Implementation Science Communications

Barriers and bottlenecks to implementation of WHO recommendations for prevention, detection, and treatment of postpartum hemorrhage: A mixed-methods triangulation study

--Manuscript Draft--

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Abstract:	Background The World Health Organization develops evidence-based recommendations for postpartum hemorrhage (PPH) prevention, detection, and treatment. However, persistently high PPH-related mortality suggests recommendations are poorly implemented, especially in low-resource settings. This study aimed to identify implementation bottlenecks to inform action. Methods Drawing on public policy, implementation science, and health behavior, we constructed a multi-level framework to identify bottlenecks affecting recommendation uptake. This informed the development of a survey assessing which bottlenecks affected specific WHO recommendations. Surveys were completed by global stakeholders and by health care workers in three high-burden countries. We also analyzed direct observations of clinical practice from those countries to see how bottlenecks affected practice. An a priori interpretive threshold of 75% was selected to indicate a bottleneck was not a severe impediment to implementation. Results Surveys from 102 global stakeholders and 246 health care workers, as well as 2039 direct observations of clinical practice revealed variation in adherence to WHO recommendations, with some through-lines. Oxytocin for PPH prevention and treatment was perceived to have national policy support (>75% for inclusion in national guidelines and Essential Medicines Lists, regulatory approval, and support from national champions) but other uterotonics were not. Tranexamic acid for PPH treatment was found to be underutilized, likely due to compounding bottlenecks. Respondents reported extensive bottlenecks to refractory PPH interventions (<75% across nearly all bottlenecks). The most substantial bottlenecks were availability/procurement of medicines and devices, affordability and quality of medicines and devices, presence of job aids, and availability of qualified staff. Observed practice generally aligned with stakeholder perceptions. Conclusions National policy bottlenecks strongly mediated implementation in clinical practice. Policy change addressing gaps in commodity procurement and availability of trained clinicians is critical. Efforts addressing only one part of the implementation ecosystem are unlikely to drive transformative change.

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Response to Reviewers:	FORMATTED RESPONSE TO REVIEWER COMMENTS DOCUMENT SUBMITTED ALONG WITH MANUSCRIPT FILE (MAY BE EASIER TO READ THAN THIS FORMAT). FOR POSTERITY, ALL COMMENTS AND RESPONSES REPRODUCED HERE. Reviewer FeedbackAuthors' Response Reviewer #1: This interesting work addresses a critical gap in maternal health and makes valuable contributions to both the PPH field and implementation science methodology more broadly. The mixed-methods triangulation design is well-conceived, and the development of a consolidated conceptual framework spanning outer and inner settings is a notable theoretical contribution. However, I have identified substantive concerns that I believe need to be addressed before the manuscript is suitable for publication. I offer these comments in the spirit of strengthening what is already a solid piece of work. >> Thank you for your constructive comments and feedback to strengthen the manuscript. My most significant concern relates to your use of 75% as the threshold for identifying bottlenecks. This is a crucial methodological decision that underpins all of your

conclusions, yet the manuscript provides no justification for why 75% was selected rather than 70%, 80%, or any other value. You mention this was "a priori," but readers need to understand the rationale. Was this based on prior literature, expert consensus, statistical considerations, or practical judgment?
I strongly recommend that you: (1) provide explicit justification for the 75% threshold in your methods section, (2) conduct sensitivity analyses showing how your conclusions might differ using 70% and 80% thresholds, and (3) discuss in your limitations how this methodological choice might affect interpretation. Without this, readers cannot fully evaluate the robustness of your findings.

>> Thank you for raising this important point.

The 75% threshold was selected as a practical judgement because the mean ≥0.75 indicates that the aggregate group response was at least “Agree.” Our intent was to use this value as an interpretive anchor aligned with the scale labels, rather than as a statistically optimized cutoff. We have clarified this rationale in the Methods section (lines 234-242).

At the analysis stage, aggregate scores were calculated as simple means of item responses, using a linear transformation in which 0 corresponded to “Strongly disagree” and 1 to “Strongly agree”; “Don’t know” responses were excluded from analysis by design. Aggregate scores were visualized using heatmaps to facilitate identification of potential bottlenecks. To aid interpretation, a score of 75% was used as an a priori interpretive threshold to distinguish pathway steps for which, on average, respondents indicated agreement that the step was in place from those falling below this level. Under the linear transformation used, a score of 0.75 corresponds to the Likert response option “Agree.” This threshold was selected for interpretability and consistency with the scale anchors rather than as a statistical decision rule.

In response to the reviewer’s suggestion, we also examined alternative thresholds (70% and 80%) and found that the overall pattern of identified bottlenecks was robust, with only minor differences for items close to the threshold. We have added text to the Results (lines 297-9) and Limitations (lines 442-7) sections noting this and emphasizing that conclusions focus on relative patterns rather than absolute classification.

Lines 304-6: The overall pattern of identified bottlenecks was robust to alternative interpretive thresholds (70% and 80%), with differences limited to a small number of items near the cutoff.

Lines 449-54: Second, although we used a 75% threshold aligned with the ‘Agree’ anchor to structure interpretation, this value is inherently interpretive. Importantly, all item-level aggregate scores are reported, allowing readers to assess how alternative thresholds would affect classification, particularly for items near the cutoff. As the study was not designed to support probabilistic inference, we did not assess statistical significance of differences between interventions or countries; instead, credibility of findings rests on consistency of patterns across multiple data sources.

Finally, while the 75% threshold was used as a narrative heuristic to highlight items meeting or exceeding the ‘Agree’ anchor, all aggregate item scores are presented in full in Figures 2-4, allowing readers to apply alternative thresholds if desired.

Related to this, your statistical analysis could be strengthened considerably. You report aggregate scores but provide no measures of statistical uncertainty. Are the differences you observe between interventions (for example, oxytocin versus other uterotonics) statistically significant, or could they have occurred by chance? Are the country-level differences meaningful? Without inferential statistics or at minimum confidence intervals, it's difficult to know which patterns represent true signals versus noise.

>> We appreciate the reviewer’s suggestion regarding statistical uncertainty. The

analyses presented in this manuscript are intentionally descriptive and were designed to identify patterns of perceived implementation bottlenecks rather than to formally test hypotheses or estimate population parameters. The survey samples were purposive and embedded within a multi-country implementation trial, and thus do not support probabilistic inference or claims of statistical significance between interventions or countries.

Instead, robustness of findings is assessed through convergence across data sources, including parallel surveys in different stakeholder populations and direct facility-level observations. Given the large number of items and comparisons, formal hypothesis testing could risk emphasizing statistically significant but substantively trivial differences and would not align with the study's diagnostic aims. We have clarified the descriptive nature of the analysis and the role of triangulation in strengthening inference in the Methods (lines 282-5) and Limitations (lines 445-7) sections. We agree that future work could apply inferential approaches in studies explicitly designed and powered for that purpose.

Lines 289-92: All analyses were descriptive in nature and intended to identify patterns of perceived implementation bottlenecks rather than to formally test hypotheses or estimate population-level effects. Given the purposive sampling strategy and the diagnostic aim of the study, inferential statistical testing was not performed.

Lines 449-54: Second, although we used a 75% threshold aligned with the 'Agree' anchor to structure interpretation, this value is inherently interpretive. Importantly, all item-level aggregate scores are reported, allowing readers to assess how alternative thresholds would affect classification, particularly for items near the cutoff. As the study was not designed to support probabilistic inference, we did not assess statistical significance of differences between interventions or countries; instead, credibility of findings rests on consistency of patterns across multiple data sources.

I also encourage you to report and discuss the proportion of "don't know" responses by item. High rates of "don't know" on particular questions might indicate that the question wasn't relevant to certain respondents or that the bottleneck is context-dependent in important ways. This information would enrich your interpretation.

>> Thank you for this thoughtful suggestion.

The "don't know" response option was intentionally included during survey design to reduce noise and avoid forcing responses from participants who did not feel sufficiently knowledgeable to assess a given bottleneck. At the analysis stage, these responses were excluded by design so that aggregate scores reflected the perceptions of respondents with relevant knowledge or experience.

On review of the data, "don't know" responses were rare (<3%) for widely disseminated and heavily advocated recommendations (e.g., oxytocin for PPH prevention), and more common (15-25%) for highly technical clinical interventions (e.g., specific approaches to fluid resuscitation or management of refractory PPH), particularly among non-clinical respondents. This pattern likely reflects differential role relevance and exposure rather than uncertainty or controversy regarding the recommendations themselves.

Given the diagnostic aim of the study—to identify broad patterns of implementation bottlenecks across the pathway—we did not present item-level "don't know" proportions, as these would be unlikely to add substantial interpretive value beyond what is already conveyed by the aggregate scores and triangulated observational findings. We have added clarifying text to the Methods/Results to explain the rationale for including and excluding "don't know" responses and to note the observed pattern qualitatively.

We have added clarifying text to the manuscript in Methods (Lines 232-3: "To minimize forced responses and reduce noise, respondents were able to select "don't know" for items they felt unable to assess.") and Results (Lines 299-304: ""Don't know" responses were rare for widely disseminated recommendations (e.g., oxytocin for PPH

	prevention) and more frequent for more technical clinical interventions, particularly among non-clinical respondents, reflecting differences in role relevance and exposure. This pattern was consistent with the study's intent to capture informed perceptions of implementation bottlenecks rather than uncertainty regarding the recommendations themselves.")
	Your direct observations provide valuable data, but the manuscript doesn't adequately address the observer effect (Hawthorne effect). Health care workers being observed are likely to perform better than usual, which means your observations probably represent best-case scenarios even within these trial-participating facilities. Combined with the fact that trial facilities likely have better-than-average implementation to begin with, the true state of PPH care in these countries may be considerably worse than your data suggest. I recommend explicitly discussing the observer effect and its likely direction of bias. You should also explain the rationale for different observation periods across countries (2 weeks in Nigeria and Tanzania versus 3-4 days in Pakistan) and discuss whether this might affect comparability. If multiple observers were used, inter-rater reliability data would strengthen confidence in the observational findings. >> We thank the reviewer for highlighting the potential influence of the observer (Hawthorne) effect and the trial context on the observational findings. We agree that direct observation may lead to better-than-usual performance and that, combined with selection of trial-participating facilities, our observations likely represent best-case scenarios. We have expanded the Limitations section (lines 452-7) to explicitly discuss this source of bias and its likely direction, noting that implementation gaps in routine, non-trial settings may be larger than observed here. Lines 459-62: In addition, direct observation of clinical care may have influenced provider behavior (Hawthorne effect), such that observed practices represent best-case scenarios even within these facilities. Together, these factors suggest that the true extent of implementation gaps in typical real-world settings may be greater than observed here. Regarding observation duration, differences across countries reflected logistical and contextual constraints, with observation periods in each setting designed to capture routine care processes rather than to estimate rates or make formal cross-country comparisons. We have clarified this point in the manuscript (lines 272-4). "Observation periods varied across countries due to logistical and contextual constraints; however, observations in all settings were designed to capture routine care processes rather than to estimate frequencies or rates." Finally, detailed descriptions of observational procedures, observer training, and inter-rater reliability are reported in previously published implementation trial (and companion manuscripts) focused specifically on the direct observation component. Because the present paper integrates observational findings with survey and qualitative data for diagnostic purposes, we did not replicate those methodological details here. Details of the primary manuscript is provided below and also referenced in the manuscript: Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized trial of early detection and treatment of postpartum hemorrhage. N Engl J Med. 2023 Jul 9;389(1):11–21.
	The manuscript provides insufficient detail about your 105 global stakeholders. Who were they? What regions did they represent? What were their specific roles? How were they selected? Were certain types of stakeholders over- or under-represented? This information is essential for readers to evaluate potential selection bias and assess the generalizability of stakeholder perspectives. I recommend adding a table (similar to

standard baseline characteristics tables in clinical trials) describing your stakeholder sample: geographic region, organizational affiliation, role (clinician, policymaker, researcher, etc.), and years of experience.

>>We thank the reviewer for this suggestion. The global stakeholder sample has been described previously in publicly available publications (details below), and the same stakeholder group was used for the present survey.

We have added a citation and clarifying text in the Methods section (lines 223-5) to make this explicit. Stakeholders were purposively drawn from a range of sectors relevant to PPH policy and practice and were not intended to be statistically representative; rather, the aim was to capture diverse expert perspectives.

“The composition and selection of this global stakeholder group have been described previously and were not modified for the present study (41).”

Ref 41: World Health Organization. A roadmap to combat postpartum haemorrhage between 2023 and 2030. World Health Organization; 2023 Oct 11.

