

# Improving Childbirth Outcomes by Optimizing the Use of Uterotonics

Sharing Learning and Tools

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July 25, 2024



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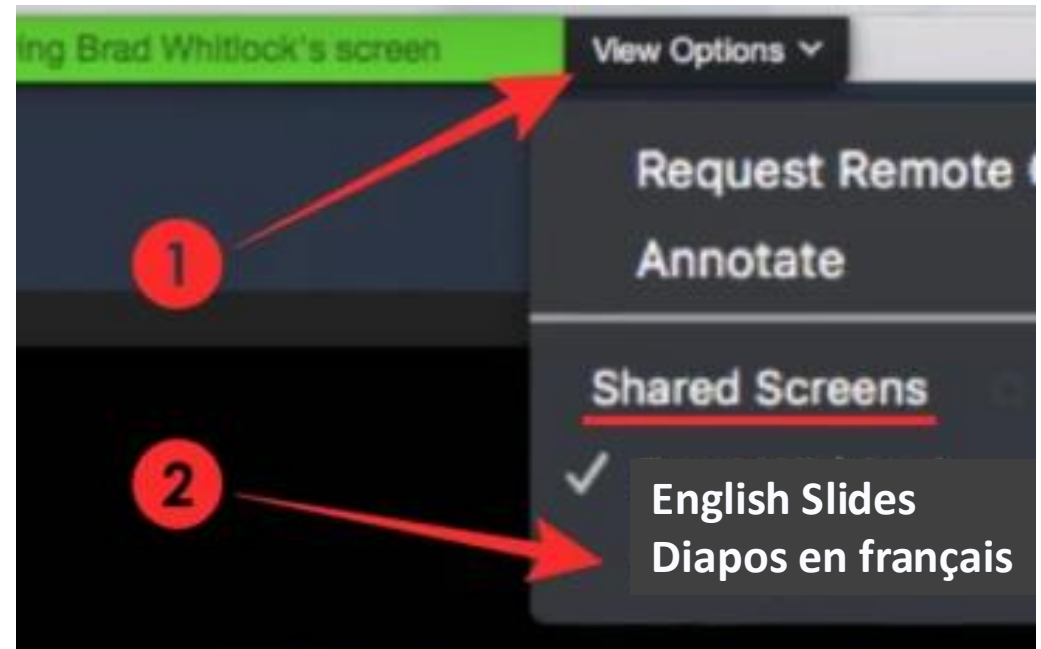
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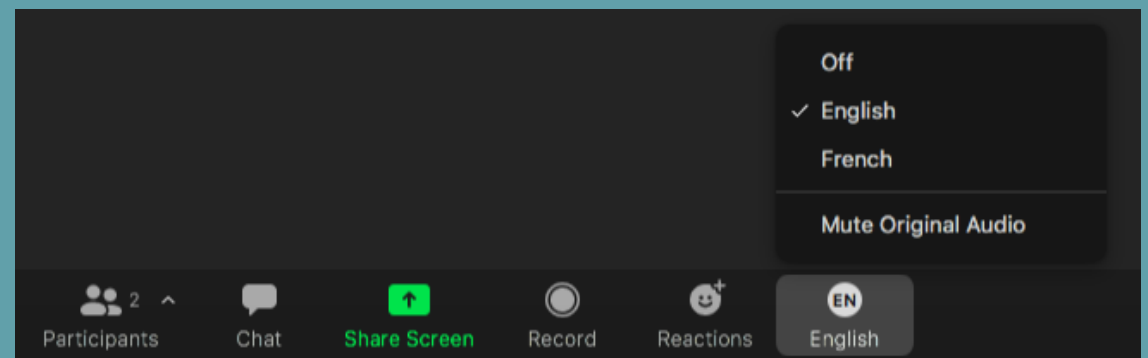
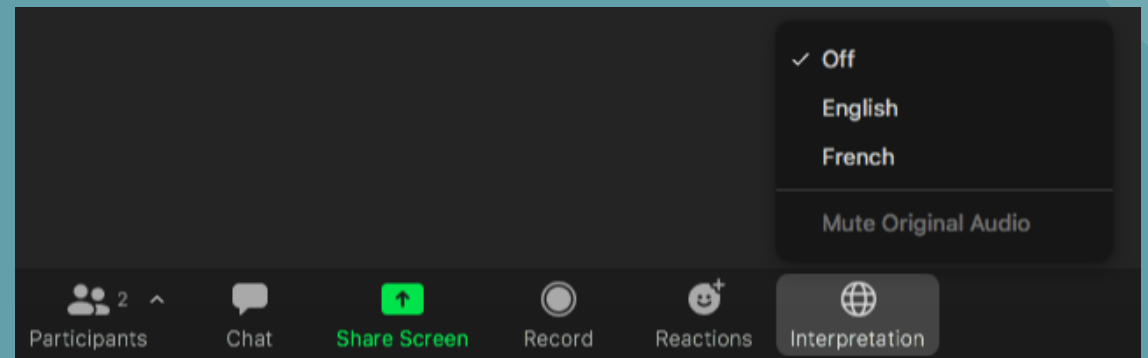
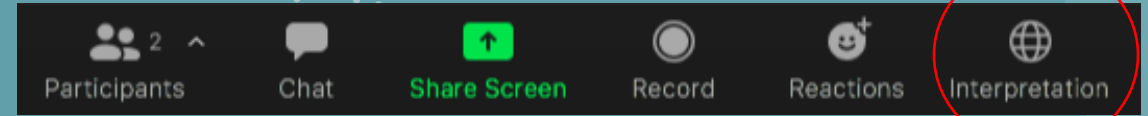
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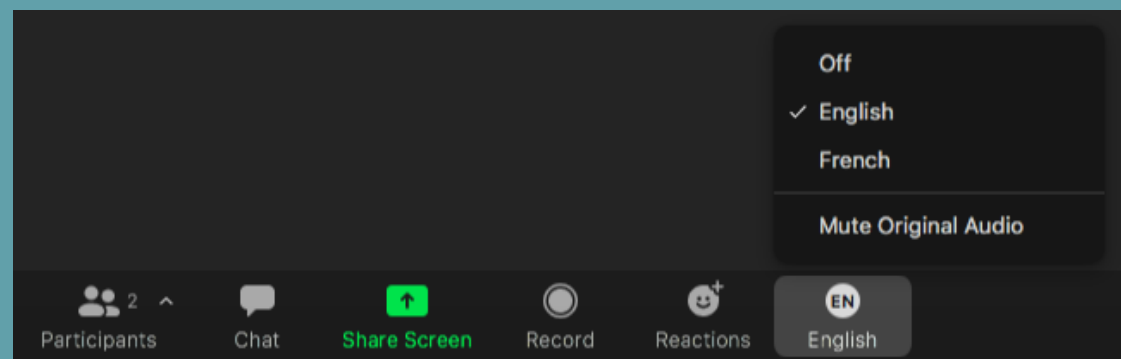
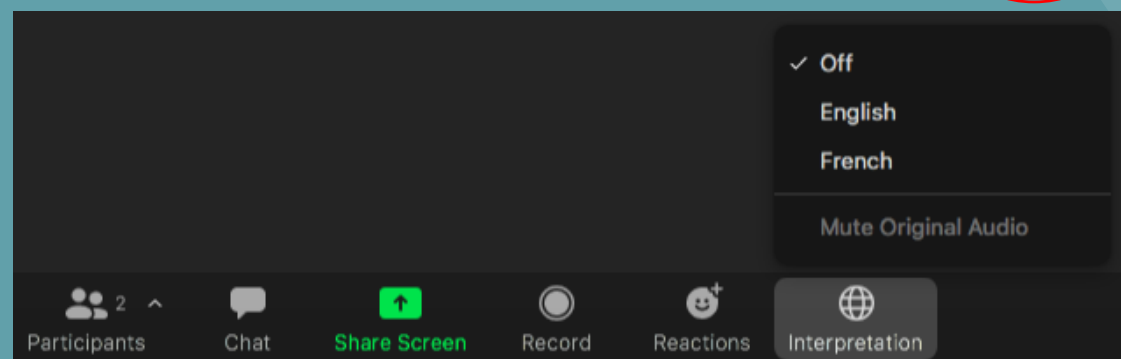
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# Opening Remarks

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Deborah Armbruster, Senior Maternal and Newborn Health Advisor, USAID



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# Labor Induction and Augmentation Practices in India

How the Use of Uterotonic Medications Affects Stillbirth, Neonatal Mortality, and Use of Cesarean Deliveries

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Megan Marx Delaney, RN, MSN, MPH  
MOMENTUM Knowledge Accelerator

RESEARCH CONSOLIDATION | July 2024



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SECTION 01

# Background on Uterotonics and Potential for Harm

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# **What are uterotonics?**

Medications (e.g., oxytocin) that cause the uterus to contract.

# Uterotonics Can Save Lives and Reduce Harm

By preventing and treating excessive bleeding after birth

By starting labor (induction)

By strengthening and speeding up labor (augmentation)



After delivery, **every woman** should get uterotonics to prevent hemorrhage

However, to be safe when used before birth, uterotonics require a **good medical reason for use and close monitoring**

# Monitoring Requires **Adequate Numbers of Skilled Staff** to Recognize Danger Signs and Take Action When Needed

Monitoring includes:



Fetal heart rate



Uterine contractions



Never leaving the patient unattended (WHO)<sup>1,2</sup>



1. World Health Organization. (2014). Recommendations for augmentation of labour.  
2. World Health Organization. (2022). Recommendations on induction of labour, at or beyond term.

**Without monitoring, uterotonics to start or strengthen labor can cause harm.**

Risks include stillbirth, birth asphyxia, neonatal encephalopathy, early neonatal death, and unnecessary cesarean deliveries.

