Addressing the Burden of Prematurity through Implementation and Discovery Research:

Insights from the East Africa Preterm Birth Initiative

Session chair:

Dilys Walker, MD, FACOG | *UCSF*

Speakers:

Sabine Musange MD, MSc | *University of Rwanda*

Phelgona Otieno MBChB, MPH | *Kenya Medical Research Institute*

Nicole Santos, PhD, MSc | *UCSF*

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Disclosures

	Relationship(s)
Dilys Walker	Co-Founder of PRONTO International™
Sabine Musange	No disclosures to report
Phelgona Otieno	No disclosures to report
Nicole Santos	No disclosures to report
Peter Waiswa	No disclosures to report

Today's speakers

Dr. Dilys Walker
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Dr. Sabine Musange
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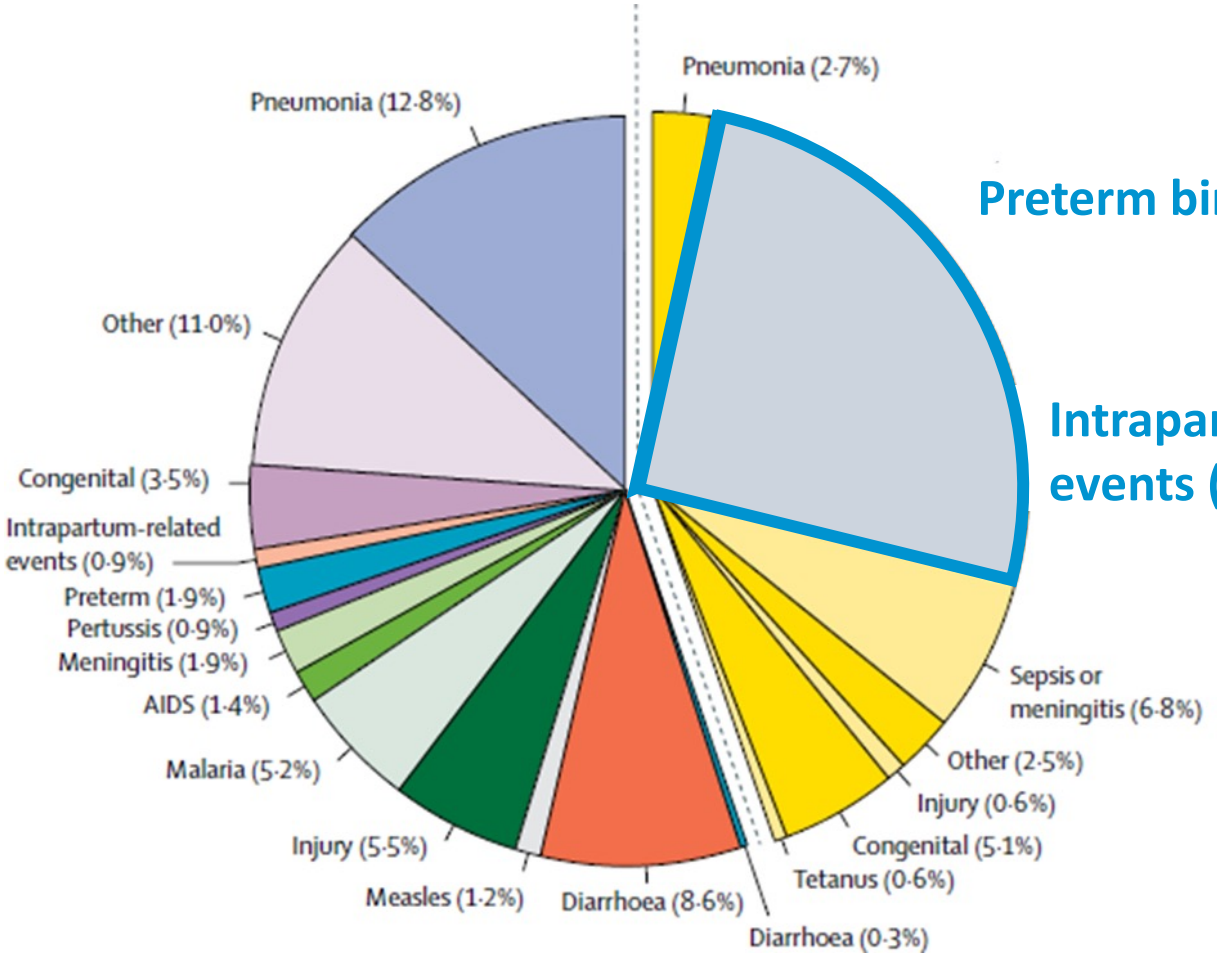
Dr. Phelgona Otieno
Kenya Medical Research Institute

KENYA MEDICAL RESEARCH INSTITUTE KEMRI

Dr. Peter Waiswa
Makerere University

MAKERERE UNIVERSITY

Preterm birth is the leading cause of death among newborns and children under 5 years

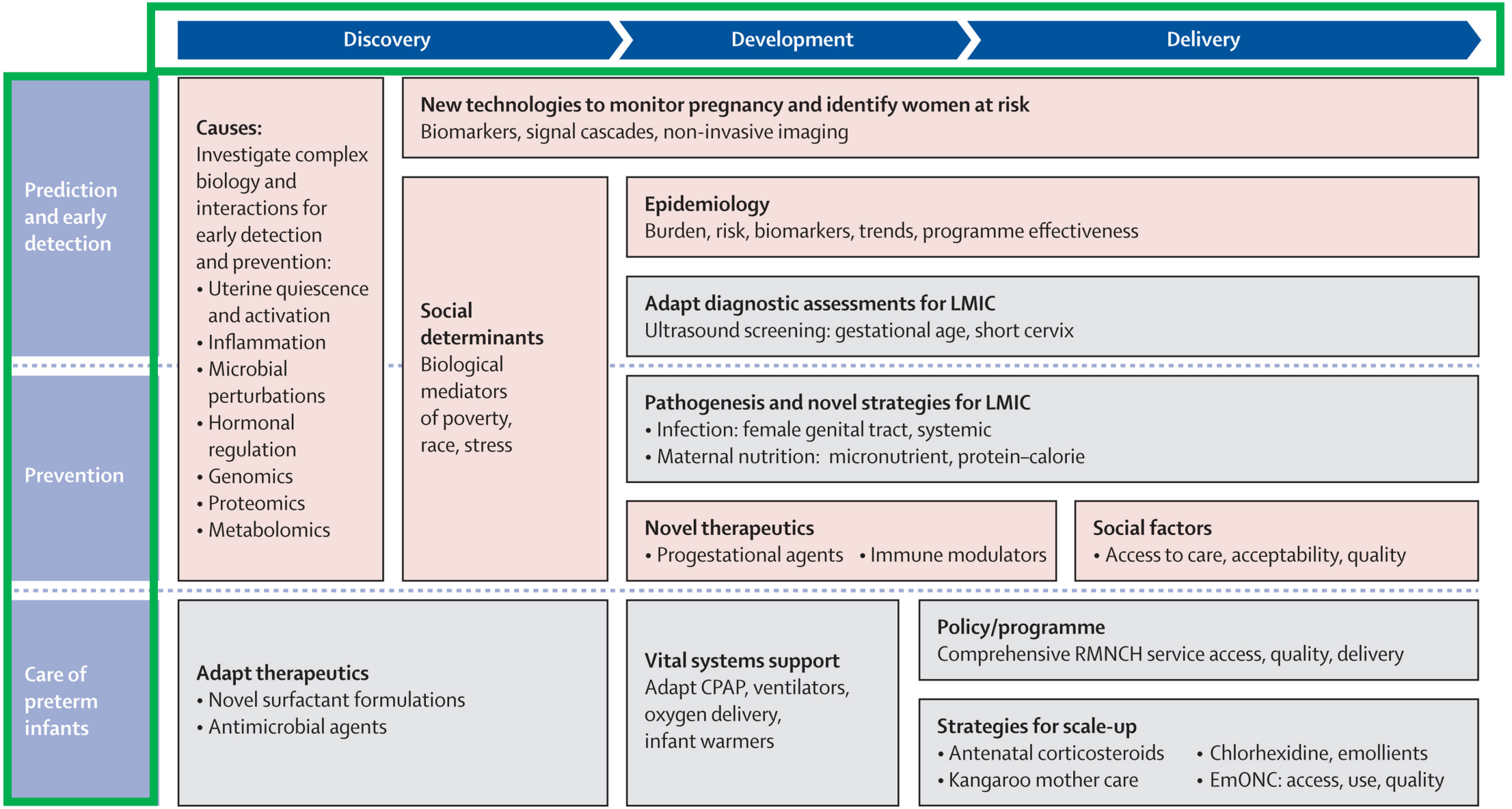


1-59 months (54.9%)

Neonatal death (45.1%)

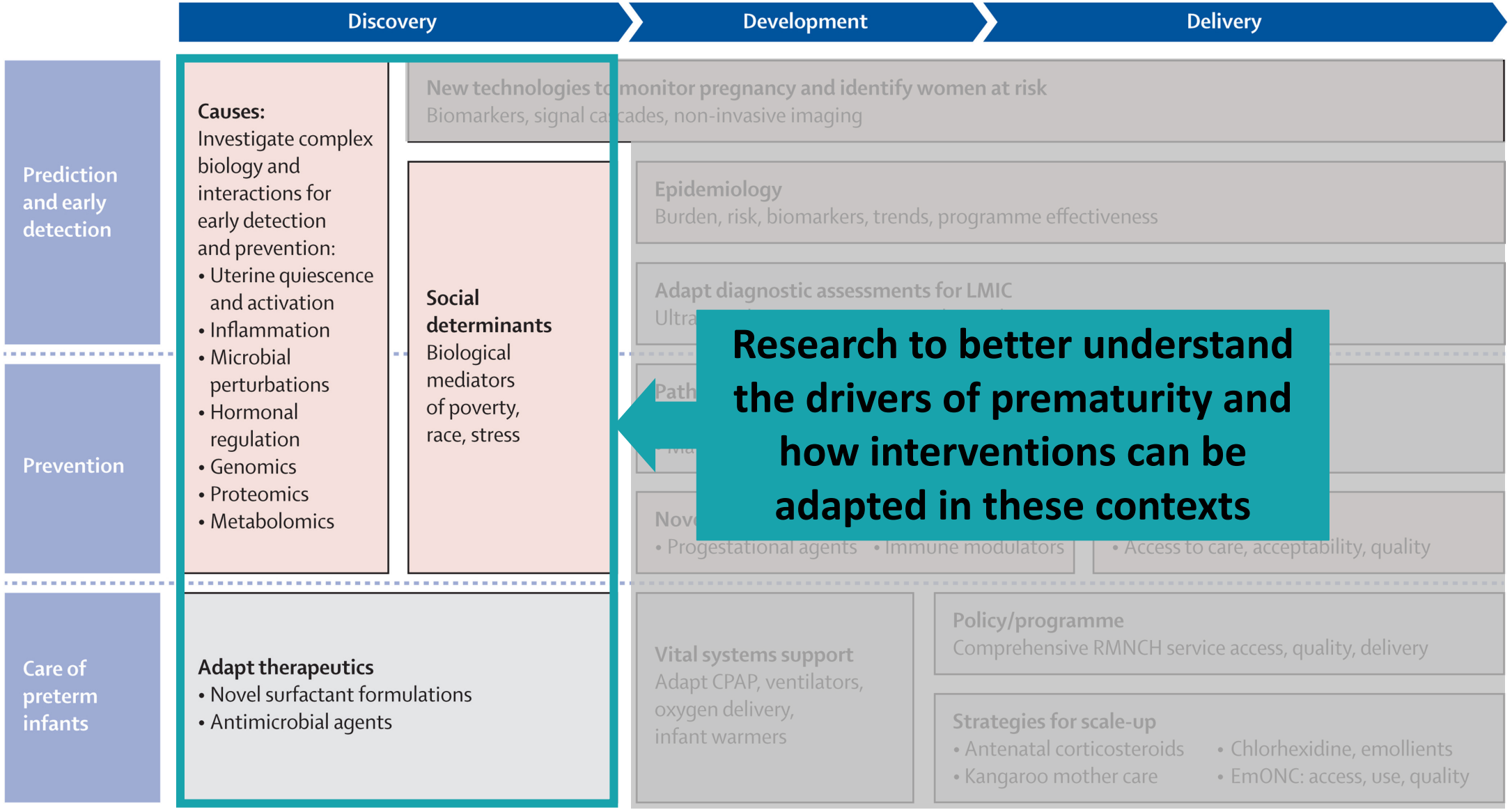
Adapted from Liu et al. Lancet 2016.

“Solution Pathway” to address the complexity of preterm birth



Lackritz et al. Lancet Glob Health. 2013 Dec;1(6):e328-30.

Diverse stakeholders identified specific priorities



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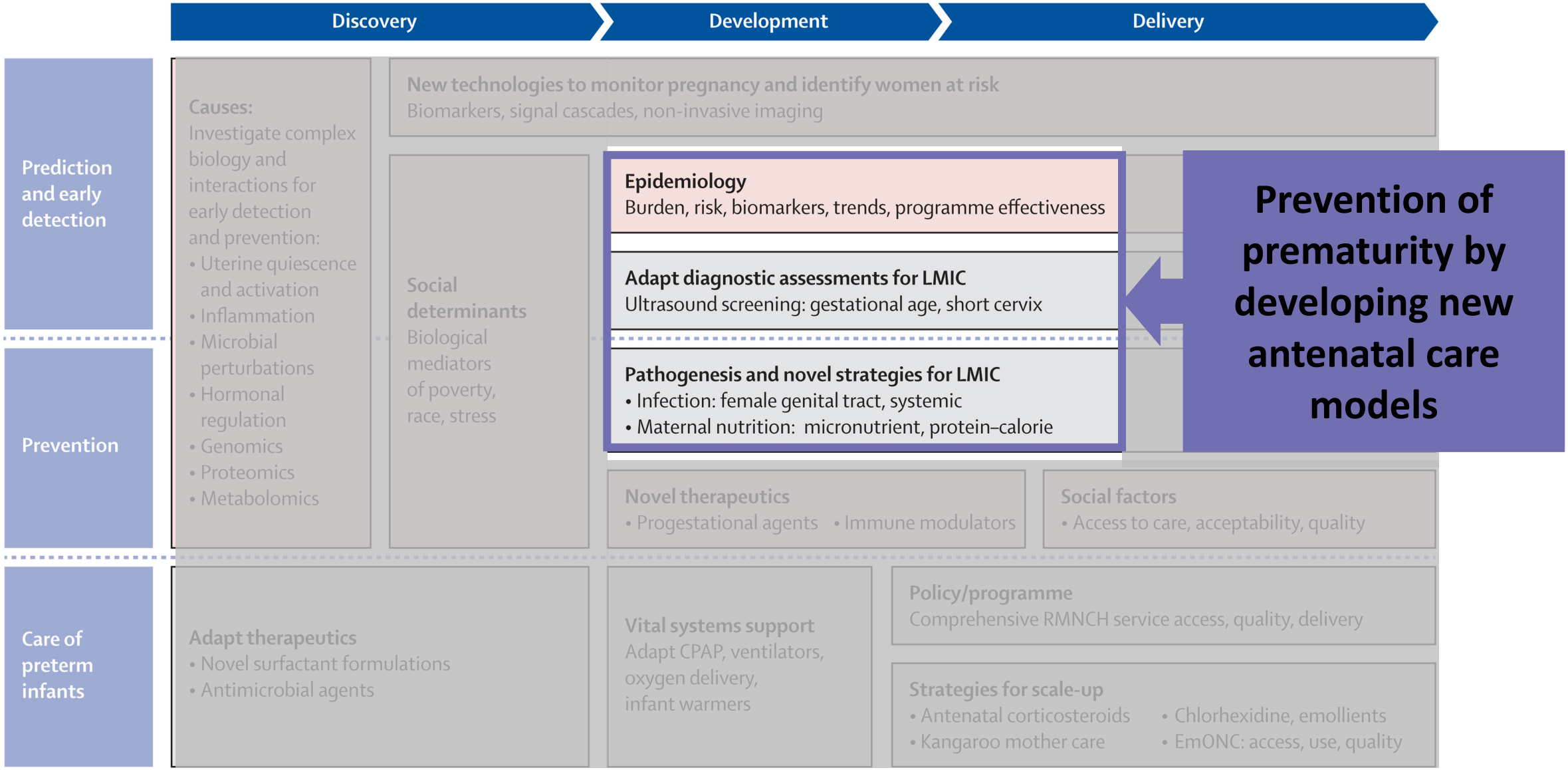