The discussion effectively describes what bottlenecks exist and links these appropriately to the WHO Roadmap. However, it's light on how to address these bottlenecks. Readers, particularly implementers and policymakers, will want to know: What specific implementation strategies would address each major bottleneck? How should countries prioritize among competing demands? What resources would be required? For example, you identify "availability/procurement of medicines and devices" as a major bottleneck, but don't discuss specific procurement reforms, financing mechanisms, or supply chain strengthening approaches that could address this. Similarly, "availability of qualified staff" is identified as critical, but you don't discuss task-sharing, training programs, retention strategies, or other workforce solutions. I encourage you to add a subsection discussing specific implementation strategies for each of your major bottleneck categories. The Expert Recommendations for Implementing Change (ERIC) compilation or similar implementation strategy taxonomies could help you be more precise. This would greatly enhance the practical utility of your work.

>> Thank you for this thoughtful suggestion, which speaks to the important question of how identified bottlenecks can be addressed in practice. The present study was designed as a diagnostic, first-stage analysis to identify and characterize key barriers to implementation of existing WHO recommendations for the prevention, diagnosis, and treatment of postpartum haemorrhage.

Findings from this work directly informed a subsequent global prioritization process, in which stakeholders identified the most critical barriers to address, culminating in the publication of the WHO Roadmap to Combat Postpartum Haemorrhage (2023–2030). That Roadmap highlighted the need to update and clarify global normative guidance as a prerequisite to effective country-level implementation. In response, WHO released updated PPH guidelines in October 2025 and is preparing an accompanying implementation guide and toolkit that provide detailed, evidence-based implementation strategies—drawing on established frameworks and taxonomies—to address the bottlenecks identified in the present study.

Given this planned and ongoing body of work, we have retained the focus of the current manuscript on problem identification and characterization, while explicitly situating the findings within the broader WHO implementation agenda.

Let me reiterate that this is fundamentally strong work addressing an important problem. Your theoretical framework is innovative, your methods are generally rigorous, and your findings have clear relevance to ongoing global efforts to reduce maternal mortality. The integration with the WHO Roadmap is particularly valuable and increases the likelihood that your findings will inform actual policy and practice.

>> Thank you for this positive evaluation of the manuscript and your helpful suggestions for strengthening the overall body of work. We are heartened to know that the work feels innovative and relevant.

Reviewer #2: Thank you for the opportunity to review this interesting mixed-methods triangulation study focused on the implementation of guidelines addressing PPH prevention, diagnosis, and treatment. The authors are to be commended for presenting a thoughtful framework that can be used for other guideline implementation studies and provides a systematic approach. Overall, the paper is very well written and clear. The detailed information on framework development is beneficial, and the extensive analysis of the three data collection approaches is valuable. There are a few minor comments for consideration:

>> Thank you for your encouragement and positive evaluation of this manuscript. We appreciate the constructive suggestions to strengthen the presentation of the study.

Abstract: While the manuscript is very clear, I found the abstract challenging to read and choppy. Please consider revising for readability; a few examples include:
1. The statement "We then developed a survey to understand which bottlenecks affected which PPH recommendations." Does this mean bottlenecks affected the implementation of the PPH recommendation?

>> Thank you for the suggestion to revise the abstract to make it clearer and less choppy. We have made edits that we hope clarify and improve readability.

2. Can you clarify how "global stakeholders" were identified for the survey participation?

>> We thank the reviewer for this suggestion. While the space in the Abstract does not permit a full clarification, we have added a citation and clarifying text to the relevant portion of the Methods section
(lines 223-5).

“The composition and selection of this global stakeholder group have been described previously and were not modified for the present study (41).”

Ref 41: World Health Organization. A roadmap to combat postpartum haemorrhage between 2023 and 2030. World Health Organization; 2023 Oct 11.

3. The statement "An a priori threshold of 75% indicated a bottleneck did not hinder implementation," meaning 75% and above indicated non-hinderence? Please consider rewording.

>> Thank you for flagging this. We have altered that sentence in the abstract: “An a priori interpretive threshold of was selected 75% to indicate a bottleneck was not a severe impediment to implementation.”

4. Conclusion: Consider specifying which part of the implementation pathway the policy change will impact. Consider making it clear in the conclusion that this is about the PPH guidelines.

>> We thank the reviewer for this comment.

The national policy changes that may be needed are inclusive of developing/revising national PPH guidelines, but may also pertain to other related national policies, depending on the specific country context. Due to space limitations, we were not able to elaborate in the Abstract, but had provided concrete examples in the Conclusions

section of the full text (lines 506-11):

“Notably, implementation bottlenecks occurring within the national policy space had far-reaching implications and contributed to compounding failure to implement evidence-based practices at lower-levels in the health system. In contexts where policy presents a barrier to implementation (for example, because midwives are not legally authorized to offer certain interventions), urgent actions to address outdated policies and create enabling environments for implementation are needed.”

Methods:
1. Please clarify how the global stakeholders were identified for survey inclusion [line 210].

>> We thank the reviewer for this suggestion. The global stakeholder sample has been described previously in publicly available publications (details below), and the same stakeholder group was used for the present survey.

We have added a citation and clarifying text in the Methods section (lines 223-5) to make this explicit. Stakeholders were purposively drawn from a range of sectors relevant to PPH policy and practice and were not intended to be statistically representative; rather, the aim was to capture diverse expert perspectives.

“The composition and selection of this global stakeholder group have been described previously and were not modified for the present study (41).”

Ref 41: World Health Organization. A roadmap to combat postpartum haemorrhage between 2023 and 2030. Geneva: World Health Organization; 2023 Oct 11. Available from: https://iris.who.int/handle/10665/373221

2. While the authors state that observations in Nigeria and Tanzania were before the EMOTIVE trial implementation, it is unclear if the observations in Pakistan were before, during, or after EMOTIVE trial implementation. Consider clarifying the timing [lines 246-250] of observation and study implementation.

>> Thank you for flagging this. In Pakistan, direct observations were also conducted prior to the start of implementation. We have clarified this in the manuscript (line 271): “…between January and February 2023 (prior to the start of implementation of the early detection and treatment intervention).”

Figures:
1. Consider clarifying the titles and legends in Figures 2-4. A "Low score" is a severe bottleneck and "High score" is a non-bottleneck. [Figures 2-4]

>> Thank you for this suggestion to improve clarity and interpretability of the figures. We have revised so the legends read “More severe barrier/bottleneck” and “Less severe barrier/bottleneck”

Discussion:
1. Lines 368-373 read as if they contradict each other with the two "However" introduction to the sentence. Consider combining or rewording.

>> Thank you for this suggestion. We have reworded as follows: “Among uterotonics, only oxytocin and misoprostol seemed to be readily available. However, but there are known quality concerns with oxytocin and misoprostol in many low-resource settings (42–46)”

Additional Information:	
Question	**Response**
Is this study a clinical trial?<p>A clinical trial is defined by the World Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’.	No
Adherence to reporting guidelines Plase indicate which reporting guideline(s) the submission adheres to, including any rationale for the checklist(s) used, or alternatively indicate if this does not apply to the submission. <hr>All submissions must adhere to the relevant reporting guideline(s) appropriate for the study design or type of report and include the populated checklist(s) with the submission. The completed checklist(s) should be provided as an ‘Additional file’ and referenced in the text. Authors should use their discretion in selecting the appropriate checklist(s). Authors should briefly indicate the reason for their decision to select the checklist(s) used. For further information, please see the specific article type guidelines here.	None applicable.

Barriers and bottlenecks to implementation of WHO recommendations for prevention, detection, and treatment of postpartum hemorrhage: A mixed-methods triangulation study

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ABSTRACT

Background: The World Health Organization develops evidence-based recommendations for postpartum hemorrhage (PPH) prevention, detection, and treatment. However, persistently high PPH-related mortality suggests recommendations are poorly implemented, especially in low-resource settings. This study aimed to identify implementation bottlenecks to inform action.

Methods: Drawing on public policy, implementation science, and health behavior, we constructed a multi-level framework to identify bottlenecks affecting recommendation uptake. This informed the development of a survey assessing which bottlenecks affected specific WHO recommendations. Surveys were completed by global stakeholders and by health care workers in three high-burden countries. ~~. We then developed a survey to understand which bottlenecks affected which PPH recommendations. Global stakeholders were invited to participate.~~ We also analyzed direct observations of clinical practice from those~~e~~ countries ~~with high PPH burden~~ to see how bottlenecks affected practice ~~and invited observed health care workers to complete the survey to identify country-specific trends~~. An *a priori* interpretive threshold of 75% was selected to indicate~~d~~ a bottleneck was not a severe impediment to~~did not hinder~~ implementation.

Results: Surveys from 102 global stakeholders and 246 health care workers, as well as 2039 direct observations of clinical practice revealed variation in adherence to WHO recommendations, with some through-lines. Oxytocin ~~(~~for PPH prevention and treatment~~)~~ was perceived to have national policy support (>75% for inclusion in national guidelines and Essential Medicines Lists, ~~and having~~ regulatory approval, ~~s~~ and support from national champions) but other uterotonics were not. Tranexamic acid for PPH treatment was found to be underutilized, likely due to compounding bottlenecks. Respondents reported extensive bottlenecks to refractory PPH interventions (<75% across nearly ~~for~~ all bottlenecks ~~for all interventions except health care worker awareness of laparotomy~~). The most substantial bottlenecks were availability/procurement of medicines and devices, affordability and quality of medicines and devices, presence of job aids, and availability of qualified staff. Observed practice generally aligned with stakeholder perceptions.

Conclusions: National policy bottlenecks strongly mediated implementation in clinical practice. Policy change addressing gaps in commodity procurement and availability of trained clinicians is critical. Efforts addressing only one part of the implementation ecosystem are unlikely to drive transformative change.

CONTRIBUTIONS TO THE LITERATURE

- This paper synthesizes theoretical insights spanning the outer and inner settings of implementation to develop a consolidated multi-level theory of why implementation of evidence-based interventions stall.
- The empiric results show that bottlenecks in national policy hinder subsequent downstream implementation of WHO recommendations to prevent, detect, and treat postpartum hemorrhage. With most implementation strategies targeting the inner setting, our findings highlight the need to develop and test strategies for affecting change in the outer setting.
- The study offers one approach for using theory-derived implementation research to identify gaps where targeted interventions have catalytic potential to drive improvements in global maternal health.

KEYWORDS

postpartum hemorrhage, implementation science, health planning, health services research, resource-limited settings

BACKGROUND

Combating postpartum hemorrhage (PPH) is a key global maternal health priority. Obstetric hemorrhage is the leading cause of maternal death worldwide, accounting for an estimated 27% of maternal mortality, with PPH constituting the largest share of hemorrhage-related mortality (1). In addition, PPH is an important contributor to long-term maternal morbidity, with far-reaching consequences including mental health conditions like post-traumatic stress disorder and postpartum depression (2,3). To aid health care workers in more effectively preventing and treating PPH, the World Health Organization (WHO) has issued several PPH guidelines, distilling research evidence into clinical and health systems recommendations for providing quality PPH care (4–12). Yet these recommendations have not translated into the improvements in maternal health outcomes needed to meet Sustainable Development Goal (SDG target 3.1) (13). There is a need to better understand why.

This study presents a novel theory-based approach to describe key steps on the pathway to implementation of global guidelines and assess how current efforts to translate WHO's evidence-based PPH recommendations into routine practice have stalled. The results of this study can be used to inform global efforts to accelerate uptake of WHO guidelines, as well as address barriers and bottlenecks to implementation – particularly those that arise in the outer setting of implementation (14).

Understanding barriers and bottlenecks to implementation

The need to understand why implementation does not go according to plan has spawned numerous fields of inquiry, among them implementation science, process evaluation, and policy implementation research. Within implementation science, barriers to implementation are defined as those determinant factors that can slow, stall, or derail the uptake or sustainment of an intervention (15). "Barriers to implementation" is an overarching category that encompasses problems which may arise at various levels or stages within implementation. Efforts are underway to more precisely categorize the mechanisms by which barriers may impede implementation (16). Yet thus far, these categorizations have remained largely descriptive with limited explanatory utility (17). A different type of conceptual framing is needed to move from describing *what* barriers exist to explaining *why* and *how* barriers impede implementation.

Tanahashi's model of bottlenecks to health service provision suggests that implementation may break down at discrete points in a service delivery process, which can be detected by comparing coverage measures drawn from adjacent levels of service delivery (e.g., coverage of a screening intervention versus coverage of a treatment intervention among individuals screened positive) (18). Baker *et al*. extend this concept to posit that there are identifiable moments in an implementation pathway—implementation bottlenecks—when implementation becomes stuck (19). For example, efforts to bring a new medical device to market worldwide may slow at the regulatory approval stage, especially in countries with poorly resourced regulatory agencies (20). Where "barriers to implementation" are theory-agnostic, "bottlenecks to implementation" imply a presupposed mechanism by which implementation should occur, and the existence of an impediment thwarting a specific step in that mechanism. Thus, identifying bottlenecks to implementation can help determine how to unstick efforts to translate evidence to policy and practice and get life-saving interventions into the field (21).