# Avoiding Breathing failure

Newborns' inability to breathe at birth is a major cause of neonatal deaths and stillbirths globally.<sup>1</sup>

Unmonitored use of uterotonics for labor augmentation can cause a woman's uterus to have excessively long contractions, reducing oxygen to the fetus.

This can result in stillbirth, need for resuscitation, neonatal encephalopathy, and early neonatal death.<sup>2</sup>

1. World Health Organization (2022). Newborn mortality fact sheet. Available at <https://www.who.int/news-room/fact-sheets/detail/levels-and-trends-in-child-mortality-report-2021#:~:text=Preterm%20birth%2C%20intrapartum%2Drelated%20complications,causes%20of%20most%20neonatal%20deaths..> Accessed on February 10, 2024.
2. Kujabi, M.L. et al. (2022). Labor augmentation with oxytocin in low- and lower-middle-income countries: a systematic review and meta-analysis. *AJOG Global Reports*, 2(4):100123. <https://doi.org/10.1016%2Fj.xagr.2022.100123>.



# Preventing Unnecessary Cesarean Deliveries

Inducing labor without protocols, monitoring, or adequate information about the pregnancy has risks, including:

- fetal distress
- meconium aspiration
- uterine rupture
- premature birth<sup>1</sup>

**This can lead to emergency cesareans** that would not have otherwise happened.

1. Vogel, J.P. et al. (2014). Global perspectives on elective induction of labor. *Clinical Obstetrics and Gynecology*, 57(2), 331-42. <http://dx.doi.org/10.1097/GRF.0000000000000031>.





# Magnitude of Harm

A recent meta-analysis found uterotonic use for labor augmentation in low- and middle-income countries<sup>1</sup> is associated with an **increased risk** of:

- Stillbirth and Day 1 neonatal mortality [RR 1.46; 95%CI 1.05, 2.02]
- Neonatal resuscitation [RR 2.69; 95%CI 1.87, 3.88]
- Neonatal encephalopathy [RR 2.90; 95%CI 1.87, 4.49]
- Low Apgar score at birth [1.54; 95%CI 1.21, 1.96]

1. Kujabi, M.L. et al. (2022). Labor augmentation with oxytocin in low- and lower-middle-income countries: a systematic review and meta-analysis. *AJOG Global Reports*, 2(4):100123. <https://doi.org/10.1016%2Fj.xagr.2022.100123>.

Reducing unindicated and under-monitored uterotonics use can **reduce these risks and save lives.**

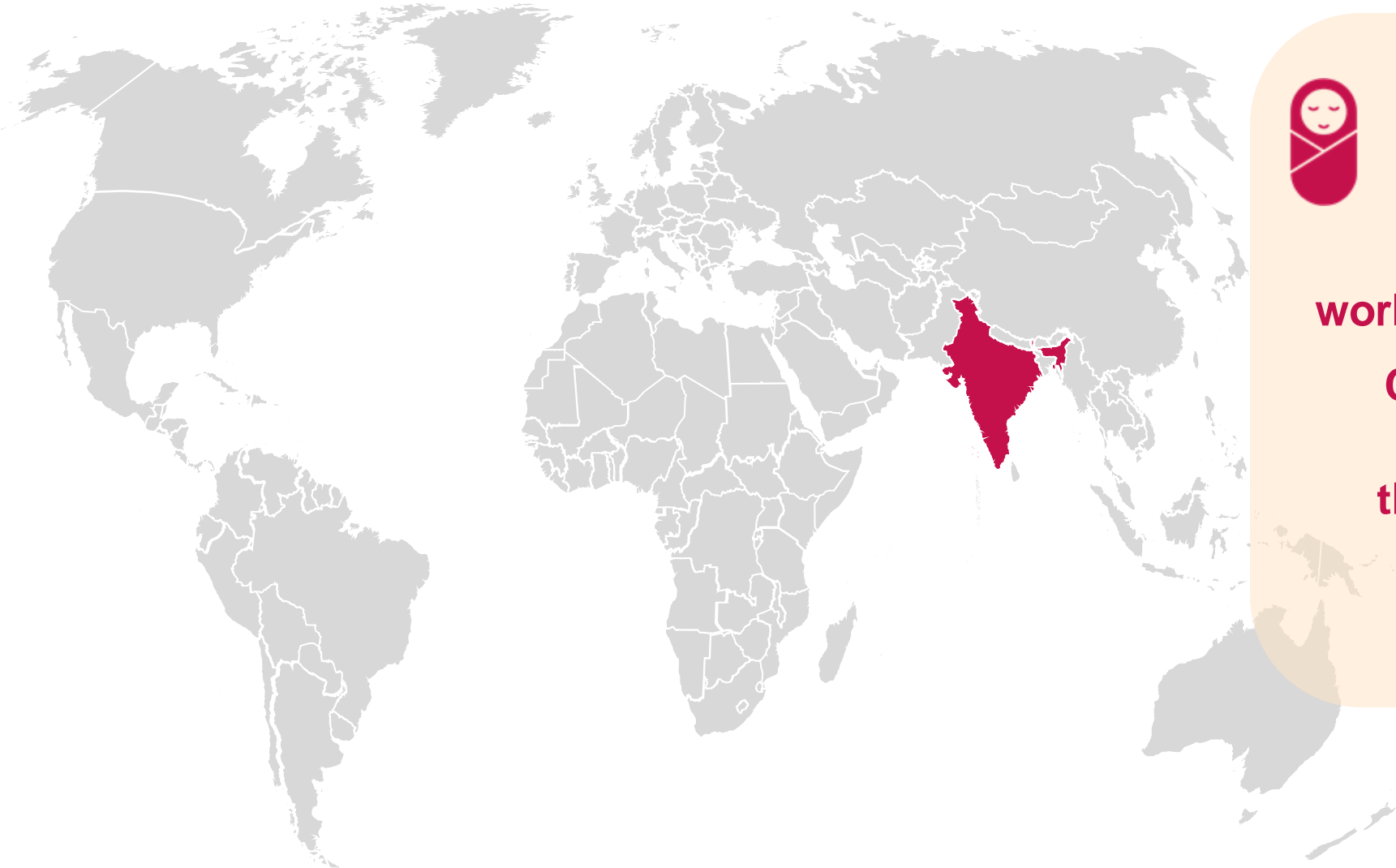


SECTION 02

# Uterotonics Use in India

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# Opportunities for India to Lead Childbirth Improvements Globally



**Nearly 1 in 5 babies worldwide are born in India.**

**Changes in India can influence changes throughout the world.**

# Uterotonics Use During Labor Varies Both Globally and in India, But It Can Be Very Common

*Data from systematic reviews on the prevalence of uterotonics use*

## FOR STARTING LABOR (induction)

- **India:** 3%–84% of births<sup>1</sup>
  - Wide variation

## FOR STRENGTHENING LABOR (augmentation)

- **Global:** 0.7% to 97% of births<sup>2</sup>
- **India:** > 50% of labors augmented with oxytocin (among the highest rates)<sup>2</sup>

1. MOMENTUM Safe Surgery in Family Planning and Obstetrics; Systematic review of pharmacological labor induction and augmentation in South Asia. Manuscript forthcoming in 2024.

2. Kujabi, M.L. et al. (2022). Labor augmentation with oxytocin in low- and lower-middle-income countries: a systematic review and meta-analysis. *AJOG Global Reports*, 2(4):100123. <https://doi.org/10.1016%2Fj.xagr.2022.100123>.

# What Drives Uterotonics Use For Doctors And Nurses in India, Even When Safeguards and Staffing Are Lacking?



## **“LEGACY” PRACTICES**

Common practice at  
medical colleges

Practices repeated in  
less-resourced primary  
and community settings



## **TIME AND SPACE CONSTRAINTS**

Pressure to expedite  
deliveries to free up  
staff and beds



## **DEMAND FROM PATIENTS/FAMILIES**

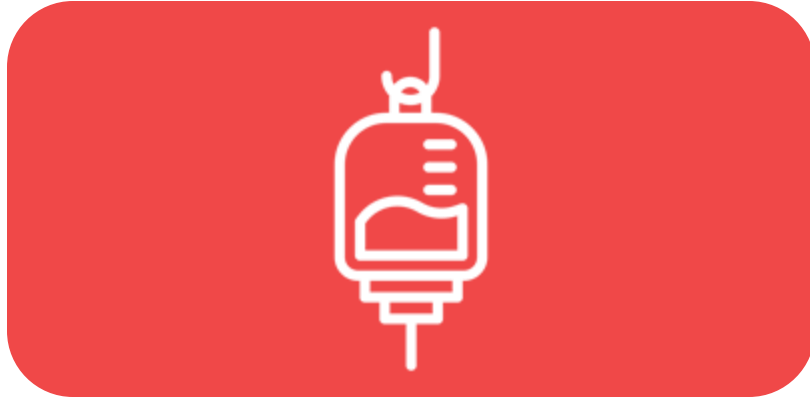
Cultural practice for  
women to request  
uterotonics to make labor  
strong and fast



## **LOW PERCEPTION OF HARM**

Little recognition that  
routine uterotonic use  
and lack of fetal and labor  
monitoring increase  
danger

