

# Exploring the role of QES in trial intervention design and WHO guideline development

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# Presentation outline

- Project overview
- Using QES findings in intervention design
- Using QES findings in WHO guideline development
- Discussion

# Declarations of interest

- Investigator on the E-MOTIVE Trial discussed today, funded by Bill and Melinda Gates Foundation (2019-2024)
- Member of evidence synthesis team for the WHO PPH guidelines (2023-2025)

# Project overview

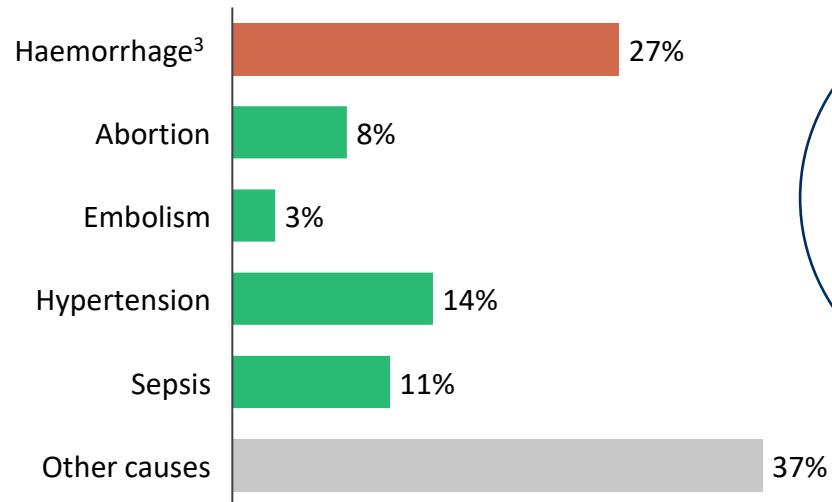
Globally, haemorrhage accounts for >25% of maternal mortality

Out of ~140 million women giving birth every year, **6-10% experience PPH**<sup>1</sup>

**~14mil**  
women with PPH  
annually

Maternal blood loss of  
≥500 ml within 24h of birth

PPH remains the leading cause of  
maternal mortality world-wide<sup>2</sup>



**~70,000**  
PPH related  
deaths yearly

<sup>1</sup> Innovations in the prevention and treatment of postpartum hemorrhage: Analysis of a novel medicines development pipeline database (FIGO); A review of postpartum hemorrhage in low-income countries and implications for strengthening health systems (FIGO)

<sup>2</sup> Global causes of maternal death: a WHO systematic analysis

<sup>3</sup> Most Haemorrhage cases are PPH

## WHY?

# Why PPH continues to be problem? (at the facility level)

## Challenge

01

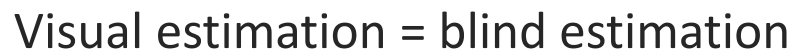
Missed or delayed **diagnosis of PPH**

## Challenge

02

Missed or delayed **treatment of PPH**

## Missed diagnosis: Visual estimation

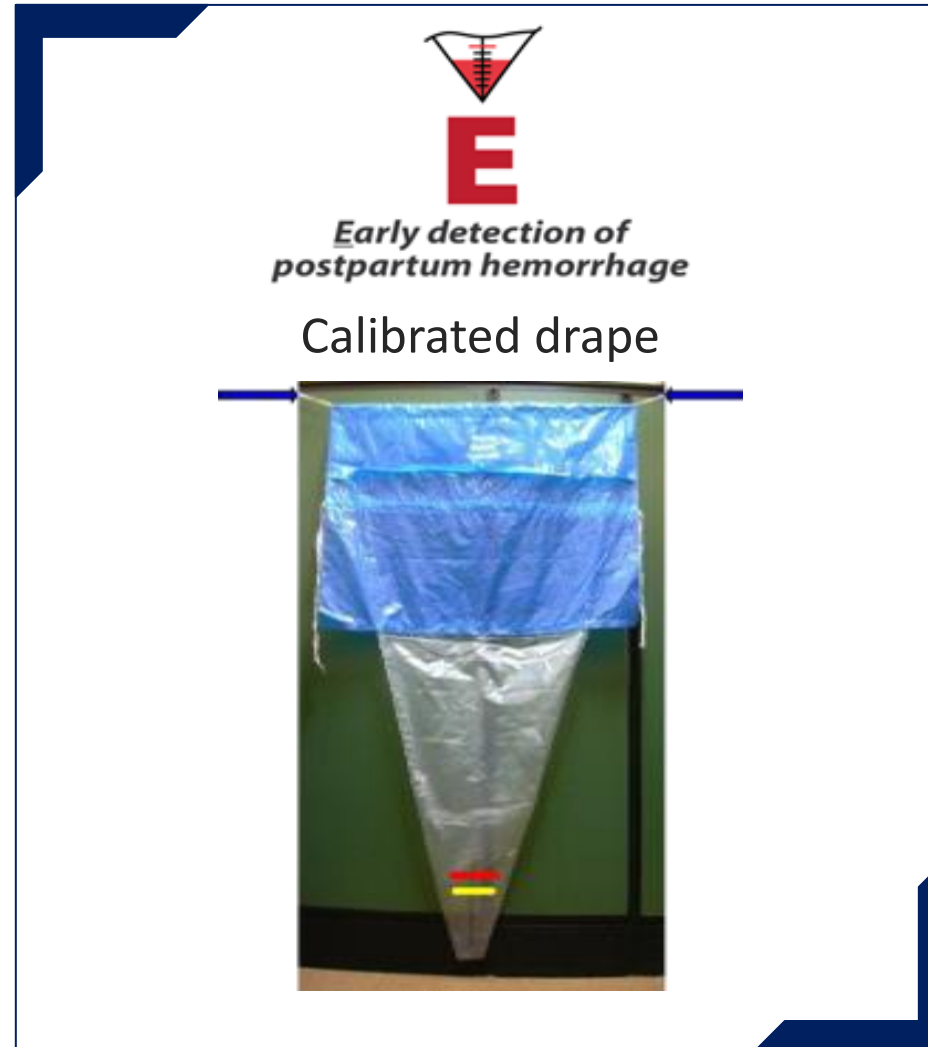


human  
reproduction  
programme **hrp** 50  
research for impact  
UNEP-UNFPA-UNICEF-WHO-WORLD BANK



WHY?

How can we improve diagnosis?