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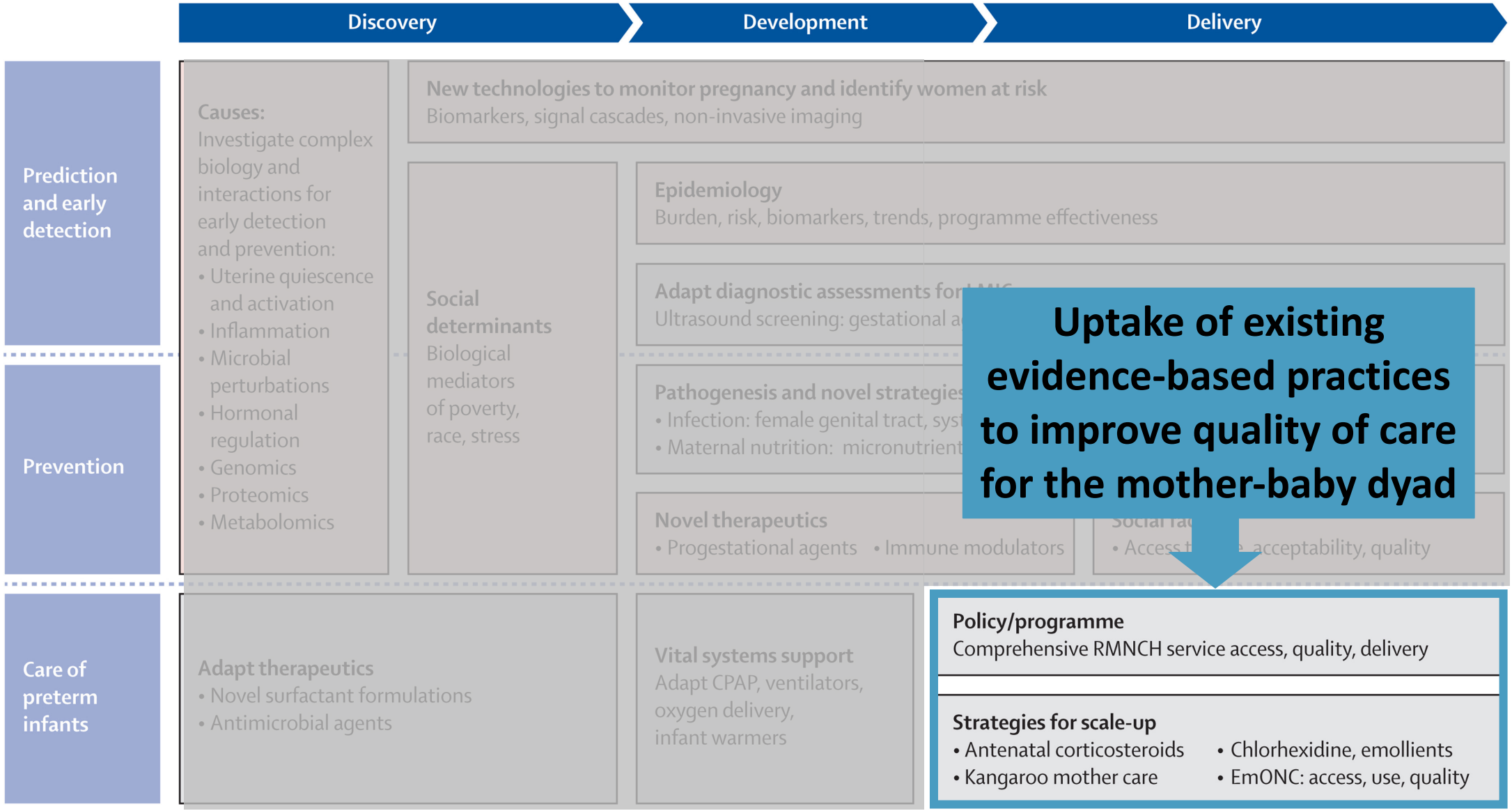
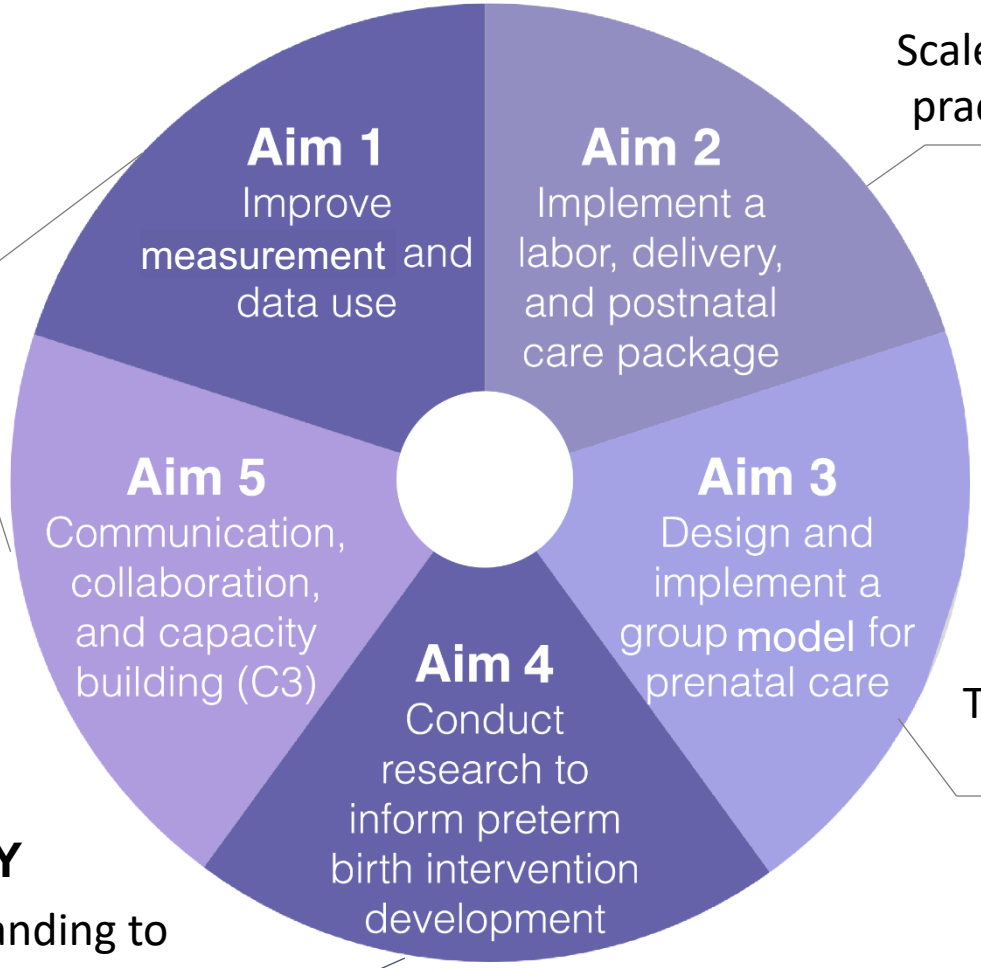


Lackritz et al. Lancet Glob Health. 2013 Dec;1(6):e328-30.

Our multi-pronged approach to reducing the burden of prematurity in East Africa

FOUNDATION
Measurement, collaboration and capacity strengthening



DELIVERY
Scale-up existing evidence-based practices for mother-baby dyad

Kenya & Uganda

DEVELOPMENT
Test new and adapted interventions to build evidence base

Rwanda

DISCOVERY
Improve understanding to inform new interventions

Session Agenda

- **Discovery:** Investigating context-specific drivers of and solutions to prematurity
- **Development:** Developing and testing group antenatal care in Rwanda for preterm prevention
- **Delivery:** Evaluating the effect of a package of intrapartum/postnatal interventions to improve preterm mortality in Kenya and Uganda

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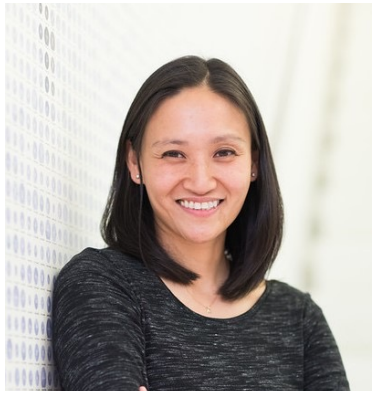
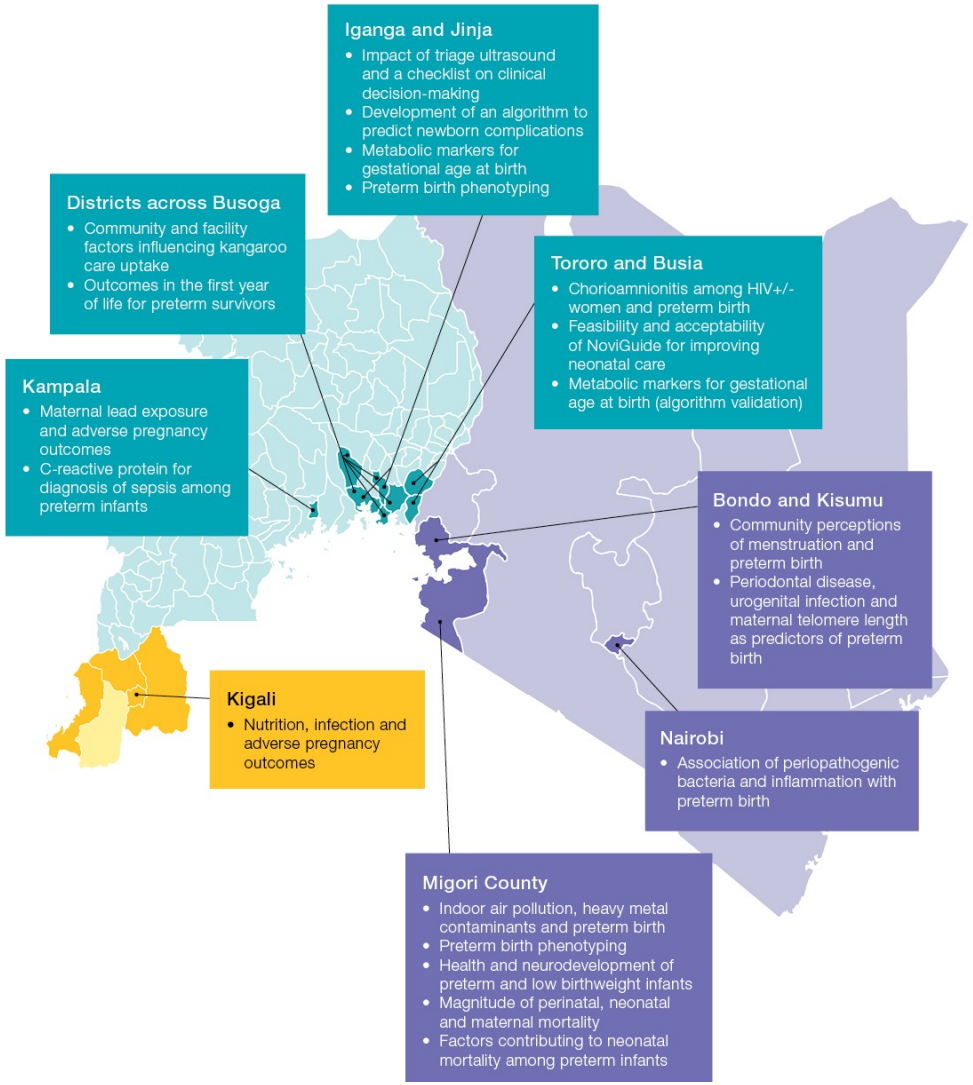


Nicole Santos, PhD, MS

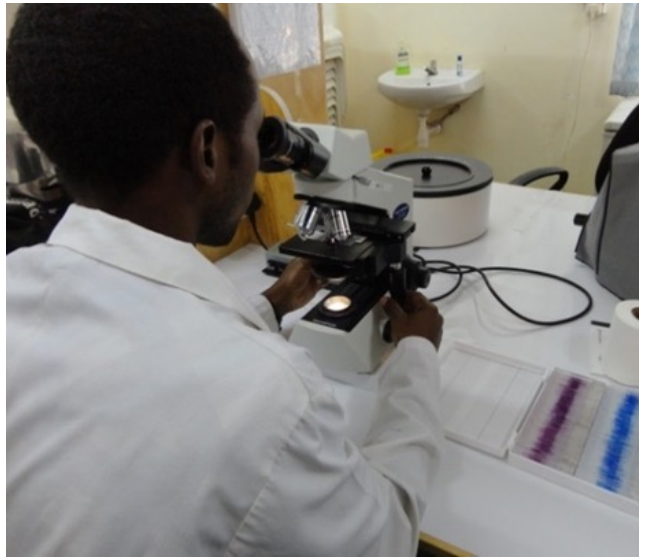
PTBi East Africa Discovery & Fellowship Program

Discovery portfolio comprised pilot projects led by EA investigators

- 3 cycles of competitive RFP
- Funded EA-led projects $25k-100k
- 16 PIs from 8 institutions
- 14 early career investigators
- 7 received mentorship from UCSF faculty; 4 from other institutions



