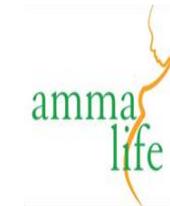




EMOTIVE: Implementation Project PPH Bundle to Enhance Guideline Adherence and Improve Maternal Outcomes

PPH COP
July 2020

Prof. Suellen Miller, CNM, PhD
University of California, San Francisco



Background: WHO PPH Bundle Development

- 2016 Lancet Maternal Health Series: Why, despite technology, interventions, increased facility births, published guidelines, were too many women still dying from pregnancy and birth?
- TLTL/TMTS:
 - Lack of dignity and respect in childbirth
 - Lack of early recognition and early action for complications, delays
 - Lack of adherence to evidence-based care promulgated in guidelines

THE LANCET

September 15, 2016
Maternal Health
An Executive Summary for The Lancet's Series



"Every woman, every newborn, everywhere
has the right to good quality care."

Maternal Health 2

Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity

care worldwide, Suellen Miller, Edgardo Abalos, Monica Chamillard, Agustin Ciapponi, Daniela Colaci, Daniel Comandé, Virginia Diaz, Stacie Geller,

Claudia Hanson, Ana Langer, Victoria Manuelli, Kathryn Millar, Imran Morhason-Bello, Cynthia Pileggi Castro, Vicky Nogueira Pileggi,

Nuriya Robinson, Michelle Skaer, João Paulo Souza, Joshua P Vogel, Fernando Althabe, Lancet, September 15, 2016

[http://dx.doi.org/10.1016/S0140-6736\(16\)31472-6](http://dx.doi.org/10.1016/S0140-6736(16)31472-6)

2018, WHO & BMGF Asked:



BILL & MELINDA
GATES *foundation*

- Question: Would a PPH Bundle comprised of evidence-based technologies and strategies improve guideline adherence and improve outcomes?
- Question: What interventions would be included in a PPH Bundle?
- BMGF/WHO/UCSF/MGH/ICES: a Delphi consultation on PPH interventions for PPH Bundles

What is a Clinical Care Bundle?

- Institute for Healthcare Improvement (IHI) Definition:
 - *Small set of evidence-based interventions for a defined patient population and care setting that, when implemented together, results in significantly better outcomes than when implemented individually*
- “Bundling” care improves **quality of care** and **efficiency of care delivery**
- **Emphasis on clinical activities, but also**
 - **Teamwork**
 - **Communication**
 - **Cooperation**

Resar R, Griffin Fa, et al. Using Care Bundles to Improve Health Care Quality. IHI Innovation Series white paper. Cambridge, MA IHI, 2012.

2018 WHO Technical Consultation on PPH Bundles

- Primary Response PPH Bundle
 - IV Fluids
 - Massage Uterus
 - Uterotonic Medication
 - TXA (if < 3 h post delivery)

Received: 5 May 2019 | Revised: 14 September 2019 | Accepted: 8 November 2019
DOI: 10.1002/ijgo.13028

CLINICAL ARTICLE
Obstetrics

WILEY



Postpartum hemorrhage care bundles to improve adherence to guidelines: A WHO technical consultation^{1†}

Fernando Althabe^{1,2} | Michelle N.S. Themien^{3,4} | Veronica Pingray^{1,5} | Jorge Hermida³ | Ahmet M. Gülmezoglu² | Deborah Ambruster⁶ | Neelima Singh⁷ | Moytrayee Guha⁸ | Lorraine F. Garg⁹ | Joao P. Souza^{2,9} | Jeffrey M. Smith¹⁰ | Beverly Winikoff¹¹ | Kusum Thapa¹² | Emmanuelle Hébert¹³ | Jerker Liljestrand^{1,4} | Soo Downe¹³ | Ezequiel Garcia Elomio¹⁴ | Sabaratnam Arulkumaran¹⁷ | Emmanuel K. Byaruhanga¹⁸ | David M. Lissauer¹⁹ | Monica Ogutu²⁰ | Alexandre Dumont²¹ | Maria F. Escobar²² | Carlos Fuchtnr²³ | Pisake Lumbiganon²⁴ | Thomas F. Burke^{5,23,‡} | Suellen Miller^{1,26,‡}

- If the above, with two doses of Uterotonic and TXA did not arrest bleeding, move on (Escalate) to a REFRACTORY BUNDLE

2019 BMGF RFP for PPH Bundle Implementation Project

- Response was the collaboration that became the E-motive Project
- Designed to address challenges to implementation and adherence to evidence based PPH guidelines by using a bundle approach