## WHY?

# Why PPH continues to be problem? (at the facility level)

Challenge

01

Missed or delayed diagnosis of PPH

Challenge

02

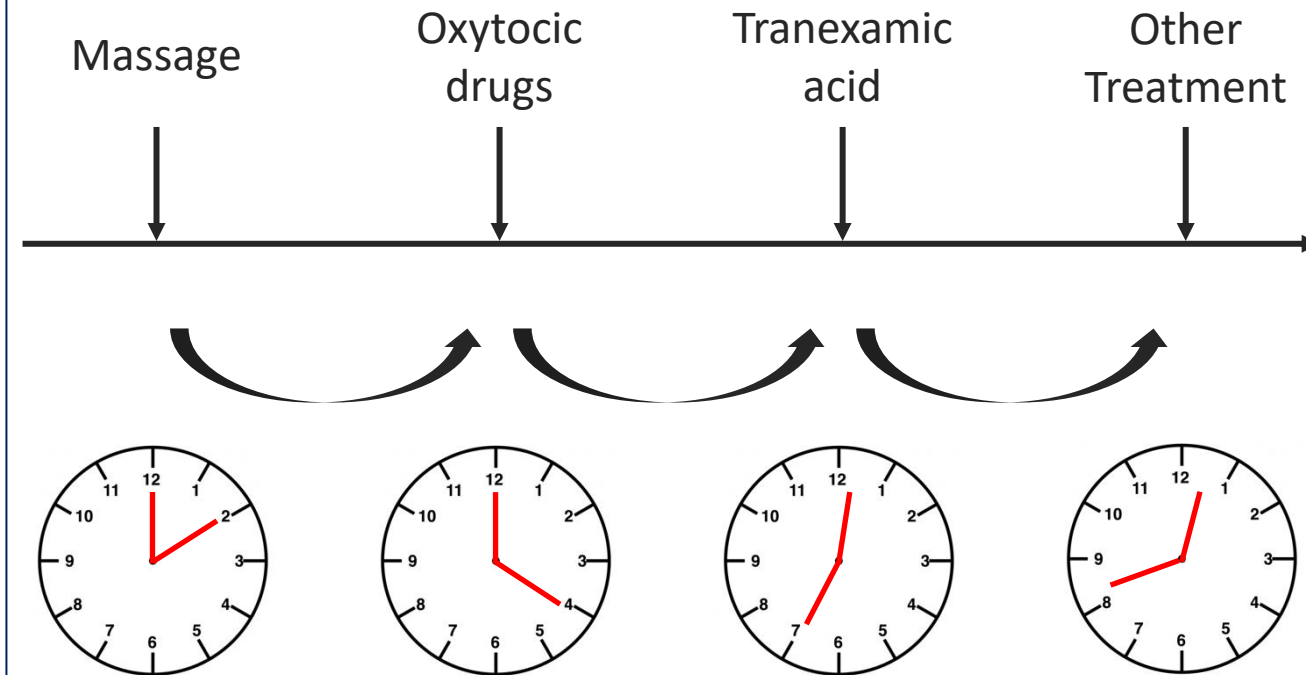
Missed or delayed treatment of PPH

WHY?

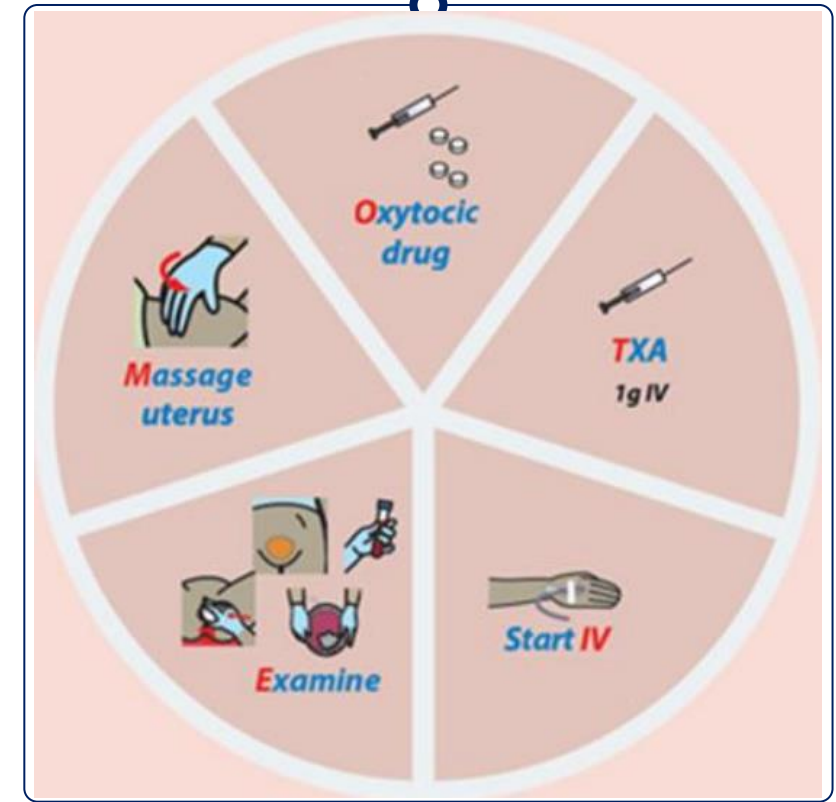
## Missed or delayed treatment

Bundle: small simple set of evidence-based practices, when performed together improve outcomes

