, is often not available in many LMICs. Recognizing questionable accuracy of gestational estimation, our eligibility criteria was a novel approach to defining preterm birth based on provider-documented, routinely recorded birthweight and gestational age data. Use of both variables guided by international newborn growth standards helped address data quality concerns and enabled us to capture the most fragile babies. In addition to all low birthweight babies (most of whom are either preterm or small for gestational age), we also estimated that the upper limit of 2,999g would capture 90-97% of < 34-week infants and 60-70% of < 37-week infants.

Unpacking the package

In addition to measurable newborn outcomes, our study also collected key indicators that demonstrate the impact of each intervention component, some of which are showcased in Table 2. A commitment to rigor in data and measurement provided valuable benchmarking for all four package components.

Table 2. Intervention component indicators

Component	Demonstrated effect / Key learnings	
Data Strengthening	Maternity registry completion for the key indicators (e.g. ges- tational age, Apgar, birthweight and discharge status) went from 33% to 77% in Uganda to 51% to 94% in Kenya.	
Modified Safe Childbirth Checklist	Integration of the mSCC into patient charts improved utiliza- tion by providers. While the first two pause points focused on triage and admission had higher uptake rates, 64% and 42% of providers in Kenya and Uganda, respectively, reported that the checklist repeated information in the patient chart.	
PRONTO Simulation and Team Training	Based on knowledge reviews and simulation data, provider knowledge about preterm birth increased from 62% to 73%. Ap- propriate antenatal corticosteroid use increased from 9% to 87%.	
Quality Improvement Collaboratives	Across intervention sites, gesta- tional age recording in maternity registers increased from 61% to 87%. Appropriate Kangaroo care increased from 29% to 90%.	

Additionally, our process evaluations captured qualitative sentiments expressing the perceived value of these activities. For example, with regards to PRONTO and QI Collaboratives:

"It [PRONTO training and mentorship] makes you the have courage when you are handling emergencies, and it is because whenever we have a training you have to go through simulations, it makes you not fear..."

- Health worker

"One thing I have seen is that people have realized that problems can be solved in a system...they can't say we are waiting for Ministry of Health, they can say we can do something about it – which to me is problem solving – and it has been translated at the local level... that attitude of 'we can't wait for Ministry, we can do this as us in our department.'"

– QI Mentor



QI team session Photo by Lubowa Abubaker

Health providers working as a team during PRONTO training

Photo by Kimberly Calkins

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Why the Package Worked

The package in action

The PTBi EA theory of change was based on the idea that the best opportunity to save preterm babies' lives was to improve the quality of care delivered during critical moments around the time of birth. While we recognized that many factors affect the quality of care, we concentrated on the factors that relied on existing infrastructure and required minimal new investment. We focused on providers and their ability and motivation to consistently deliver appropriate care. Our study set out to determine if a carefully designed package of low-cost, low-tech interventions targeting providers in their facilities could be enough to compel them to take the right actions and make the right decisions that would result in improved outcomes.

It was.

To better understand how these intervention activities interacted with each other to support providers' ability to make different decisions, it is helpful to explore what resulted from each component. Launching this initiative gave the condition a name, while counting these babies through data strengthening quantified the condition. Strengthening the capacity of the providers to address the condition improved their confidence to act and changed their attitudes towards these small and vulnerable babies. And finally, seeing the improved outcomes through quality improvement activities reinforced that they were doing the right things. It is this cohesive package that provided the opportunity for providers to practice in simulation and implement change in reality. A positive reinforcing cycle was created (Figure 7).

Critical implementation factors that facilitated uptake

The PTBi EA package was an implementation research trial where the design of the interventions and roll-out of activities were important considerations. In looking at the implementation design, what emerged both organically and deliberately are three factors that help create the right environment to transform the culture of care.

These factors include:

- Visibility
- Teamwork
- Engagement



Figure 7. Establishing a continuous cycle for long-lasting change

Visibility: Defining an issue sparks change

Initially, we were met with spotty birth data. Gestational age measurement, in particular, is the most critical element in accurately understanding preterm birth rates, but it was unreliable in our facilities. Although gestational age is recorded in facility-based registers, a lack of staff training, inconsistent approaches and/or failure to adhere to assessment protocols often led to inaccurate data. Additionally, busy, overworked health care teams often under-valued and under-utilized facility data for decision-making.

We found that the simple act of identifying and defining an issue can catalyze a culture of change. We strengthened maternity registers by treating them as high-quality data sources to track progress and facilitate delivery of the right services to the right people at the right time. Intervention activities reinforced the value of moms in preterm labor and babies born prematurely every time a provider filled out a register, ticked off a checklist, ran through a simulation or reviewed data in a QI Collaborative. Counting and valuing these women and their babies made this epidemic visible to families, communities, Ministries of Health, researchers and funders.