# Why Do Patients And Families Desire Uterotonics?



## POSITIVE PERCEPTION OF UTEROTONICS

Speed up labor, shortening  
time spent at a facility

IV drip or injection seen as  
good care



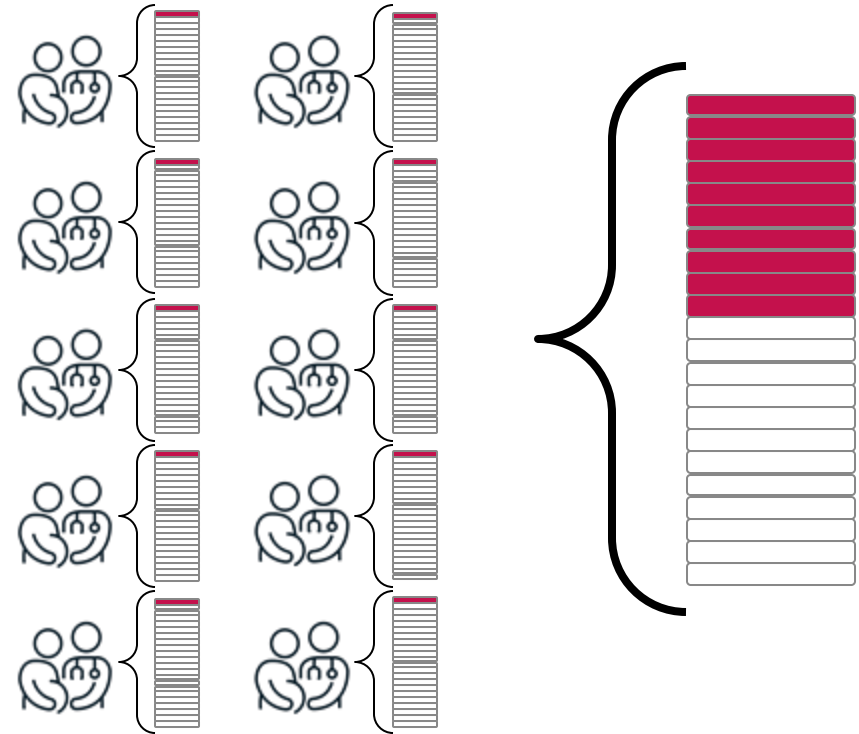
## LOW PERCEPTION OF HARM

Most unaware that unindicated  
and unmonitored uterotonics  
use can lead to poor outcomes  
in typical settings

# From Individuals to Systems



What might seem like a small risk of harm in an individual case...



...can lead to a large risk of harm at the current scale of use.



# GUIDELINES: Documents Exist, But Gaps Persist

- Guidelines exist globally and in India for labor induction and augmentation but are **not put into practice**
- Within the guidelines, there are several points that are unclear. For example:
  - Guidance on case selection
  - What constitutes “failed induction?”
  - Management strategies if a patient’s antenatal care history is unknown
- **There is no standard protocol** on drug types, doses, timing, and documentation



Across stakeholders, the potential for harm from uterotonics use was not a major concern

“It is harmful, but a little bit might not do too much harm. We don’t measure ingredients when we cook. It is all about a little of this, a little of that. This attitude extends to medication administration.”

-Nurse

(Paraphrased from interview)

*In other words, uterotonics use is a calculated risk, even when safeguards are lacking*



SECTION 04

# Next Steps

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## Next Steps for Changing Practices in India (1/2)

- **Build consensus** and awareness of negative health effects of uterotonics overuse among doctors, nurses, ASHAs, patients, and families.
- **Consolidate the research agenda** to systematically explore and document overuse in a standardized way.
- **Address ambiguity in guidelines** related to indications and what cases should—and should not—have labor induction or augmentation.



## Next Steps for Changing Practices in India (2/2)

- **Explore strategies to improve safety** of uterotonic use during labor in resource-constrained settings.
- **Standardize protocols for labor induction and augmentation**, emphasizing proper monitoring, dosing, variations depending on indication, and management of adverse events.
- **Secure joint support** from the public sector, private sector, and community groups to develop aligned messaging and strategies.



# Acknowledgments

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Thank you to each of the key informants who shared their time, passion, and knowledge to inform this slide deck. Thank you to the MOMENTUM Safe Surgery in Family Planning and Obstetrics team at the London School of Hygiene and Tropical Medicine for their thorough systematic review of labor induction and augmentation in India. Thank you to the Community Empowerment Lab for their guidance and for enabling feedback from nurses and ASHAs. Thank you to all the additional stakeholders who have been consulted on this topic informally. Thank you to the MOMENTUM Knowledge Accelerator staff who provided input into this slide deck.

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# Systematic Review of Labor Induction and Augmentation in India

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MOMENTUM Safe Surgery in Family Planning and Obstetrics



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# Outline

- Background & Review Aims
- Review Search Strategy
- Review Results
- Key Messages
- Further Reading



# Background & Review Aims

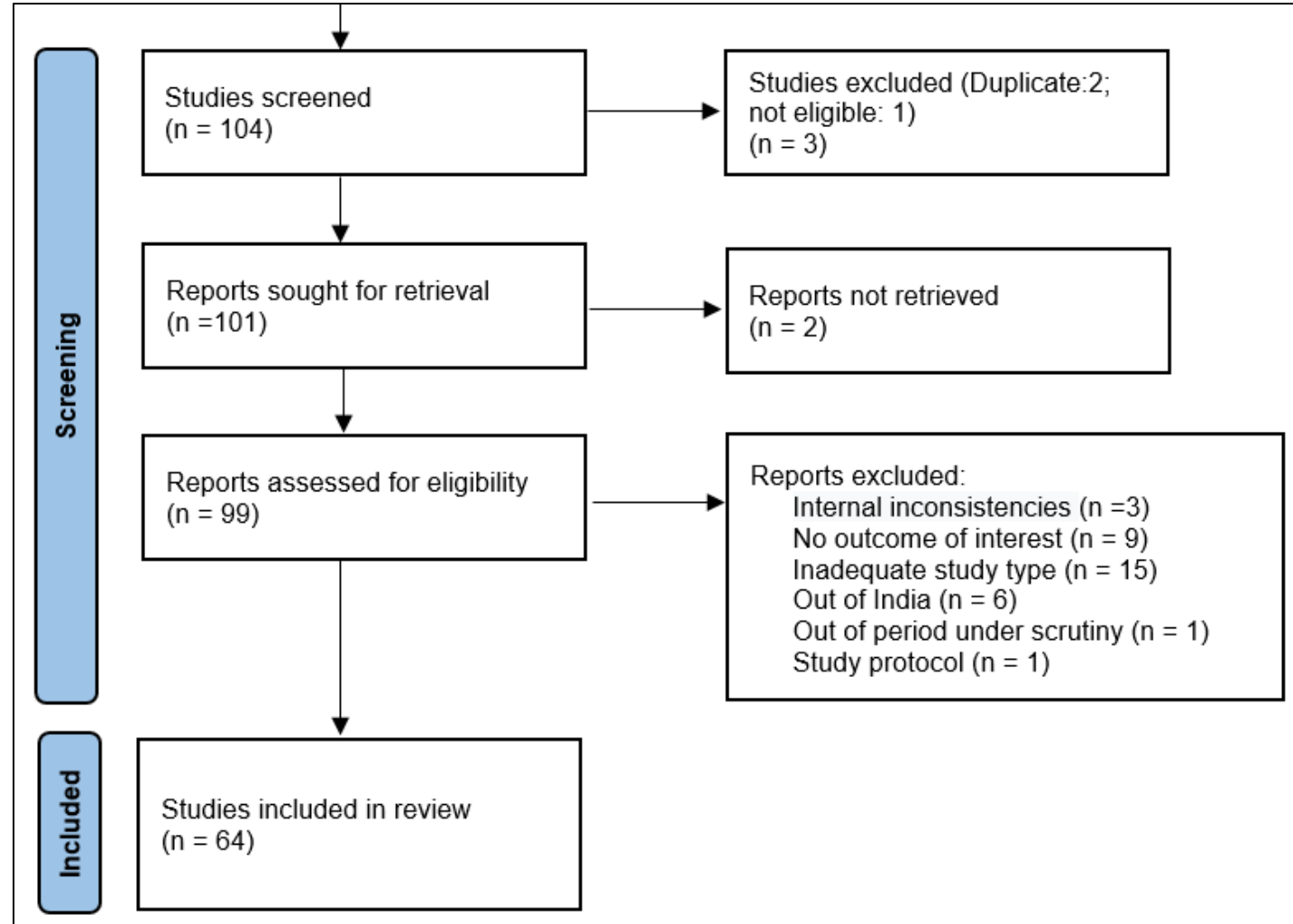
- **What we know:** Inappropriate induction and/or augmentation ↑↑ labor complications (e.g., ruptured uterus, acute fetal distress, stillbirth, uterine hyperstimulation)
- Review aims:
  - To describe **formal & informal** use of **pharm. induction** & assess outcomes
  - To describe **formal & informal** use of **pharm. augmentation** & assess outcomes
  - To identify **prevalence** of induction/augmentation **non-adherent WHO guidelines**
  - To describe **patient experiences** of induction & augmentation