### Usual care: sequential treatment



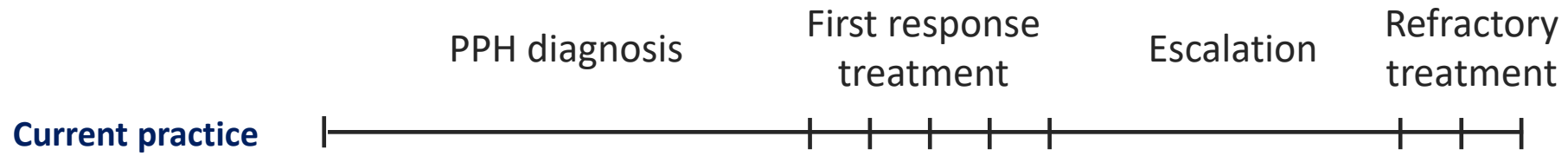
### WHO 'MOTIVE' bundle



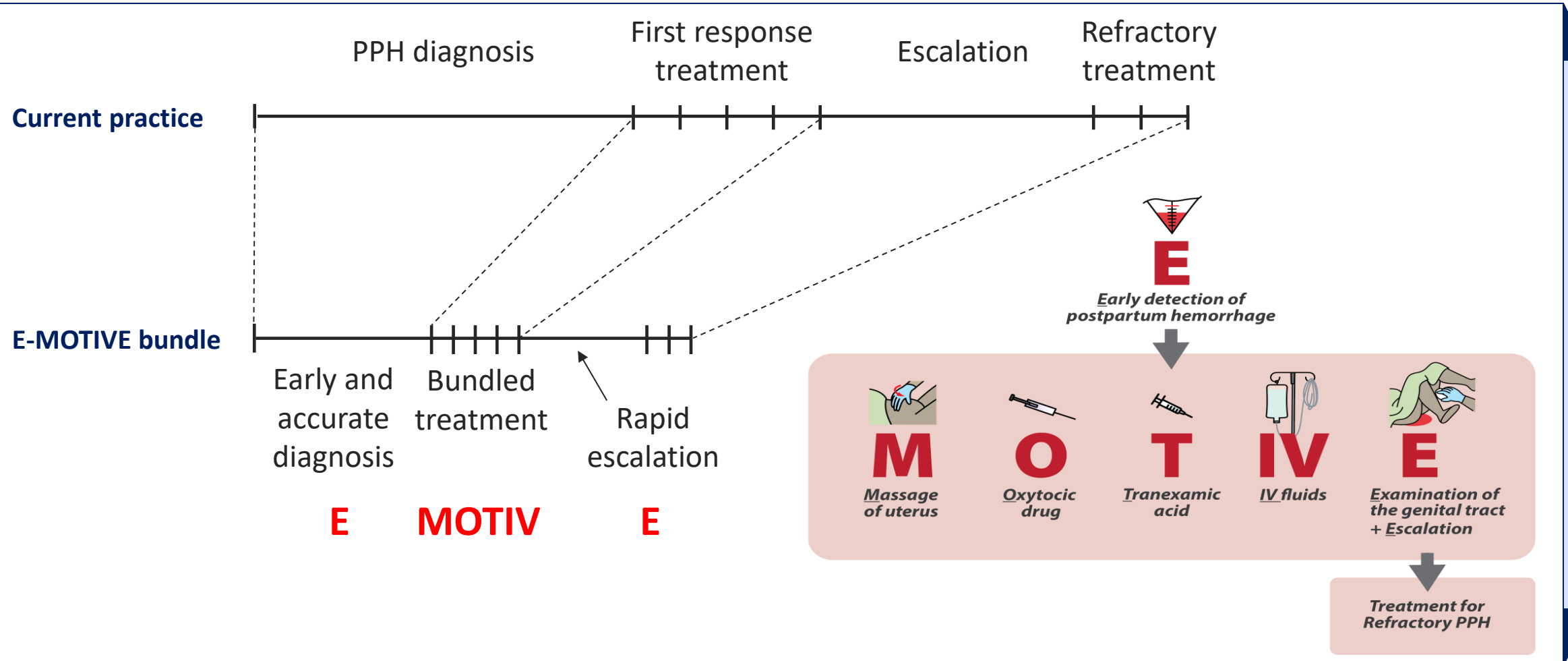


WHY?

## The E-MOTIVE intervention



# The E-MOTIVE intervention



## WHY?

# Why PPH continues to be problem? (at the facility level)

## Challenge

01

## Missed or delayed diagnosis of PPH

## Challenge

02

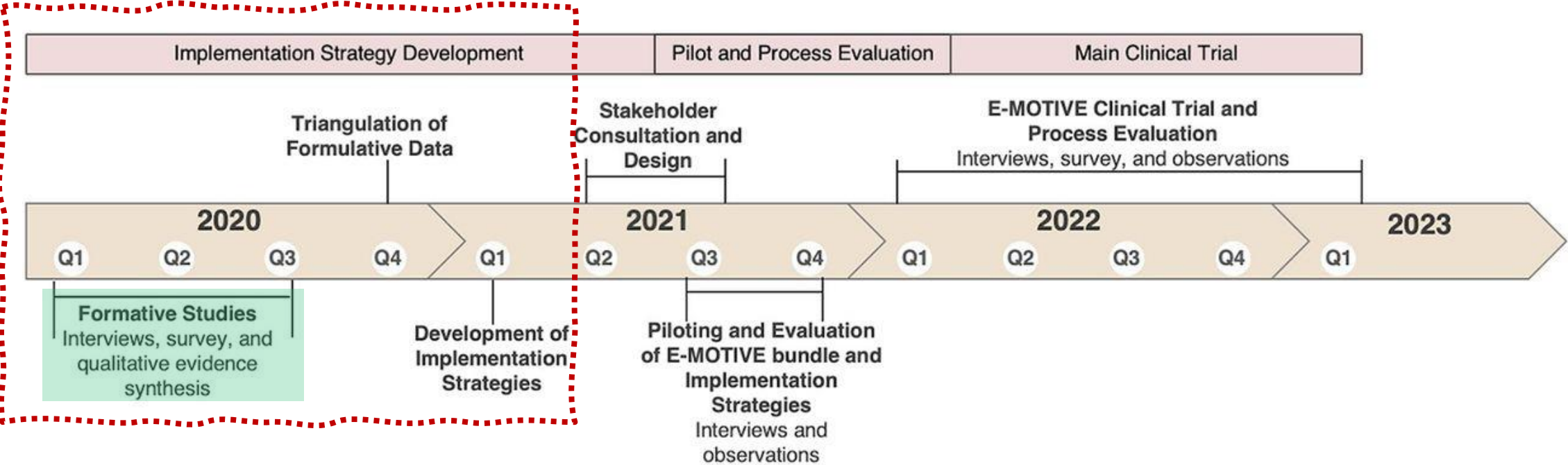
## Missed or delayed treatment of PPH

### Implementation questions

**What are the factors (barriers, enablers) that may affect the introduction of these significant changes of practice:**

- Introduce calibrated drape for blood loss collection
- To bundle PPH care
- To introduce tranexamic acid

# E-MOTIVE project design



**E-MOTIVE trial  
implemented in 78 hospitals  
in Nigeria, Kenya, South  
Africa and Tanzania**

# E-MOTIVE formative research: Purpose

To understand **current practices** about PPH detection and management, and **design considerations** for the trial

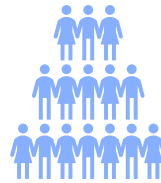
To identify **factors that may affect implementation** of the trial, to ensure highest likelihood of success

To explore **feasibility and acceptability** of the E-MOTIVE intervention

# E-MOTIVE formative research: Design



**Primary qualitative research  
with health workers**  
(n=45, 12 hospitals)



**Survey with health workers**  
(n=972, 91 hospitals)



**Cochrane qualitative  
evidence synthesis**



**Stakeholder consultation &  
co-design**



**Adaptive cycles + mini  
process evaluation**



# QES: an overview



**Cochrane**  
**Library**

Cochrane Database of Systematic Reviews

**Perceptions and experiences of the prevention, detection, and management of postpartum haemorrhage: a qualitative evidence synthesis (Review)**