Despite the utility of mapping bottlenecks to implementation, this step is often overlooked. One reason is that identifying bottlenecks to implementation can be costly and time-consuming. Traditional efforts may entail conducting facility audits, detailed needs assessments, or in-depth interviews with key stakeholders (22). These approaches generate useful information but can be limited by the perspectives included and excluded, since different stakeholder groups may have varying understandings of where and why implementation has stalled. Developing a comprehensive picture of the factors influencing uptake of evidence-based interventions often requires engaging multiple stakeholder groups, thus increasing cost and logistical complexity. Further, traditional approaches are typically atheoretical and thus may miss important aspects of implementation. Innovative methods are needed that systematize data collection on implementation bottlenecks while reducing burden on researchers, policymakers, and others interested in gathering and using such information. Our study offers one such approach.

METHODS

This mixed-methods triangulation study (23) used three sources of data—1) global stakeholder responses to a theory-derived survey on potential bottlenecks to implementation, 2) direct observations of clinical practice conducted in three countries (Nigeria, Pakistan, and Tanzania), and 3) observed health care workers' responses to a theory-derived survey of potential bottlenecks to implementation—to identify specific factors potentially hindering implementation of evidence-based recommendations for PPH prevention and management. More specifically, data were used to detect evidence-based recommendations that were not well-implemented in the field and to identify common recommendations that had proved challenging to implement across all three settings. Though implementation is often described as highly contextualized (24), common challenges may suggest a

need for global cooperation to address supranational barriers (e.g., conflicting normative guidance, regulatory ambiguity, procurement and supply chain issues). To organize and structure data collection and integration, a consolidated conceptual framework was developed, drawing from the existing theoretical implementation science literature.

Consolidated conceptual framework

The Consolidated Framework for Implementation Research (CFIR) suggests that clinical interventions are provided within a care ecosystem that has both an inner setting (within-facility context) and an outer setting (policy, economy, society) (14). For a new intervention to be administered at bedside, there is a series of changes that must first occur in the outer and inner settings in which service delivery occurs. For example, the intervention needs to have been approved by national regulatory bodies, integrated into domestic policy and guidance, embedded into pre-/in-service training, and actively encouraged within the facility (through, for example, inclusion in clinical protocols, reinforcement by supportive supervision, and active engagement of facility leadership). Without undertaking these steps to transform the domestic care ecosystem into an enabling environment, the intervention cannot be effectively delivered to patients. Yet despite a wealth of implementation-related theorizing, no existing implementation science theory, model, or framework currently covers the steps involved in restructuring the outer and inner settings to produce an enabling environment (25,26). Creating an enabling environment requires multiple instances of policy transfer and knowledge translation across different levels and stakeholder groups, each with their own mental models and operating procedures (27–29). Academics have traditionally partitioned theorizing around these levels and groups, with discrete epistemic communities (e.g., policy implementation, organizational theory, health behavior) developing different bodies of theoretical work (e.g., top-down implementation, organizational readiness, theory of planned behavior) (30–32). Yet effectively moving global recommendations into

local practice requires integrating theoretical constructs from across these disparate academic traditions into a single consolidated framework.

Over the past decade, UNICEF has developed and refined an approach for mapping bottlenecks to implementation that extends the Tanahashi model to show how bottlenecks to implementation can be characterized as determinants of supply, demand, or quality (33). That approach has been used by UNICEF as a first step to improve complex health system performance within countries (21). Our analysis builds from the UNICEF approach to conceptually map the supply, demand, and quality considerations of implementing WHO PPH recommendations from policy to clinical practice (i.e., transferring from global to national to sub-national to facility) in a single consolidated framework. The consolidated framework draws on theorizing in policy implementation and implementation science, as well as global health practice-based evidence and WHO normative work. Using a top-down conceptualization of policy implementation (30) and following from Baker *et al*.'s operationalization of Tanahashi's model (19), the process of moving from evidence-based recommendations to clinical practice was envisioned as a unidirectional implementation pathway in which addressing bottlenecks in earlier steps created more enabling environments for subsequent steps. Discrete steps required to embed global guidelines into national policy were identified, using concepts from the literature on policy transfer (27–29). Next, steps needed to translate national policy into clinical practice were identified, building from the literature on implementation research and practice (34–37). Finally, each of these steps was mapped against the WHO building blocks of health systems (38), to ensure that no elements had been overlooked. Given the critical role of commodities such as uterotonics, tranexamic acid, and devices for refractory PPH in PPH prevention and management, special attention was paid to tracing the steps involved in ensuring access to quality commodities at the bedside. The integrated conceptual framework is provided in Figure 1.

Survey of global stakeholders

To better understand the upstream factors contributing to poor implementation at the point of care, a targeted online survey was conducted to capture global stakeholders' perceptions of the specific steps in the cascade at which implementation of PPH recommendations was stalled. Within policy research, in-depth interviews with key informants are commonly used to efficiently gather insight into policy-related processes, including policy transfer (39). However, managing large-scale qualitative data analysis can be time-consuming and resource intensive. Theory-derived surveys can offer a more efficient approach to large-scale data collection (40). The conceptual framework was used to inform the development of the survey questions, with one question developed for each step in the implementation pathway. Recognizing that different recommendations might face different challenges to implementation, the survey was structured so that respondents answered the questions in the pathway for one evidence-based recommendation at a time. The full set of questions was posed for recommendations regarding specific PPH commodities (medicines and devices). A subset of questions was posed for recommendations on clinical or health system interventions, where the items on procurement and regulatory approval were not applicable. A blank copy of the survey questionnaire is provided in Supplementary file S1.

The survey was shared with 105 global stakeholders for an initial round of prioritization. These stakeholders were drawn from Ministries of Health, women and women's groups, implementers (including non-governmental organizations and civil society organizations), professional associations, guideline developers, the research community, international donors, and the private sector – all acting in an individual capacity and not representing any specific organization. The composition and selection of this global stakeholder group have been described previously and were not modified for the present study (41). Participants were sent a unique link to an online survey (via SurveyMonkey). Submission of

the survey indicated consent to participate. The survey was open for five weeks (25 January 2023 – 1 March 2023).

Questions were posed by WHO PPH recommendation. Participants were asked to report the extent to which they agreed that the statement posed was true (e.g., "Medicine or device is registered and licensed for this/these indication/s in the country"). Responses were on a 5-point Likert scale, ranging from "Strong disagree" to "Strongly agree." To minimize forced responses and reduce noise, respondents were able to select "don't know" for items they felt unable to assess. ~~Respondents also had the option to indicate "Don't know" to skip a question.~~ At the analysis stage, aggregate scores were calculated as simple means of item responses, using a linear transformation in which 0 corresponded to "Strongly disagree" and 1 to "Strongly agree"; "Don't know" responses were excluded from analysis by design. Aggregate scores were visualized using heatmaps to facilitate identification of potential bottlenecks. To aid interpretation, a score of 75% was used as an *a priori* interpretive threshold to distinguish pathway steps for which, on average, respondents indicated agreement that the step was in place from those falling below this level. Under the linear transformation used, a score of 0.75 corresponds to the Likert response option "Agree." This threshold was selected for interpretability and consistency with the scale anchors rather than as a statistical decision rule. ~~scores were assigned for each response category, ranging from 0 (Strongly disagree) to 1 (Strongly agree); "don't know" responses were dropped from the analysis. Simple means were calculated to develop aggregate scores, which were then plotted on a heatmap to facilitate identification of bottlenecks. An aggregate score of 75% or higher was considered to indicate that the step in the pathway did not constitute a bottleneck for a given recommendation (75% corresponded with the participant response of "Agree").~~ Respondents ~~also had the opportunity~~were also invited to provide explanatory comments on each intervention ~~in an~~via open-ended questions, including descriptions of barriers not captured by the structured

items~~where they could also indicate the existence of other important barriers not captured by the questions about specific bottlenecks~~. These comments were reviewed, grouped by theme, and summarized.

Direct observations of clinical practice

To test the face validity of the findings of the global survey, direct observations of health care providers' clinical practice in three countries with high burden of PPH-related morbidity and mortality (Nigeria, Pakistan, and Tanzania) were reviewed and triangulated with global participants' survey responses. Direct observations were drawn from a nested study within a large implementation trial for the early detection and treatment of postpartum hemorrhage and a pre-post evaluation of an effort to implement the same complex intervention (42-~~41~~). ~~The aim of that nested study was to gain an in-depth understanding of how variations in facility-based care affect clinical outcomes associated with PPH.~~ For the purposes of the current study, the direct observations constitute a convenience sample.

Observations were drawn from 19 facilities in Nigeria, 6 facilities in Tanzania, and 2 facilities in Pakistan. In Nigeria and Tanzania, observations were conducted at each facility over a two-week period between August 2022 and December 2022 (prior to the start of implementation of the early detection and treatment intervention), covering 24 hours Monday to Sunday to reduce risk of selection bias and gain insights into the care provided across all shifts during the day, night, weekdays, and weekends. In Pakistan, observations were conducted over a 3–4-day period in both sites between January and February 2023 (prior to the start of implementation of the early detection and treatment intervention). Observation periods varied across countries due to logistical and contextual constraints; however, observations in all settings were designed to capture routine care processes rather than to estimate

frequencies or rates. Research staff observed in real time, as health care workers employed by the facility attended vaginal births, administered preventive interventions, conducted direct observations, and managed any PPHs that occurred. Data were collected using a purpose-designed structured guide. Observations were conducted in the labor ward. If a woman was transferred to theatre for escalated treatments, some data on refractory care was obtained from the main study database, which was entered by the research staff after confirmation of treatment by the treating clinician.

Survey of health care workers

For completion, health care workers whose care provision was observed were invited to fill in the same survey as global stakeholders, to assess generalizability of the global findings to their contexts. Scores were tabulated, aggregated, and analyzed in the same way as for the global stakeholder survey, but analyses were conducted independently for each country.

All analyses were descriptive in nature and intended to identify patterns of perceived implementation bottlenecks rather than to formally test hypotheses or estimate population-level effects. Given the purposive sampling strategy and the diagnostic aim of the study, inferential statistical testing was not performed.

RESULTS

Global Stakeholder Survey

The global survey was sent to 105 global stakeholders, of whom 102 consented and responded (response rate: 97.1%). Aggregate scores are plotted on the heatmap in Figures 2-4. "Don't know" responses were rare for widely disseminated recommendations (e.g., oxytocin for PPH prevention) and more frequent for more technical clinical interventions, particularly among non-clinical respondents, reflecting differences in role relevance and exposure. This pattern was consistent with the study's intent to capture informed perceptions of implementation bottlenecks rather than uncertainty regarding the recommendations themselves. The overall pattern of identified bottlenecks was robust to alternative interpretive thresholds (70% and 80%), with differences limited to a small number of items near the cutoff. Certain interventions were perceived as broadly facing bottlenecks to implementation across the entire implementation pathway, while others were perceived to be reasonably well-implemented across the pathway. Four steps in the pathway (availability/procurement of medicines and devices; affordability and quality of medicines and devices; presence of job aids in the facility; and availability of qualified staff) consistently posed more substantial bottlenecks to implementation than others, regardless of the intervention. Stakeholder comments in the open-ended questions helped to contextualize the aggregate scores and showcase the existence of other important barriers.

Oxytocin use was generally perceived to face few bottlenecks to implementation for both PPH prevention and treatment, whereas stakeholders reported bottlenecks to implementation across the entire implementation pathway for other uterotonics recommended for PPH prevention (or treatment if oxytocin was unavailable). In open-ended comments, participants indicated that implementation was sometimes stalled due to barriers not captured by the pathway. For example, ergometrine was perceived to be underused because of concerns about side-effects; fixed-dose oxytocin-ergometrine was perceived to be "out of fashion"; and heat-stable carbetocin was reported to be still relatively new, unknown, and costly as compared to other prophylactic uterotonic options. Global stakeholders

perceived oral misoprostol for PPH prevention and treatment, tranexamic acid for PPH treatment, prophylactic oxytocin with controlled cord traction, and isotonic crystalloids for fluid resuscitation as facing fewer challenges as compared to other interventions.