UNIVERSITY OF
BIRMINGHAM



UCSF School of Medicine



UNIVERSITY OF
LIVERPOOL



Challenges & Solutions of Implementing PPH guidelines



Challenge

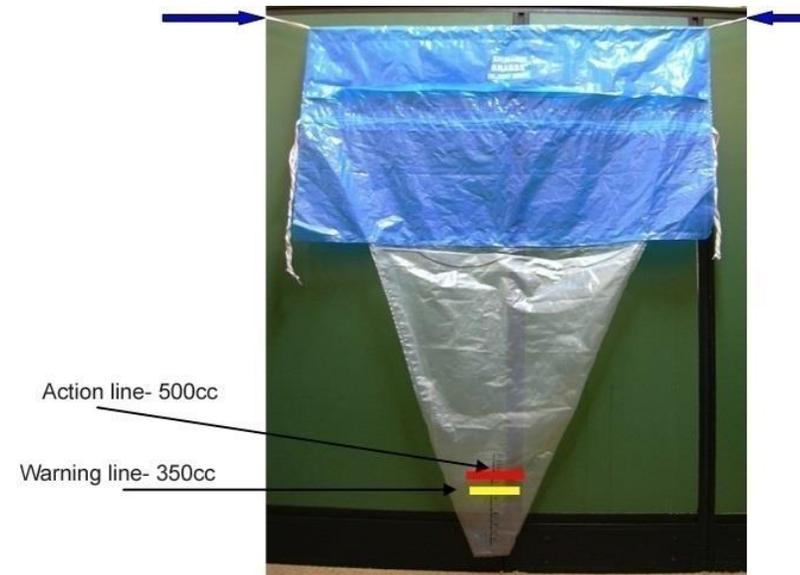
#1

- Delays detecting PPH
- Life-saving treatment is not promptly initiated



Solution

Early detection and treatment of PPH



Challenges of implementing the PPH guideline and solutions

(contd.)

Challenge #2



- Delayed or inconsistent use of interventions for PPH management

- Late, delayed, or non-use of tranexamic acid (TXA)
- Inconsistent application of uterine massage and IV fluids

Solution

The Bundle

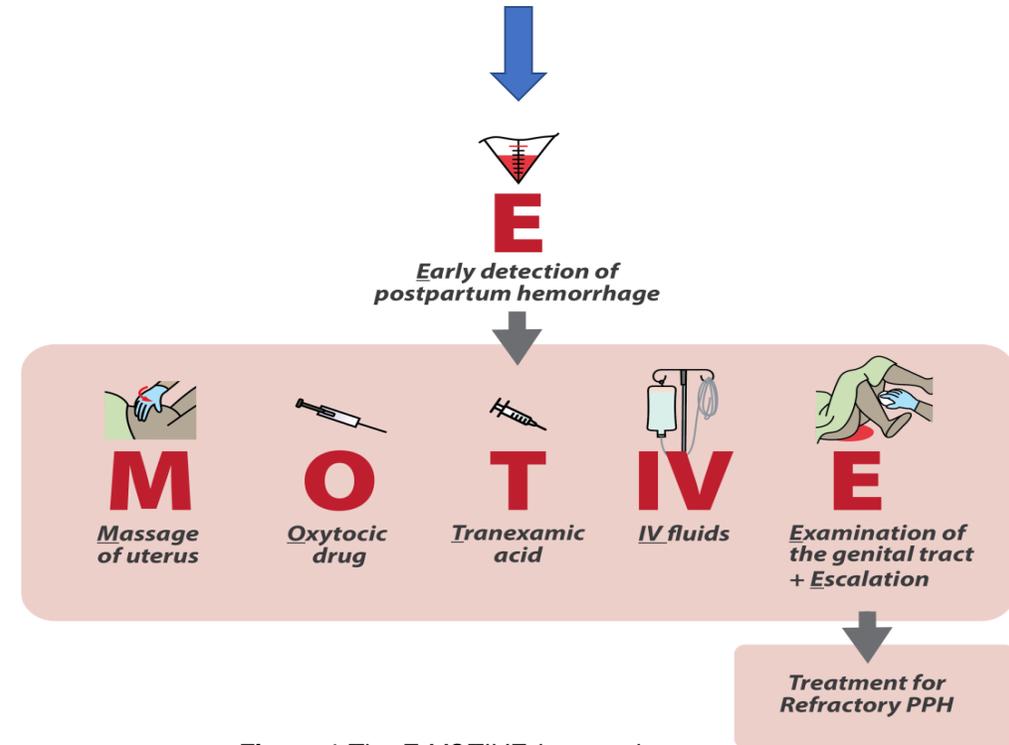


Figure 1 The E-MOTIVE intervention

Challenges of implementing the PPH guideline and solutions

(contd.)

Challenge # 3

- Many health providers do not follow PPH guidelines



Solution

Implementation strategy targeting Capabilities, Opportunities and Motivations for Behaviour change (COM-B)