Projects were multi-disciplinary



Qualitative methods to capture community perceptions

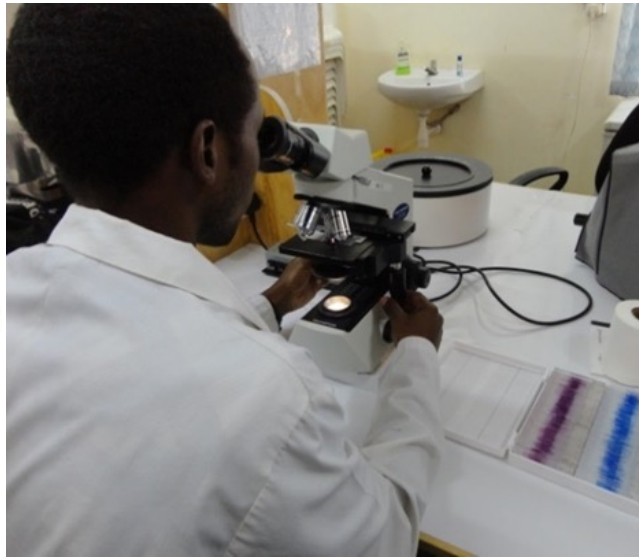
Perceptions of contraceptives as factors in birth outcomes and menstruation patterns in a rural community in Siaya county, Western Kenya

George O Onyango[1], George Ayodo[2], Nadia Smith- Diamond[3], Salome Wawire[4]

Laboratory-based studies to investigate risk factors

Maternal genitourinary infections and poor nutritional status increase risk of preterm birth in Gasabo District, Rwanda: a prospective, longitudinal, cohort study

Etienne Nsereko[1*], Aline Uwase[1], Assumpta Mukabutera[2], Claude Mambo Muvunyi[3], Stephen Rulisa[3], David Ntirushwa[3], Patricia Moreland[4], Elizabeth J. Corwin[5], Nicole Santos[6], Manasse Nzayirambaho[2] and Janet M. Wojcicki[6]



The prevalence of histologic acute chorioamnionitis among HIV infected pregnant women in Uganda and its association with adverse birth outcomes

John Ategeka[1], Razack Wasswa[1], Peter Olwoch[1], Abel Kakuru[1], Paul Natureeba[1], Atis Muehlenbachs[2], Moses R. Kamya[3], Grant Dorsey[4], Gabrielle Rizzuto[5]*

Facility-based interventions research

Midwife-performed checklist and ultrasound to identify obstetric conditions at labour triage in Uganda: A quasi-experimental study

Jude Mulowooza[a,1], Nicole Santos[b,1,*], Nathan Isabirye[a], Innocent Inhensiko[a], Nancy L. Sloan[b], Sachita Shah[c], Elizabeth Butrick[b], Peter Waiswa[a,d], Dilys Walker[b,e]

Implementation of a Newborn Clinical Decision Support Software (NoviGuide) in a Rural District Hospital in Eastern Uganda: Feasibility and Acceptability Study

Mary Muhindo[1,2*], MBChB, MPH; Joshua Bress[3*], MD; Rogers Kalanda[2*], DMCH; Jean Armas[3*], MPH; Elon Danziger[3*], MArch; Moses R Kamya[4*], MBChB, DPhil; Lisa M Butler[5*], MPH, DPhil; Theodore Ruel[6*], MD, DPhil

Invested in additional priority areas

Biomarkers to predict gestational age

Gestational age dating using newborn metabolic screening: A validation study in Busia, Uganda

Scott P Oltman[1,2], Elizabeth A Jasper[3], Richard Kajubi[4], Teddy Ochieng[4], Abel Kakuru[4], Harriet Adrama[4], Martin Okitwi[4], Peter Olwoch[4], Moses Kamya[4,5], Bruce Bedell[6], Molly McCarthy[2], John Dagle[6], Prasanna Jagannathan[7], Tamara D Clark[8], Grant Dorsey[8], Larry Rand[2,9], Theodore Ruel[10], Elizabeth E Rogers[10], Kelli K Ryckman[3], Laura L Jelliffe-Pawlowski[1,2]

Causes of preterm and low birth weight neonatal mortality in a rural community in Kenya: evidence from verbal and social autopsy

Beatrice Olack[1*], Nicole Santos[2], Mary Inziani[1], Vincent Moshi[1], Polycarp Oyoo[1], Grace Nalwa[3], Linet Christopher OumaOtare[1,1], Dilys Walker[2] and Phelgona A. Otieno[1]

Mortality and morbidity among preterm infants

Discovery efforts helped raise awareness about preterm birth among early career researchers

- Over a dozen publications and counting from EA Discovery grantees
- Several early career investigators have
  - presented work in both local and global forums
  - obtained additional grants
  - pursued advanced training, including PhD programs and post-doctoral fellowships

Transdisciplinary Postdoctoral Fellowship in Preterm Birth

- Jointly funded by the California and East Africa arms of PTBi
- 3 recruitment cycles open to US and East African researchers

GOAL: to train and mentor the next generation of prematurity-focused transdisciplinary researchers in their path towards independence

Fellows span basic science, clinical research, social sciences, and epidemiology

- 11 graduates between 2015 – 2021
- 5 fellows focused their research in EA
  - Stress during pregnancy
  - Impact of HIV and antiretroviral treatment on preterm birth
  - Respectful maternity care
  - Kangaroo care for clinically unstable babies
  - Innovation in newborn clinical decision-making
- All 11 graduates have secured faculty positions at UCSF or other universities

Through our capacity strengthening efforts, PTBi EA has helped build a cohort of prematurity-focused researchers.

East African PIs:

- Joseph Akuze
- John Ategeka
- George Ayodo
- Doris Kwesiga
- Jude Mulowooza
- Mary Muhindo
- Victoria Nakibuuka
- Fatuma Namusoke
- Linus Ndegwa
- Etienne Nsereko
- Charles Opio
- Beatrice Olack
- Lydia Olaka
- Margaret Oluka
- Julius Oyugi
- Phillip Wanduru
- Veronica Wangari

East Africa-focused post-doctoral fellows

- Patience Afulani
- Moses Madadi
- Melissa Morgan
- Mary Muhindo
- Joseph Musana

UCSF PIs and mentors:

- Nadia Diamond-Smith
- Grant Dorsey
- Susan Fisher
- Linda Franck
- Laura Jelliffe
- Jue Lin
- Ted Ruel
- John Weinstein
- Janet Wojcicki

KENYA MEDICAL RESEARCH INSTITUTE KEMRI

UNIVERSITY OF RWANDA

MAKERERE UNIVERSITY

IDRC INFECTIOUS DISEASES RESEARCH COLLABORATION

ST FRANCIS HOSPITAL NSAMBYA

MULAGO HOSPITAL

UCSF University of California San Francisco

Session Agenda

- **Discovery:** Investigating context-specific drivers of and solutions to prematurity
- **Development:** Developing and testing group antenatal care in Rwanda for preterm prevention
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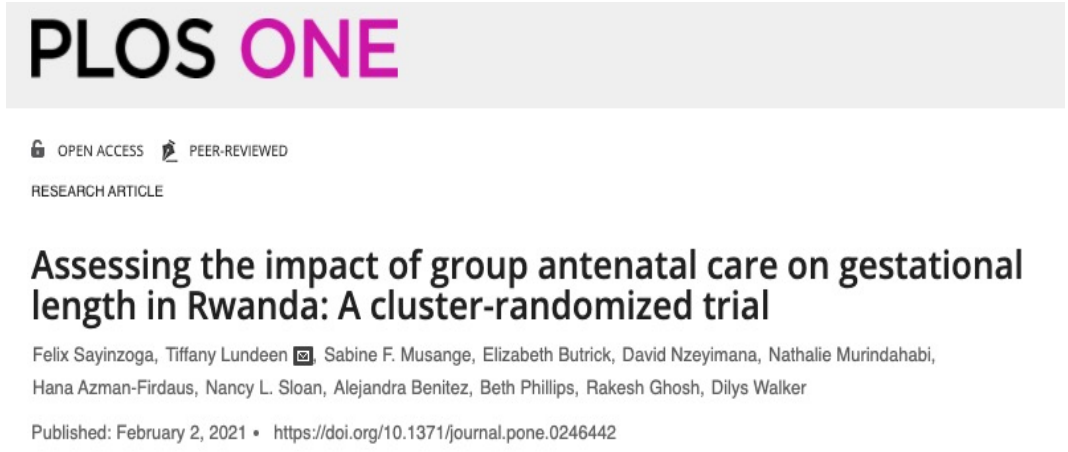


PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Assessing the impact of group antenatal care on gestational length in Rwanda: A cluster-randomized trial

Felix Sayinzoga, Tiffany Lundeen, Sabine F. Musange, Elizabeth Butrick, David Nzeyimana, Nathalie Murindahabi, Hana Azman-Firdaus, Nancy L. Sloan, Alejandra Benitez, Beth Phillips, Rakesh Ghosh, Dilys Walker

Published: February 2, 2021 • https://doi.org/10.1371/journal.pone.0246442

Sabine Musange, MD

Rwanda Group Antenatal and Postnatal Care Trial

RWANDA BIOMEDICAL CENTER

UCSF

UNIVERSITY OF RWANDA

Group antenatal care is a service delivery model that may improve quality of care

- 2015 Cochrane: no effect on PTB, no adverse outcomes, high acceptability
- Lower rates of PTB among women at higher risk in HIC settings
  - Compared to individual care, risk of PTB and LBW decreased (RR 0.63, 0.62)
  - higher in those who received 5+ visits

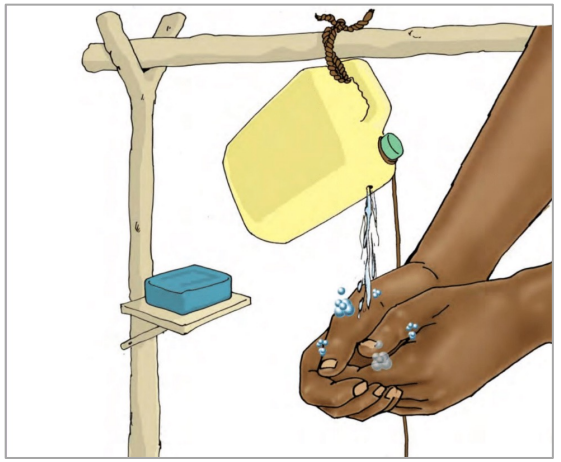
- Feasibility and acceptability shown in LMICs: Ghana, Tanzania, Malawi
- CRCT powered to detect facility-based births in Nigeria and Kenya
  - Higher facility based birth rate in Nigeria
  - Increased coverage of 4+ANC visits/quality ANC in both countries

Catling et al. Cochrane Database of Systematic Reviews 2015, Issue 2; Ickovics et al. Obstet Gynecol. 2007, 110(2 Pt 1): 330–339; Cunnighan et al. J. Women's Health. 2019, 28:1; Grenier et al. PLoS ONE 2019, 14(10): e0222177.

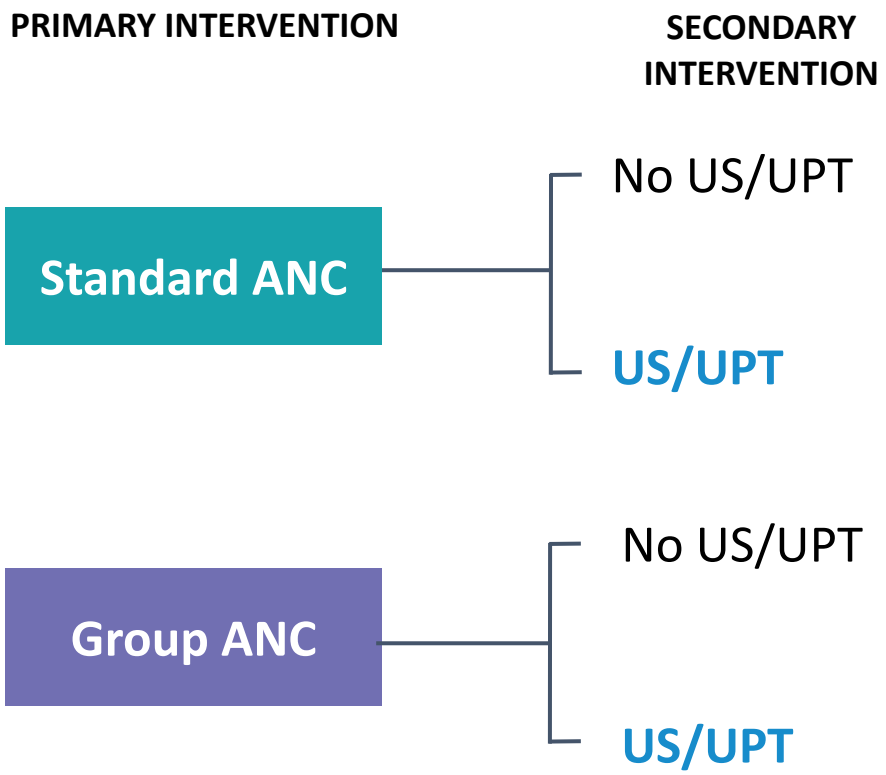
Group care followed the 4 focused ANC visit model

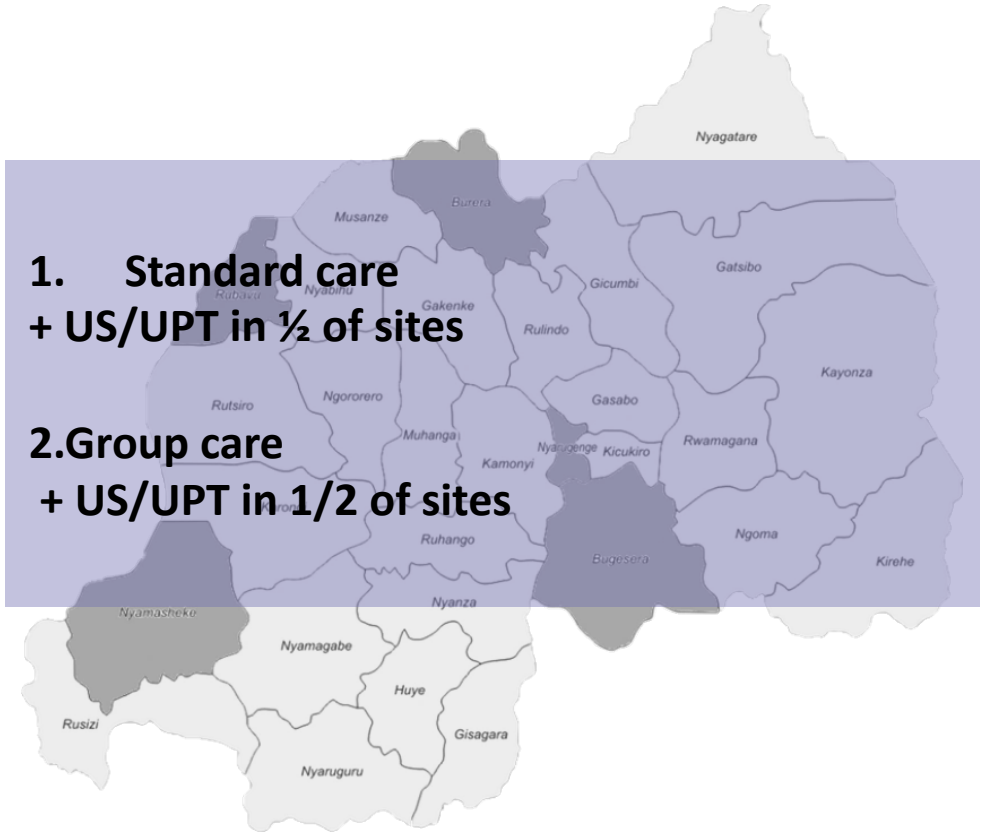
- **Visit 1:** Individual visit, invited to group care
- **Visits 2-4:** 2-hour visits in groups of 8-12 women
  - self-assessment of weight and blood pressure
  - brief check with nurse behind privacy screen
  - one-hour group discussion on nutrition, birth planning, danger signs, etc.
- **Visit 5 (postnatal visit)**: 2-hour group visit at 6 weeks postpartum