In contrast, stakeholders perceived device-based and surgical interventions for refractory PPH as facing extensive barriers and bottlenecks to implementation. Stakeholders commented that uterine balloon tamponade (UBT) and the non-pneumatic anti-shock garment (NASG) were rarely used in practice because the devices were largely unavailable and/or perceived to be unaffordable, were not included in facility-level protocols, and generally had not been well-promoted or championed in-country. Uterine artery embolization was perceived to be available only in high-level tertiary facilities with specialists, and even then, as often difficult to access. Similar points were raised for other surgical procedures, though to a lesser extent. Lack of available staff and staff time were the primary points raised in global stakeholder comments with respect to clinical interventions such as uterine tone assessment for identification of women with postpartum uterine atony, controlled cord traction combined with oxytocin for removal of retained placenta, and external aortic compression as a temporizing measure.

Global stakeholder perceptions on health system interventions also varied by intervention, with simulation drills having the greatest number of perceived barriers to implementation. In open-ended comments, global stakeholders reported that simulation drills were particularly hindered by lack of trained personnel to conduct drills and understaffing of frontline health care workers. In addition, simulation drills were reported to be not well-promoted domestically.

Direct observations of clinical practice and survey of health care workers

A total of 1352 direct observations were conducted in Nigeria (77 cases of PPH diagnosed and treated). In Tanzania, 649 direct observations were conducted (72 cases of PPH diagnosed and treated) and in Pakistan, 38 direct observations were conducted (7 cases on PPH diagnosed and treated). Direct observation results are reported in Table 1. In addition, a total of 246 health care workers responded to the theory-based survey (31 in Nigeria, 126 in Pakistan, and 50 in Tanzania). Heatmaps of health care workers' aggregate survey scores for each of the countries are provided in Supplementary file S2.

Oxytocin was widely observed in use for PPH prevention (Nigeria: 99.7% of observed births; Pakistan: 100.0%; Tanzania: 100.0%). Although oral misoprostol was only recommended for prevention when oxytocin was unavailable or the quality could not be assured, a substantial proportion of women in Nigeria and Pakistan were administered both oxytocin and oral misoprostol for PPH prevention (Nigeria: 61.5% of observed births; Pakistan: 78.9%; Tanzania: 2.0%). In Nigeria, the aggregate health care worker survey score indicated that "Available products in the markets are perceived as affordable and of good quality" was a barrier to implementation of oxytocin but not to that of oral misoprostol. In direct observations, ergometrine, fixed-dose oxytocin and ergometrine combination, and heat-stable carbetocin were rarely used for prevention (fewer than 1% of observed births in all three countries). In Pakistan and Tanzania, health care worker aggregate survey scores indicated extensive perceived barriers to implementation of recommendations of second-line uterotonics.

Postpartum uterine tone was assessed to help detect PPH in most cases (Nigeria: 64.4% of observed births; Pakistan: 100.0%; Tanzania: 73.0%). In the health care worker aggregate survey responses, adequate staffing was the single reported barrier or bottleneck to implementation of this recommendation in Nigeria and Tanzania.

When it came to PPH treatment, oxytocin was widely observed in use (Nigeria: 78.1% of observed PPH cases; Pakistan: 100.00%; Tanzania: 98.6%). Oral misoprostol was used extensively for treatment (Nigeria: 41.6% of observed PPH cases; Pakistan: 28.6%; Tanzania: 36.1%). Ergometrine and fixed-dose oxytocin and ergometrine combination were rarely used for PPH treatment (fewer than 1% of observed PPH cases in all three countries). Although tranexamic acid is recommended as a first-response treatment for PPH, use varied widely across settings (Nigeria: 27.3% of observed PPH cases; Pakistan: 100.0%; Tanzania: 48.6%). In Pakistan, health care workers did not report perceived barriers to implementation of tranexamic acid. In Nigeria and Tanzania, however, aggregate health care worker survey responses indicated that there were multiple barriers to implementation, ranging from availability challenges to poor health care worker awareness of its utility through adequate training and support for use in practice. Use of isotonic crystalloids for fluid resuscitation was also context-dependent (Nigeria: 62.3% of observed PPH cases; Pakistan: 100.0%; Tanzania: 79.2%), though health care worker survey responses did not identify any specific barriers or bottlenecks to implementation. Uterine massage for conservative treatment of PPH was conducted nearly universally (Nigeria: 92.2% of observed PPH cases; Pakistan: 100.0%; Tanzania: 91.7%).

Use of recommended interventions for refractory PPH were rarely observed, though this is primarily reflective of the small numbers of refractory PPH cases observed. However, health care worker aggregate survey responses indicated the existence of substantial barriers and bottlenecks to implementation across the entire pathway for recommended interventions to treat refractory PPH.

Notable findings among health system interventions include the lack of referral protocols for transferring women with refractory PPH to higher levels of care (Nigeria: 0% of facilities had a protocol; Pakistan: 50%; Tanzania: 0%) and the limited use of simulation drills in Nigeria (only 1 of the 19

participating facilities reported using simulation drills). Interestingly, only health care worker aggregate survey responses in Nigeria indicated that there were bottlenecks to implementation of these kinds of health system interventions. Health care workers in the other two countries did not perceive any bottlenecks to implementation of these recommendations.

DISCUSSION

This study sought to identify WHO evidence-based recommendations for PPH prevention and treatment whose implementation are stalled and characterize some of the bottlenecks to implementation, using a combination of real-time direct observations of clinical practice and theory-derived surveys of global stakeholders' and local health care workers' perceptions. Among uterotonics, only oxytocin and misoprostol seemed to be readily available~~. However~~ but~~,~~ there are known quality concerns with oxytocin and misoprostol in many low-resource settings (4~~5~~2–4~~9~~6). Health care workers' awareness of oxytocin quality concerns may have led them to compensate with additional oxytocin or simultaneous use of misoprostol, as observed in this study. However, it is unknown how much additional medication may be needed to compensate for poor quality, and such usages of PPH commodities may have other negative consequences. Recommended clinical maneuvers for PPH detection and treatment (uterine tone assessment and uterine massage) were observed to be widely used, likely due to the limited resources required (i.e., no commodities needed). Tranexamic acid for PPH treatment was found to be underutilized, likely due to the compounding effect of the multiple bottlenecks to implementation evidenced by this study. Some recommended interventions for treating refractory PPH were not available to health care workers, potentially contributing to underutilization and the desire to create improvised devices (50~~47~~). Health system interventions like formal facility protocols for PPH management and referral and simulation training for preparedness were found to be substantially

underutilized. Instituting these interventions is perhaps easier and faster to accomplish than ensuring other procurement-dependent interventions are consistently available to health care workers.

Global stakeholders and observed health care workers reported more challenges to implementation at lower-level steps in the conceptual framework (e.g., provider practice) than at higher-level steps (e.g., national policy) for all interventions. Interventions that stakeholders reported as facing substantial barriers at higher-level steps in the pathway had particularly low rates of utilization in direct observations. This suggests that higher-level challenges to implementation may create rate-limiting constraints that hinder implementation at lower levels, contributing to certain interventions being plagued by poor implementation across the pathway.

Findings from direct observations support the premise that implementation is context specific. These data show that observed facilities in Nigeria were less aligned with global evidence-based recommendations than those in Tanzania and Pakistan. Accordingly, there may be more bottlenecks to implementation in Nigeria or the bottlenecks may be more entrenched. These findings align with global literature suggesting that efforts to improve uptake of evidence-based interventions should begin with an exploration stage that encompasses local assessment of bottlenecks, barriers, and facilitators of/to implementation (implementation determinants) (21,51~~48~~,52~~49~~).

Strengths of this study include the use of a theory-derived approach to measuring bottlenecks to implementation, the use of data triangulation to allow for comparison of global stakeholder perceptions to facility-level practices, and the high response rate to the stakeholder survey. Further, the mixed-methods stakeholder survey illustrated the perils of relying solely on quantitative data to map barriers and bottlenecks to implementation. The open-ended stakeholder comments revealed qualitative

differences between the implementation challenges facing ergometrine and heat-stable carbetocin, for example, which would have been obscured with a solely quantitative survey. In this way, the use of multiple, complementary data sources, theories, and analytical approaches strengthened the overall study and utility of the findings to the field.

However, the study also has limitations. First~~or example~~, it is possible that the implementation pathway is missing key steps, obfuscating understanding of potentially important barriers or bottlenecks to implementation. Second, although we used a 75% threshold aligned with the 'Agree' anchor to structure interpretation, this value is inherently interpretive. Importantly, all item-level aggregate scores are reported, allowing readers to assess how alternative thresholds would affect classification, particularly for items near the cutoff. As the study was not designed to support probabilistic inference, we did not assess statistical significance of differences between interventions or countries; instead, credibility of findings rests on consistency of patterns across multiple data sources. ~~Further~~Third, it is likely that these results understate the extent to which evidence-based PPH recommendations are underutilized in the field. Although direct observations were conducted in facilities not yet implementing an intervention, by nature of participating in a multi-country trial, these facilities were likely to have better than average implementation of evidence-based recommendations (given proximity to/involvement in global research networks and location and type of facility). In addition, direct observation of clinical care may have influenced provider behavior (Hawthorne effect), such that observed practices represent best-case scenarios even within these facilities. Together, these factors suggest that the true extent of implementation gaps in typical real-world settings may be greater than observed here. As the findings are intended to be illustrative rather than generalizable, this limitation does not diminish their value for identifying relative patterns of implementation bottlenecks. ~~However, as these findings were not intended to be generalizable but rather illustrative, this limitation should not reduce the utility of the~~

findings. Finally, reflecting existing WHO PPH recommendations, this study focused primarily on interventions intended to be delivered within health facilities. These findings may have limited relevance for the many PPHs that occur in communities. More work may be needed to understand the kinds of community-level interventions that may be useful to prevent, detect, and treat PPH.

This study makes two primary contributions to the literature. The first is specific to PPH. By systematically mapping barriers to the implementation of evidence-based PPH recommendations, this study facilitates priority-setting within global maternal health. The global stakeholder survey identified four bottlenecks to implementation that were largely intervention-agnostic: availability/procurement of medicines and devices; affordability and quality of medicines and devices; presence of job aids in the facility; and availability of qualified staff. In addition, lack of supportive national policy (e.g., inclusion in national guidelines and Essential Medicines Lists) was identified as a key precipitating bottleneck – if national policy was not supportive, it was very difficult for the intervention to be utilized. During the WHO-convened Global Summit on Postpartum Haemorrhage held in Dubai, United Arab Emirates in March 2023, stakeholders further underscored the importance of addressing these common bottlenecks across contexts. Consequently, these bottlenecks have been prioritized for global action within the Implementation strategic area of the *WHO Roadmap to Combat Postpartum Haemorrhage, 2023-2030* (4150). Specifically, the first three categories of priority actions are: building clear national health policy and strengthening national and subnational leadership, improving availability and access to quality-assured and affordable PPH commodities at all levels of the health system, and ensuring availability of competent health care workers to deliver relevant good-quality facility-based services and commodities.

In addition to the topic-specific contribution, this study makes a methodological contribution to implementation science by demonstrating how theory can be used to organize and structure empiric

studies of implementation. The theoretical landscape in implementation science is currently dominated by determinant frameworks and process models, with fewer explanatory theories (24,5~~3~~1,5~~4~~2). In recent years, there have been calls for developing more theory-based approaches to implementation, but little guidance on how to do so (17,5~~5~~3). This paper offers one approach, using theoretical *bricolage* (syncretic integration of theories from disparate academic traditions (5~~4~~6,5~~5~~7)) to develop a fit-for-purpose mid-range theory of pre-requisites to implementation that could then be used to identify barriers and bottlenecks. This mid-range theory intentionally linked different levels of the health system to illustrate one way in which the outer setting of implementation (e.g., policy and regulatory spaces) can shape the enabling environment for implementation within the inner setting (e.g., health facilities). This approach provides one example of how implementation-focused researchers might further integrate implementation science with health systems research and policy implementation to create more cohesive theorizing and research (5~~6~~8,5~~7~~9).

CONCLUSIONS

This study identified several critical implementation bottlenecks hindering further improvements in PPH-related morbidity and mortality. Notably, implementation bottlenecks occurring within the national policy space had far-reaching implications and contributed to compounding failure to implement evidence-based practices at lower-levels in the health system. In contexts where policy presents a barrier to implementation (for example, because midwives are not legally authorized to offer certain interventions), urgent actions to address outdated policies and create enabling environments for implementation are needed. Health care workers and facility leaders are important agents for change, but results will be underwhelming if efforts are limited to the implementation inner setting (e.g., health facilities) alone. Rather, systems approaches are needed.

As trusted professionals, health care workers are well-positioned to advocate with policymakers for the need for supportive policy environments that allow them to use evidence-based and life-saving interventions in their clinical practice. Securing high-level leadership from policymakers can set the stage for transformative change. Consequently, evidence on the most effective advocacy strategies for engaging these leaders is needed (60~~58~~).