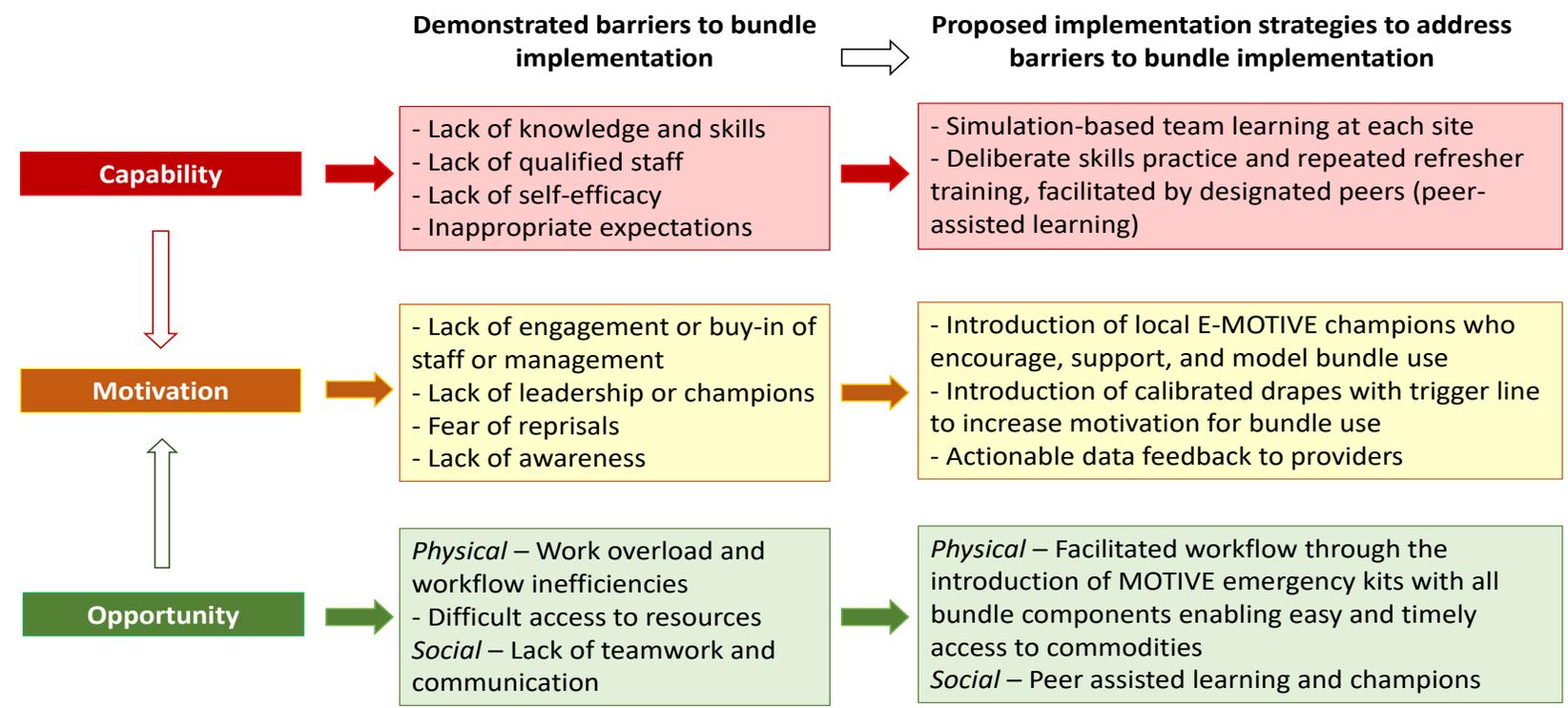
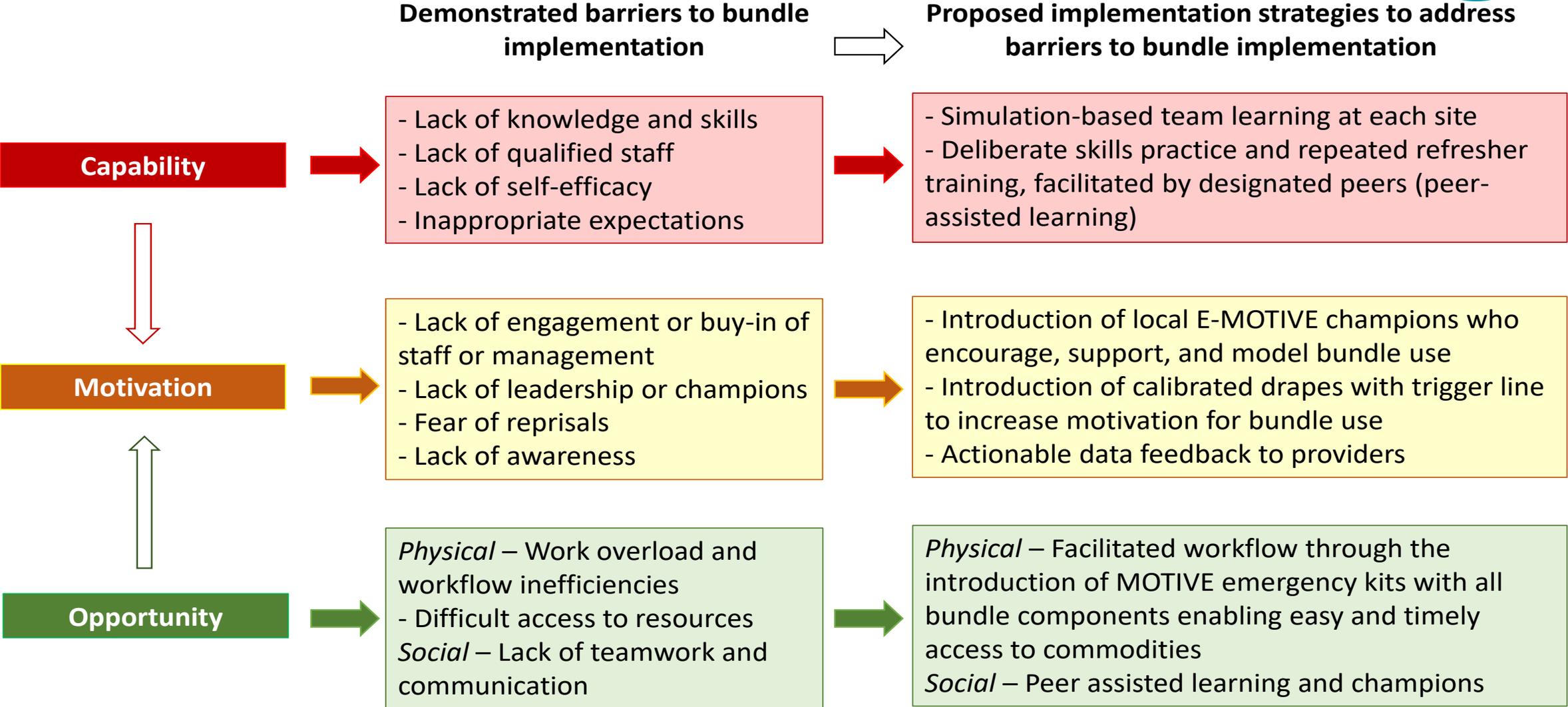