Groups consist of women of similar gestational age, but drop-ins welcome



CRCT across 36 health centers in 5 districts
Primary outcome: gestational age at birth

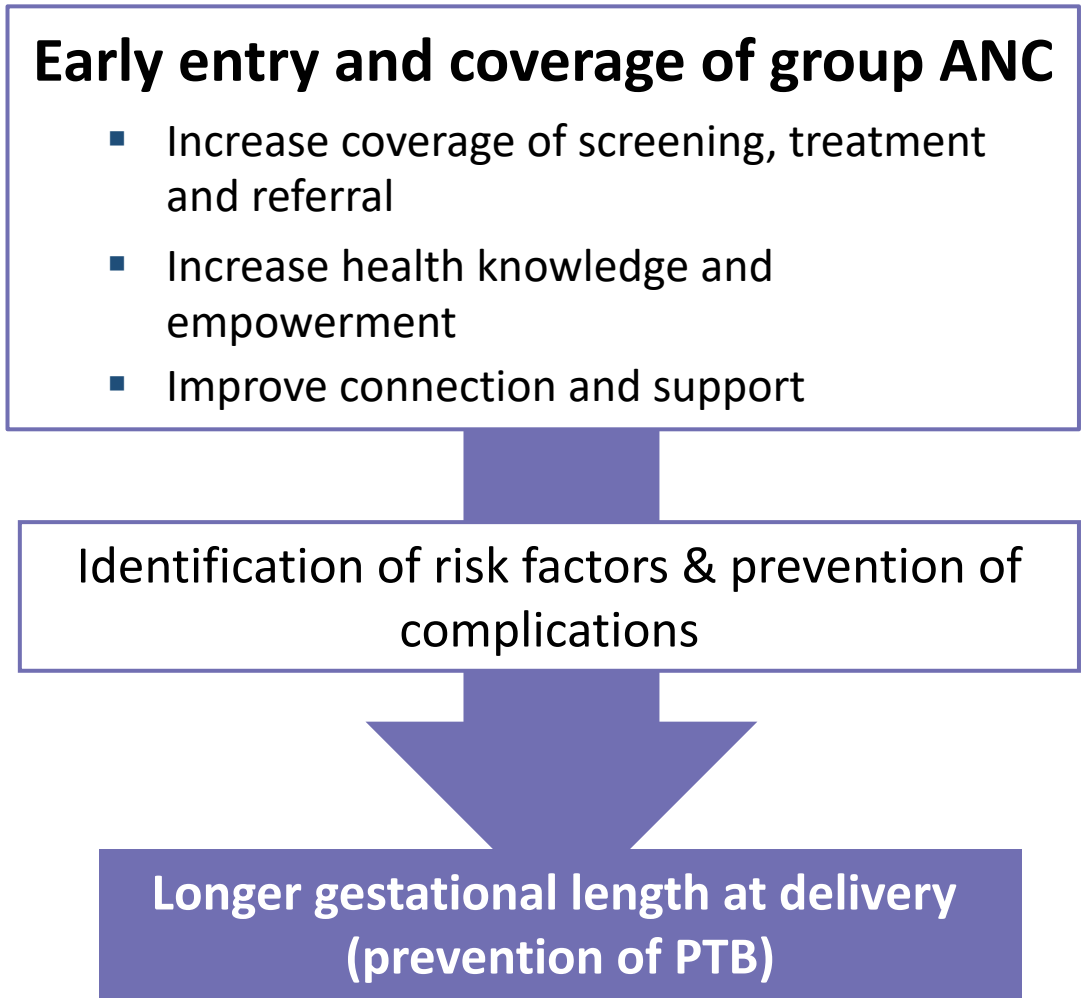




Inclusion of ultrasound (US) and urine pregnancy testing (UPT) aligned with MOH interests

Hypothesis

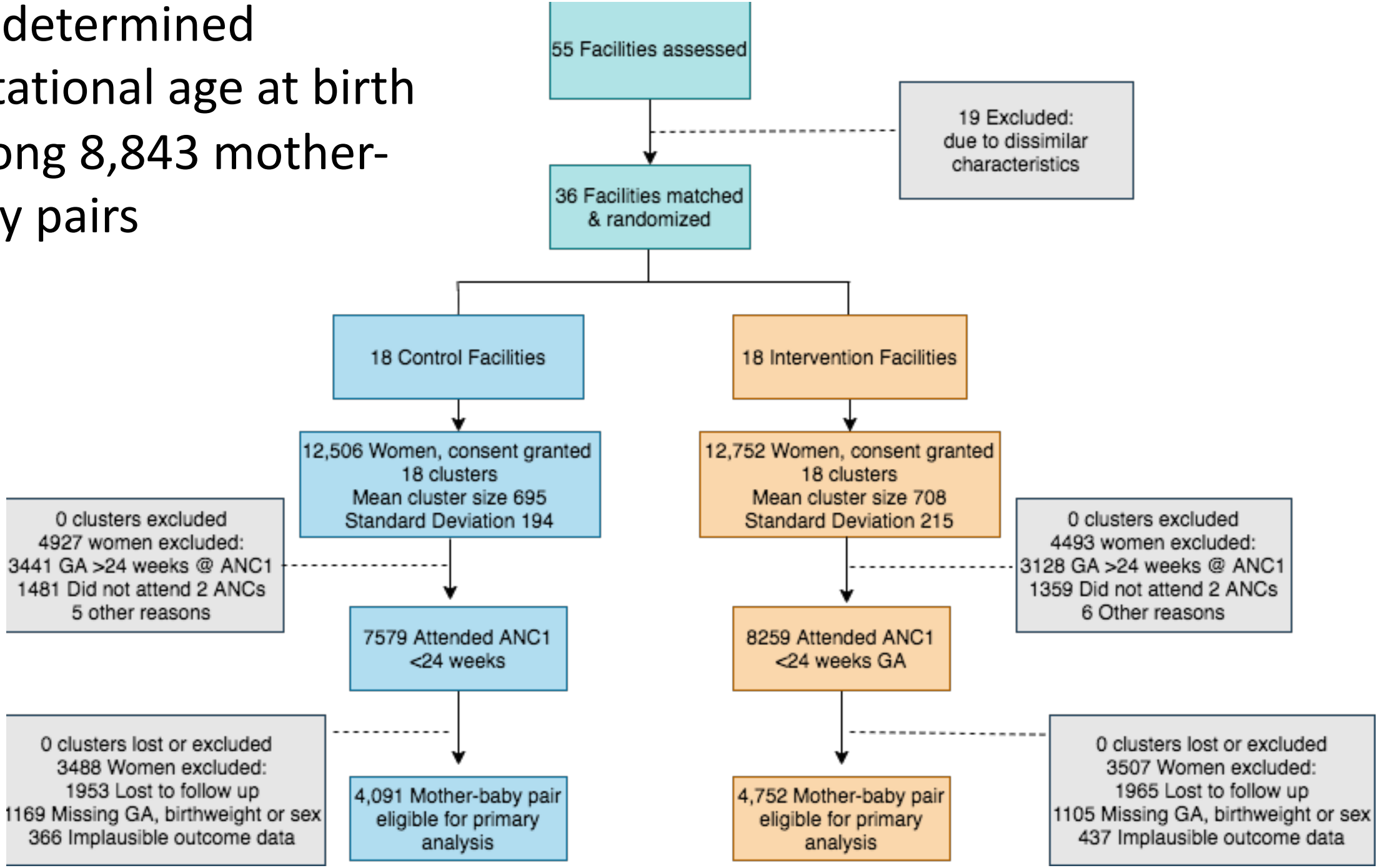
Group ANC in women presenting for ANC at <24 weeks gestation who attend ≥2 ANCs at the study health centers will increase gestational age at birth by 0.5 ±4.3 weeks compared to women who receive standard ANC



Setting

- 78% in rural settings
- 11 nurses per facility on average, no physicians
- All government or missionary facilities
- Provide uncomplicated, vaginal delivery only
- Average distance to referral hospital is 30 km
- Monthly delivery volume between 35 and 125 births

We determined gestational age at birth among 8,843 mother-baby pairs



Primary outcome: gestational age at birth in weeks

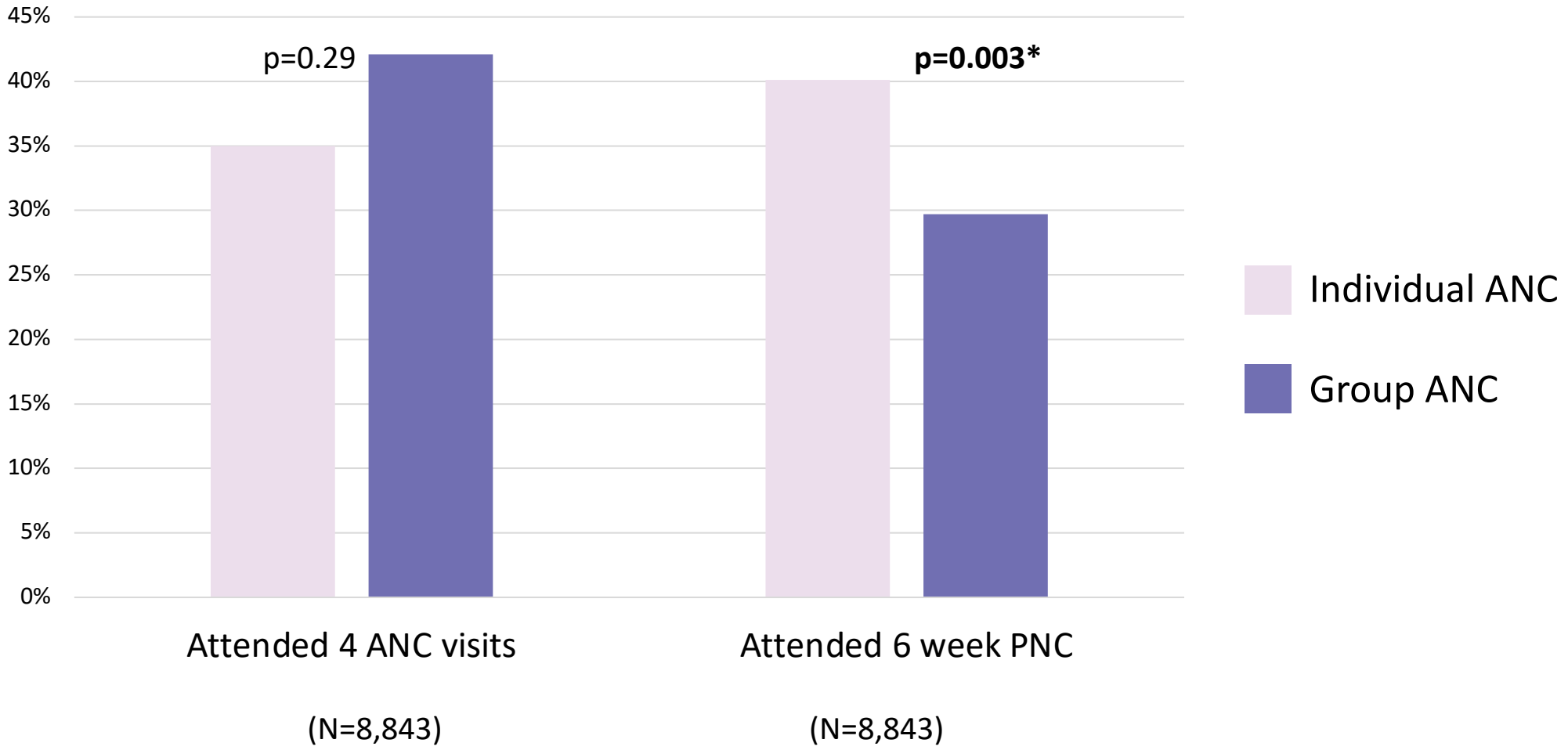
Individual ANC		Group ANC		Adjusted for cluster and pairing		
Mean	SD	Mean	SD	Coefficient	95% CI	p
39.3	±1.5	39.3	±1.6	-0.07	(-0.18, 0.04)	0.24

Group ANC did not increase gestational age at delivery

Group ANC increased attendance 3 visits but not 4, did not affect entry to care

	Control (Standard ANC) N=7579	Intervention (group ANC) N=8259	p-value
	% / Mean (SD)	% / Mean (SD)	
Proportion of women who attended at least 4 ANC visits	35.0%	42.1%	.291
Proportion of women who attended at least 3 ANC visits	71.7%	80.7%	**.003**
Proportion of these women who attended ANC 1 before 14 completed weeks gestation	41.9%	37.0%	.390
Mean gestational age at first ANC visit, in weeks	15.8 (4.4)	16.0 (4.4)	.668