Akter S, Forbes G, Vazquez Corona M, Miller S, Althabe F, Coomarasamy A, Gallos ID, Oladapo OT, Vogel JP, Lorencatto F, Bohren MA

# QES Aim and objectives

Describe and explore the perceptions and experiences of women, community members, lay health workers, and skilled healthcare providers who have experience with PPH, or with preventing, detecting, and managing PPH, in both community and health facility settings



Synthesise qualitative studies exploring how PPH is perceived and understood, including the **perceptions of PPH causes and consequences**



Develop a **conceptual understanding of a woman's journey of surviving a PPH**, including her experiences, values, and challenges



Identify how **lay health workers** prevent, detect, and manage PPH at **home or in community settings**, or during **transfer or referral** to health facilities



Synthesise the **factors affecting the implementation of different PPH prevention, detection, and management interventions**, including perceptions, experiences, values, acceptability, and feasibility, in health facility settings.



# Inclusion criteria

## Types of studies

- Primary qualitative data collection and analysis
- Primary mixed-methods where extraction of qualitative findings was possible

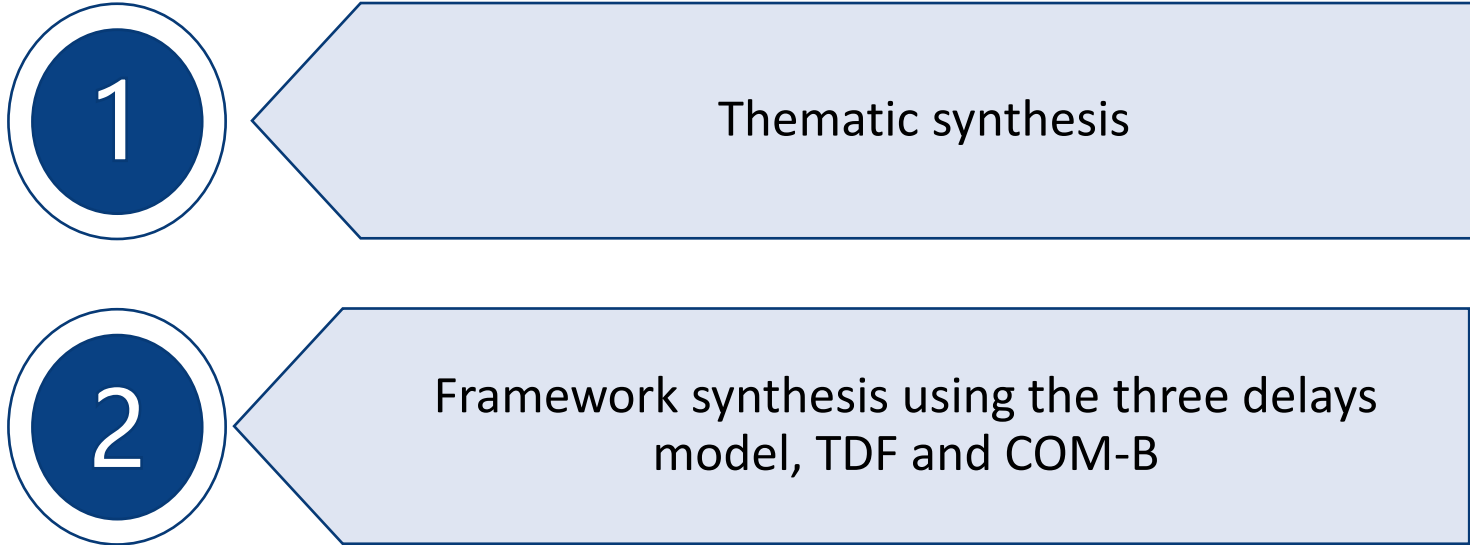
## Settings

- Any country
- Any setting, including :
  - at home
  - Community-level health facilities
  - Higher-level health facilities

## Participants

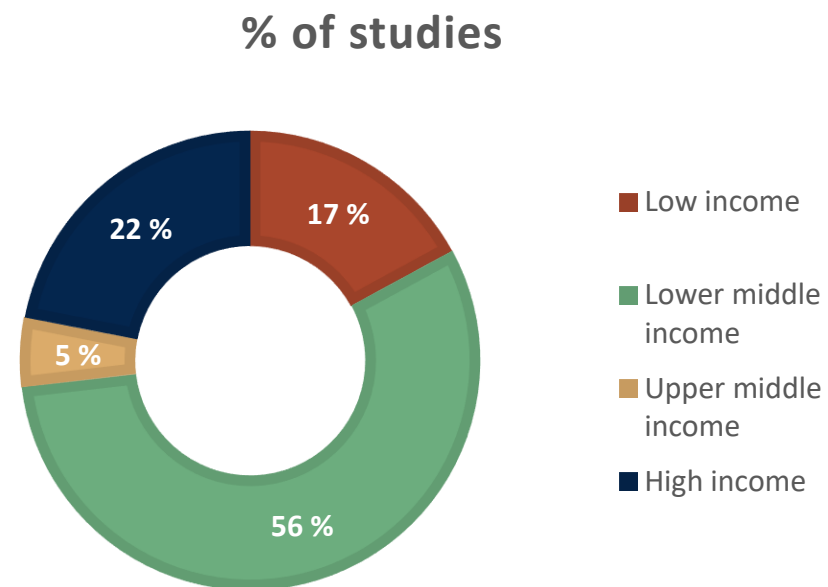
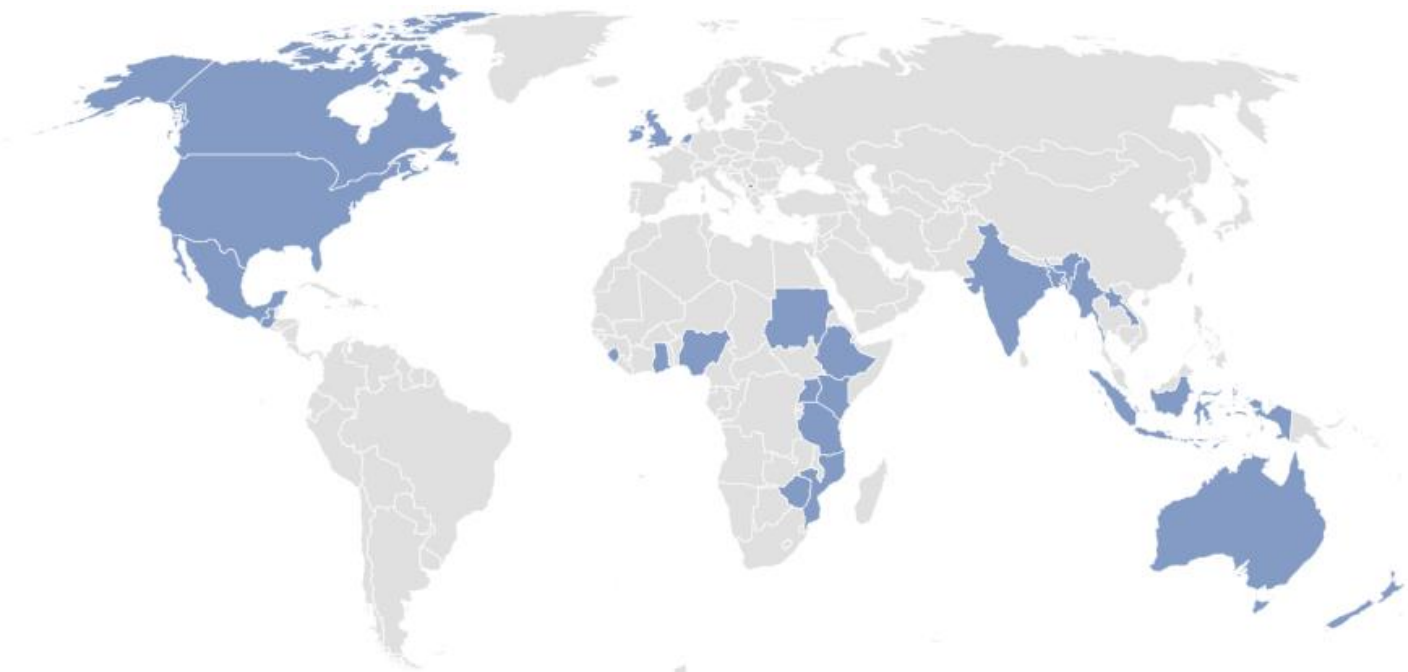
- **Women** who experienced PPH
- **Community members** who supported a woman with PPH, including women's family and partners
- **Lay health workers or other community-level traditional carers** who supported women during childbirth
- **Skilled healthcare providers and health managers** who provided maternity care services