In addition, more research is needed on the most effective implementation strategies for affecting change at the nexus between inner and outer settings. Whole-of-system theorizing and approaches to implementation research could help to drive this dimension of the field and address the top-priority implementation-related research question generated by participants at the Global Summit on Postpartum Haemorrhage (60~~58~~). Strategically embedding implementation research into future implementation efforts could reap a double dividend of generating much-needed insights while reducing PPH-related death and disability.

LIST OF ABBREVIATIONS

CFIR	Consolidated Framework for Implementation Research
NASG	Non-pneumatic anti-shock garment
SDG	Sustainable Development Goal
PPH	Postpartum hemorrhage
UBT	Uterine balloon tamponade
WHO	World Health Organization

DECLARATIONS

Ethics approval and consent to participate

The survey was deemed exempt from Ethical Review. Survey respondents were informed prior to beginning the survey that their participation was voluntary and indicated their consent for their responses to be included in the study. The implementation trial in which the direct observation of clinical practice study was nested was approved by the University of Birmingham, the Ethics Review Committee of WHO (for the formative phase), and the relevant ethics and regulatory review committees in each country. Hospital leadership at each site provided hospital-level permission for the observations, and health care workers provided written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The survey datasets used and analyzed in the study are available from the corresponding author on reasonable request. The data that support findings from the clinical observations were provided for the purposes of this analysis by the authors of the E-MOTIVE Trial. Data requests for that dataset will be considered by the E-MOTIVE trial management group upon request to the Principal Investigator: a.coomarasamy@bham.ac.uk.

Competing interests

None declared.

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Author contributions

OTO and IDG conceptualized the study and provided oversight. OTO, IDG and MW developed the study protocol. OTO, IG, MW, and CRW developed the consolidated implementation framework. CRW, SR, and IDG developed the implementation bottlenecks survey, with input from AMG, LC, FA, MW, and OTO. KMM analyzed and interpreted the data from the direct observations of clinical practice, with input from AC and IDG. CRW managed the analysis of the survey data. AM and US provided input and country contextualization to help shape the interpretation of the data. CRW led the drafting of the manuscript, with input from all authors. IDG, AC, and OTO substantially revised the manuscript for intellectual content. All authors reviewed and provided input on the final manuscript. IG is responsible for the overall content as guarantor (accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish).

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REFERENCES

1. Cresswell JA, Alexander M, Chong MYC, Link HM, Pejchinovska M, Gazeley U, et al. Global and regional causes of maternal deaths 2009–20: a WHO systematic analysis. Lancet Glob Heal. 2025 Mar;
2. Zaat TR, van Steijn ME, de Haan-Jebbink JM, Olff M, Stramrood CAI, van Pampus MG. Posttraumatic stress disorder related to postpartum haemorrhage: A systematic review. Eur J Obstet Gynecol Reprod Biol [Internet]. 2018 Jun;225:214–20. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0301211518301702
3. Schoretsanitis G, Gastaldon C, Ochsenbein-Koelble N, Olbrich S, Barbui C, Seifritz E. Postpartum hemorrhage and postpartum depression: A systematic review and meta-analysis of observational studies. Acta Psychiatr Scand [Internet]. 2023 Jun 7; Available from: https://onlinelibrary.wiley.com/doi/10.1111/acps.13583
4. World Health Organization (WHO), World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization; 2012.
5. World Health Organization (WHO). WHO recommendations: Uterotonics for the prevention of postpartum haemorrhage. Geneva: World Health Organization; 2018. p. 53.
6. World Health Organization, World Health Organization (WHO). WHO recommendation on routes of oxytocin administration for the prevention of postpartum haemorrhage after vaginal birth. Geneva: World Health Organization; 2020.
7. World Health Organization. WHO recommendation on umbilical vein injection of oxytocin for the treatment of retained placenta. Geneva; 2020.
8. World Health Organization (WHO), World Health Organization. WHO recommendation on

tranexamic acid for the treatment of postpartum haemorrhage. WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage. Geneva: World Health Organization; 2017.

9. World Health Organization (WHO). WHO recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage. Geneva: World Health Organization; 2021.

10. World Health Organization (WHO), World Health Organization. WHO recommendation on advance misoprostol distribution to pregnant women for prevention of postpartum haemorrhage. Geneva: World Health Organization; 2020.

11. World Health Organization. WHO recommendations on maternal and newborn care for a positive postnatal experience. Geneva; 2022.

12. World Health Organization. WHO recommendations on the assessment of postpartum blood loss and use of a treatment bundle for postpartum haemorrhage. Geneva: World Health Organization; 2023.

13. World Health Organization. Trends in maternal mortality 2000 to 2020: estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division. Geneva; 2023.

14. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander J a, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. Implement Sci. 2009;4(50):40–55.

15. Damschroder LJ, Reardon CM, Opra Widerquist MA, Lowery J. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. Implement Sci [Internet]. 2022 Dec 22;17(1):7. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-021-01181-5

16. Lewis CC, Boyd MR, Walsh-Bailey C, Lyon AR, Beidas R, Mittman B, et al. A systematic review of empirical studies examining mechanisms of implementation in health. Implement Sci [Internet].

2020 Dec 16;15(1):21. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-00983-3

17. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10(53).

18. Tanahashi T. Health service coverage and its evaluation. Bull World Health Organ [Internet]. 1978;56(2):295–303. Available from: http://www.ncbi.nlm.nih.gov/pubmed/96953

19. Baker U, Peterson S, Marchant T, Mbaruku G, Temu S, Manzi F, et al. Identifying implementation bottlenecks for maternal and newborn health interventions in rural districts of the United Republic of Tanzania. Bull World Health Organ [Internet]. 2015 Jun 1;93(6):380–9. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450702/pdf/BLT.14.141879.pdf/

20. World Health Organization. Local Production and Technology Transfer to Increase Access to Medical Devices: Addressing the barriers and challenges in low- and middle-income countries. Geneva: World Health Organization; 2012.

21. Eboreime EA, Nxumalo N, Ramaswamy R, Ibisomi L, Ihebuzor N, Eyles J. Effectiveness of the Diagnose-Intervene- Verify-Adjust (DIVA) model for integrated primary healthcare planning and performance improvement: an embedded mixed methods evaluation in Kaduna state, Nigeria. BMJ Open [Internet]. 2019 Mar 30;9(3):e026016. Available from: https://bmjopen.bmj.com/lookup/doi/10.1136/bmjopen-2018-026016

22. Whitehorn A, Fu L, Porritt K, Lizarondo L, Stephenson M, Marin T, et al. Mapping clinical barriers and evidence-based implementation strategies in low-to-middle income countries (LMICs). Worldviews Evidence-Based Nurs [Internet]. 2021 Jun 10;18(3):190–200. Available from: https://onlinelibrary.wiley.com/doi/10.1111/wvn.12503

23. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. Third. Los Angeles, CA: Sage Publications; 2018. 492 p.

24. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res [Internet]. 2019 Dec 25;19(1):189. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4015-3

25. Bullock HL, Lavis JN, Wilson MG, Mulvale G, Miatello A. Understanding the implementation of evidence-informed policies and practices from a policy perspective: a critical interpretive synthesis. Implement Sci. 2021;16(1):1–24.

26. Allen P, Pilar M, Walsh-Bailey C, Hooley C, Mazzucca S, Lewis CC, et al. Quantitative measures of health policy implementation determinants and outcomes: a systematic review. Implement Sci [Internet]. 2020 Dec 19;15(1):47. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-01007-w

27. Stone D. Learning lessons, policy transfer and the international diffusion of policy ideas. Coventry: Centre for the Study of Globalisation and Regionalisation, University of Warwick; 2001.

28. Stone D. Transfer agents and global networks in the 'transnationalization' of policy. J Eur Public Policy. 2004;11(3):545–66.

29. Stone D, Porto de Oliveira O, Pal LA. Transnational policy transfer: The circulation of ideas, power and development models. Policy Soc [Internet]. 2020 Jan 2;39(1):1–18. Available from: https://academic.oup.com/policyandsociety/article/39/1/1/6403955

30. Hill M, Hupe P. Implementing Public Policy: Governance in Theory and in Practice. Thousand Oaks, C.A.: Sage Publications Inc.; 2002.

31. Weiner BJ. A theory of organizational readiness for change. Implement Sci. 2009;4(1):1–9.

32. Glanz K, Rimer BK. Theory at a Glance: A Guide for Health Promotion Practice. Heal (San Fr. 2005;52.

33. O'Connell TS, Sharkey A. Reaching Universal Health Coverage through District Health System

Strengthening: Using a modified Tanahashi model sub-nationally to attain equitable and effective coverage. New York; 2013.

34. Scaccia JP, Cook BS, Lamont A, Wandersman A, Castellow J, Katz J, et al. A practical implementation science heuristic for organizational readiness: R=MC2. J Community Psychol. 2015;43(4):484–501.

35. Adamou B, Curran J, Wilson L, Dagadu NA, Jennigs V, Lundgren R, et al. Guide for Monitoring Scale-up of Health Practices and Interventions. Chapel Hill, N.C.: USAID; MEASURE Evalution; 2014.

36. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci [Internet]. 2011 Dec 23;6(1):42. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-42

37. MSI, ExpandNet, WHO. 20 Questions for Developing a Scaling up Case Study. 2007.

38. World Health Organization. Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies. Geneva; 2010.

39. Lokot M. Whose Voices? Whose Knowledge? A Feminist Analysis of the Value of Key Informant Interviews. Int J Qual Methods. 2021;20:1–8.

40. King G, Keohane RO, Verba S. Designing Social Inquiry: Scientific Inference in Qualitative Research, New Edition. Princeton: Princeton University Press; 2021.

41. World Health Organization. A roadmap to combat postpartum haemorrhage between 2023 and 2030. Geneva: World Health Organization; 2023 Oct 11. Available from: https://iris.who.int/handle/10665/373221

42. Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized trial of early detection and treatment of postpartum hemorrhage. N Engl J Med. 2023 Jul 9;389(1):11–21.

43. Mammoliti KM, Althabe F, Easter C, Devall A, Martin J, Funmi AL, Yusuf R, Abubakar F, Arigbede LC, Mugambi J, Oyoo P. When Is Postpartum Haemorrhage Treatment Initiated? A Nested Observational Study Within the E-MOTIVE Trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2025 Oct;132(11):1664-72.

44. Devall AJ, Nausheen S, Muhammad S, Soofi S, Karmaliani R, Lakhani A, Sajid K, Ahmed I, Raza A, Ashraf A, Shahid N. Early detection and bundled treatment of postpartum haemorrhage with the E-MOTIVE intervention: a prospective pre–post intervention study in Pakistan. The Lancet Obstetrics, Gynaecology, & Women's Health. 2025 Oct 1;1(2):e114-21.

45~~2~~. Torloni M, Gomes Freitas C, Kartoglu U, Metin Gülmezoglu A, Widmer M. Quality of oxytocin available in low- and middle-income countries: A systematic review of the literature. BJOG An Int J Obstet Gynaecol. 2016 Dec 22;123(13):2076–86.

46~~3~~. Lambert P, McIntosh MP, Widmer M, Evans L, Rauscher M, Kuwana R, et al. Oxytocin quality: Evidence to support updated global recommendations on oxytocin for postpartum hemorrhage. J Pharm Policy Pract. 2020 Dec 15;13(1):14.

47~~4~~. Hall PE. Quality of medicines: Quality of misoprostol products. WHO Drug Inf. 2016;30(1):35–9.

48~~5~~. Anyakora C, Oni Y, Ezedinachi U, Adekoya A, Ali I, Nwachukwu C, et al. Quality medicines in maternal health: Results of oxytocin, misoprostol, magnesium sulfate and calcium gluconate quality audits. BMC Pregnancy Childbirth [Internet]. 2018 Dec 30;18(1):44. Available from: https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-018-1671-y

49~~6~~. Bower J, Chinery L, Fleurent A, Gülmezoglu AM, Im-Amornphong W, Kilfedder C, et al. Quality testing of mifepristone and misoprostol in 11 countries. Int J Gynecol Obstet [Internet]. 2024 May 29;165(2):405–15. Available from: https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15148

50~~47~~. Finlayson K, Vogel JP, Althabe F, Widmer M, Oladapo OT. Healthcare providers experiences of

using uterine balloon tamponade (UBT) devices for the treatment of post-partum haemorrhage: A meta-synthesis of qualitative studies. Garzon S, editor. PLoS One [Internet]. 2021 Mar 18;16(3):e0248656. Available from: https://dx.plos.org/10.1371/journal.pone.0248656

5148. Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. Adm Policy Ment Heal Ment Heal Serv Res. 2011;38(1):4–23.

5249. Northridge ME, Metcalf SS. Enhancing implementation science by applying best principles of systems science. Heal Res policy Syst. 2016 Oct;14(1):74.