Figure 2 E-MOTIVE implementation strategy and rationale

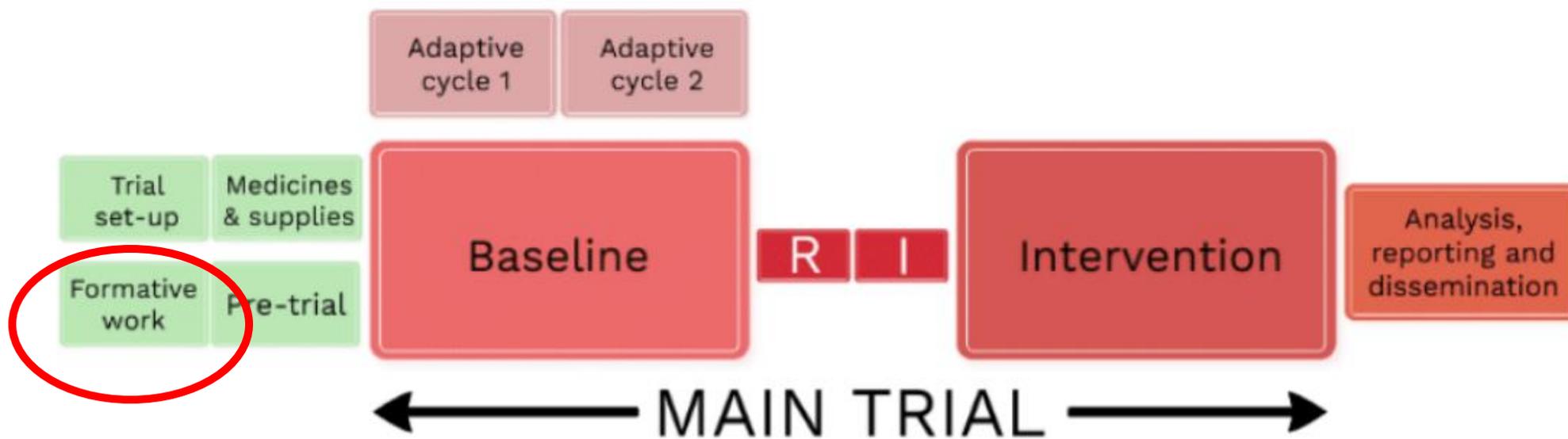
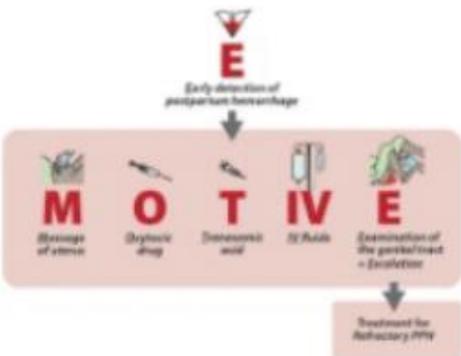
COM-B: Framework for Implementation