Group ANC did not significantly improve coverage

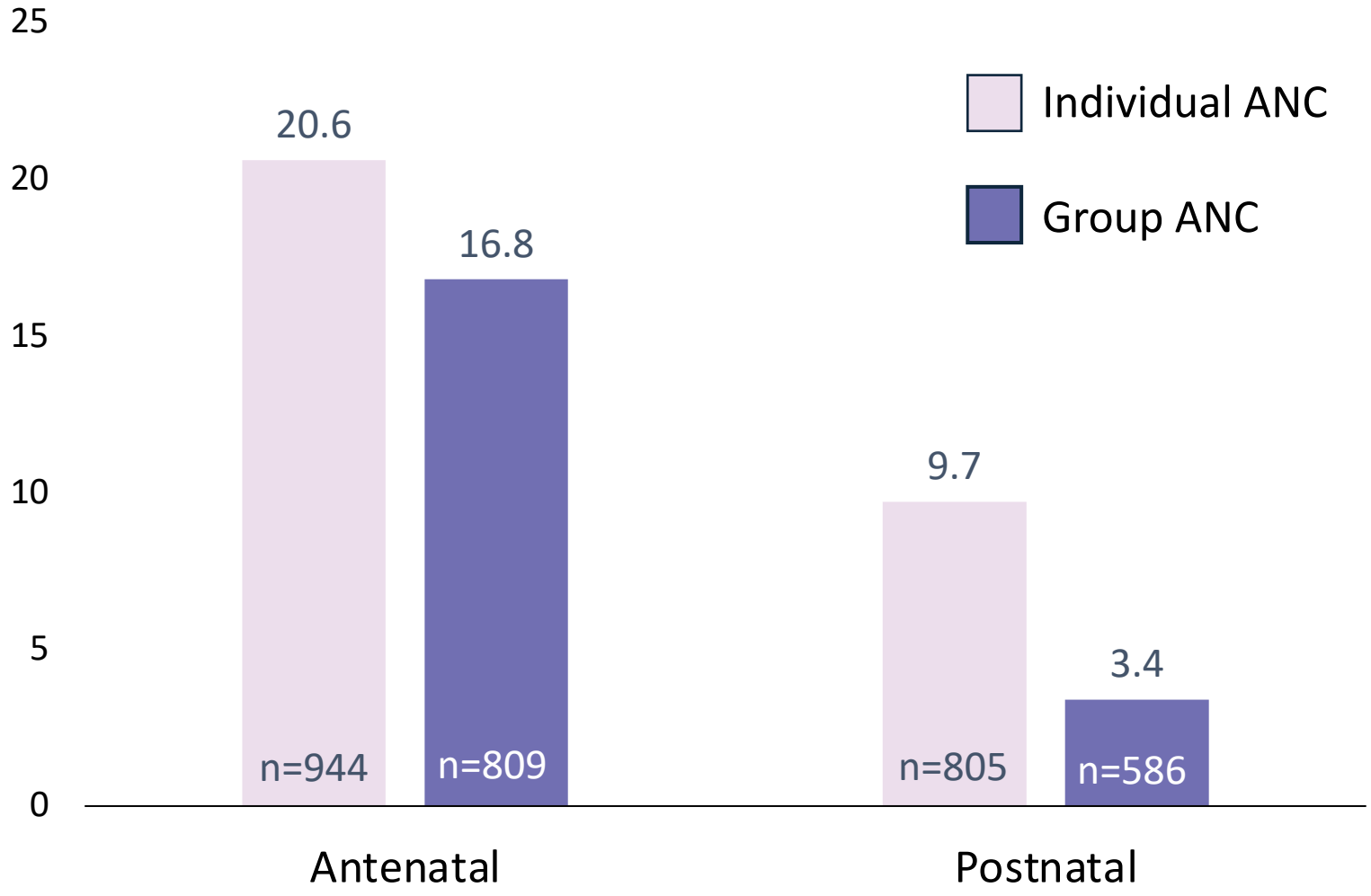


US/UPT, did not affect attendance or entry to care

	Control (No US or UPT) N=8734	Intervention (US and UPT) N=7104	p-value
	% / Mean (SD)	% / Mean (SD)	
Proportion of women who attended at least 4 ANC visits	37.3%	40.5%	.57
Proportion of women who attended at least 3 ANC visits	75.1%	78.0%	.88
Proportion of these women who attended ANC 1 before 14 completed weeks gestation	37.8%	41.2%	.54
Mean gestational age at first ANC visit, in weeks	16.1 (4.3)	15.7 (4.5)	.28

Whether group care improves maternal mental health warrants further investigation

Pooled prevalence of antenatal and postnatal depression* by study condition, respondents from 28 health centers included in multilevel multiple logistic regression



*Edinburgh Postnatal Depression Scale ≥ 13

Workload challenge: providers rotate through several services and/or cover more than one service during the same shift

"It happens sometimes for a service provider to feel stressed due to the fact that we work in more than one service; **we get a challenge of failing to render an adequate service because the group care activities require you sit in one place**… It happens that you may be urgently needed in a different service; you are thus obliged to excuse yourself for an absence of little while to provide the services called for, and this is becomes disturbance."

- Group ANC provider

Importance of dose: Number of group ANC visits planned and attended were both low

- Group ANC's requirement that women come on a certain day disrupts the flexibility of the current system
- This could have resulted in lower ANC attendance
- A hybrid or more flexible model should be better understood to promote a higher number of visits

Contextual factors impacted research

- Existing registers inflexible for capturing additional ANC visits
- Co-payments and premiums for ANC visits
- Performance-based incentive programs
- Staff reallocation between health centers

Importance of relationships: Group ANC creates interconnectedness across patients, providers and CHWs

- Consistent with many other studies, our study found that women preferred the experience of a group ANC model
- But HOW does group ANC improve experience of care? **By relationships and social support.**
- Women find social support among their peers and providers, impacting:
  - Mental health status
  - Comfortability in discuss health issues
  - Increased knowledge on modern family planning

"Two heads are better than one. When you are alone, you may be misguided by your thoughts. Being in ***group care helps you get more knowledge from others and from the nurse****, who takes time to talk to you."* *– pregnant woman*

"Today in group care, they come and sit together with the nurse and share. They are free to ask whatever they want. They ask questions and get answers to them. Today, ***they feel at ease with the nurse, and they behave like friends****."*
– provider

"To me, there has ***been a strong relationship and effective collaboration between us and nurses****… they really appreciated our assistance to the extent that they worry about losing our support."* *– community health worker*

Important insights from group ANC trial in Rwanda

- Successful implementation of group ANC model
- Integrated 4 focused-ANC model, though dose was low
- No impact on GA at birth among this low-risk population
- Behavioral interventions might take longer for impact
- May be best suited for higher risk women or other outcomes such as improved maternal mental health

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Phelgona Otieno, MBChB, MPH

Peter Waiswa, MBChB, MPH, PhD

Impact of an intrapartum and immediate newborn care quality improvement package on fresh stillbirth and neonatal mortality among preterm and low birthweight births in Kenya and Uganda

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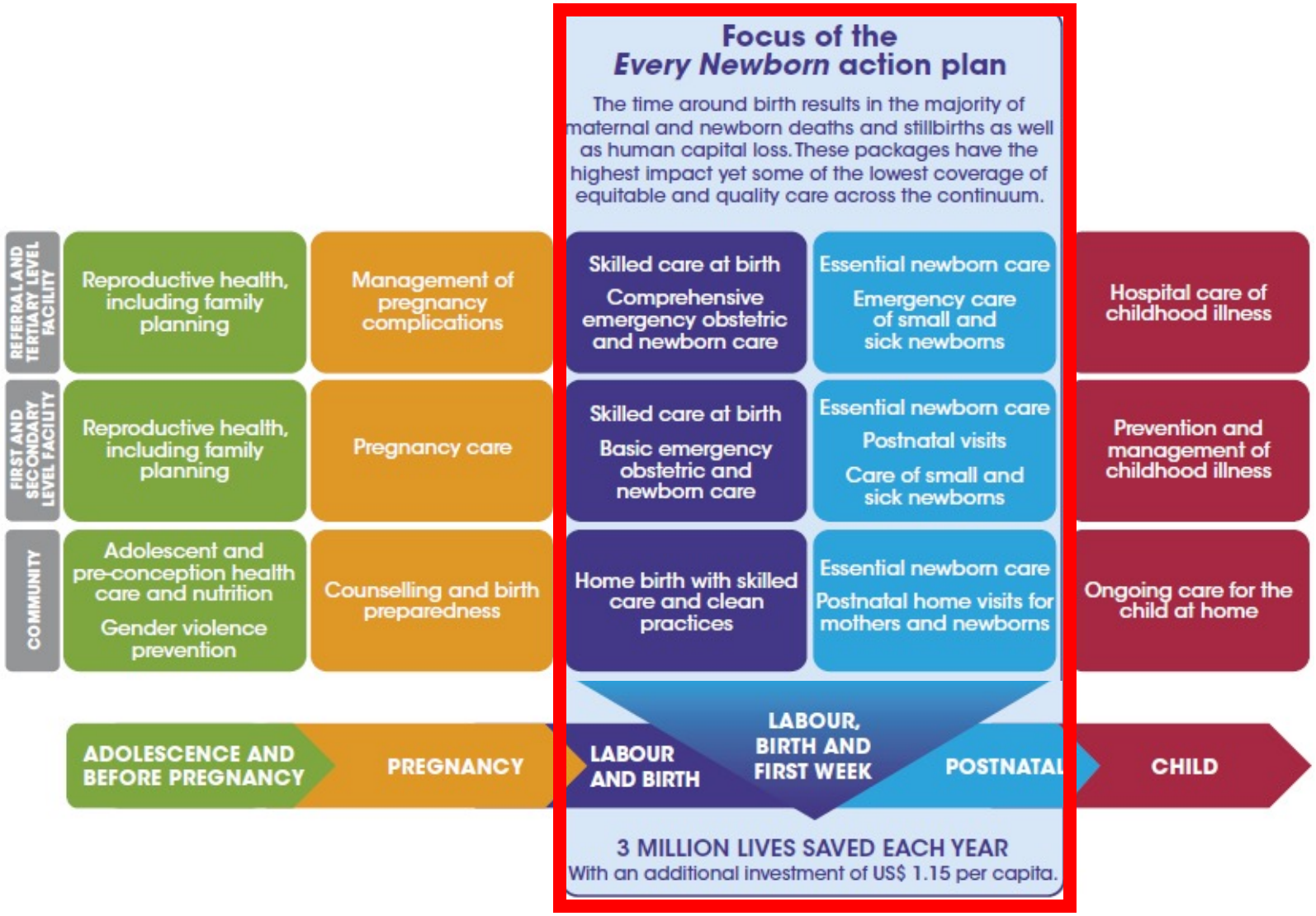
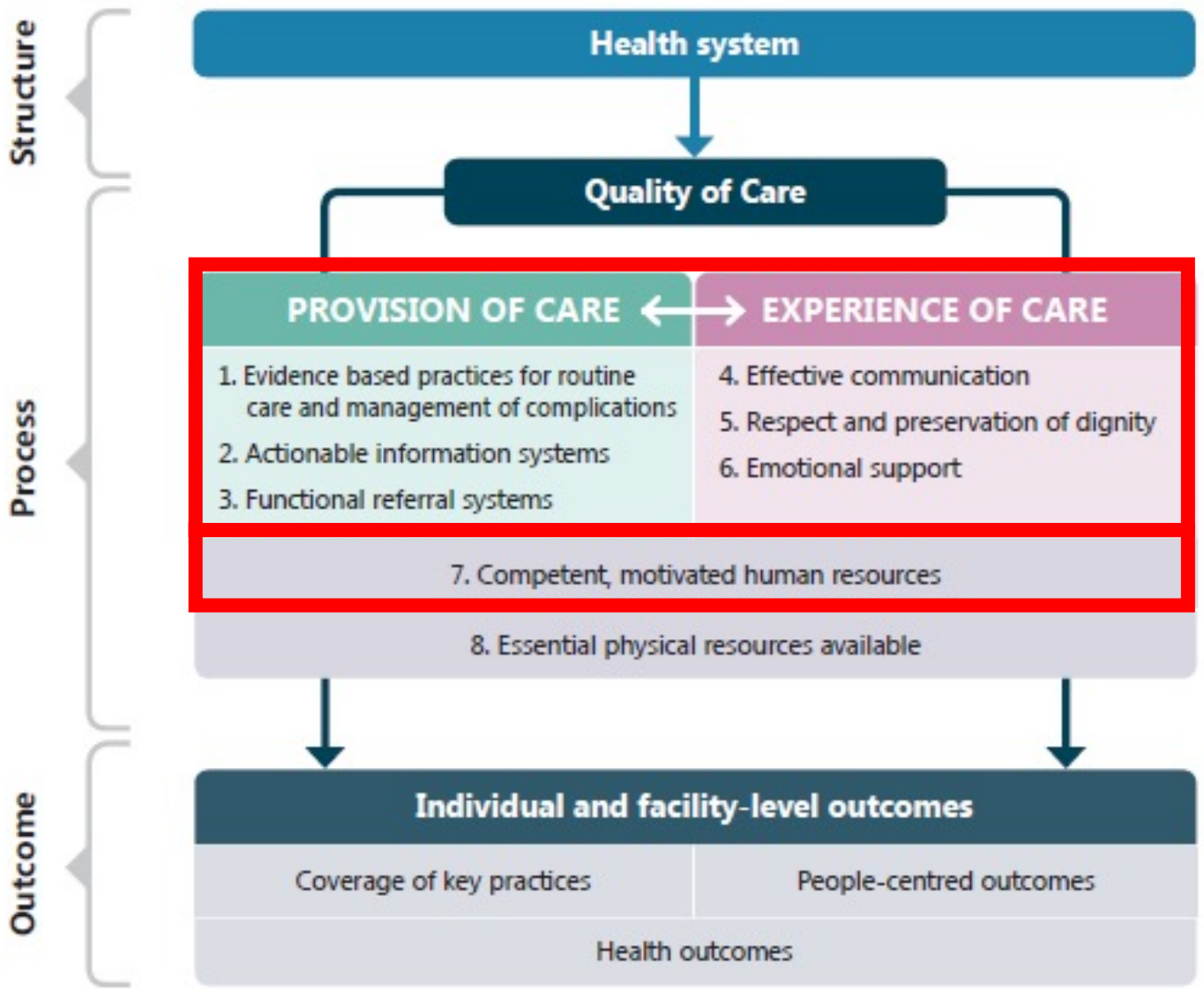
Every Newborn Action Plan strategic objectives



 Adapted from Every Newborn Action Plan, Mason E et al. Lancet, 2014

Focus on provision of quality care



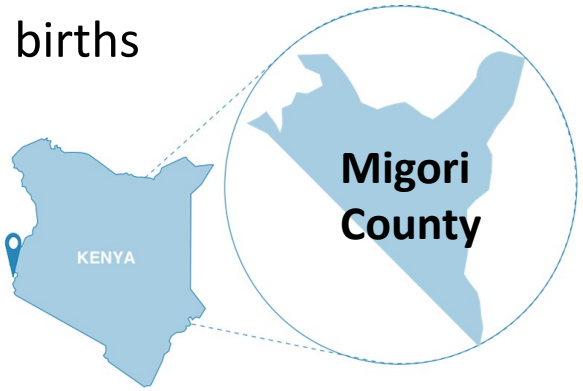
 Framework for the quality of maternal and newborn health care (WHO 2015)

Intervention theory of change

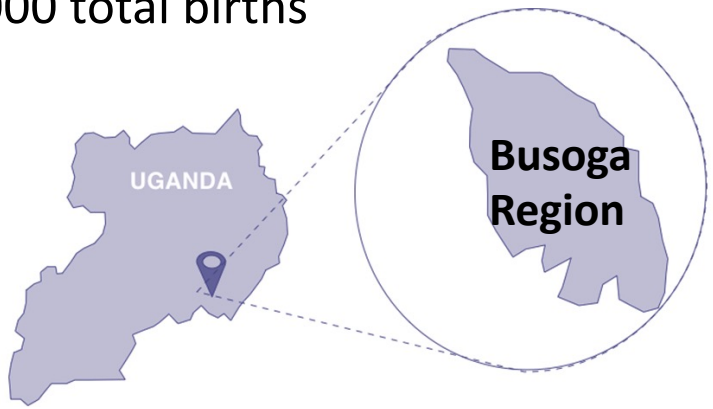
Pair-matched cluster-randomized controlled trial

- 20 public sector facilities
  - 16 Migori County
  - 4 Busoga region
- Interventions delivered at the facility level
- Focus on quality of care around the time of birth

- **NMR** 22/1000 live births
- **Stillbirth rate** 22/1000 total births
- **PTB rate** 8.6-12%



- **NMR** 27/1000 live births
- **Stillbirth rate** 21/1000 total births
- **PTB rate** 6.6-14%



Every Preemie Scale country profiles, updated May 2019.