# Systematic Review Search Strategy

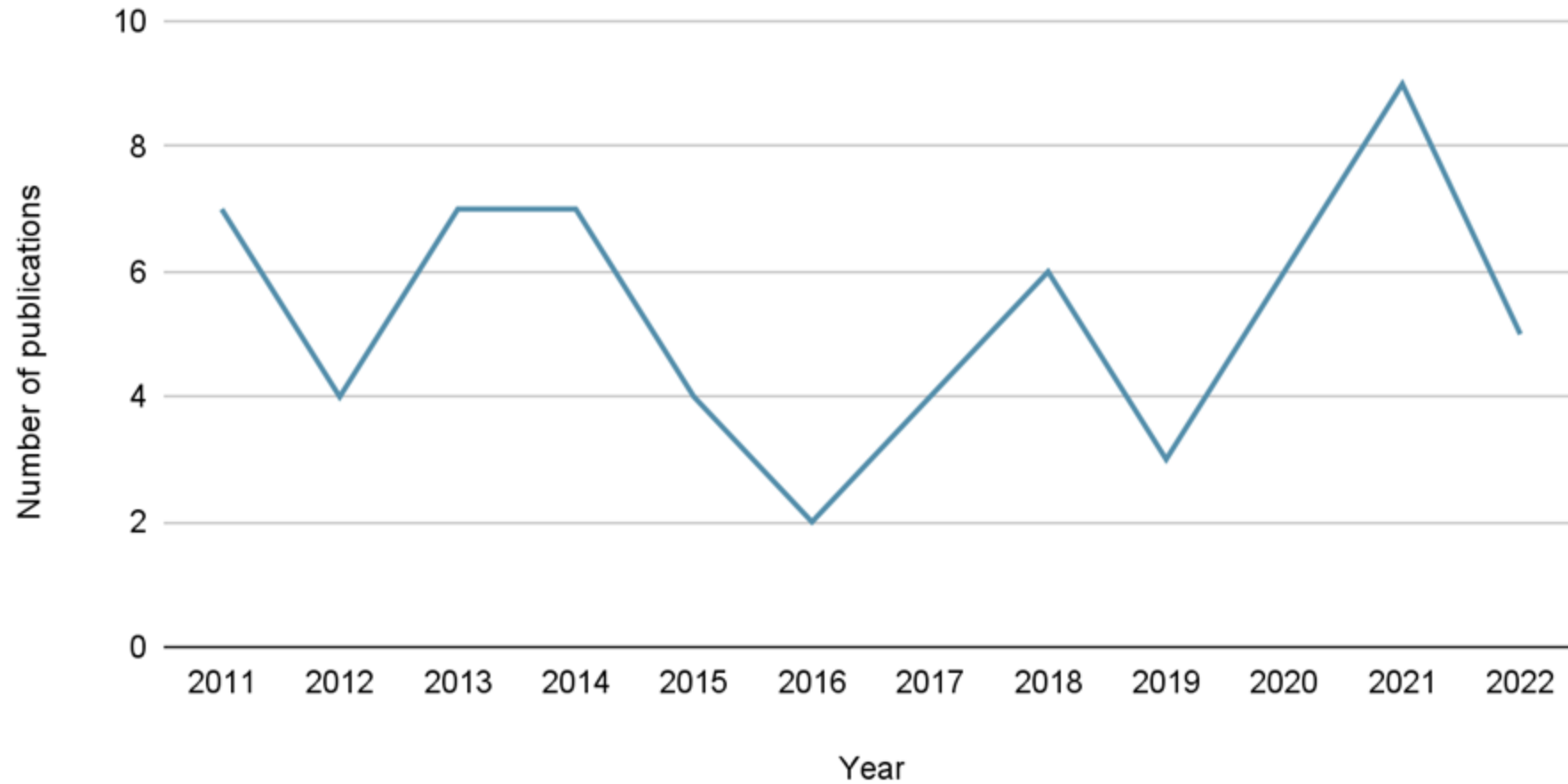
- **Published literature:** PubMed, MEDLINE, EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Web of Science, Global Health, African Journals Online, Global Health Library, Global Index Medicus, ProQuest Dissertations/Theses, Cochrane Central Register of Controlled Trials\*, EMCare, Google Scholar, STOR, Snowglobe (snowball search)
- **Grey literature:** Clinicaltrials.gov, WHO Trials, Cochrane Trials, OpenGrey, Int; Clin. Trials Reg. Platform
- **Period:** 2011 – 2022
- **Inclusion criteria:** Women with viable gestation defined by the individual study protocols who undergo induction and/or augmentation
- **Exclusion criteria:** Case reports, case studies, expert opinion, guidelines, editorials, letters to the editor, and comments will be excluded

# PRISMA Flow Chart

- 59 quantitative
- 3 qualitative
- 2 mixed methods



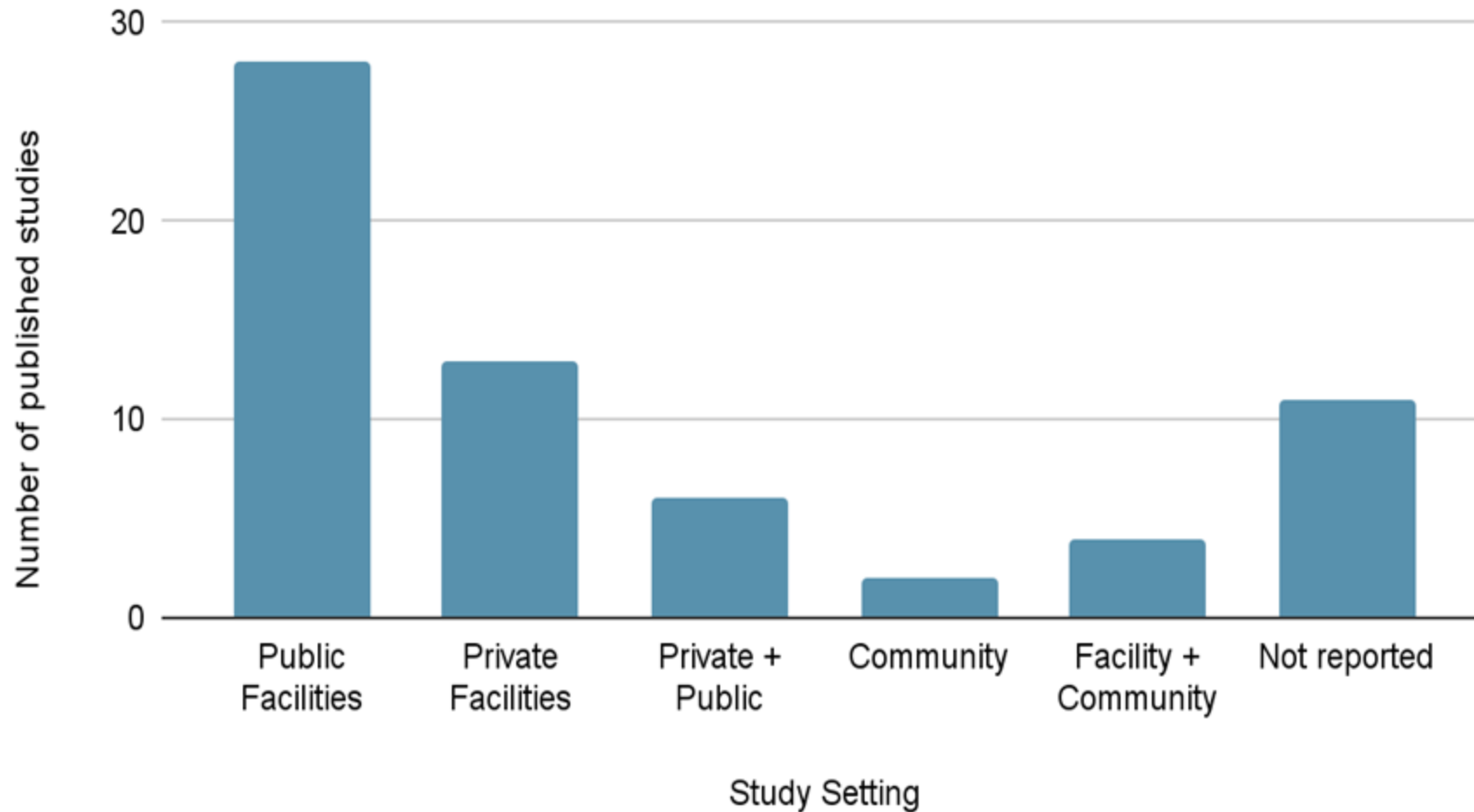
# Publications by Year



# Review Results (1)

- Many studies on augmentation and induction globally & India
- **Study characteristics:**
  - Primarily took place in public facility settings
  - Conducted across multiple regions and states in India
- **Variations** in measurement, small sample sizes, and non-standard measurement **made strong conclusions difficult and meta-analysis impossible**

# Publications by Study Setting



# Publications by Geography

State/geography (North, Central, East)	Number of studies published between 2011 and 2022
Uttar Pradesh	5
Delhi	5
Haryana	2
Punjab	3
Bihar	2
Himachal Pradesh	2
Chandigarh	2
Madhya Pradesh	1
Jharkhand	1
Chhattisgarh	1
<b>TOTAL (North, Central, East)</b>	<b>24</b>

State/geography (South and West)	Number of studies published between 2011 and 2022
Karnataka	7
Maharashtra	7
Tamil Nadu	4
Puducherry	2
Gujarat	2
Kerala	1
<b>TOTAL (South and West)</b>	<b>23</b>
Multiple geographies in India	<b>6</b>
Geography not reported/Unknown	<b>11</b>

## Review Results (2)

- **Huge variation** in pharm. induction and augmentation **practices**
- **Induction in 3–84%** of facility births (n: 50–676 women)
- **Augmentation in 10–87%** of facility births (n: 50–4689 women)
- Augmentation is more common when labor is induced
- No study reported on time elapsed between last dose of induction agent and augmentation



# Non-adherence to WHO Standards for Labor Augmentation

(Reported in 5 quantitative studies)

Studies	Findings
Study 1	> 26.1% augmentation (oxytocin) before admission in facilities (n=800)
Study 2	76.4% augmentation with oxytocin in home births Intramuscular oxytocin (23% facility births) No monitoring of augmented labor by care providers
Study 3	> 45.7% augmentation practices non-adherent (60 PHC facilities)
Study 4	75% «injudicious» use of oxytocin on scarred uterus (1 tertiary hospital)
Study 5	64.4% augmentation without medical indication (3 medical training hospitals) 61% augmentation without partograph (3 medical training hospitals) Fetal heart rate check hourly (87.3%) & half-hourly (12.6%) (3 medical training hosp.)