E-MOTIVE programme

Project outline

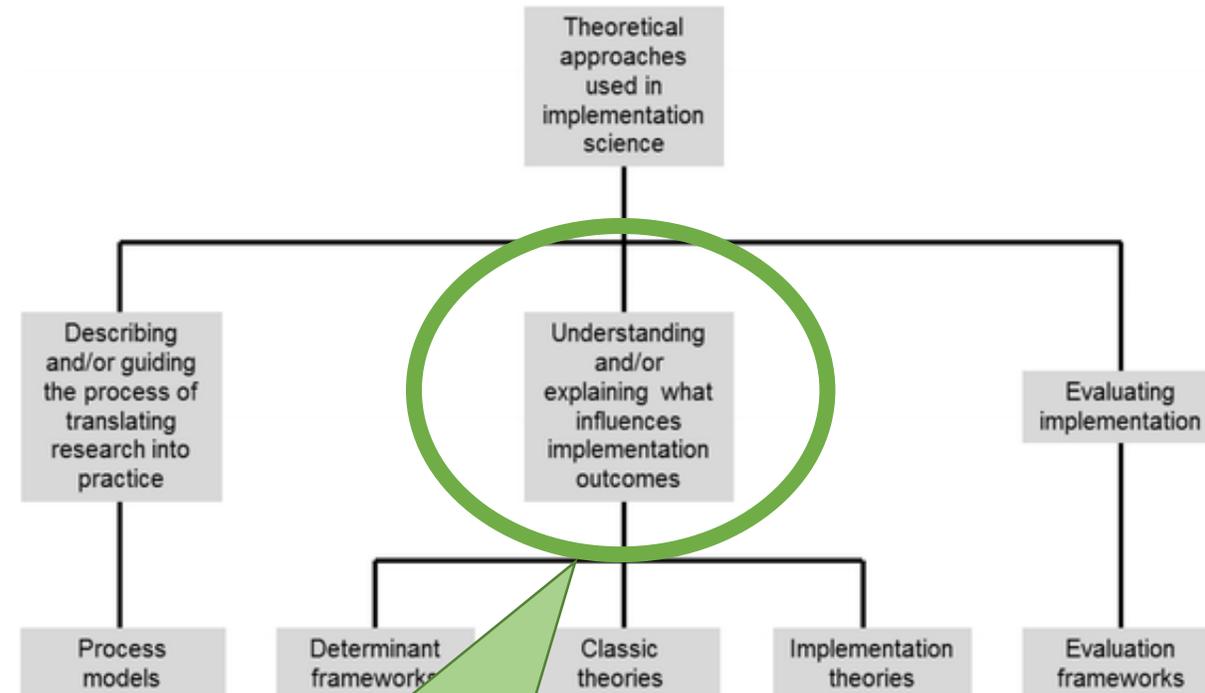
Sites:
Kenya
Tanzania
Nigeria
So. Africa
Sri Lanka



Formative research RESEARCH QUESTIONS

Research Questions:

- How is PPH currently detected and managed?
- What are the individual, socio-cultural and environmental influences on PPH detection and management?
- What are the potential barrier and enablers to implementing the E-MOTIVE care bundle?



Assess barriers and/or facilitators related to implementing the intervention

Inform development of implementation strategies/ co-interventions to overcome barriers/enablers