~~50. World Health Organization. A Roadmap to Combat Postpartum Haemorrhage between 2023 and 2030. Geneva; 2023.~~

531. Escoffery C, Sekar S, Allen CG, Madrigal L, Haardoerfer R, Mertens A. A scoping review of outer context constructs in dissemination and implementation science theories, models, and frameworks. Transl Behav Med [Internet]. 2023 May 13;13(5):327–37. Available from: http://www.ncbi.nlm.nih.gov/pubmed/36694938

524. Esmail R, Hanson HM, Holroyd-Leduc J, Brown S, Strifler L, Straus SE, et al. A scoping review of full-spectrum knowledge translation theories, models, and frameworks. Implement Sci [Internet]. 2020 Feb 14;15(1):11. Available from: http://www.ncbi.nlm.nih.gov/pubmed/32059738

535. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. Implement Sci [Internet]. 2019 Dec 11;14(103). Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-019-0957-4

546. Gilson L, editor. Health Policy and Systems Research: A Methodology Reader. Geneva: World Health Organization; 2017.

557. Jones CM, Gautier L, Ridde V. A scoping review of theories and conceptual frameworks used to analyse health financing policy processes in sub-Saharan Africa. Health Policy Plan.

2021;36(7):1197–214.

5~~6~~8. Sheikh K, Gilson L, Agyepong IA, Hanson K, Ssengooba F, Bennett S. Building the field of Health Policy and Systems Research: Framing the questions. PLoS Med [Internet]. 2011 Aug 16;8(8):e1001073. Available from: https://dx.plos.org/10.1371/journal.pmed.1001073

5~~7~~9. Nilsen P, Ståhl C, Roback K, Cairney P. Never the twain shall meet? - a comparison of implementation science and policy implementation research. Implement Sci. 2013;8(63):1–12.

6058. Williams CR, Adnet G, Gallos ID, Coomarasamy A, Gülmezoglu AM, Islam MA, et al. Research agenda for ending preventable maternal deaths from postpartum haemorrhage: a WHO research prioritisation exercise. BMJ Glob Heal [Internet]. 2024 Nov;9(11):e015342. Available from: https://gh.bmj.com/lookup/doi/10.1136/bmjgh-2024-015342

~~59. Phillips DE, Bhutta ZA, Binagwaho A, Boerma T, Freeman MC, Hirschhorn LR, et al. Learning from Exemplars in Global Health: a road map for mitigating indirect effects of COVID-19 on maternal and child health. BMJ Glob Heal [Internet]. 2020 Jul 31;5(7):e003430. Available from: https://gh.bmj.com/lookup/doi/10.1136/bmjgh-2020-003430~~

Figure 1: Conceptual model of barriers and bottlenecks to national implementation of WHO-recommended interventions to prevent, detect, and treat postpartum hemorrhage

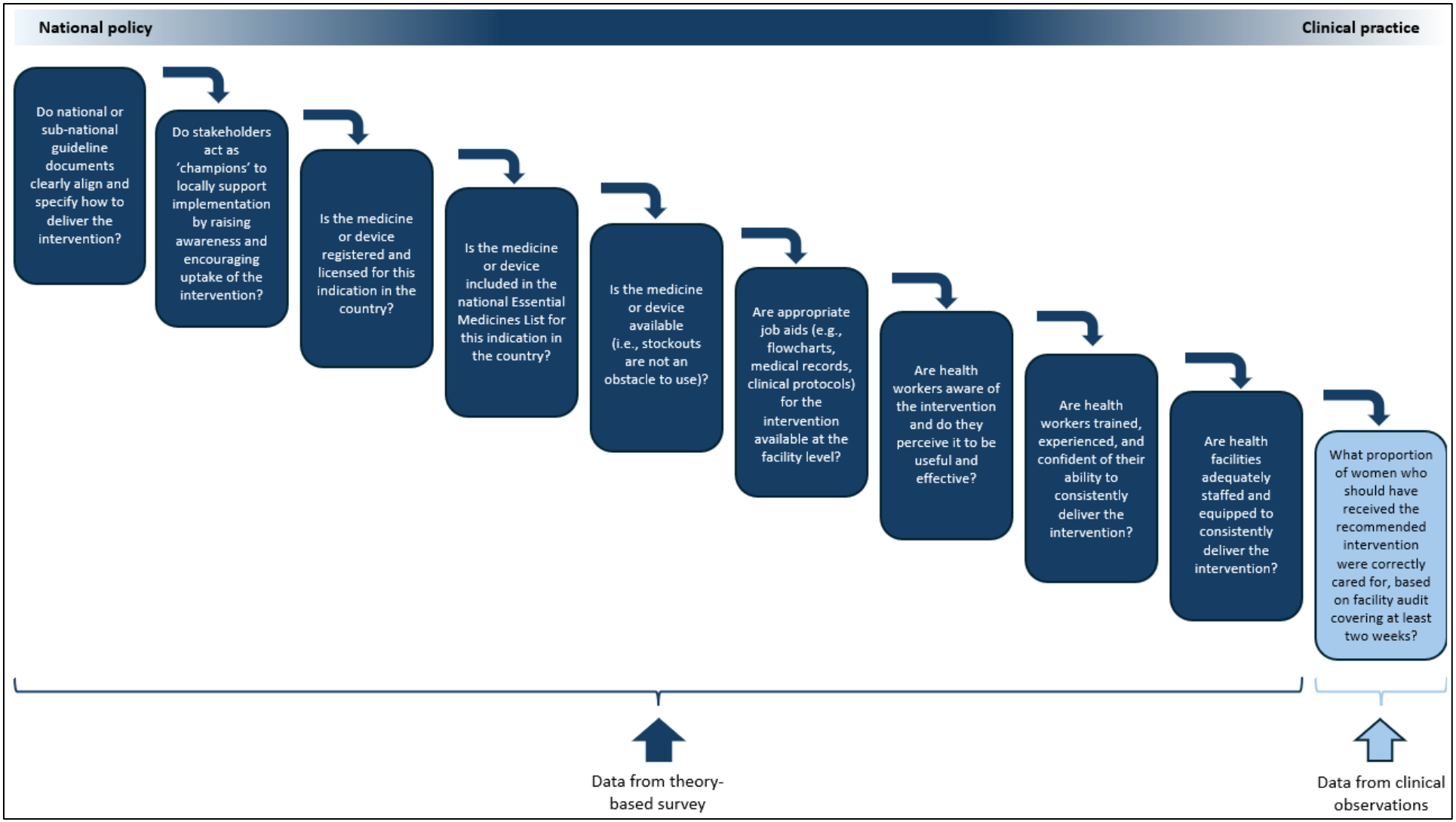
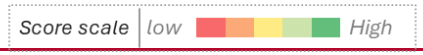


Figure 2: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the prevention and detection of postpartum hemorrhage

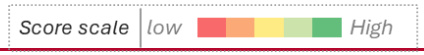
Recommended interventions for PPH prevention	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH prevention	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH prevention (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Heat-stable carbetocin injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	45%	50%	53%	47%	29%	37%	45%	48%	37%	37%
Oral misoprostol for PPH prevention (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Oxytocin in combination with controlled cord traction for retained placenta	71%	67%	78%	78%	63%	60%	69%	60%	62%	54%
Controlled cord traction is the recommended method for removal of the placenta in caesarean section	70%	70%				66%	70%		68%	67%
Recommended interventions for PPH detection										
Abdominal uterine tonus assessment for early identification of uterine atony for all women postpartum	71%	71%				67%	73%		69%	63%



Recommended interventions for PPH prevention	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH prevention	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH prevention (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Heat-stable carbetocin injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	45%	50%	53%	47%	29%	37%	45%	48%	37%	37%
Oral misoprostol for PPH prevention (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Oxytocin in combination with controlled cord traction for retained placenta	71%	67%	78%	78%	63%	60%	69%	60%	62%	54%
Controlled cord traction is the recommended method for removal of the placenta in caesarean section	70%	70%				66%	70%		68%	67%
Recommended interventions for PPH detection										
Abdominal uterine tonus assessment for early identification of uterine atony for all women postpartum	71%	71%				67%	73%		69%	63%

Figure 3: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the first-response treatment of postpartum hemorrhage

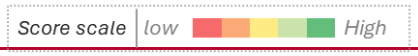
Recommended interventions for PPH treatment (first-response)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH treatment	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH treatment (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH treatment (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Oral misoprostol for PPH treatment (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Isotonic crystalloids for fluid resuscitation of women with PPH	76%	75%	80%	79%	66%	69%	76%	75%	74%	63%
Tranexamic acid (TXA) injection plus standard care for PPH treatment	66%	65%	66%	63%	48%	51%	57%	59%	48%	50%
Uterine massage for conservative treatment of PPH	81%	81%				77%	82%		79%	73%



Recommended interventions for PPH treatment (first-response)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH treatment	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH treatment (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH treatment (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Oral misoprostol for PPH treatment (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Isotonic crystalloids for fluid resuscitation of women with PPH	76%	75%	80%	79%	66%	69%	76%	75%	74%	63%
Tranexamic acid (TXA) injection plus standard care for PPH treatment	66%	65%	66%	63%	48%	51%	57%	59%	48%	50%
Uterine massage for conservative treatment of PPH	81%	81%				77%	82%		79%	73%

Figure 4: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the treatment of refractory postpartum hemorrhage and health system interventions

Recommended interventions for PPH treatment (refractory)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Uterine balloon tamponade (UBT) for refractory PPH treatment	54%	59%	52%	46%	39%	45%	55%	43%	39%	37%
Non-pneumatic anti-shock garment (NASG) as temporizing measure for definitive PPH care	50%	54%	47%	44%	33%	37%	43%	43%	34%	35%
Uterine artery embolization for refractory PPH treatment	43%	43%				34%	41%		26%	25%
Bimanual uterine compression as temporizing measure before definitive PPH care	74%	69%				61%	71%		56%	54%
External aortic compression as temporizing measure for definitive PPH care	56%	48%				43%	46%		38%	45%
Surgical interventions (laparotomy with vessel ligation or compressive sutures or hysterectomy) for refractory PPH treatment	72%	69%				61%	76%		51%	46%
Health system interventions										
Formal protocols at health facilities for prevention and treatment of PPH	72%	70%				64%	72%		59%	51%
Formal protocols for referral of women to a higher level of care for treatment of PPH	64%	64%				52%	69%		56%	45%
Simulations of PPH treatment for pre-service and in-service training programs	53%	62%				48%	61%		45%	39%



Recommended interventions for PPH treatment (refractory)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Uterine balloon tamponade (UBT) for refractory PPH treatment	54%	59%	52%	46%	39%	45%	55%	43%	39%	37%
Non-pneumatic anti-shock garment (NASG) as temporizing measure for definitive PPH care	50%	54%	47%	44%	33%	37%	43%	43%	34%	35%
Uterine artery embolization for refractory PPH treatment	43%	43%				34%	41%		26%	25%
Bimanual uterine compression as temporizing measure before definitive PPH care	74%	69%				61%	71%		56%	54%
External aortic compression as temporizing measure for definitive PPH care	56%	48%				43%	46%		38%	45%
Surgical interventions (laparotomy with vessel ligation or compressive sutures or hysterectomy) for refractory PPH treatment	72%	69%				61%	76%		51%	46%
Health system interventions										
Formal protocols at health facilities for prevention and treatment of PPH	72%	70%				64%	72%		59%	51%
Formal protocols for referral of women to a higher level of care for treatment of PPH	64%	64%				52%	69%		56%	45%
Simulations of PPH treatment for pre-service and in-service training programs	53%	62%				48%	61%		45%	39%

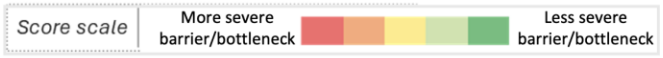


Table 1: Administration of recommended interventions for PPH prevention, detection, and treatment during direct observations in Nigeria, Pakistan, and Tanzania