# Data analysis



# Characteristics of sampled studies

## Country setting



# Characteristics of sampled studies

## Type of participants



**Women who recently  
gave birth / had PPH**  
17 studies



**Partner / family  
members**  
15 studies



**Lay health workers /  
traditional carers**  
15 studies



**Health workers**  
29 studies



**Pharmacists**  
4 studies



**Blood brokers**  
2 studies



**NGO staff**  
7 studies



**Policy-makers**  
5 studies

# High-level QES findings

**Community perspectives  
about bleeding after  
birth and PPH**

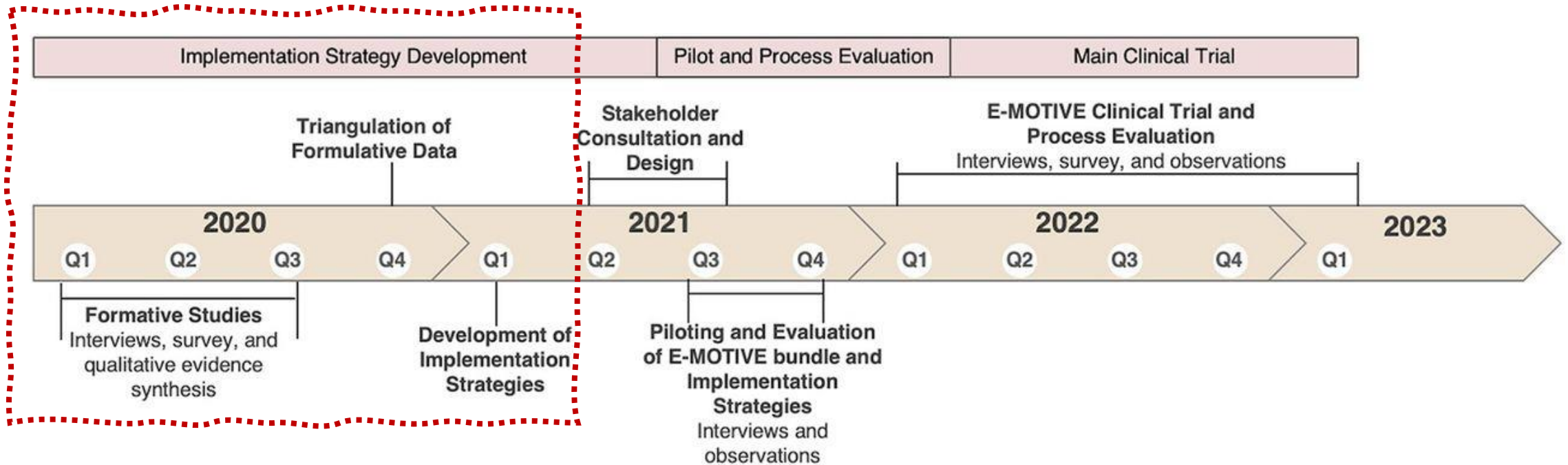
**Decision-making to seek  
and access care**

**Perceptions and  
experiences of PPH  
prevention, detection,  
and management**

**System-level factors**

**Intervention  
implementation  
strategies and lessons  
learnt**

# Design



QES initial findings developed



Primary qualitative research complete

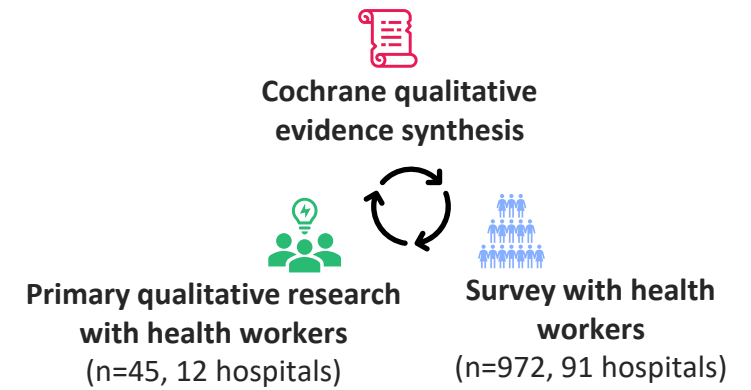


Triangulation of data sources



Development of implementation strategies

# Triangulating data sources



## Goal

Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention

Create triangulation matrix to map convergence, divergence



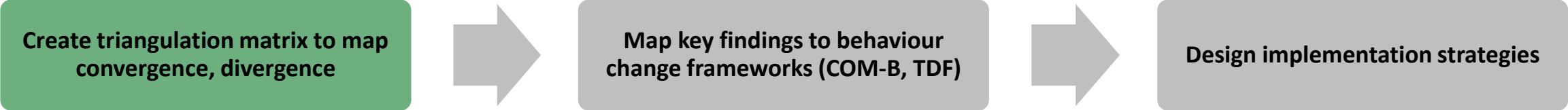
Map key findings to behaviour change frameworks (COM-B, TDF)