# Non-adherence to WHO Standards for Labor Augmentation

(Reported in 5 qualitative or mixed-methods studies)

## Decision to augment labor

- Augmentation without medical indication, as routine practice
- Augmentation is common in inappropriate settings (under-equipped facilities & home)

## Process of augmentation

- Use of misoprostol for augmentation
- Departure from protocols: quasi-systematic augmentation by care providers
- Augmentation by unskilled providers (traditional birth attendants, Dais)
- Augmentation without partograph
- Pain as a monitoring indicator

# Potential Drivers of Induction and Augmentation Reported in Studies

- Augmentation seen by community as a sign of high-quality labor care, which increases demand
- Augmentation may be a management tool in overcrowded labor and delivery wards

# Key Messages

- Induction and augmentation are common and occurring in all types and levels of health facilities; also reported in home births
- Many practices reported in the included studies were non-adherent to protocols (even in high-level facilities)
- Quality of care gaps may reflect normative and knowledge challenges, including:
  - Normalization of oxytocin use by providers aligns with pop. beliefs/demand
  - Low awareness and little action on risks

# Considerations

- **Caution:** Findings may not reflect current practices or emerging trends
  - Even studies published in 2022 are likely based on data that is now 5+ years old
- **New national guidelines** provide a framework for improved practices

# Further Reading

**MOMENTUM**  
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## INDUCTION AND AUGMENTATION OF LABOR IN INDIA: EXCESSIVE AND INAPPROPRIATE USE OF UTEROTONICS IN AND OUT OF HEALTH FACILITIES

**Key findings from a systematic review**

**INDUCTION AND AUGMENTATION OF LABOR**, when medically indicated and safely provided, can improve outcomes for women and newborns. The following measures make induction and augmentation safe: careful dose titration, close maternal and fetal monitoring, and rapid management of complications. The World Health Organization (WHO) Labor Care Guide, designed to replace the partograph, includes indications for augmentation.<sup>1,2,3</sup>



Improving quality of care for women and newborns is a major priority in India, which accounts for 12% of global maternal deaths, 17% of global stillbirths, and 20% of global neonatal deaths. Previous research in India has shown high augmentation rates, with estimates that more than half of births occur after augmentation of labor.<sup>4,5</sup> Less is known regarding induction of labor in India.

The MOMENTUM Safe Surgery in Family Planning and Obstetrics project conducted a systematic review of peer-reviewed publications reporting primary data on pharmacological induction and augmentation of labor in India published between January 1, 2011 and December 31, 2022. The goal was to determine the prevalence and features of induction and augmentation of labor. This review identified 59 high-quality studies, highly variable in design, geographies, women's profiles, and outcome measures.

**Induction of labor** is the artificial stimulation of cervical ripening and progressive uterine contractions to initiate birth.<sup>1</sup>

**Augmentation of labor** is the process of stimulating the uterus to increase the frequency, duration, and intensity of contractions after the onset of labor.<sup>2</sup>

**Uterotonics** are drugs that can increase uterine contractions and be used for induction or augmentation.

APRIL 2024



[usaidmomentum.org/resource/induction-and-augmentation-of-labor-in-india-excessive-and-inappropriate-use-of-uterotonics-in-and-out-of-health-facilities](https://usaidmomentum.org/resource/induction-and-augmentation-of-labor-in-india-excessive-and-inappropriate-use-of-uterotonics-in-and-out-of-health-facilities)



# Q&A

Please submit and upvote questions for presenters using the Zoom Q&A function.



# Results of the 2022 Global Survey on National Programs for the Prevention and Management of Postpartum Hemorrhage and Hypertensive Disorders of Pregnancy

Gaurav Sharma, MOMENTUM Private Healthcare Delivery and Suzanne Stalls, MOMENTUM Country and Global Leadership

Webinar on Improving Childbirth Outcomes by Optimizing the Use of Uterotonics: Sharing Learning and Tools; July 25, 2024



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Theme 6: National Reporting on Select Maternal and Newborn Health Indicators

Theme 7: Bottlenecks and Scale-Up Opportunities

## **SECTION 3:** Summary and Recommendations



SECTION 1

# Background and Methods

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# Background—Postpartum Hemorrhage and Hypertensive Disorders of Pregnancy

Direct causes of maternal deaths account for nearly 75% of maternal deaths. (Say et al. Lancet 2014)

- Hemorrhage (27.1%), mostly postpartum hemorrhage (PPH)
- Hypertensive disorders of pregnancy (HDP) (14%), e.g., pre-eclampsia/eclampsia (PE/E)
- Sepsis (10.7%), usually following birth

In 2011/2012, U.S. Agency for International Development (USAID) and the Maternal and Child Integrated Program conducted a survey of national programs working on reducing maternal mortality from PPH and PE/E.

Since 2012, several important updates have occurred in the global guidance on preventing and managing PPH and HDP.

However, we know little about policies, commodities, and quality of care provided in the private sector and the extent to which global guidelines, updated in the last 10 years, have been integrated into public and private sectors.

Additionally, we aim to understand the role of professional associations in policy development and whether updated guidelines are integrated into national education and training curricula.

# Methods

**Timeline:** January–May 2022

**Where:** 31 countries in sub-Saharan Africa, South and Southeast Asia, and Latin America and Caribbean (LAC)

**Sampling:** Purposive sampling of USAID priority countries, countries with MOMENTUM presence, and UNFPA priority countries

**Survey Instrument:** 69-question survey instrument developed and validated through a robust and iterative process with the Postpartum Hemorrhage Community of Practice (PPH CoP), USAID maternal health team, UNFPA, and the Jhpiego maternal and newborn health team. Translated into French, Spanish, and Portuguese by experienced translators and programmed into Survey Monkey.

**Data collection:** Led by JHPIEGO, except in 7 LAC countries where UNFPA led the process.

**Data analysis:**

- Quantitative data analyzed using Power BI and Excel and composite scores developed
- Thematic analysis for qualitative data



SECTION 2

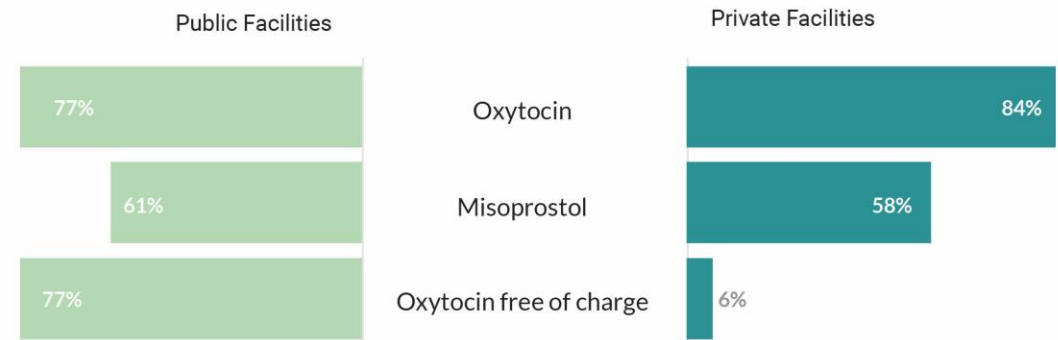
# Findings

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# Theme 1: Essential Drug Availability (PPH)

- Rates of essential drugs for PPH and HDP on Essential Medicines Lists (EMLs) are generally reported as high.
- All countries report that oxytocin and magnesium sulfate (MgSO<sub>4</sub>) are on the EML, as well as high rates of anti-hypertensive and other uterotonic drugs on the EML.
- Adequate drug availability at medical stores is reported in most countries, but there are lower rates of medications at the facility level compared to medical stores.

## Regular availability of PPH drugs in public and private sectors 2022

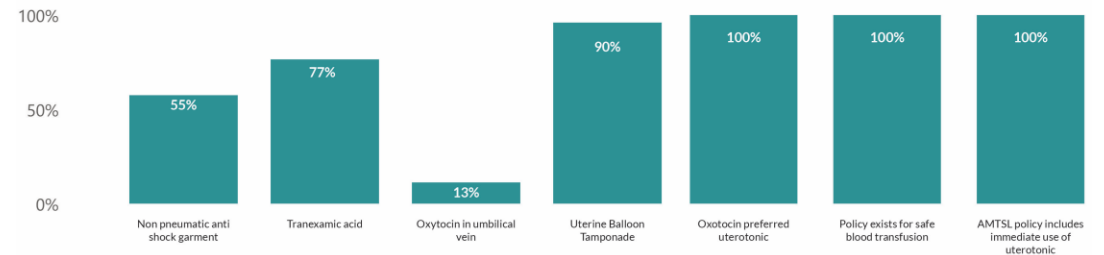


Regularly available is defined as > 80% of the time

# Theme 2: Updated National Guidelines

- More than half of countries report all WHO recommendations have been included in the national guidelines. Additional work is necessary to integrate all recent WHO updates for PPH and HDP into national guidelines across public and private sectors.
- Though in 2012 misoprostol was reported as rarely available at most facilities with very few countries having misoprostol in its EML or in its national guidelines, misoprostol is now reported by 97% of countries to be on the EML and regularly available in approximately 60% of all countries surveyed.