Visibility in action

Prior to PTBi EA' study, our partners in Uganda had identified a gap whereby babies, even sick babies under special care, were only recorded as a note in the mother's medical record. They developed a newborn register to more accurately track the babies' outcomes, which we implemented across study sites in Busoga. For the first time, this gave facilities a systematic recording of how many of these fragile babies survived to facility discharge, and the ability to report on these outcomes. Recognizing its utility, the Uganda Ministry of Health has formally adopted this neonatal register for nationwide use. In Kenya, the Ministry of Health is currently piloting a version of the newborn register.

Teamwork: Powering supportive communities

The study facilities were like those that you would expect to find in rural communities in Western Kenya and Eastern Uganda. In the smaller facilities, providers were often alone during emergencies and in the larger facilities, providers were often too busy, hurried and stressed, to feel anything but unsupported and alone. Taking appropriate actions and making the right decisions at critical moments requires more than skills and knowledge; it requires the confidence that comes with practice and the accountability that comes with being part of a team, part of a community.

The PTBi EA package included two interventions that reinforced teamwork and community principles: PRONTO training and QI Collaboratives. In one, the community that emerged was organic, and in the other it was facilitated, but both were powerful. The providers were now part of teams that formed peer communities that supported each other.



Preterm neonatal resuscitation skill strengthening *Photo by Lubowa Abubaker*

Teamwork in action

Our partners at the Makerere University Centre of Excellent for Maternal Newborn and Child Health have an active communications program where they share stories from their research and implementation work. We have included excerpts from two stories that capture how PTBi EA's intervention supported communities in teamwork:

"...We decided to create an MNCH WhatsApp group in August 2018. This was after the initiation of a vibrant Quality Improvement Collaborative under the Preterm Birth Initiative study which brought together health workers from five hospitals in South Eastern Uganda (Busoga). We needed to keep this collaboration alive even after the project. We also had a group from lower level health facilities especially Level 4 Health Centres who had been brought together through our Maternal and Newborn Scale -Up project. These health workers form the bulk of the group's membership who also include specialists from within the region and national level who have worked as their trainers and mentors over time...The group is now synonymous with sharing of experiences, peer to peer support, consultations on medical conditions and course of action for the treatment and dosage, improved referral to a health facility that has a particular service, knowledge and protocols sharing on procedures, engaging champions and experts on technical issues, leadership engagement and continuing mentorship, among others. This is a



nearly 24-hour functional group where specialists respond to questions on case specific condition(s) and advise on the next course of action and treatment as appropriate. This reminds me of some amazing cases that saw members hooked online for hours. One such case involved a 20-year-old woman that bled to near death and needed an emergency blood transfusion and blood was not available at Bugiri hospital, referred to Jinja, given one unit of blood that was mobilized through the WhatsApp messaging within the group and later referred to Mulago National hospital in better health condition."

Makerere University Centre of Excellence for Maternal Newborn and Child Health Website

"We are glad that colleagues at these lower health facilities whose capacity we have built over time were able to effect timely referral. We have been emphasizing early identification of complications and timely referral," says MNCH Centre Lead Prof Peter Waiswa. "It is not usual that five small babies are born, and all survive through the newborn period even in the best of settings. We are glad that the specialised newborn care capacity we have been building over time at Iganga did not go to waste." Studies show that multiple pregnancies often come with an increased risk of death for women and children because of higher rates of obstetrical complications and quality of care issues in resource limited settings. To mitigate bad neonatal outcomes, institutional deliveries with possible caesarean sections are highly recommended.

When Safiyati arrived at Iganga with an accompanying nurse from Nsinze Health Centre IV, they found Midwife Mary Lugolole (Centre) on duty, a beneficiary of the MNCH Centre capacity building programmes.

"When I got transferred to Iganga Hospital from a Health Centre III, everything looked new to me and I did not know how to handle obstetric emergencies. I am not sure if I would have managed the Safiyati case if it had come at that time," Midwife Lugolole recalls. "However, after a week at the new station my superiors seconded me to PRONTO training under the Preterm Birth Initiative project where I learnt the skills I am applying, complemented by ongoing on-site mentorship from my superiors who also benefitted from the same training."

Makerere University Centre of Excellence for Maternal Newborn and Child Health Website

Engagement: Leveraging local leadership to ensure local ownership

A one-size-fits-all model of research would never work on the complex problem of preterm birth, with drivers and challenges that are unique to place. Understanding local context is crucial in both study design and implementation, and engaging stakeholders is crucial in the uptake. The PTBi EA implementation plan incorporated engagement activities throughout the study period. From National Ministry of Health stakeholders to local facility and community leadership, we started early and kept it going throughout.