Design implementation strategies

# Triangulating data sources

**Goal**  
Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention



	Kenya		Nigeria		South Africa		Tanzania		QES
	Interviews	Survey	Interviews	Survey	Interviews	Survey	Interviews	Survey	
PPH treatment									
All components of the care bundle are part of current PPH management except tranexamic acid which is not routinely administered	Agree	Partially Agree	Agree	Partially Agree	Agree	Partially Agree	Not found	Partially Agree	Not found
Overall use of a “bundled” approach to PPH treatment									
Uptake of MOTIVE bundle relies on having sufficient staff on wards and having a reliable supply and consistent stock of the necessary drugs and equipment	Agree	Agree	Agree	Agree	Agree	Agree	Agree	Agree	Agree

**Mixed agreement:**  
Most bundle components are current practice, except tranexamic acid (QES, primary research)

**Strong agreement:**  
importance of staffing, reliable supplies & medicine



# Triangulating data sources

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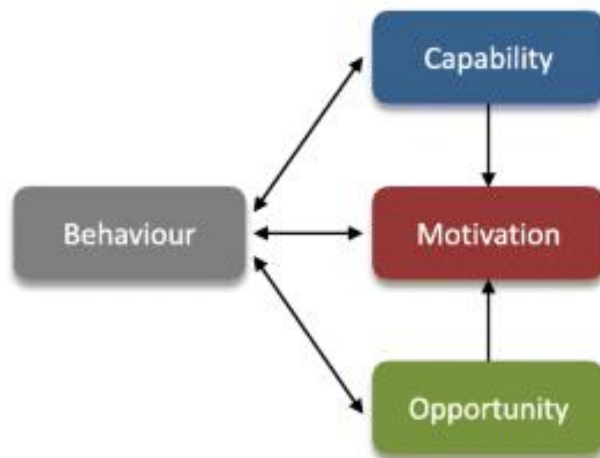


Map key findings to behaviour change frameworks (COM-B, TDF, Behavior change wheel)



Design implementation strategies

**Identify what needs to change**  
for PPH detection & management?



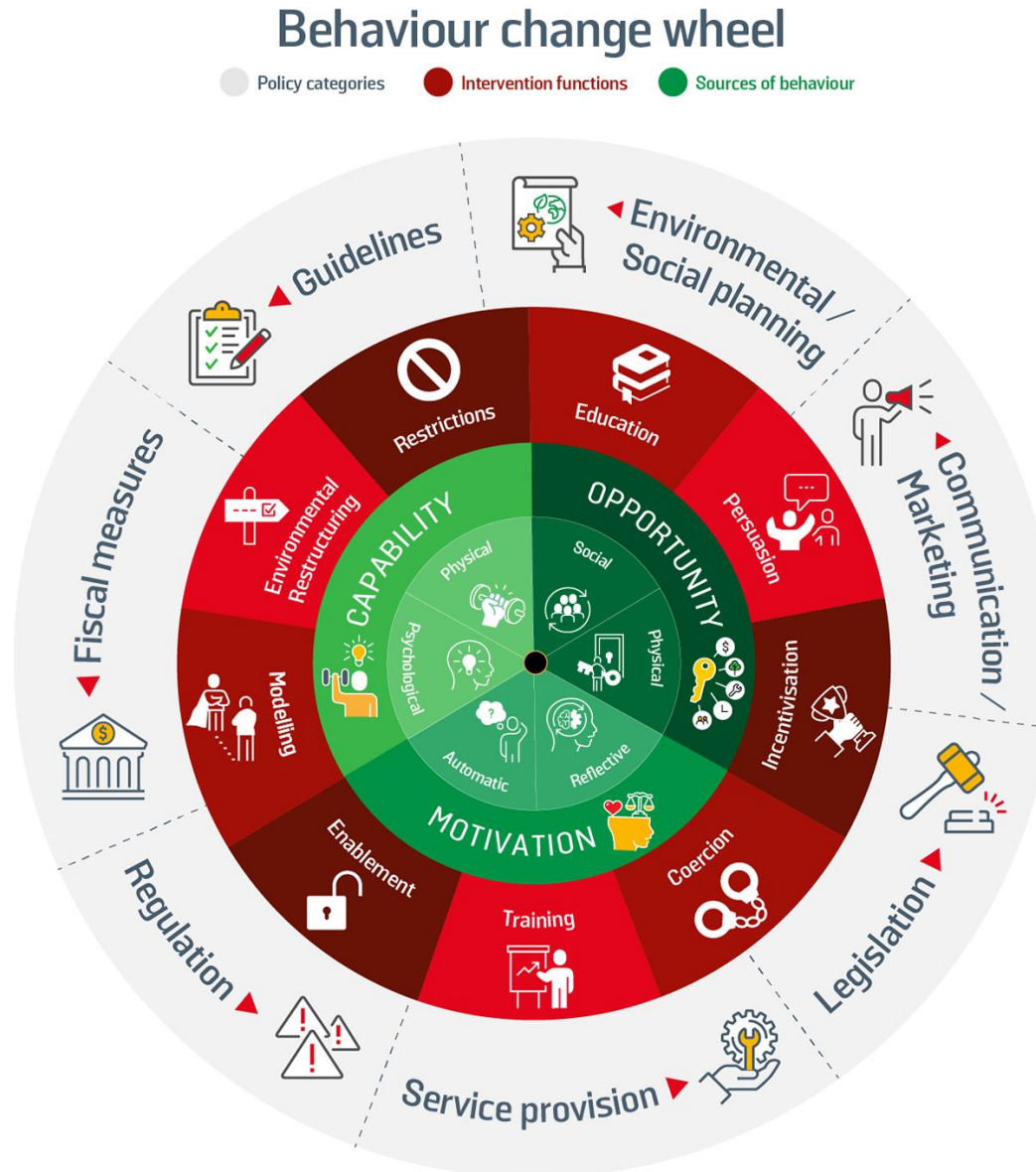
Am I aware of what I need to do (guidelines, evidence)?  
Appropriate skills/training? How do I decide to do X?

Is doing X part of my clinical role? What happens if I do or don't do X? Is X a priority? How confident am I? What are my worries?