National guidelines updated to WHO recommendations for PPH 2022

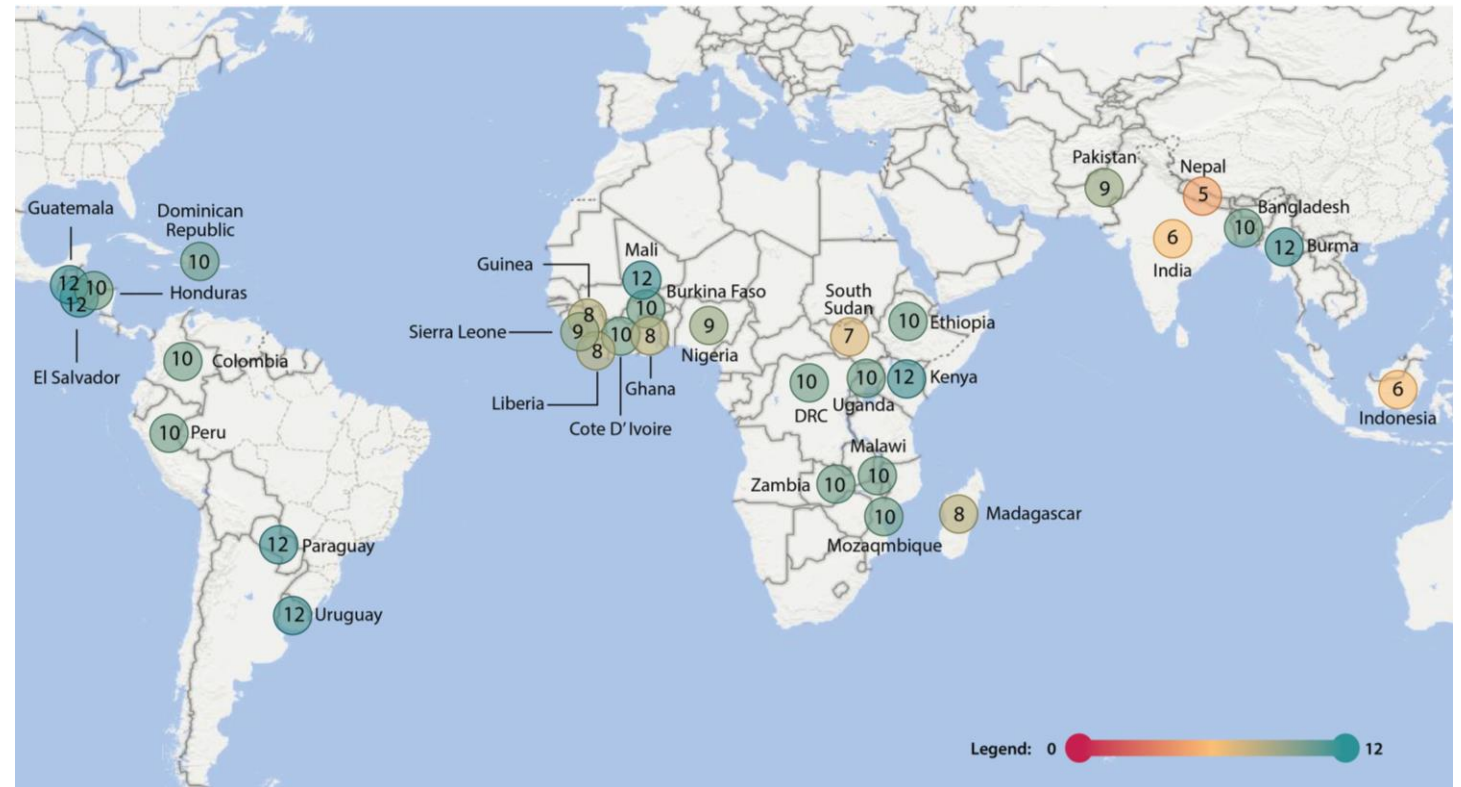




# Theme 3: Quality and Procurement Policies

- Data shows need and interest in addressing the quality of medications at point of delivery.
- Composite scores show variable progress across countries, ranging from 5–12.
- Quality, storage, and safety for oxytocin and MgSO<sub>4</sub> in both public and private sectors need to be improved.

Figure 1: Quality and procurement policies for PPH and HDP in 2022

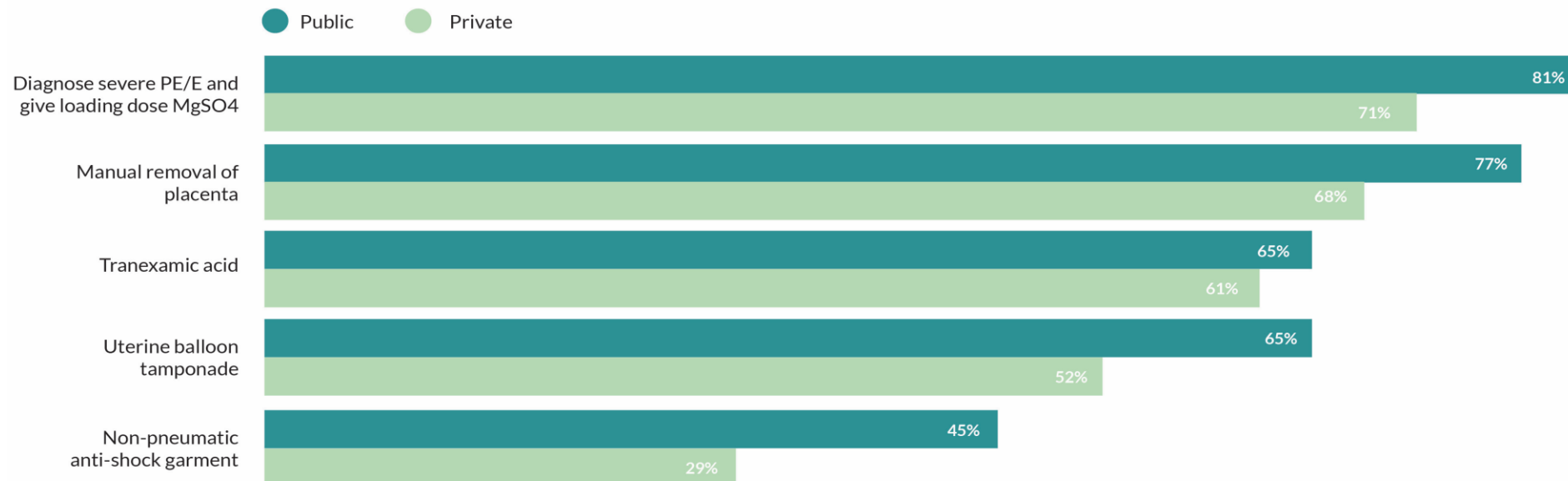


Note: Composite score for medication quality and procurement policies is comprised of 12 indicators including: whether national procurement and distribution policies exist for oxytocin, misoprostol, and ergometrine; whether systems exist to manage controlled cold-chain for oxytocin and to ensure a 50% solution of MgSO<sub>4</sub> in public and private facilities; and whether logistics systems exist to procure and distribute essential PPH and HDP drugs in the private sector.

# Theme 4: Midwife Scope of Practice

- Limited scope in providing basic emergency obstetric and newborn care (BEmONC) skills in some countries.
- Few key global updates in PPH management have been updated in the scope of practice of midwives in some countries—for example, use of tranexamic acid and uterine balloon tamponade.
- Private sector seems to lag behind public sector in updating midwives' scope of practice.

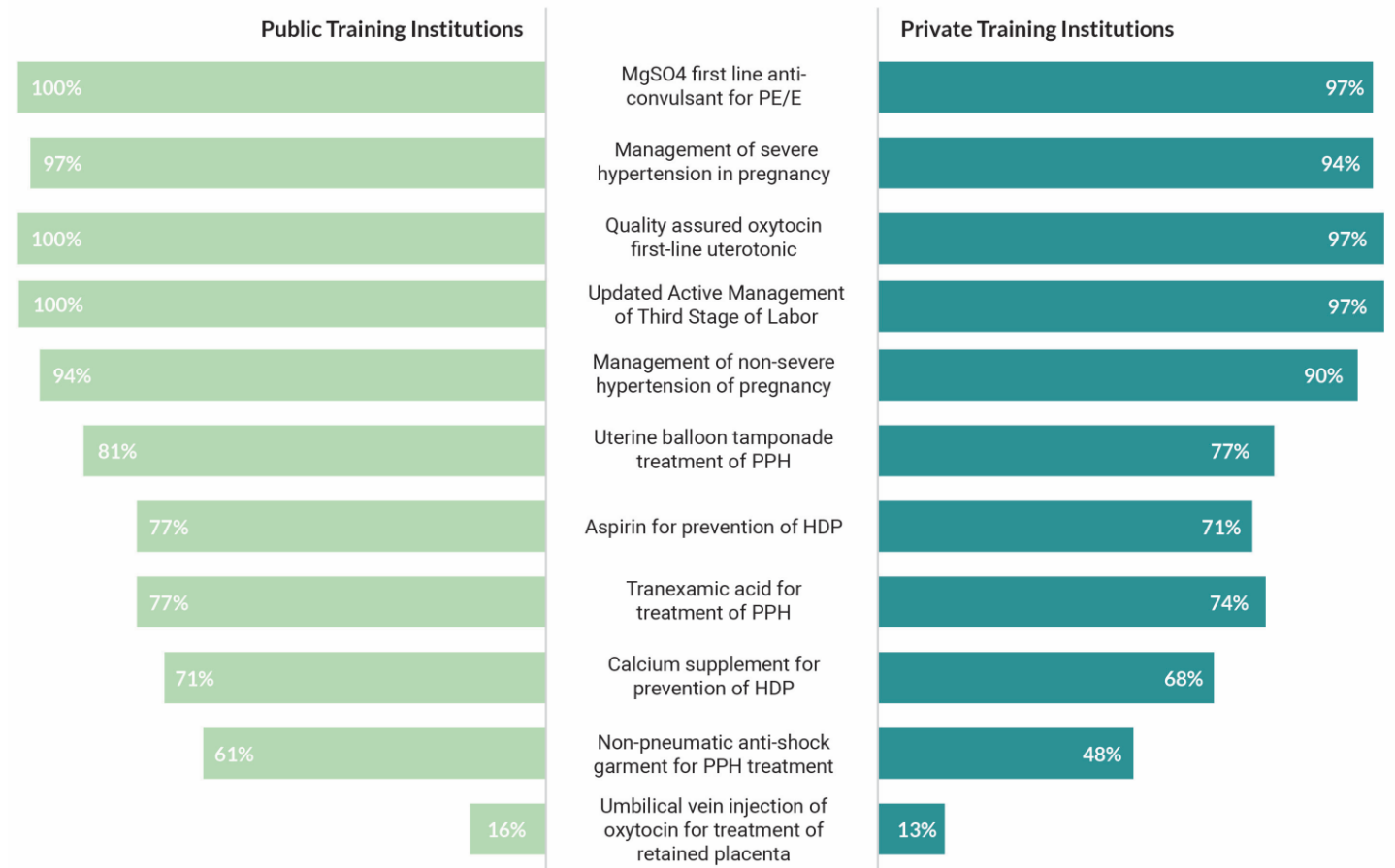
## Midwife scope of practice for PPH and HDP interventions 2022



# Theme 5: Capacity Building and Training

- Overall, many countries report that pre-service and in-service curricula have been updated.
- Private sector reports lower coverage in comparison to public sector for most practice updates.
- Further examination of training curricula is needed.
- Capacity building and training across public and private sectors was consistently identified as a bottleneck.