When we began this work, preterm birth was recognized as a problem but not necessarily as a top priority. In working to raise awareness of the issue, strengthen provider skills and confidence and encourage facility-based problem solving, providers and facility leadership saw with their own eyes the effects small efforts could have. They themselves became champions for the cause. Since the project began, we worked with our partners to develop and implement tailored sustainability plans, including hand-over of activities to the facility staff and local Ministry of Health offices. After concluding the trial, we implemented intervention activities in the control sites and helped to transition intervention activities to sustainable local programs where desired.

Our study has convinced numerous partners to consider components of our model for scale-up as part of health system strengthening programs. Sites that worked with PTBi EA have continued to focus on improving care for small and preterm babies, equipped with tools to monitor their own data, trained and knowledgeable facility-based mentors, and resources to promote continuous learning. As others adopt some or all of the elements of the intervention package, they are supported by local leaders to carry on this important work.

Most importantly, the emphasis on mothers in preterm labor and preterm babies was maintained.

Engagement in action

In Migori, the county Reproductive Health Coordinator, Beatrice Oloo became a champion of PTBi through her engagement with the study team, mentors, coordinators, data collectors and providers. In a recent PTBi Community Advisory Board meeting, held in December 2019 in Kisumu, Beatrice shared in her slide presentation that with Afya Halisi, a large USAID-funded program launched in several counties including Migori County, she worked to incorporate nearly all of the intervention components and activities into the new health system strengthening program. In fact, the PTBi Modified Safe Childbirth Checklist was digitized and made available on mobile phones. Oloo shared that PRONTO simulation trainings continued along with tracking of key indicators. Their data showed that neonatal deaths continued to decrease, and maternal death due to postpartum hemorrhage also decreased in the county.

We found that changing the culture of care is not a linear process. It is dynamic with many factors working together to create an environment that can nurture change. This environment was established in our 23 facilities in Kenya and Uganda where opportunity, motivation and technical knowledge and skill coalesced enabling providers to improve outcomes for women in preterm labor and their preterm babies. A mother practices skin to skin with her newborn. *Photo by Lubowa Abubaker*

Next Steps

In addition to this anchor trial, several sub-studies were conducted that further addressed prematurity in these regions. For example, results are forthcoming from the following projects:

- Cost-effectiveness of an intrapartum quality of care improvement package to improve preterm survival in Kenya and Uganda
- Gestational dating at birth by metabolic profile: Translation into hospital settings in Uganda
- Use of a checklist and ultrasound at labor triage to improve identification and management of high-risk obstetric complications
- Understanding causes and determinants of neonatal preterm deaths in Migori County, Kenya using verbal and social autopsy
- Health and neurodevelopment status of preterm and low birthweight babies in Migori County

Health providers participate in PTBi EA training Photo by Matthew Gillooley

Acknowledgements

PTBi East Africa was launched to address the global burden of prematurity. Throughout this journey, the meaning of "global burden" changed as the urgency of our work in the places where we worked brought us so close to the "local burden" of prematurity. It is here where we must begin with our acknowledgements and our gratitude. We would like to acknowledge and thank the thousands of women, their infants and their families who provided consent to participate in this study. Next, we must thank the hundreds of providers in each of the study hospitals whose partnership made this study possible and whose daily work humbles us all.

As we discussed in our findings, our success relied on strong engagement and partnership with the Ministries of Health of Kenya and Uganda, as well as the local health authorities in Migori County and the Busoga region. We are very grateful to them for their partnership and trust in this joint endeavor. We thank the community health volunteers in Kenya for their effort and commitment to the work in Migori. We are grateful to the local and national advisory boards in each country, members of the Preterm Birth Initiative East Africa External Advisory Committee, our colleagues at the California Preterm Birth Initiative, and the members of our joint Strategic Advisory Board. We would like to acknowledge and express our sincere gratitude to our funders at the Bill & Melinda Gates Foundation for their collaboration, guidance, encouragement, and generous funding. Specifically, we would like to acknowledge our team of program officers who partnered with us through each phase of the Initiative: France Donnay, Janna Patterson, Jerker Liljestrand, and Manpreet Singh.

Sometimes awareness of global research initiatives reaches individuals outside its sphere. Ours managed to reach the hearts and minds of thousands of volunteers around the world who hand-knit and crocheted more than 50,000 hats for preterm babies. Many of these volunteers were made aware of global prematurity through the advocacy of the nonprofit organization Warm-Up America. We are so grateful to them and their army of volunteers.

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