Do I have sufficient resources (time, staff, supplies) to do X?  
How is X influenced by peers, managers, patients, culture, norms...?

# Triangulating data sources

Map key findings to  
behaviour change  
frameworks (COM-B, TDF,  
Behavior change wheel)



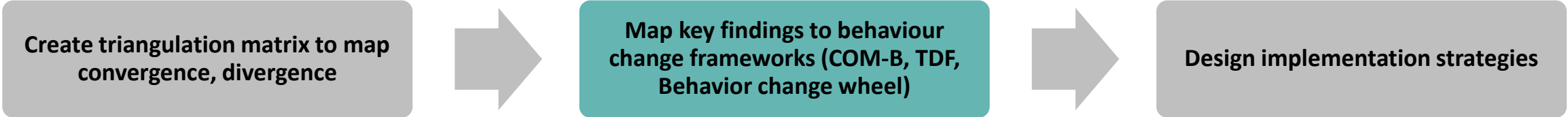
## Goal

Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention

**Identify intervention functions, behavior change techniques and mode of delivery**  
to improve PPH detection & management?

# Triangulating data sources

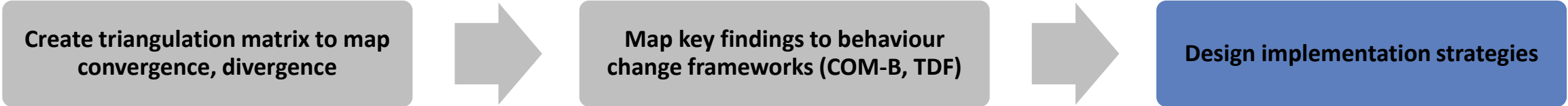
**Goal**  
Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention



Summary of Findings	COM-B	Intervention  Types From BCW
Need for sufficient staff and adequate stocks of PPH drugs and equipment	Opportunity (social and environmental)	Environmental restructuring Modeling Enablement
Need for teamwork to implement intervention		
Intervention use will bring about positive changes to PPH treatment	Motivation (reflective)	Education Persuasion Modeling Enablement
Uncertainty about how using the calibrated drape will fit in with current methods for collecting blood		
Perceptions that intervention use can potentially reduce PPH mortality		

# Triangulating data sources

**Goal**  
Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention



Summary of Findings	COM-B	Intervention Types From BCW	Proposed Implementation Strategies for E-MOTIVE Trial Context
Need for sufficient staff and adequate stocks of PPH drugs and equipment	Opportunity (social and environmental)	Environmental restructuring Modeling Enablement	Introduce PPH trolley or carry case to organize PPH drugs and equipment in 1 place accompanied by a checklist detailing the medicines and equipment to be stocked (country and site specific).
Need for teamwork to implement intervention			Team-based training with simulation practice and drills to encourage and enable better coordination, teamwork, and communication when managing a PPH.
Intervention use will bring about positive changes to PPH treatment	Motivation (reflective)	Education Persuasion Modeling Enablement	Introduce audit and feedback to monitor MOTIVE bundle uptake.
Uncertainty about how using the calibrated drape will fit in with current methods for collecting blood			Introduce a person in leadership role to "champion" the E-MOTIVE intervention implementation.
Perceptions that intervention use can potentially reduce			

- 1.PPH Trolley with supplies
- 2.Team-based simulation training
- 3.Audit and feedback
- 4.PPH Champions

# Triangulating data sources

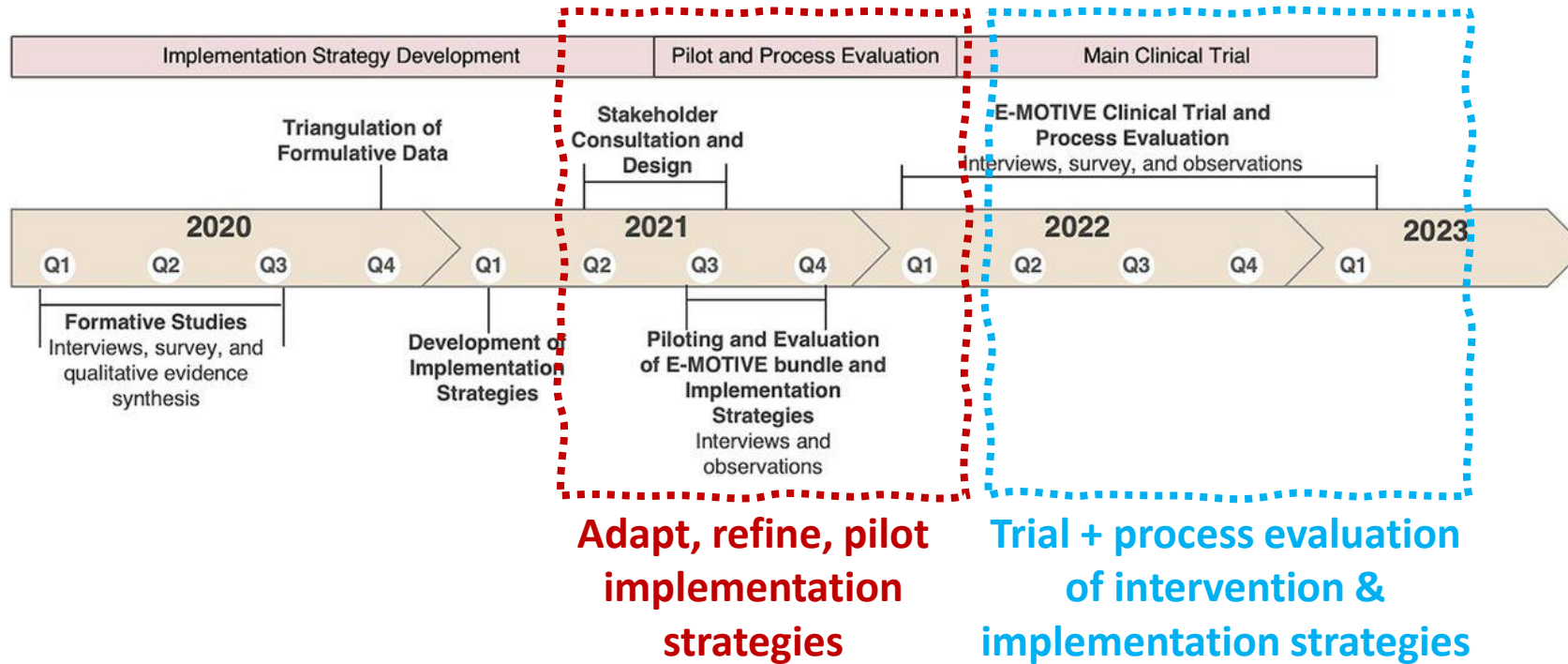
## Goal

Integrate findings across 3 formative research activities to distil set of key findings of current PPH practices and influences on E-MOTIVE intervention