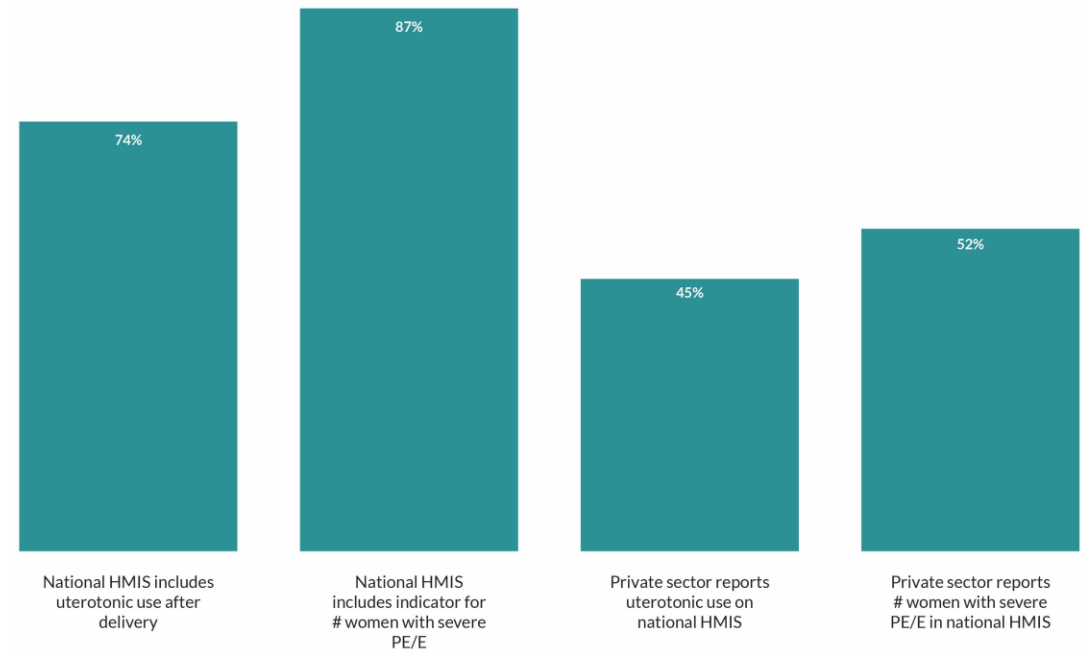
## Pre-service curricula updated to global best practices for PPH and HDP 2022



# Theme 6: National Reporting on MNH Indicators

- Considerable improvements in national reporting on key coverage and prevalence indicators.
- 74% of countries reporting on use of uterotonics, compared to 43% of countries in 2012.
- 87% of countries reporting number of women with severe PE/E in the HMIS, compared to 51% in 2012.
- Private sector reporting at lower rates overall

PPH and HDP indicators on HMIS for public and private sectors 2022



# Theme 7: Bottlenecks and Scale-Up Opportunities

Public and Private Sector Collaboration	Quality Assurance	Quality Improvement
<ul style="list-style-type: none"><li>• Improve systems to ensure public and private sector adherence to the same national guidelines.</li><li>• Improve referral system within and between public and private sectors.</li><li>• Improve capacity of skilled MNH workforce across sectors in clinical areas.</li><li>• Strengthen coordination and M&amp;E systems between public and private sectors.</li></ul>	<ul style="list-style-type: none"><li>• Improve quality control of medicines, including cold chain and availability of 50% MgSO<sub>4</sub>.</li><li>• Strengthen the policy environment that enables quality assurance of commodities and adherence to evidence-based practices.</li></ul>	<ul style="list-style-type: none"><li>• Sub-optimal quality of care across facilities in both sectors.</li><li>• Insufficient systems to address and improve existing quality gaps in both sectors.</li><li>• Strengthen quality improvement approaches through collaborative learning and adapting/data use.</li></ul>



SECTION 3

# Summary and Recommendations

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# Key Takeaways

Prioritize integration of all current global evidence and interventions into national policies and guidelines.

Amplify the dissemination of the current global evidence and guidelines through pre-service education and in-service training.

Strengthen professional associations' role in MNCH national fora, policy development, and ministry of health oversight across sectors.

Address lifesaving medication availability by focusing on national-level policy and guidelines to address district/regional medical store availability and distribution systems to facilities.

Expand the midwife scope of practice to include management of BEmONC as recommended by the International Confederation of Midwives' core competencies.

Create opportunities for public and private sectors to work together in capacity building, commodity supply chain, M&E and reporting, guideline standardization, emergency referral systems between sectors; and include private sector in strategic planning.

Continue to strengthen data collection on key MNH indicators to improve PPH and HDP surveillance.

# Call to Action:

## Bottlenecks identified

### Lack of collaboration between the public and private sector

- Inconsistent use of national guidelines in both private and public sectors
- Inadequate emergency referral systems between and within the public and private sectors
- Lack of coordinated capacity building and training for both the public and private sectors
- Weak M&E systems in both sectors

### Limited quality assurance mechanisms in place for optimal provision of MNH services

- Inconsistent availability of quality assured essential drugs at facilities
- Suboptimal policy environment to enable quality assurance at facilities
- Inconsistent quality of care at facilities

### Inadequate quality improvement systems for commodities, services and practices

- Insufficient systems to address and improve existing quality gaps in both sectors
- Lack of systems to ensure quality control of essential medications
- Inadequate policy environment to enable quality improvement of commodities and practices

## Potential interventions and opportunities identified

### NATIONAL LEVEL OPPORTUNITIES

- Update policies and align with existing national guidelines and standards.
- Consider a national strategy for consistent distribution of essential drugs and commodities.
- Introduce newer, evidence-based prevention and treatment strategies for postpartum hemorrhage (PPH) and hypertensive disorders of pregnancy (HDP) into national policy.
- National governance mechanisms and policies exist to ensure the private sector uses national guidelines and standards and to monitor adherence to guidelines/standards.
- The Ministry of Health provides oversight for sensitization and implementation of guidelines and standards to private and public sectors.
- Use the same regulatory frameworks to support public and private sectors.
- Strengthen accountability mechanisms in data reporting for both sectors.
- Increase financing for essential drugs, e.g., magnesium sulfate.
- Strengthen financing for M&E.
- Strengthen systems to provide safe blood and essential drugs at all facilities providing MNH care.
- Build systems to reinforce national policies to ensure quality control of essential drugs and commodities in public and private sectors.
- Build collaboration between public and private sectors on referral systems.

### SUB-NATIONAL LEVEL OPPORTUNITIES

- Provide in-service training and updates on guidelines to public and private sector providers simultaneously.
- Strengthen logistics of referral transport to enable adequate and timely referrals (e.g., functional ambulances, passable roads).
- Build collaboration between public and private sectors on referral systems.
- Monitor systems to assure adequate supply of essential drugs and commodities at all facilities providing MNH services.

### FACILITY LEVEL OPPORTUNITIES

- Strengthen identification of high-risk cases and appropriate referral for higher level care.
- Provide safe blood and essential drugs at all facilities providing MNH care.
- Address mechanisms to assure quality of essential drugs along the procurement and distribution chain to point of care.
- Use policy to reinforce use of guidelines at the point of care.
- Address capacity of MNH skilled personnel with competency-based training and post-training follow-up.
- Initiate quality improvement projects to improve utilization of evidence-based practices for PPH and HDP management.

## Outcomes



Improved public-private collaboration for more effective, efficient, and coordinate MNH service delivery to every woman



Improved quality assurance of drugs, commodities, and services for an enabling clinical environment to optimize MNH interventions and care to every woman



Improved quality improvement processes to optimize MNH interventions and care to every woman

## Impact



**Decrease preventable maternal death from PPH and HDP**





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# Thank you!

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# Heat Stable Carbetocin

Proposed Evaluation Strategy for the Introduction  
of a New Medication to Prevent Postpartum  
Hemorrhage: Learnings From Madagascar

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Megan Marx Delaney, Research Scientist, Ariadne Labs, Harvard T.H Chan School of Public Health  
MOMENTUM Knowledge Accelerator

Optimizing Uterotonics Webinar | July 2024



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SECTION 01

# Background

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# Postpartum Hemorrhage Is a Major Cause of Maternal Death

- **Major Obstetric Complication (1)**

- Globally, approximately one-quarter of the annual 300,000 maternal deaths are related to complications of PPH.