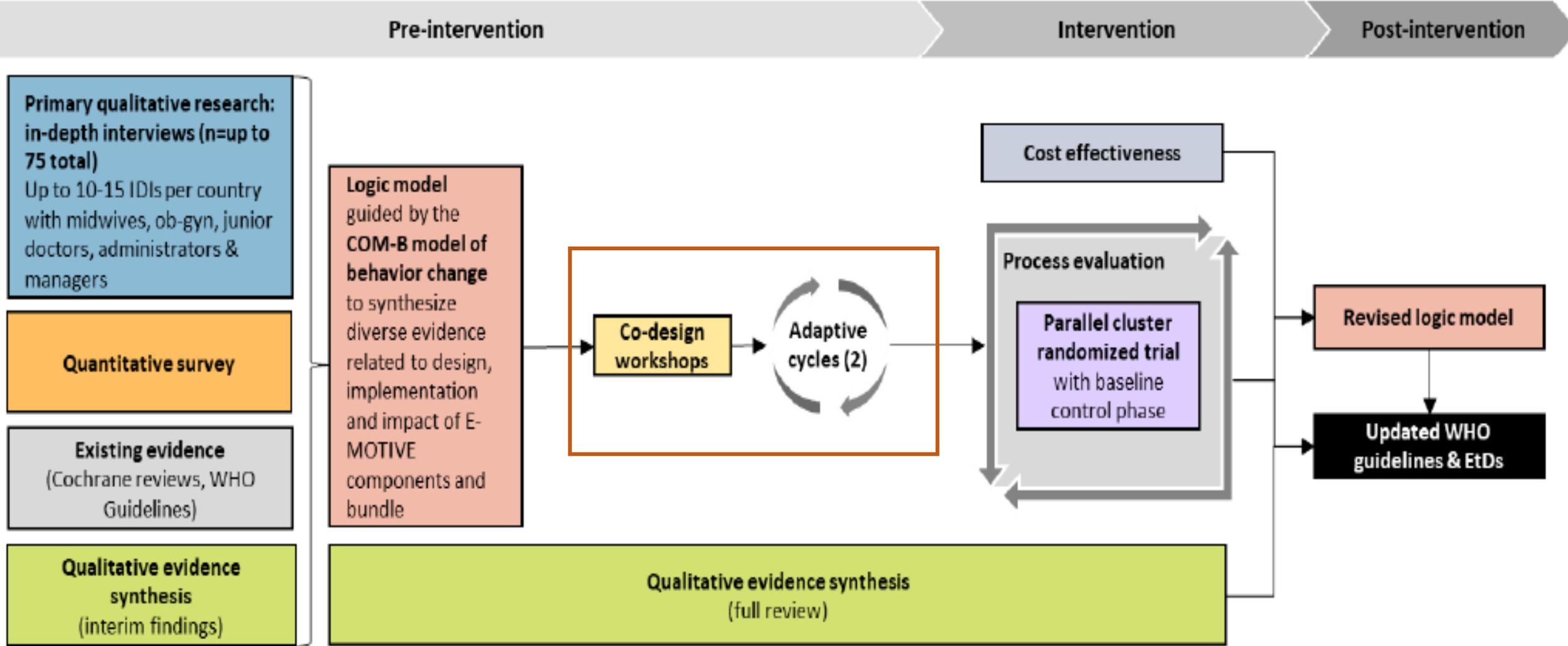


THE UNIVERSITY OF
MELBOURNE

Formative Research: Methods

- 10-15 IDIs per country with Health Care Providers on current practice, barriers/opportunities to implementation of PPH guidelines
- 800 surveys online
- Existing Evidence: systematic review of Cochrane guidelines
- QES: Qualitative Evidence Synthesis