Create triangulation matrix to map convergence, divergence

Map key findings to behaviour change frameworks (COM-B, TDF)

Design implementation strategies



- ✓ QES initial findings developed
- ✓ Primary qualitative research complete

- ✓ Triangulation of data sources
- ✓ Development of implementation strategies

# Using QES evidence in WHO guidelines

**2023 PPH new  
recommendations**

**2024-2025 PPH  
consolidated  
guideline**

# Using QES evidence in WHO guidelines

2023 PPH new  
recommendations

2024-2025 PPH  
consolidated  
guideline

- E-MOTIVE trial showed **60% relative reduction** in adverse PPH outcomes
- Based on findings from E-MOTIVE, 2 new recommendations on:
  - Objective blood loss assessment
  - PPH treatment bundle

WHO recommendations on the  
assessment of postpartum blood  
loss and use of a treatment bundle  
for postpartum haemorrhage

# Using QES evidence in WHO guidelines

2023 PPH new  
recommendations

2024-2025 PPH  
consolidated  
guideline

- As evidence emerged, WHO updated guideline recommendations → 7 guideline documents 2012-2023
- Consolidated guideline **brings together a series of existing recommendations** and **updates/adds new recommendations**
- Currently underway, expected publication mid-2025



# Using QES evidence in WHO guideline

Values	Acceptability	Feasibility	Equity	Implementation issues
<ul style="list-style-type: none"><li>• What do people think about having a condition, being in a situation, having an intervention?</li></ul>	<ul style="list-style-type: none"><li>• In what ways does the intervention or policy fit (or not) with the situation of the person and/or context of care?</li></ul>	<ul style="list-style-type: none"><li>• The extent to which the intervention or policy is physically, culturally, or financially practical or possible in a given context?</li></ul>	<ul style="list-style-type: none"><li>• In what ways did the intervention reduce unfair and avoidable or remediable differences in health among different groups of people?</li></ul>	<ul style="list-style-type: none"><li>• What is it about this intervention that works, why and how?</li><li>• Will it work in this context?</li><li>• What's the best way to implement it?</li></ul>

# Example

WHO recommendations on the assessment of postpartum blood loss and use of a treatment bundle for postpartum haemorrhage

Web Annex A. Methods of assessing postpartum blood loss for the detection of postpartum haemorrhage: evidence-to-decision framework

Acceptability

Feasibility

## 3.5 Acceptability

Are different methods of measuring postpartum blood loss acceptable to key stakeholders?

### Research evidence

#### Acceptability to implementers

The QES (25) drew on 32 studies based in health-care facilities (23 in health-care facilities and 9 in both community and health-care facility settings). It found that quantifying blood loss with drapes placed under the buttocks and weighing blood-soaked materials, rather than estimating blood loss, can be a complex and contentious change of practice for health workers. Some health workers struggled with changes to the workflow and how to measure accurately (*low confidence*).

Seven studies in the QES evaluated existing interventions or quality improvement initiatives to improve PPH prevention, detection and management. A persistent challenge identified across these studies was the complexity and time intensiveness of collecting routine health data, and the high staff workloads associated with implementing PPH-related interventions. Routine collection of blood loss data, health outcomes and treatments required staff to use different data sources and contact staff from other specialties (such as anaesthesia) to identify what treatments were used. In some cases, these factors discouraged health workers from participating in PPH initiatives altogether (*very low confidence*).

The QES did not identify any studies on the acceptability of different blood loss assessment methods in relation to home or community settings.

#### Acceptability to women and families

There was no direct evidence in the QES regarding the acceptability to women and families of different methods of measuring postpartum blood loss.

Judgement					
<input type="checkbox"/> Don't know	<input checked="" type="checkbox"/> Varies	<input type="checkbox"/> No	<input type="checkbox"/> Probably no	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Yes

## 3.6 Feasibility

Are different methods of measuring postpartum blood loss feasible to implement?

### Research evidence

The QES (25) found that, in health-care facilities, midwives may consider collecting blood loss using a kidney dish or under-pad to be easily implemented, but difficult and inaccurate to estimate the amount of blood loss, with large variation between individual health workers. Facilities may lack clinical protocols or guidelines for measuring blood loss, complicating their adoption in regular practice. Therefore, midwives may detect blood loss by physiological assessment (e.g. blood pressure, pulse, appearance), which was considered easy to implement. Some health workers believed that clinical signs are more important than the amount of blood lost in detecting PPH but did not feel confident in diagnosing women with PPH based solely on physiological signs (*low confidence*).

Health workers described working on the maternity ward as stressful and intense because of short-staffing, long shifts and the unpredictability of emergencies. Exhausted and overwhelmed staff may not be able to appropriately monitor all women, particularly when multiple women are giving birth simultaneously or on the floor of the health-care facility, which leads to delays in detecting PPH. These conditions can lead to health workers feeling dissatisfied and unappreciated; in some settings, health workers feared blame when PPH occurred (*moderate confidence*).

Inadequate staffing, high turnover of skilled health workers and staffing comprising lower-level cadres of health workers were key challenges to providing quality PPH care (including blood loss measurement), particularly in facilities in rural areas. Health managers described that many health workers did not have adequate or appropriate skills, even after attending in-service training; continuous mentoring, coaching and training were important to counter this (*high confidence*).

The QES did not identify any studies on the feasibility of different blood loss assessment methods in relation to the home or community setting.

Judgement					
<input type="checkbox"/> Don't know	<input checked="" type="checkbox"/> Varies	<input type="checkbox"/> No	<input type="checkbox"/> Probably no	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Yes

# Contribution of QES to trial design and WHO Guidelines

## E-MOTIVE trial design:

- Allowed learning from integration of evidence from different contexts and populations
- Triangulation from QES and primary research → robust development of intervention/implementation strategies
- Identification of what worked/didn't work in other PPH intervention studies

## WHO Guidelines:

- Bringing key stakeholder voices (women, health workers, etc) to guideline process
- Better understanding of key implementation issues (acceptability, feasibility)
- Improved consideration of how to move from guideline recommendation → real world implementation
- Identification of evidence gaps (e.g.: women's/community perspectives of approaches to blood loss collection)

# Thank you!

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## Acknowledgements

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**E-MOTIVE country PIs:** Hadiza Galadanci, Sue Fawcus, Neil Moran, Justus Hofmeyr, Zahida Qureshi, Fadhlun Alwy Al-beity

**WHO:** Femi Oladapo, Ioannis Gallos, Caitlin Williams