All facilities received data strengthening and the modified Safe Childbirth Checklist

Data strengthening

Modified Safe Childbirth Checklist

Quality improvement collaborative

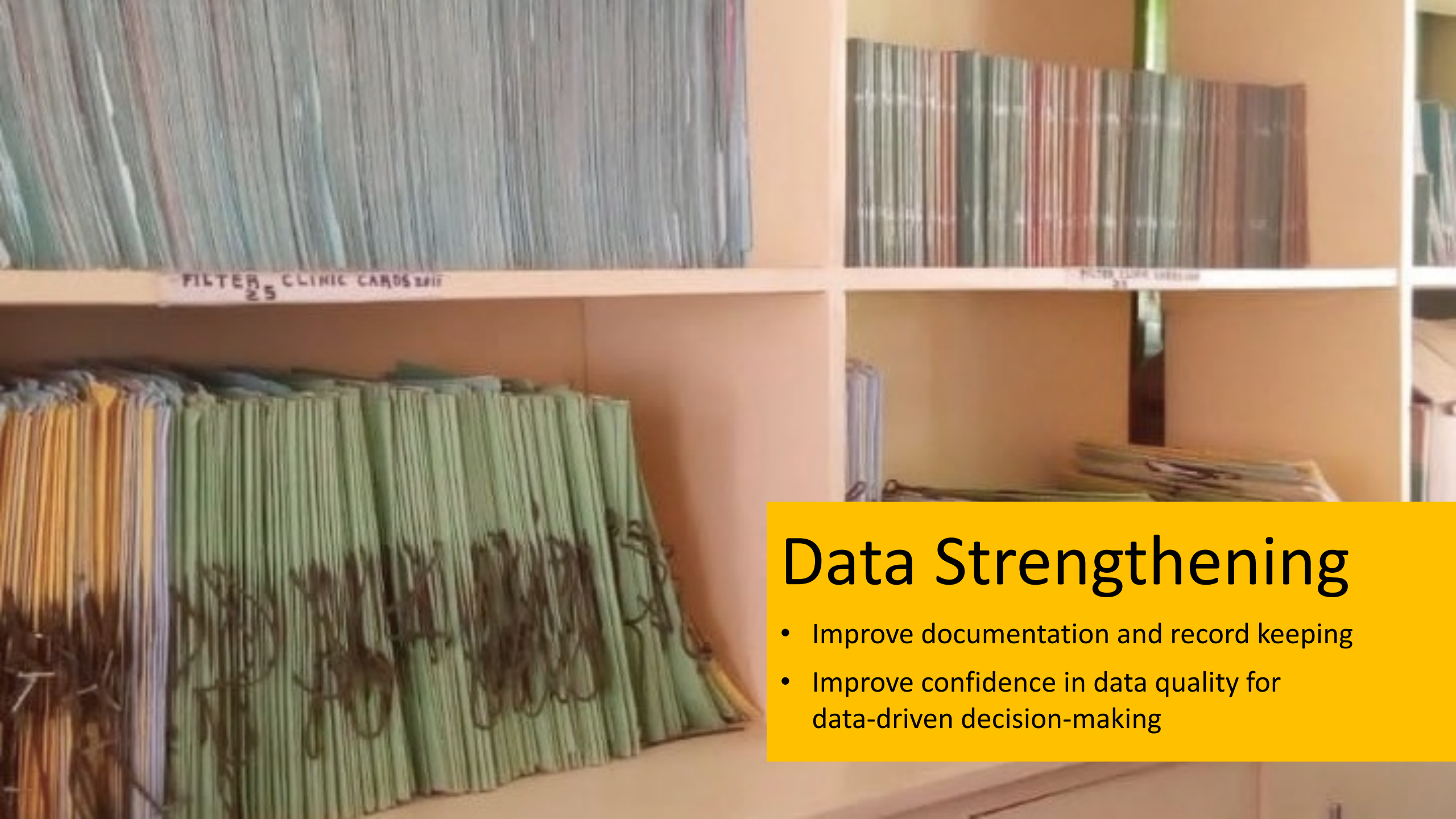
PRONTO simulation & team training

Intervention facilities received Quality Improvement Collaboratives and PRONTO

- Data strengthening
- Modified Safe Childbirth Checklist
- Quality improvement collaborative
- PRONTO simulation & team training

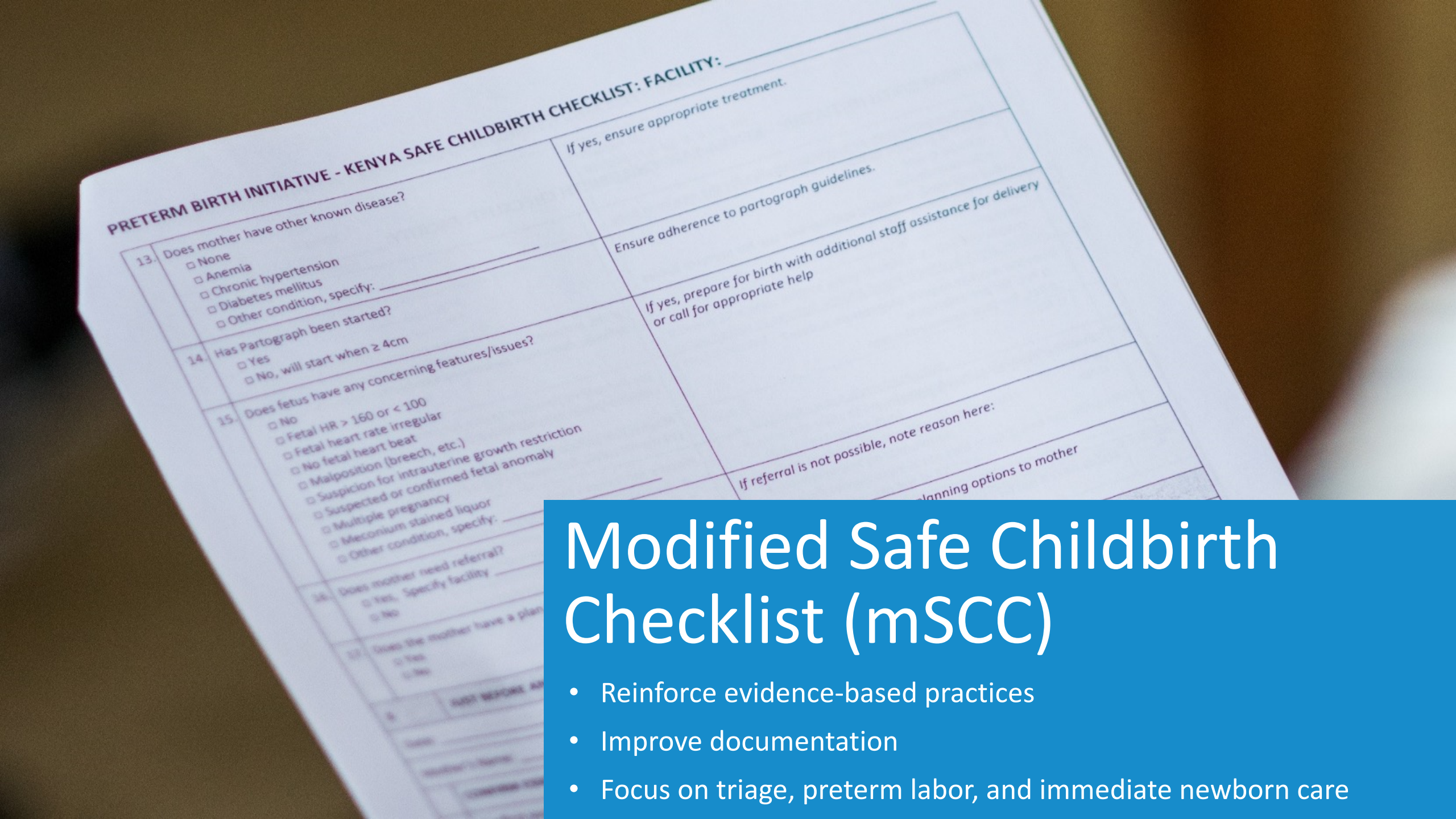
Hypothesis

Our full intervention package will **reduce the odds of combined fresh stillbirth and neonatal mortality by 30% among eligible infants** in the intervention group compared with the control group.



Data Strengthening

- Improve documentation and record keeping
- Improve confidence in data quality for data-driven decision-making



Modified Safe Childbirth Checklist (mSCC)

- Reinforce evidence-based practices
- Improve documentation
- Focus on triage, preterm labor, and immediate newborn care

Quality Improvement Collaboratives

- Improve documentation of key indicators
- Increase identification of bottlenecks and problem-solving through data use

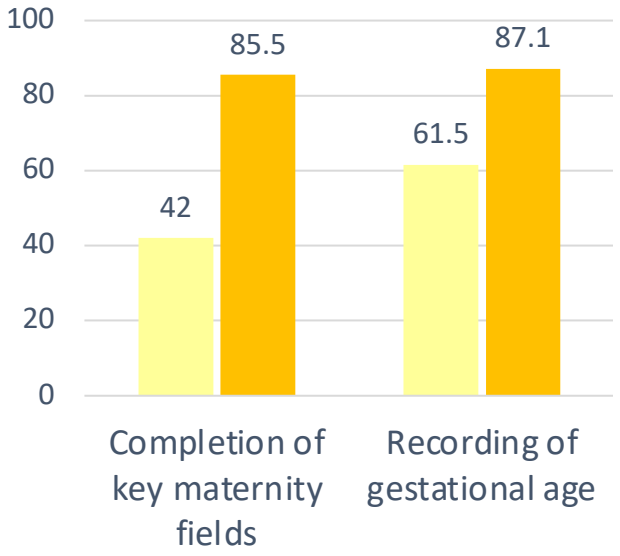
Intervention sites only

PRONTO Simulation and Team Training

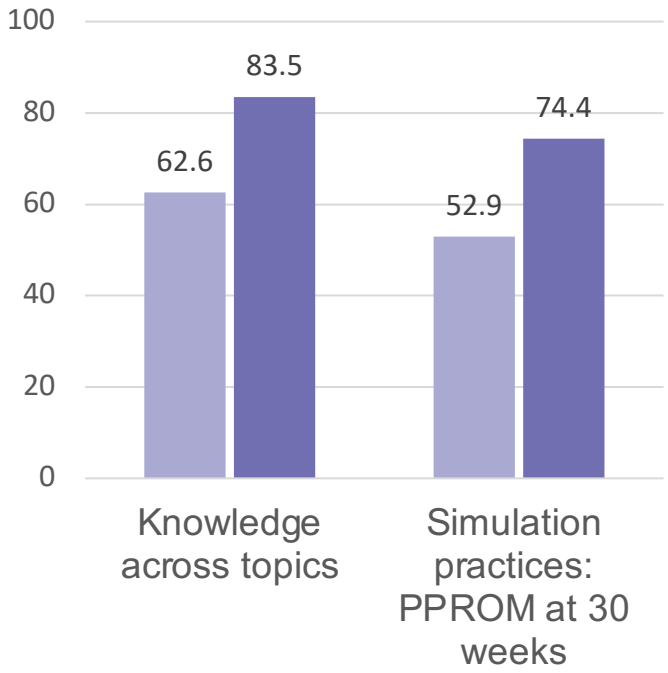
- Safe space to practice life-saving skills in real-life settings
- Improve teamwork and communication

Intervention sites only

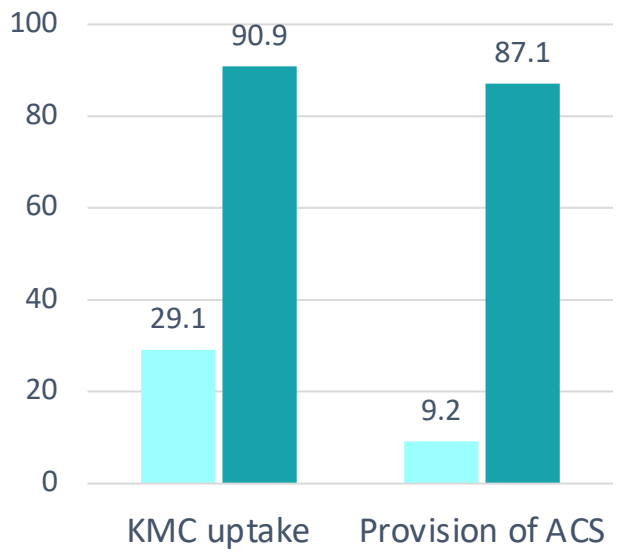
Process data show gains in data quality and provider capacity between baseline and endline



Data strengthening: quality and use



PRONTO: knowledge and awareness

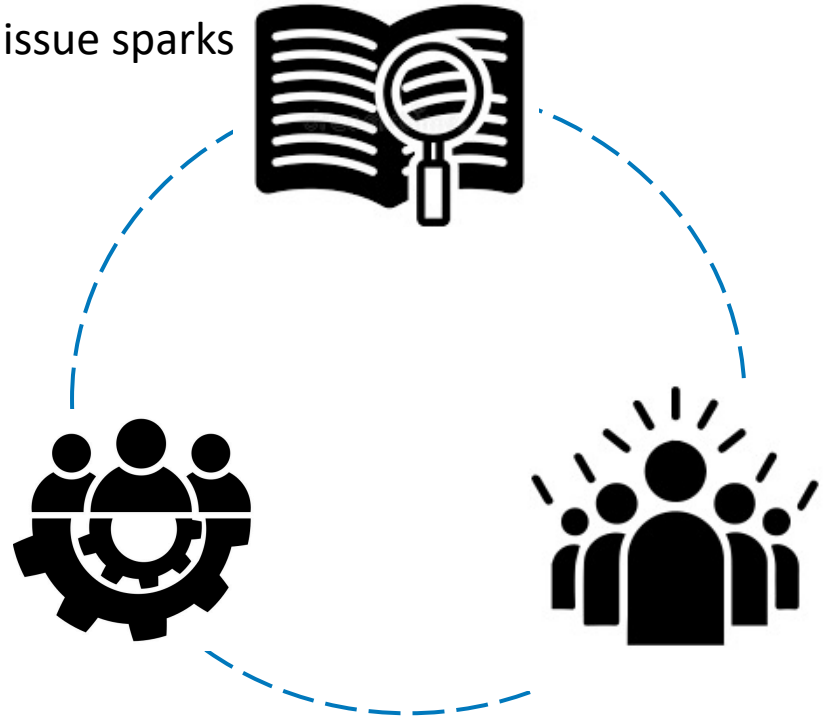


QI: evidence-based practices

Critical factors that facilitated implementation

Visibility: Defining an issue sparks change

Teamwork: Powering supportive communities



Engagement: Leveraging local leadership to ensure local ownership

Interplay helped create an environment where opportunity, motivation and technical knowledge and skills coalesced to improve outcomes