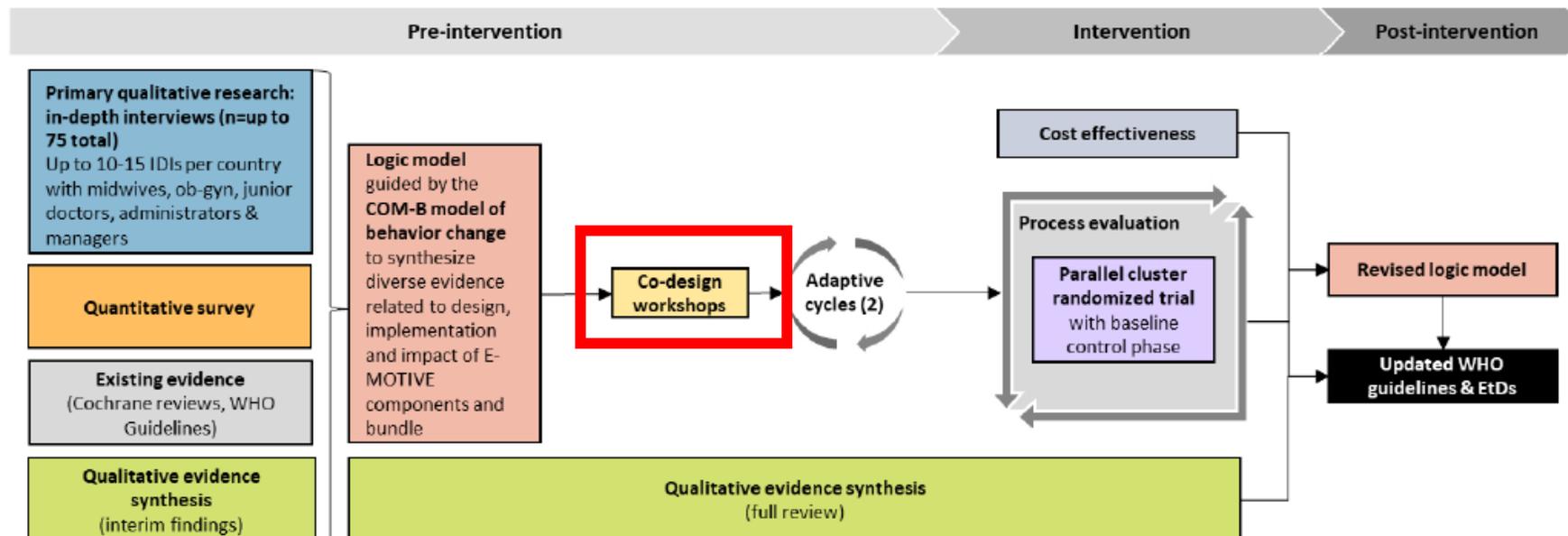
E-motive Bundle Project



Co-design Workshops

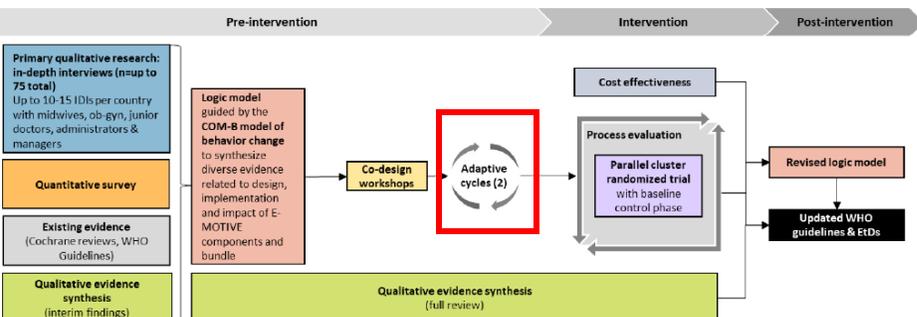
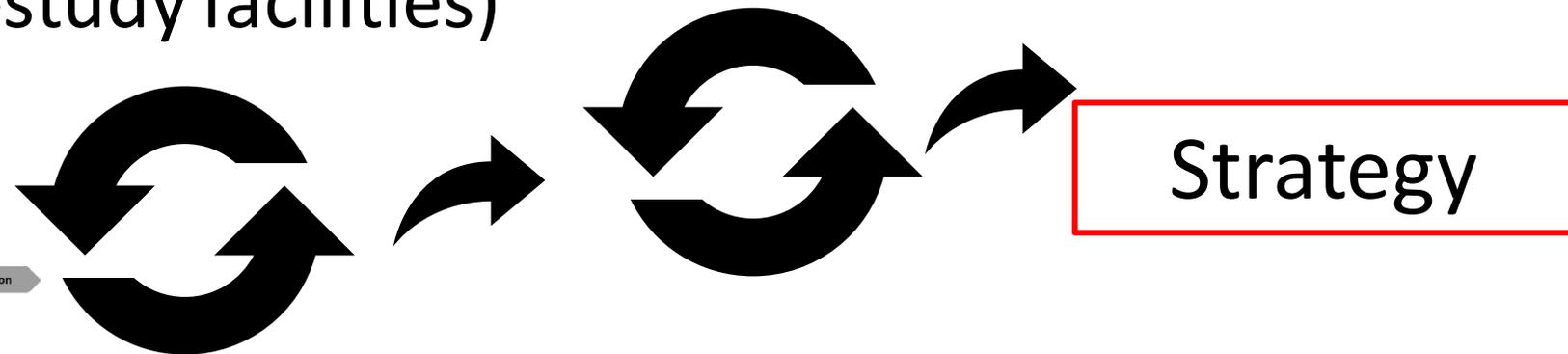
Co-design of the E-MOTIVE bundle implementation **strategy** will involve stages:

- 1) Triangulation of findings across data sources by the research team
- 2) Report back findings to country teams
- 3) Stakeholder consultation workshops to refine and adapt the implementation strategy to each country's local context



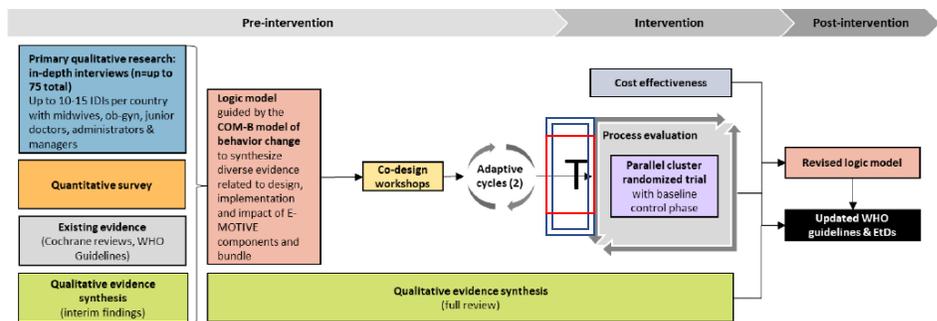
IMPLEMENTATION STRATEGY: Tested in Adaptive Cycles

- Trialing the strategy (non-study facilities)
- Obtaining feedback and outcomes
- Course Correction and adaptation
- Repeat cycle (non-study facilities)
- Finalize strategy