	Nigeria		Pakistan		Tanzania	
Recommended interventions for PPH prevention	**%**	**n** (N=1352 observations in 19 facilities)	**%**	**n** (N=38 observations in 2 facilities)	**%**	**n** (N=649 observations in 6 facilities)
Oxytocin injection for PPH prevention	99.7%	1348	100.0%	38	100.0%	649
Oxytocin infusion also administered	*3.4%*	*46*	*0.0%*	*0*	*5.5%*	*36*
Ergometrine injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.4%	6	0.0%	0	0.0%	0
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0
Heat-stable carbetocin injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.7%	9	0.0%	0	0.0%	0
Misoprostol for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	61.5%	832	78.9%	30	2.0%	13
Oral or sublingual	*13.8%*	*186*	*2.6*	*1*	*0.2%*	*1*
Per Rectal	*51.8%*	*700*	*78.9%*	*30*	*1.8%*	*12*
Both Oral or Sublingual and Per Rectal	*4.0%*	*54*	*2.6%*	*1*	*0.0%*	*0*
Recommended interventions for PPH detection	**%**	**n** (N=1352 observations in 19 facilities)	**%**	**n** (N=38 observations in 2 facilities)	**%**	**n** (N=649 observations in 6 facilities)
Abdominal uterine tonus assessment for early identification of uterine atony for all women postpartum during direct observations*	64.4%	898	100.0% %	38	73.0%	474
* Numerator: number of times uterine tone checked for 1st direct observation; Denominator: number of discrete HCP observations (women)						
Recommended interventions for PPH treatment (first-response)	**%**	**n** (N=77 PPHs diagnosed)	**%**	**n** (N=7 PPHs diagnosed)	**%**	**n** (N=72 PPHs diagnosed)
Oxytocin injection for PPH treatment	70.1%	54	100.0%	7	98.6%	71
Ergometrine injection for PPH treatment (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0

Misoprostol for PPH treatment (if oxytocin is unavailable, quality cannot be guaranteed or did not stop the bleeding)	41.6%	32	28.6%	2	36.1%	26
Oral or sublingual	*15.6%*	*12*	*0.0%*	*0*	*1.4%*	*1*
Per Rectal	*29.9%*	*23*	*28.6%*	*2*	*34.7%*	*25*
Both Oral or Sublingual and Per Rectal	*3.9%*	*3*	*0.0%*	*0*	*0.0%*	*0*
Tranexamic acid (TXA) injection for PPH treatment	27.3%‡	21‡	100.0%‡	7‡	48.6%‡	35‡
Isotonic crystalloids for fluid resuscitation of women with PPH	62.3%	48	100.0%	7	79.2%	57
Oxytocin in combination with controlled cord traction for retained placenta	-	1	-	None occurred	-	3
Uterine massage for conservative treatment of PPH	92.2%	71/77	100.0%	7/7	91.7%	66

‡ Variations occur in standard care

Recommended interventions for PPH treatment (refractory)	**%**	**n**	**%**	**n**	**%**	**n**
Uterine balloon tamponade (UBT) for refractory PPH treatment	-	None occurred	-	None occurred	-	2
Non-pneumatic anti-shock garment (NASG) as temporizing measure for definitive PPH care	-	1	-	None occurred	-	None occurred
Uterine artery embolization for refractory PPH treatment	-	None occurred	-	None occurred	-	None occurred
Bimanual uterine compression as temporizing measure	-	4	-	None occurred	-	26
External aortic compression as temporizing measure for definitive PPH care	-	None occurred	-	None occurred	-	None occurred
Surgical interventions (laparotomy with vessel ligation or compressive sutures or hysterectomy) for refractory PPH treatment	-	1	-	None occurred	-	None occurred
Health system interventions	**%**	**n** (N=19 facilities)	**%**	**n** (N=2 facilities)	**%**	**n** (N=6 facilities)
Formal protocols at health facilities for prevention and treatment of PPH	Yes: 42.1% No: 47.4% Unknown: 10.5%	8 9 2	Yes:100.0% No: 0.0 % Unknown: 0.0%	2 0 0	Yes: 83.3 % No: 16.7 % Unknown: 0.0%	5 1 0
Formal protocols for referral of women to a higher level of care for treatment of PPH	Yes: 0.0% No: 100.0%	0 19	Yes: 50.0% No: 50.0%	1 1	Yes: 0.0% No: 100.0%	0 6
Simulations of PPH treatment for pre-service and in-service training programs	Yes: 5.3% No: 94.7%	1 18	Yes: 100.0% No: 0.0%	2 0	Yes: 83.3% No: 16.7%	5 6

Barriers and bottlenecks to implementation of WHO recommendations for prevention, detection, and treatment of postpartum hemorrhage: A mixed-methods triangulation study

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ABSTRACT

Background: The World Health Organization develops evidence-based recommendations for postpartum hemorrhage (PPH) prevention, detection, and treatment. However, persistently high PPH-related mortality suggests recommendations are poorly implemented, especially in low-resource settings. This study aimed to identify implementation bottlenecks to inform action.
Methods: Drawing on public policy, implementation science, and health behavior, we constructed a multi-level framework to identify bottlenecks affecting recommendation uptake. This informed the development of a survey assessing which bottlenecks affected specific WHO recommendations. Surveys were completed by global stakeholders and by health care workers in three high-burden countries. We also analyzed direct observations of clinical practice from those countries to see how bottlenecks affected practice. An *a priori* interpretive threshold of 75% was selected to indicate a bottleneck was not a severe impediment to implementation.
Results: Surveys from 102 global stakeholders and 246 health care workers, as well as 2039 direct observations of clinical practice revealed variation in adherence to WHO recommendations, with some through-lines. Oxytocin for PPH prevention and treatment was perceived to have national policy support (>75% for inclusion in national guidelines and Essential Medicines Lists, regulatory approval, and support from national champions) but other uterotonics were not. Tranexamic acid for PPH treatment was found to be underutilized, likely due to compounding bottlenecks. Respondents reported extensive bottlenecks to refractory PPH interventions (<75% across nearly all bottlenecks). The most substantial bottlenecks were availability/procurement of medicines and devices, affordability and quality of medicines and devices, presence of job aids, and availability of qualified staff. Observed practice generally aligned with stakeholder perceptions.
Conclusions: National policy bottlenecks strongly mediated implementation in clinical practice. Policy change addressing gaps in commodity procurement and availability of trained clinicians is critical. Efforts addressing only one part of the implementation ecosystem are unlikely to drive transformative change.

CONTRIBUTIONS TO THE LITERATURE

- This paper synthesizes theoretical insights spanning the outer and inner settings of implementation to develop a consolidated multi-level theory of why implementation of evidence-based interventions stall.
- The empiric results show that bottlenecks in national policy hinder subsequent downstream implementation of WHO recommendations to prevent, detect, and treat postpartum hemorrhage. With most implementation strategies targeting the inner setting, our findings highlight the need to develop and test strategies for affecting change in the outer setting.
- The study offers one approach for using theory-derived implementation research to identify gaps where targeted interventions have catalytic potential to drive improvements in global maternal health.

KEYWORDS
postpartum hemorrhage, implementation science, health planning, health services research, resource-limited settings

BACKGROUND

Combating postpartum hemorrhage (PPH) is a key global maternal health priority. Obstetric hemorrhage is the leading cause of maternal death worldwide, accounting for an estimated 27% of maternal mortality, with PPH constituting the largest share of hemorrhage-related mortality (1). In addition, PPH is an important contributor to long-term maternal morbidity, with far-reaching consequences including mental health conditions like post-traumatic stress disorder and postpartum depression (2,3). To aid health care workers in more effectively preventing and treating PPH, the World Health Organization (WHO) has issued several PPH guidelines, distilling research evidence into clinical and health systems recommendations for providing quality PPH care (4–12). Yet these recommendations have not translated into the improvements in maternal health outcomes needed to meet Sustainable Development Goal (SDG target 3.1) (13). There is a need to better understand why.

This study presents a novel theory-based approach to describe key steps on the pathway to implementation of global guidelines and assess how current efforts to translate WHO's evidence-based PPH recommendations into routine practice have stalled. The results of this study can be used to inform global efforts to accelerate uptake of WHO guidelines, as well as address barriers and bottlenecks to implementation – particularly those that arise in the outer setting of implementation (14).

Understanding barriers and bottlenecks to implementation

The need to understand why implementation does not go according to plan has spawned numerous fields of inquiry, among them implementation science, process evaluation, and policy implementation

research. Within implementation science, barriers to implementation are defined as those determinant factors that can slow, stall, or derail the uptake or sustainment of an intervention (15). “Barriers to implementation” is an overarching category that encompasses problems which may arise at various levels or stages within implementation. Efforts are underway to more precisely categorize the mechanisms by which barriers may impede implementation (16). Yet thus far, these categorizations have remained largely descriptive with limited explanatory utility (17). A different type of conceptual framing is needed to move from describing *what* barriers exist to explaining *why* and *how* barriers impede implementation.

Tanahashi’s model of bottlenecks to health service provision suggests that implementation may break down at discrete points in a service delivery process, which can be detected by comparing coverage measures drawn from adjacent levels of service delivery (e.g., coverage of a screening intervention versus coverage of a treatment intervention among individuals screened positive) (18). Baker *et al*. extend this concept to posit that there are identifiable moments in an implementation pathway—implementation bottlenecks—when implementation becomes stuck (19). For example, efforts to bring a new medical device to market worldwide may slow at the regulatory approval stage, especially in countries with poorly resourced regulatory agencies (20). Where “barriers to implementation” are theory-agnostic, “bottlenecks to implementation” imply a presupposed mechanism by which implementation should occur, and the existence of an impediment thwarting a specific step in that mechanism. Thus, identifying bottlenecks to implementation can help determine how to unstick efforts to translate evidence to policy and practice and get life-saving interventions into the field (21).

Despite the utility of mapping bottlenecks to implementation, this step is often overlooked. One reason is that identifying bottlenecks to implementation can be costly and time-consuming. Traditional efforts

may entail conducting facility audits, detailed needs assessments, or in-depth interviews with key stakeholders (22). These approaches generate useful information but can be limited by the perspectives included and excluded, since different stakeholder groups may have varying understandings of where and why implementation has stalled. Developing a comprehensive picture of the factors influencing uptake of evidence-based interventions often requires engaging multiple stakeholder groups, thus increasing cost and logistical complexity. Further, traditional approaches are typically atheoretical and thus may miss important aspects of implementation. Innovative methods are needed that systematize data collection on implementation bottlenecks while reducing burden on researchers, policymakers, and others interested in gathering and using such information. Our study offers one such approach.

METHODS

This mixed-methods triangulation study (23) used three sources of data—1) global stakeholder responses to a theory-derived survey on potential bottlenecks to implementation, 2) direct observations of clinical practice conducted in three countries (Nigeria, Pakistan, and Tanzania), and 3) observed health care workers' responses to a theory-derived survey of potential bottlenecks to implementation—to identify specific factors potentially hindering implementation of evidence-based recommendations for PPH prevention and management. More specifically, data were used to detect evidence-based recommendations that were not well-implemented in the field and to identify common recommendations that had proved challenging to implement across all three settings. Though implementation is often described as highly contextualized (24), common challenges may suggest a need for global cooperation to address supranational barriers (e.g., conflicting normative guidance, regulatory ambiguity, procurement and supply chain issues). To organize and structure data collection

and integration, a consolidated conceptual framework was developed, drawing from the existing theoretical implementation science literature.

Consolidated conceptual framework

The Consolidated Framework for Implementation Research (CFIR) suggests that clinical interventions are provided within a care ecosystem that has both an inner setting (within-facility context) and an outer setting (policy, economy, society) (14). For a new intervention to be administered at bedside, there is a series of changes that must first occur in the outer and inner settings in which service delivery occurs. For example, the intervention needs to have been approved by national regulatory bodies, integrated into domestic policy and guidance, embedded into pre-/in-service training, and actively encouraged within the facility (through, for example, inclusion in clinical protocols, reinforcement by supportive supervision, and active engagement of facility leadership). Without undertaking these steps to transform the domestic care ecosystem into an enabling environment, the intervention cannot be effectively delivered to patients. Yet despite a wealth of implementation-related theorizing, no existing implementation science theory, model, or framework currently covers the steps involved in restructuring the outer and inner settings to produce an enabling environment (25,26). Creating an enabling environment requires multiple instances of policy transfer and knowledge translation across different levels and stakeholder groups, each with their own mental models and operating procedures (27–29). Academics have traditionally partitioned theorizing around these levels and groups, with discrete epistemic communities (e.g., policy implementation, organizational theory, health behavior) developing different bodies of theoretical work (e.g., top-down implementation, organizational readiness, theory of planned behavior) (30–32). Yet effectively moving global recommendations into local practice requires integrating theoretical constructs from across these disparate academic traditions into a single consolidated framework.