Results

Primary outcome

Combined fresh stillbirth and neonatal mortality among eligible infants

Eligibility criteria

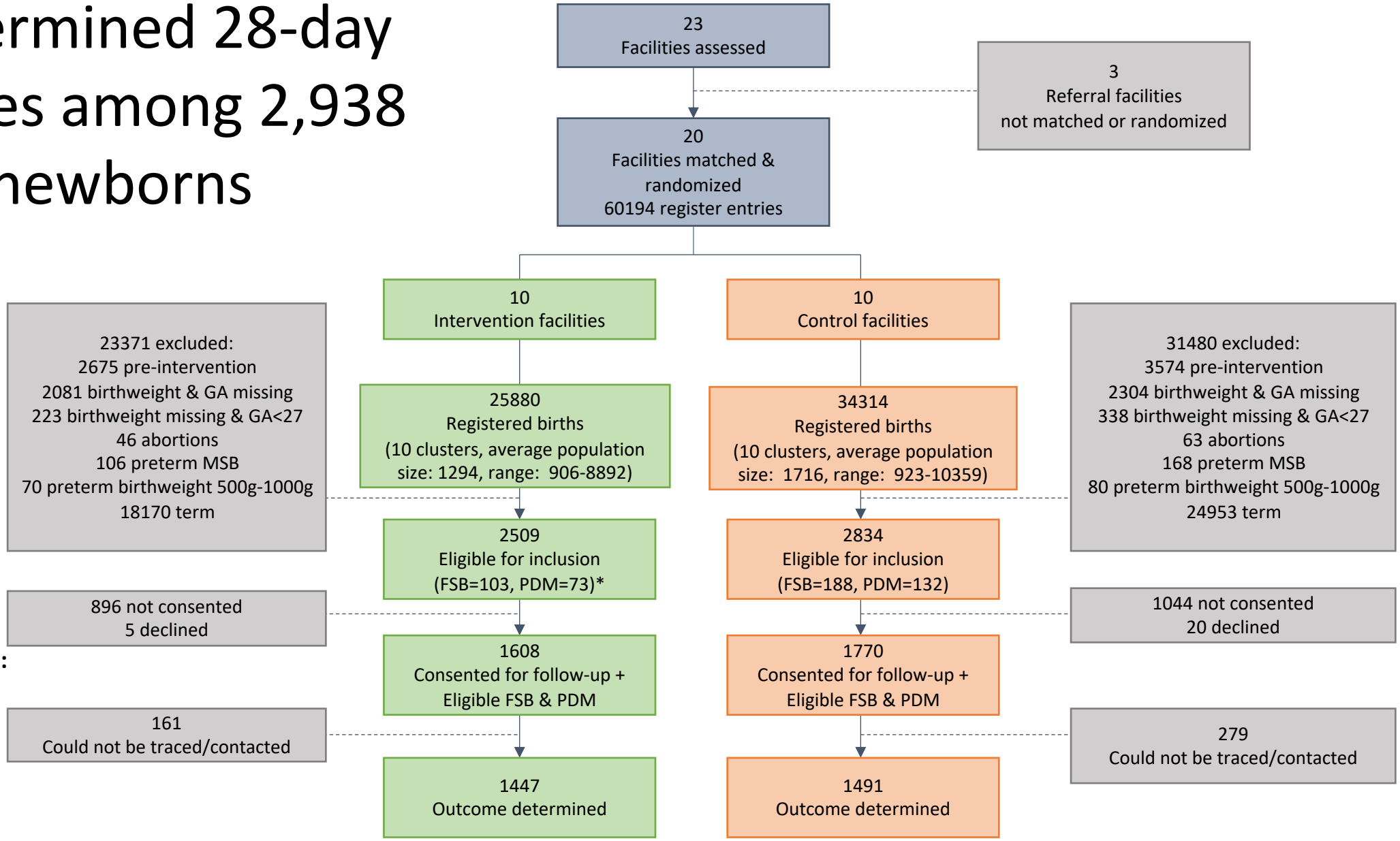
Fresh stillbirths and live births:

- Birth weight 1000-2500g or
- <3000g with a recorded gestational age <37 weeks

Analysis

Intention to treat logistic regression adjusted for pairing and cluster using robust standard error estimates

We determined 28-day outcomes among 2,938 eligible newborns



Exclusions: all full term, MSB, weight <1000g

Average consent rate: 63%

Average LTFU rate: 13%

Facility characteristics were similar at matching

	Control N=10 facilities	Intervention N=10 facilities	p-value
Monthly delivery volume, mean (SD)	93 (82)	75 (51)	0.57
Deliveries to staff ratio, mean (SD)	63 (28)	52 (25)	0.39
Stillbirth proportion, median % (IQR)	1 (0.3-4)	2 (1-4)	0.38
LBW proportion, median % (IQR)	4 (3-7)	6 (2-6)	0.97
Pre-discharge newborn mortality, median % (IQR)	0 (0-1)	0.5 (0-1)	0.83

Maternal and infant characteristics across study arms

	Control			Intervention		
Maternal characteristics	n	N	%	n	N	%
Maternal age <18 years	155	1385	**11.2**	200	1288	**15.5**
18-35 years	1157	1385	**83.5**	1033	1288	**80.2**
>35years	73	1385	**5.3**	55	1288	**4.3**
Multiple gestation	382	1770	**21.6**	313	1608	**19.5**
Infant characteristics						
Low birthweight	1343	1770	**75.9**	1187	1608	**73.8**
Gestational age <37 weeks	1182	1725	**68.5**	1098	1577	**69.6**
Sex, male	840	1755	**47.9**	758	1603	**47.3**

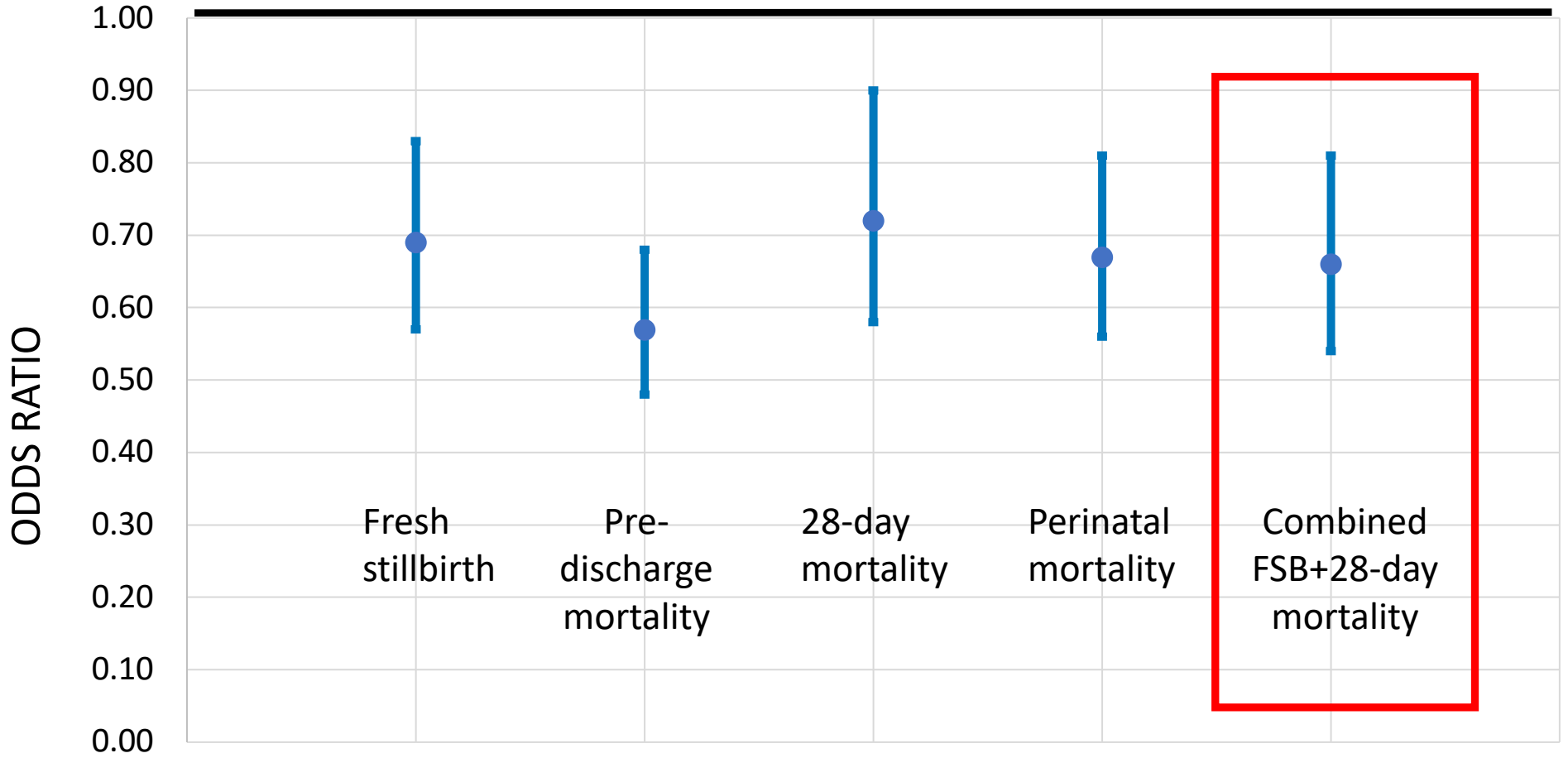
n=numerator for the specific category
N=total number of non-missing observations

Our full intervention package **reduced the odds** of combined fresh stillbirth and neonatal mortality among eligible infants **by 34%** compared with the control group.

Primary outcome	Control	Intervention	Odds Ratio	CI	Adjusted p-value
Combined FSB and 28-day mortality among eligible infants	23.3%	15.3%	0.66	0.54-0.81	<0.0001

- Data adjusted for pairing and cluster.
- Further adjustments for C-section, infant sex, multiplicity, country, birthweight delivery volume and facility readiness were conducted but did not change the estimate substantially.

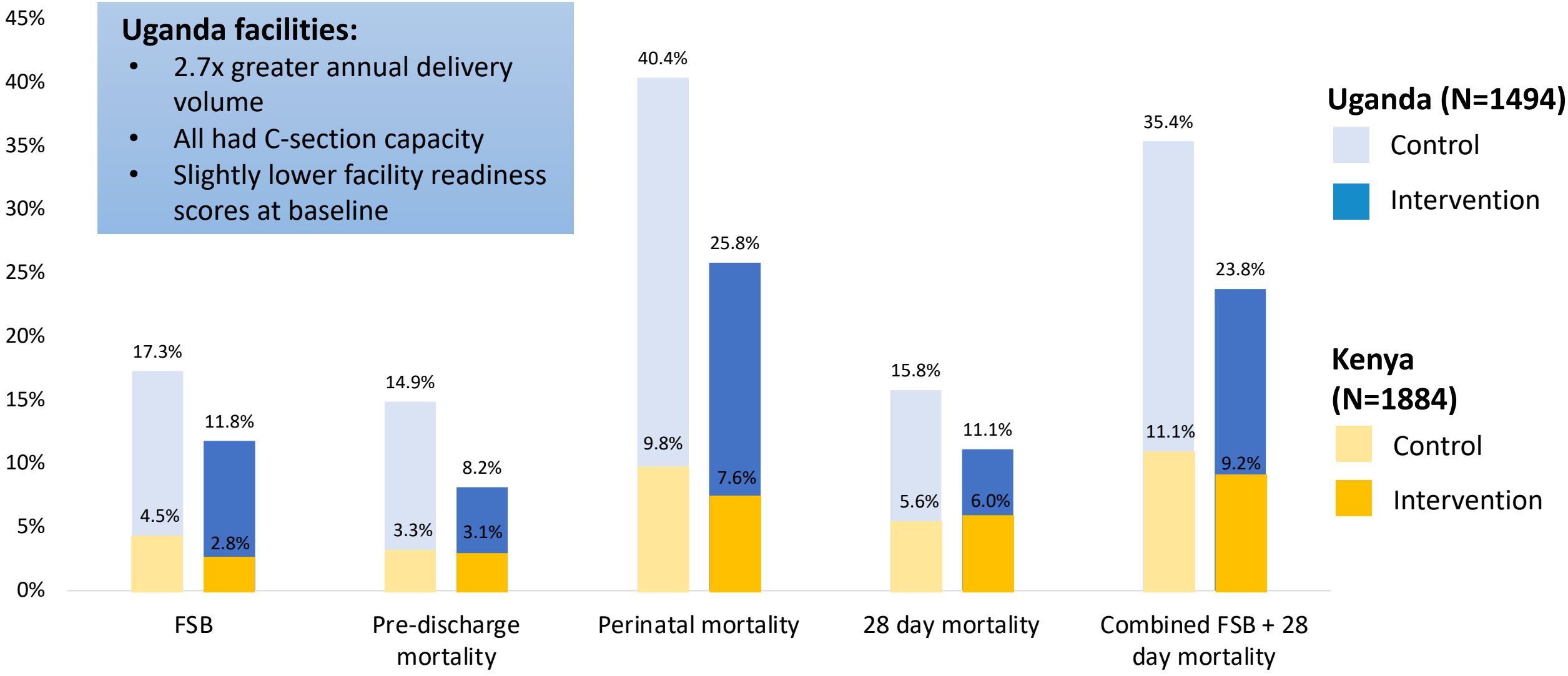
Reduced mortality odds is significant across all outcomes



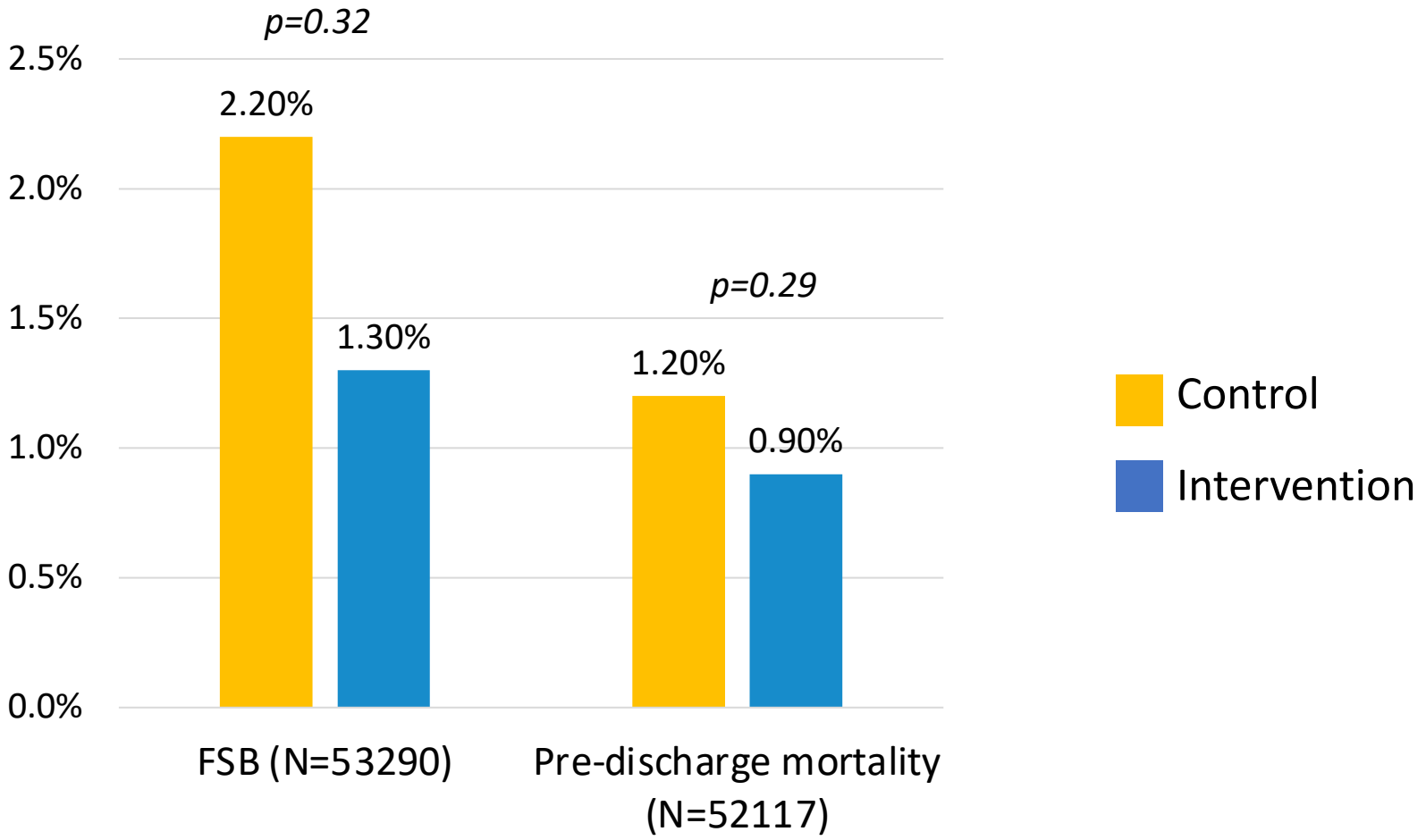
Trends were consistent by country

Uganda facilities:

- 2.7x greater annual delivery volume
- All had C-section capacity
- Slightly lower facility readiness scores at baseline



All births benefitted from exposure to the package



Our intrapartum package showed benefit, but some study limitations exist

Gestational age limitations

Referrals before delivery excluded

Potential selection bias

Health worker strike

Robust cluster-adjusted analyses were able to detect significant effects on the primary and secondary outcomes.

At what cost?

Cost analysis: General design and approach

Cost PTBi package as delivered in PTBi Study

Total costs – research costs = program delivery costs

Cost PTBi package if delivered through public sector

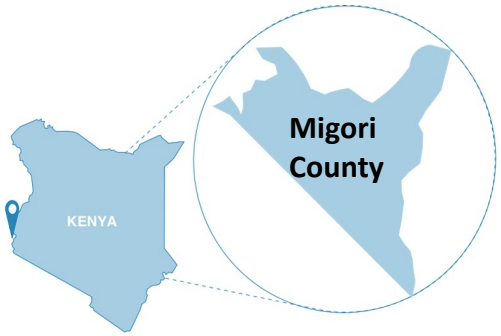
- Hypothetical “Ministry of Health” scenario
- Bottom-up, activity-based micro-costing
- Development of “living” costing tool
  - Study ledgers
  - Team Interviews
  - MoH guidance and list prices

Easter Olwanda
KEMRI

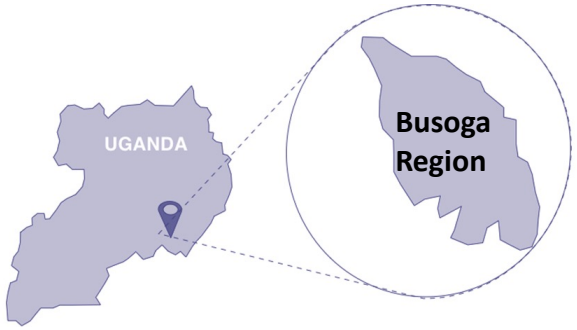
Juliana Namutundu
Makerere University

Carolyn Smith Hughes
UCSF

Total program costs for first 3 years of implementation



- **$767,025 all phases**
- **$45,120 per facility**
  - Higher salaries
- **$21.36 per birth**
  - Fewer births
  - 17 facilities

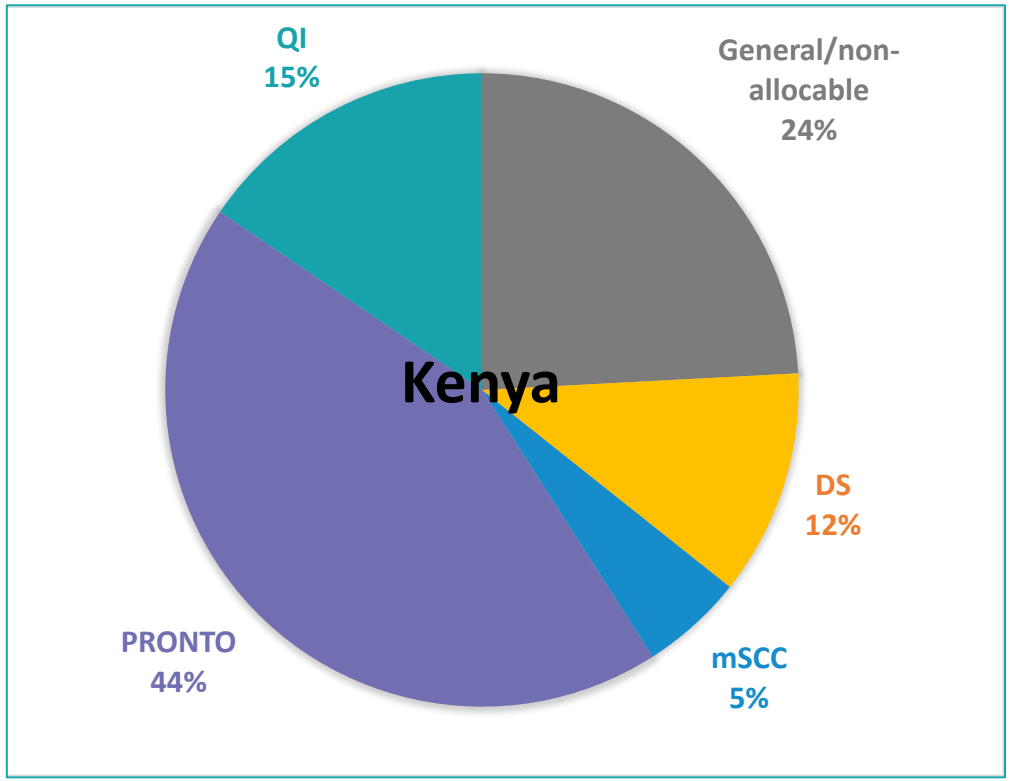


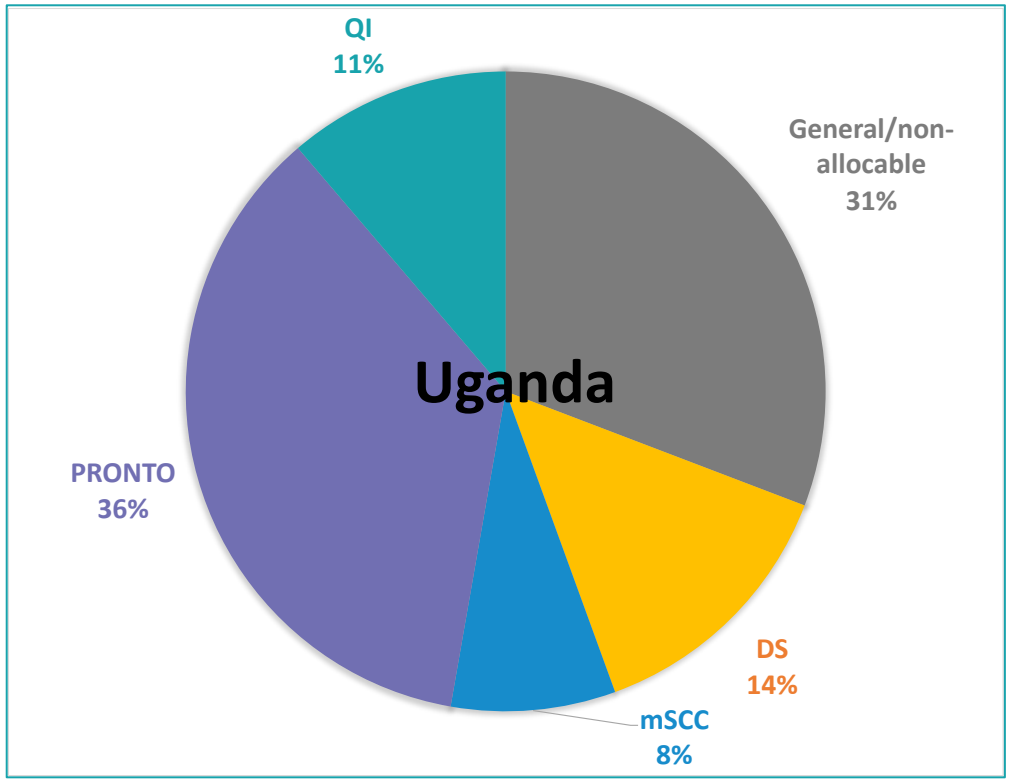
- **$184,062 all phases**
- **$30,677 per facility**
  - Lower salaries
- **$3.77 per birth**
  - Higher volume
  - 6 facilities

Costs driven primarily by personnel, salaries and facility volume

For context, average cost per facility-based birth (2011 IHME data): $106 (KE), $75 (UG)

Distribution of costs by intervention component similar across settings



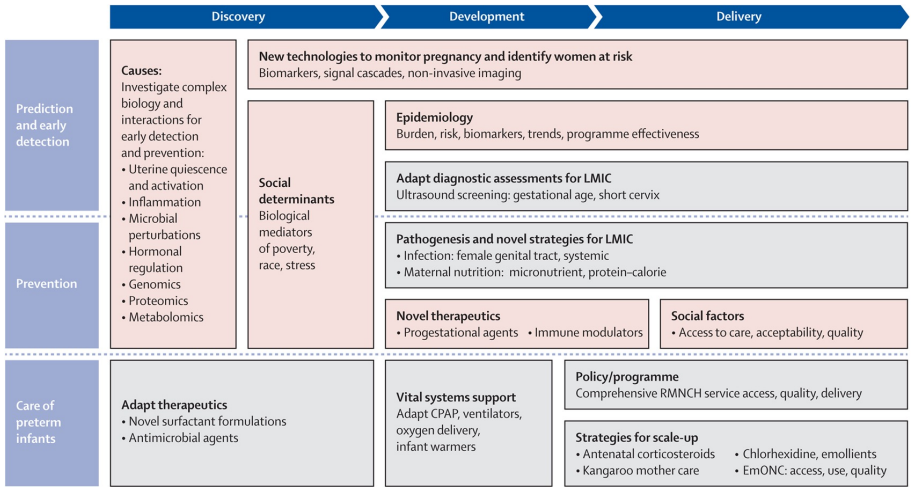


Kenya & Uganda intrapartum package | Summary

- Intervention package was effective in reducing intrapartum stillbirths and neonatal death among preterm infants
- Cost-effectiveness work ongoing
- Package could be adapted to other priority issues, such as stillbirth, preeclampsia, Cesarean section, etc.

PTBi took a multi-faceted approach to address preterm birth through the Solutions Pathway

- **Discovery:** investment in local priorities and researchers can lead to optimal interventions and continued impact
- **Development:** contextualization and adaptation of interventions can reveal new insights on factors important for impact
- **Delivery:** complex problems like preterm birth require integrated solutions to improve outcomes



Lackritz et al. Lancet Glob Health. 2013 Dec;1(6):e328-30.

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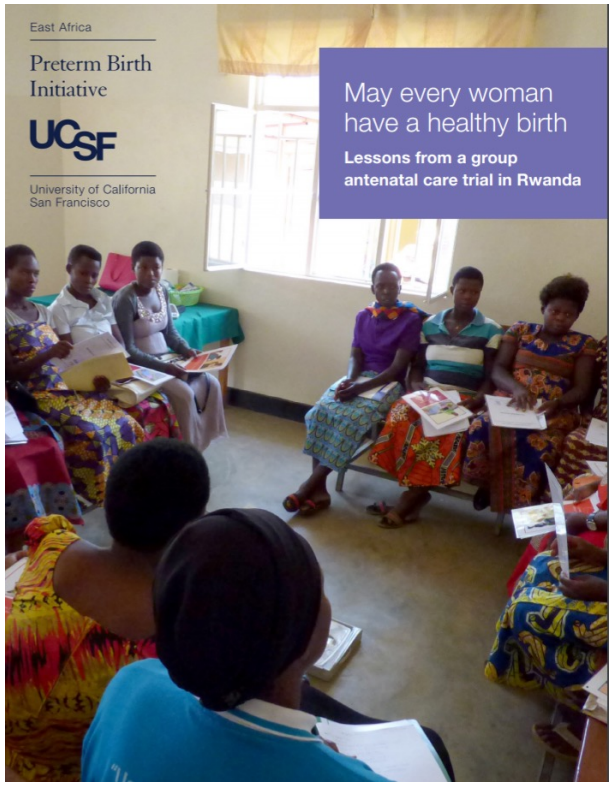

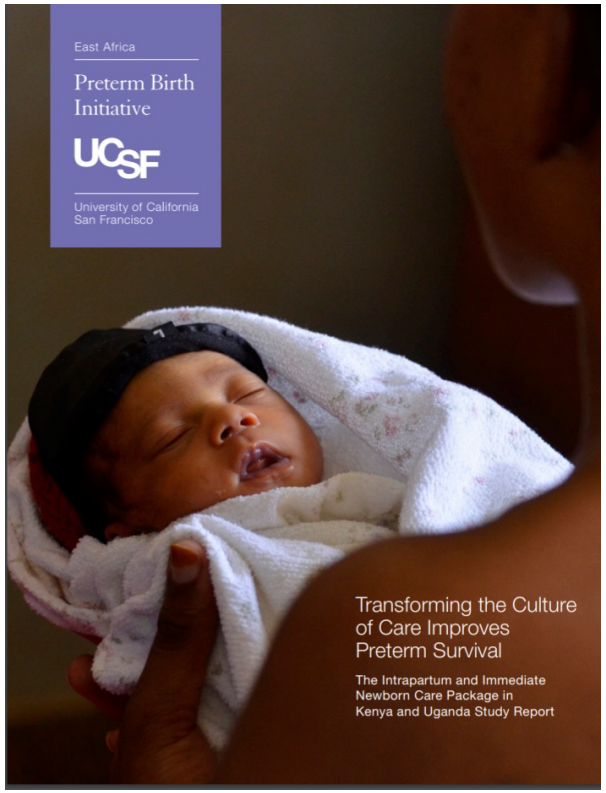

CLOSING REMARKS: How has the Preterm Birth Initiative influenced your work moving forward?

Acknowledgements

- Bill & Melinda Gates Foundation
- PTBi East Africa Strategic Advisory Board
- Ministries of Health
- Facility administrators and leadership
- Research teams