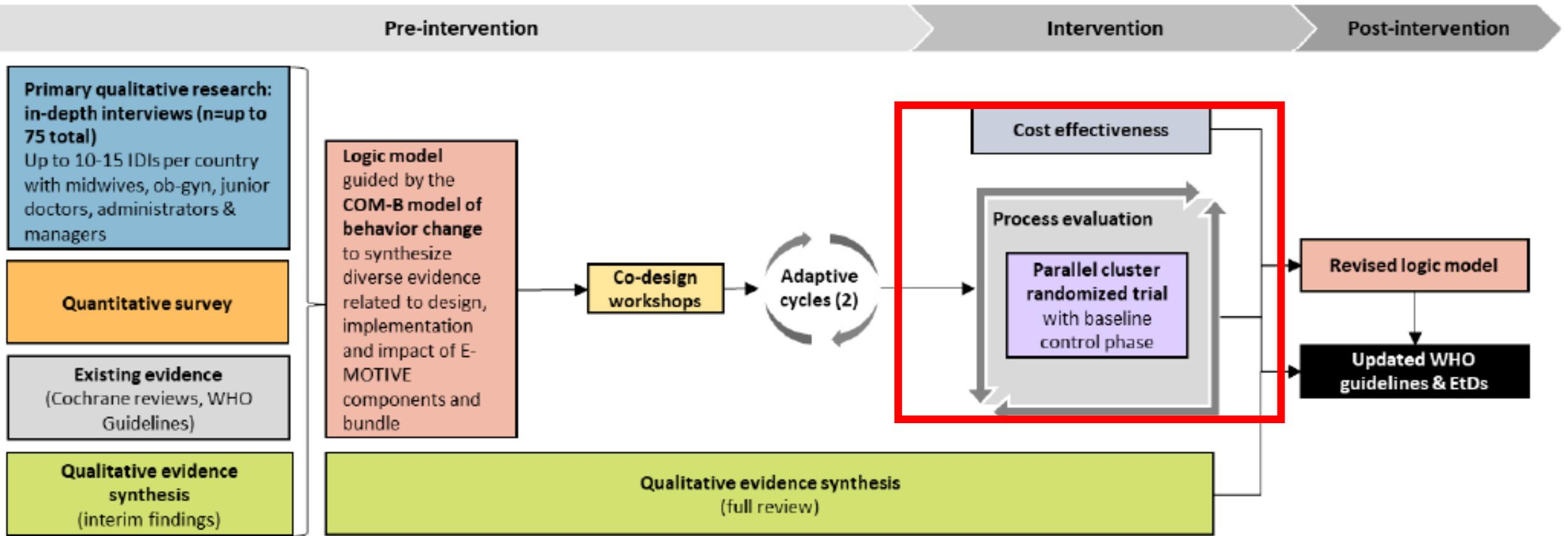


Training: Bleeding After Birth Training Package Adapted for EMOTIVE Bundle

Helping Mothers Survive **Bleeding after Birth Complete** Provider Guide



The E-MOTIVE Intervention Parallel Cluster Randomized Trial



Bundle Trial: Randomized Cluster Trial (PICO)

- Multi-country, parallel cluster randomised trial with a baseline control phase, along with mixed-methods and health economic evaluations
- **Population**
 - **Cluster:** Health facility (1,000-4,000 births a year, 2% incidence PPH, can provide comprehensive obstetric care with ability to perform surgery).
 - **Research participants:** All healthcare providers attending vaginal births in the clusters.
- **Interventions** 1) Strategy for early detection of PPH, which allows triggering of the 'first response' treatment bundle. 2) the Motive Bundle 3) Implementation strategy
- **Comparator**
 - Usual care with dissemination of the current guidelines

Outcomes

- **Primary:** Composite: severe PPH (blood loss ≥ 1000 ml) or postpartum laparotomy for bleeding or postpartum maternal death from bleeding
- **Secondary:** Implementation adherence, resource use, plus clinical outcomes, such as blood transfusion, uterine tamponade, Intensive Care Unit admissions or higher level facility transfers, and newborn deaths,

Sample Size

- 80 clusters randomized to control and intervention
- Average of 2,300 vaginal births per cluster per year
- 337,920 births over 2 years
- 2% PPH incidence
- 6800 PPH cases

This sample size gives over 90% power (at 5% significance) to detect a 25% relative reduction in the composite primary outcome from 2% to 1.5%.

Progress

- Country visits to assess health facility feasibility conducted in 6 countries
 - (Kenya, Tanzania, Nigeria, South Africa, Sri Lanka and India)
- 80 health facilities selected for trial: Secondary level Facilities delivering 1-4,000 per year and with an incidence rate of PPH 2%
 - Sri Lanka, 10, Tanzania, 14, Kenya 16, Nigeria 20, South Africa, 20
- First version of main trial protocol, formative protocol and Concept Foundation protocol finalised
- Full ethical approval granted by the sponsor (University of Birmingham), University of Melbourne, and Nigeria

Progress and Next Steps

- Study Coordinators and Data Managers hired or being hired
- Formative Mixed Methods Research
 - July 2020 Virtual study orientation and training of data collectors in Nigeria
 - August IDIs and Survey in Nigeria
 - September IDIs and Survey Kenya, perhaps So. Africa (may be later)
 - October Sri Lanka

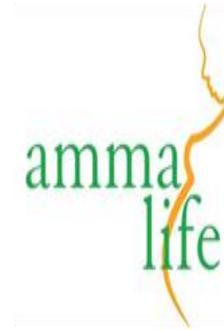
COVID-19 has and may further impact dates

Conclusion

- Innovative mixed methods implementation project
- Formative, mixed methods with a behavior change framework COM-B
- Intervention Randomized Cluster Trial of Motive Bundle and Implementation Strategy
 - Ambitious sample size, based on anticipated number of births
 - 80 clusters with ~2300 births/annum
 - 6800 PPH cases
- If successful result in package of PPH Bundle and Intervention Strategy
- Dissemination via WHO Guidelines and Evidence to Decision framework

UNIVERSITY OF BIRMINGHAM

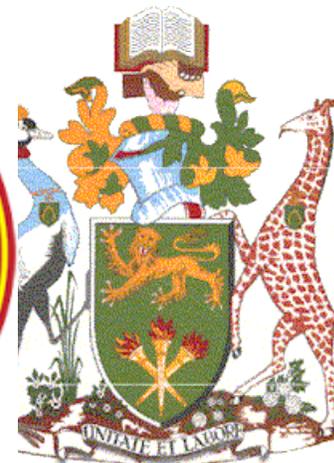
Thank YOU!!



BILL & MELINDA GATES foundation



UCSF School of Medicine



For more information contact:

- Rebecca Timms:
 - **TRL-c-emotive@adf.bham.ac.uk**

- Lead Investigators:
 - Prof Arri Corcoomasamy/U. of Birmingham
 - Dr. Fernando Althabe/ WHO
 - Dr. Ionnis Gallos/U. of Birmingham