- **Prevention Is a Key Strategy (2)**

- Uterotonic medications
- Delayed cord clamping
- Controlled cord traction by skilled staff



FIGO-ICM JOINT STATEMENT OF RECOMMENDATION FOR THE USE OF UTEROTONICS  
FOR THE PREVENTION OF POSTPARTUM HAEMORRHAGE

June 2021

There is global excitement for new medications like heat stable carbetocin.

PRESS RELEASE 2019

Heat-stable carbetocin has been added to the WHO Essential Medicines List for the prevention of excessive bleeding after childbirth

**WHO study shows drug could save thousands of women's lives**

27 June 2018 | News release | Geneva | Reading time: 2 min (499 words)

# Additional Medications Save Lives, but Complexity Can Be Confusing


	Prevention	Treatment
Adequate cold chain and storage	<p>Best option: Oxytocin</p> <p><b>Second choice:</b> If quality oxytocin is unavailable, then <b>Heat-stable carbetocin</b> <i>or</i> Misoprostol <i>or</i> ergometrine</p>	<p>Best option: Oxytocin AND tranexamic acid</p> <p>Second choice: If quality oxytocin is not available or in addition to oxytocin Misoprostol and/or ergometrine <b>(No heat stable carbetocin)</b></p>
Insufficient cold chain, competent health provider available	<p>Best option: <b>Heat stable carbetocin</b> <i>or</i> misoprostol</p>	<p>Best option: misoprostol And tranexamic acid <b>(No heat stable carbetocin)</b></p>
Insufficient cold chain, NO competent health provider available	<p>Best option: misoprostol <b>(No heat stable carbetocin)</b></p>	<p>Best option: misoprostol <b>(No heat stable carbetocin)</b></p>

# HSC and Oxytocin Are Not Interchangeable

## Potential for Harm

	Heat stable carbetocin	Oxytocin
Prevention of PPH	✓	✓
Induction of labor	✗	✓
Augmentation of labor	✗	✓
Treatment of PPH	✗	✓





Madagascar is a leader in introducing heat stable carbetocin.

Globally, implementation research is needed on how to safely integrate heat stable carbetocin into supply chains and bedside practices.



Call for Implementation Research

Learnings From  
Madagascar Can  
Inform HSC  
Introduction in Other  
Geographies



SECTION 02

# HSC Roll-Out in Madagascar

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# HSC Journey in Madagascar

2019	2021	2021-23	2024	2025	2026
<b>Heat stable carbetocin is added to the UNFPA essential medicine list</b>	<b>National action plan developed for new and lesser used commodities (including HSC) for 2021 to 2023</b>	<b>National approval for HSC; distribution to 5 districts; initial training of trainers</b>  <b>Oct 2023: New Action plan for 2024-26 developed</b>	<b>Additional implementation support to initial 5 regions</b>	<b>Scale up of HSC to additional 7 regions (USAID priority regions)</b>	<b>Nationwide scale up of HSC</b>



Attendees at the workshop on new and less used commodities, October 2023

## Stakeholder Feedback From Oct 2023 Convening

### Greatest Successes With HSC

- Overcoming cold chain challenges
- Perceived beneficial impact on PPH prevention
- Adds choice for healthcare providers

### Challenges With HSC

- Unmet needs
- Reluctance of healthcare providers
- Insufficient training
- Support policies at facility



SECTION 03

# HSC Evaluation and Research

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# Key Research Questions

1. How has the introduction of HSC affected uterotonic use for postpartum hemorrhage prevention at facilities where HSC was introduced?
2. Were there any cases of incorrect use or patient harm associated with the introduction of HSC?
3. What implementation support is needed to ensure sustained adoption and proper use?

# Domain for Evaluation

DIMENSION	DESCRIPTION	RELEVANCE TO HEAT-STABLE CARBETOCIN ROLLOUT
<b>Reach</b>	Proportion of the target population that participated in the intervention, measured at the individual level	Proportion of women correctly receiving HSC immediately after delivery for postpartum hemorrhage prevention at each facility  Incorrect use of HSC at each facility (e.g., use of HSC during labor or to treat active postpartum hemorrhage)
<b>Effectiveness</b>	Success rate if used as expected, measured at the individual level	Effects of HSC on number of cases of postpartum hemorrhage  Adverse health effects of HSC, particularly related to unindicated use
<b>Adoption</b>	Proportion of settings that adopted the intervention, measured at the organizational level	Facility uptake of the heat-stable carbetocin implementation package at a regional level (i.e., among facilities that were supposed to start using HSC, how many received the planned intervention of HSC supply, training, job aid, and HSC monitoring)
<b>Implementation</b>	Consistency of the intervention components, cost, and variations of the intervention, measured at the organizational level	Consistency, cost, and variation in the main inputs for the intervention, including: <ul style="list-style-type: none"> <li>• Training of birth attendants</li> <li>• Availability of HSC in facilities</li> <li>• Job aids</li> </ul> Data collection and monitoring
<b>Maintenance</b>	Maintenance of intervention effects in individuals and settings over time	Sustained availability, adoption, and correct use of HSC over time



# Snapshot: Evaluation Framework Details

**Table 4: Research question #1: How has the introduction of HSC affected uterotonic use for PostPartum Hemorrhage prevention at facilities where HSC was introduced?**

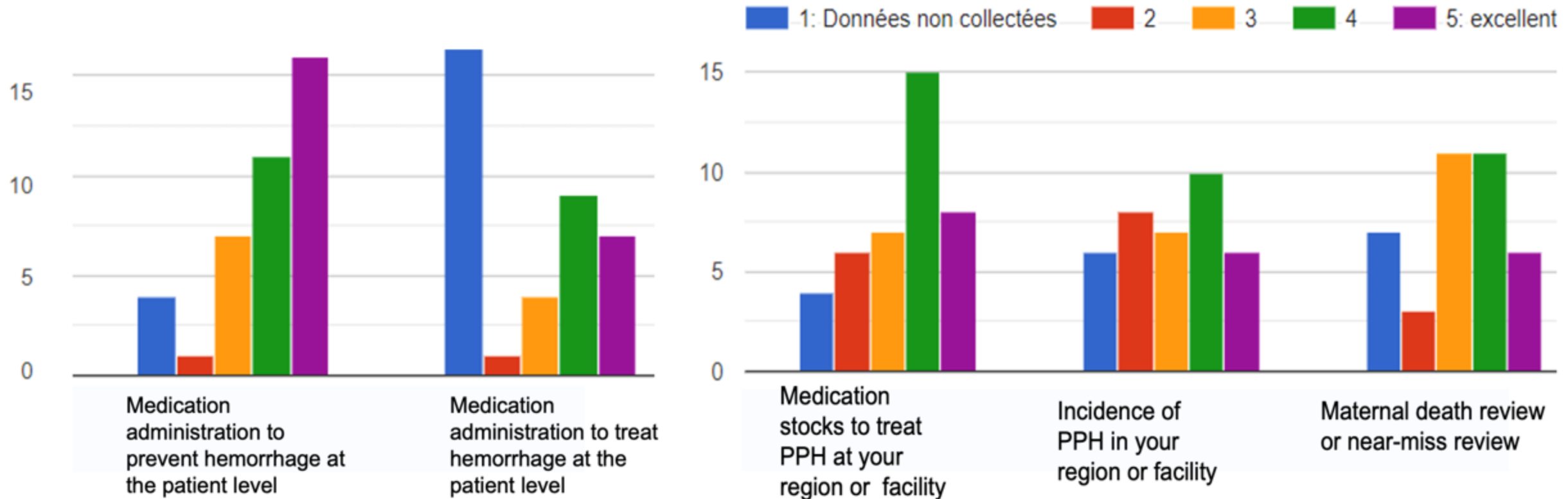
GENERAL MEASURE	MEASUREMENT DETAILS AND CONSIDERATIONS	POSSIBLE DATA SOURCES (TYPE OF DATA)	RECOMMENDED FREQUENCY	RE-AIM FRAMEWORK
Proportion of women receiving any uterotonic for postpartum hemorrhage prevention at each facility, stratified by drug type	<ul style="list-style-type: none"> <li>● Individual-level uterotonic administration (Indicator #1.1):               <ul style="list-style-type: none"> <li>– Denominator: Total number of women giving birth at an HSC rollout facility during the past month</li> <li>– Numerator: Total number of women giving birth at an HSC rollout facility during the last month who received any uterotonic after delivery for postpartum hemorrhage prevention, stratified by type of drug (HSC vs. oxytocin vs. misoprostol vs. other uterotonics)</li> </ul> </li> <li>● Additional details to capture about HSC, if available:               <ul style="list-style-type: none"> <li>– Timing of administration</li> <li>– Dose administered</li> </ul> </li> <li>● Additional details on facility characteristics, to stratify results, if available:               <ul style="list-style-type: none"> <li>– Availability of cold chain at facility</li> <li>– Type of facility (e.g., primary, secondary, tertiary; private vs. public)</li> <li>– Number of deliveries at the facility</li> <li>– Number and type of health care providers at the facility who help with childbirth on a typical shift</li> <li>– Facilities that have received the HSC implementation package vs. those that have not</li> <li>– Availability of each type of uterotonic drugs (HSC, oxytocin, misoprostol, other uterotonics)</li> </ul> </li> </ul>	Register data (Quantitative)	Monthly summary of register data  If registers do not regularly document this indicator, intentional data collection at 3 months, 12 months, and 24 months after HSC implementation	Reach

# Ideal Timeline



# Potential Data Sources to Consider in Evaluation

- Survey of participants in workshop in Oct 2023 about what data are available



# Thank you!

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# Q&A

Please submit and upvote questions for presenters using the Zoom Q&A function.