Over the past decade, UNICEF has developed and refined an approach for mapping bottlenecks to implementation that extends the Tanahashi model to show how bottlenecks to implementation can be characterized as determinants of supply, demand, or quality (33). That approach has been used by UNICEF as a first step to improve complex health system performance within countries (21). Our analysis builds from the UNICEF approach to conceptually map the supply, demand, and quality considerations of implementing WHO PPH recommendations from policy to clinical practice (i.e., transferring from global to national to sub-national to facility) in a single consolidated framework. The consolidated framework draws on theorizing in policy implementation and implementation science, as well as global health practice-based evidence and WHO normative work. Using a top-down conceptualization of policy implementation (30) and following from Baker *et al*.'s operationalization of Tanahashi's model (19), the process of moving from evidence-based recommendations to clinical practice was envisioned as a unidirectional implementation pathway in which addressing bottlenecks in earlier steps created more enabling environments for subsequent steps. Discrete steps required to embed global guidelines into national policy were identified, using concepts from the literature on policy transfer (27–29). Next, steps needed to translate national policy into clinical practice were identified, building from the literature on implementation research and practice (34–37). Finally, each of these steps was mapped against the WHO building blocks of health systems (38), to ensure that no elements had been overlooked. Given the critical role of commodities such as uterotonics, tranexamic acid, and devices for refractory PPH in PPH prevention and management, special attention was paid to tracing the steps involved in ensuring access to quality commodities at the bedside. The integrated conceptual framework is provided in Figure 1.

Survey of global stakeholders

To better understand the upstream factors contributing to poor implementation at the point of care, a targeted online survey was conducted to capture global stakeholders' perceptions of the specific steps

in the cascade at which implementation of PPH recommendations was stalled. Within policy research, in-depth interviews with key informants are commonly used to efficiently gather insight into policy-related processes, including policy transfer (39). However, managing large-scale qualitative data analysis can be time-consuming and resource intensive. Theory-derived surveys can offer a more efficient approach to large-scale data collection (40). The conceptual framework was used to inform the development of the survey questions, with one question developed for each step in the implementation pathway. Recognizing that different recommendations might face different challenges to implementation, the survey was structured so that respondents answered the questions in the pathway for one evidence-based recommendation at a time. The full set of questions was posed for recommendations regarding specific PPH commodities (medicines and devices). A subset of questions was posed for recommendations on clinical or health system interventions, where the items on procurement and regulatory approval were not applicable. A blank copy of the survey questionnaire is provided in Supplementary file S1.

The survey was shared with 105 global stakeholders for an initial round of prioritization. These stakeholders were drawn from Ministries of Health, women and women's groups, implementers (including non-governmental organizations and civil society organizations), professional associations, guideline developers, the research community, international donors, and the private sector – all acting in an individual capacity and not representing any specific organization. The composition and selection of this global stakeholder group have been described previously and were not modified for the present study (41). Participants were sent a unique link to an online survey (via SurveyMonkey). Submission of the survey indicated consent to participate. The survey was open for five weeks (25 January 2023 – 1 March 2023).

Questions were posed by WHO PPH recommendation. Participants were asked to report the extent to which they agreed that the statement posed was true (e.g., “Medicine or device is registered and licensed for this/these indication/s in the country”). Responses were on a 5-point Likert scale, ranging from “Strong disagree” to “Strongly agree.” To minimize forced responses and reduce noise, respondents were able to select “don’t know” for items they felt unable to assess. At the analysis stage, aggregate scores were calculated as simple means of item responses, using a linear transformation in which 0 corresponded to “Strongly disagree” and 1 to “Strongly agree”; “Don’t know” responses were excluded from analysis by design. Aggregate scores were visualized using heatmaps to facilitate identification of potential bottlenecks. To aid interpretation, a score of 75% was used as an *a priori* interpretive threshold to distinguish pathway steps for which, on average, respondents indicated agreement that the step was in place from those falling below this level. Under the linear transformation used, a score of 0.75 corresponds to the Likert response option “Agree.” This threshold was selected for interpretability and consistency with the scale anchors rather than as a statistical decision rule. Respondents were also invited to provide explanatory comments on each intervention via open-ended questions, including descriptions of barriers not captured by the structured items. These comments were reviewed, grouped by theme, and summarized.

Direct observations of clinical practice

To test the face validity of the findings of the global survey, direct observations of health care providers’ clinical practice in three countries with high burden of PPH-related morbidity and mortality (Nigeria, Pakistan, and Tanzania) were reviewed and triangulated with global participants’ survey responses. Direct observations were drawn from a nested study within a large implementation trial for the early detection and treatment of postpartum hemorrhage and a pre-post evaluation of an effort to

implement the same complex intervention (42-4). For the purposes of the current study, the direct observations constitute a convenience sample.

Observations were drawn from 19 facilities in Nigeria, 6 facilities in Tanzania, and 2 facilities in Pakistan. In Nigeria and Tanzania, observations were conducted at each facility over a two-week period between August 2022 and December 2022 (prior to the start of implementation of the early detection and treatment intervention), covering 24 hours Monday to Sunday to reduce risk of selection bias and gain insights into the care provided across all shifts during the day, night, weekdays, and weekends. In Pakistan, observations were conducted over a 3–4-day period in both sites between January and February 2023 (prior to the start of implementation of the early detection and treatment intervention). Observation periods varied across countries due to logistical and contextual constraints; however, observations in all settings were designed to capture routine care processes rather than to estimate frequencies or rates. Research staff observed in real time, as health care workers employed by the facility attended vaginal births, administered preventive interventions, conducted direct observations, and managed any PPHs that occurred. Data were collected using a purpose-designed structured guide. Observations were conducted in the labor ward. If a woman was transferred to theatre for escalated treatments, some data on refractory care was obtained from the main study database, which was entered by the research staff after confirmation of treatment by the treating clinician.

Survey of health care workers

For completion, health care workers whose care provision was observed were invited to fill in the same survey as global stakeholders, to assess generalizability of the global findings to their contexts. Scores

were tabulated, aggregated, and analyzed in the same way as for the global stakeholder survey, but analyses were conducted independently for each country.

All analyses were descriptive in nature and intended to identify patterns of perceived implementation bottlenecks rather than to formally test hypotheses or estimate population-level effects. Given the purposive sampling strategy and the diagnostic aim of the study, inferential statistical testing was not performed.

RESULTS

Global Stakeholder Survey

The global survey was sent to 105 global stakeholders, of whom 102 consented and responded (response rate: 97.1%). Aggregate scores are plotted on the heatmap in Figures 2-4. “Don’t know” responses were rare for widely disseminated recommendations (e.g., oxytocin for PPH prevention) and more frequent for more technical clinical interventions, particularly among non-clinical respondents, reflecting differences in role relevance and exposure. This pattern was consistent with the study’s intent to capture informed perceptions of implementation bottlenecks rather than uncertainty regarding the recommendations themselves. The overall pattern of identified bottlenecks was robust to alternative interpretive thresholds (70% and 80%), with differences limited to a small number of items near the cutoff. Certain interventions were perceived as broadly facing bottlenecks to implementation across the entire implementation pathway, while others were perceived to be reasonably well-implemented across the pathway. Four steps in the pathway (availability/procurement of medicines and devices; affordability and quality of medicines and devices; presence of job aids in the facility; and availability of

qualified staff) consistently posed more substantial bottlenecks to implementation than others, regardless of the intervention. Stakeholder comments in the open-ended questions helped to contextualize the aggregate scores and showcase the existence of other important barriers.

Oxytocin use was generally perceived to face few bottlenecks to implementation for both PPH prevention and treatment, whereas stakeholders reported bottlenecks to implementation across the entire implementation pathway for other uterotonics recommended for PPH prevention (or treatment if oxytocin was unavailable). In open-ended comments, participants indicated that implementation was sometimes stalled due to barriers not captured by the pathway. For example, ergometrine was perceived to be underused because of concerns about side-effects; fixed-dose oxytocin-ergometrine was perceived to be "out of fashion"; and heat-stable carbetocin was reported to be still relatively new, unknown, and costly as compared to other prophylactic uterotonic options. Global stakeholders perceived oral misoprostol for PPH prevention and treatment, tranexamic acid for PPH treatment, prophylactic oxytocin with controlled cord traction, and isotonic crystalloids for fluid resuscitation as facing fewer challenges as compared to other interventions.

In contrast, stakeholders perceived device-based and surgical interventions for refractory PPH as facing extensive barriers and bottlenecks to implementation. Stakeholders commented that uterine balloon tamponade (UBT) and the non-pneumatic anti-shock garment (NASG) were rarely used in practice because the devices were largely unavailable and/or perceived to be unaffordable, were not included in facility-level protocols, and generally had not been well-promoted or championed in-country. Uterine artery embolization was perceived to be available only in high-level tertiary facilities with specialists, and even then, as often difficult to access. Similar points were raised for other surgical procedures, though to a lesser extent. Lack of available staff and staff time were the primary points raised in global

stakeholder comments with respect to clinical interventions such as uterine tone assessment for identification of women with postpartum uterine atony, controlled cord traction combined with oxytocin for removal of retained placenta, and external aortic compression as a temporizing measure.

Global stakeholder perceptions on health system interventions also varied by intervention, with simulation drills having the greatest number of perceived barriers to implementation. In open-ended comments, global stakeholders reported that simulation drills were particularly hindered by lack of trained personnel to conduct drills and understaffing of frontline health care workers. In addition, simulation drills were reported to be not well-promoted domestically.

Direct observations of clinical practice and survey of health care workers

A total of 1352 direct observations were conducted in Nigeria (77 cases of PPH diagnosed and treated). In Tanzania, 649 direct observations were conducted (72 cases of PPH diagnosed and treated) and in Pakistan, 38 direct observations were conducted (7 cases on PPH diagnosed and treated). Direct observation results are reported in Table 1. In addition, a total of 246 health care workers responded to the theory-based survey (31 in Nigeria, 126 in Pakistan, and 50 in Tanzania). Heatmaps of health care workers' aggregate survey scores for each of the countries are provided in Supplementary file S2.

Oxytocin was widely observed in use for PPH prevention (Nigeria: 99.7% of observed births; Pakistan: 100.0%; Tanzania: 100.0%). Although oral misoprostol was only recommended for prevention when oxytocin was unavailable or the quality could not be assured, a substantial proportion of women in Nigeria and Pakistan were administered both oxytocin and oral misoprostol for PPH prevention (Nigeria: 61.5% of observed births; Pakistan: 78.9%; Tanzania: 2.0%). In Nigeria, the aggregate health care worker

survey score indicated that “Available products in the markets are perceived as affordable and of good quality” was a barrier to implementation of oxytocin but not to that of oral misoprostol. In direct observations, ergometrine, fixed-dose oxytocin and ergometrine combination, and heat-stable carbetocin were rarely used for prevention (fewer than 1% of observed births in all three countries). In Pakistan and Tanzania, health care worker aggregate survey scores indicated extensive perceived barriers to implementation of recommendations of second-line uterotonics.

Postpartum uterine tone was assessed to help detect PPH in most cases (Nigeria: 64.4% of observed births; Pakistan: 100.0%; Tanzania: 73.0%). In the health care worker aggregate survey responses, adequate staffing was the single reported barrier or bottleneck to implementation of this recommendation in Nigeria and Tanzania.

When it came to PPH treatment, oxytocin was widely observed in use (Nigeria: 78.1% of observed PPH cases; Pakistan: 100.00%; Tanzania: 98.6%). Oral misoprostol was used extensively for treatment (Nigeria: 41.6% of observed PPH cases; Pakistan: 28.6%; Tanzania: 36.1%). Ergometrine and fixed-dose oxytocin and ergometrine combination were rarely used for PPH treatment (fewer than 1% of observed PPH cases in all three countries). Although tranexamic acid is recommended as a first-response treatment for PPH, use varied widely across settings (Nigeria: 27.3% of observed PPH cases; Pakistan: 100.0%; Tanzania: 48.6%). In Pakistan, health care workers did not report perceived barriers to implementation of tranexamic acid. In Nigeria and Tanzania, however, aggregate health care worker survey responses indicated that there were multiple barriers to implementation, ranging from availability challenges to poor health care worker awareness of its utility through adequate training and support for use in practice. Use of isotonic crystalloids for fluid resuscitation was also context-dependent (Nigeria: 62.3% of observed PPH cases; Pakistan: 100.0%; Tanzania: 79.2%), though health

care worker survey responses did not identify any specific barriers or bottlenecks to implementation. Uterine massage for conservative treatment of PPH was conducted nearly universally (Nigeria: 92.2% of observed PPH cases; Pakistan: 100.0%; Tanzania: 91.7%).

Use of recommended interventions for refractory PPH were rarely observed, though this is primarily reflective of the small numbers of refractory PPH cases observed. However, health care worker aggregate survey responses indicated the existence of substantial barriers and bottlenecks to implementation across the entire pathway for recommended interventions to treat refractory PPH.

Notable findings among health system interventions include the lack of referral protocols for transferring women with refractory PPH to higher levels of care (Nigeria: 0% of facilities had a protocol; Pakistan: 50%; Tanzania: 0%) and the limited use of simulation drills in Nigeria (only 1 of the 19 participating facilities reported using simulation drills). Interestingly, only health care worker aggregate survey responses in Nigeria indicated that there were bottlenecks to implementation of these kinds of health system interventions. Health care workers in the other two countries did not perceive any bottlenecks to implementation of these recommendations.

DISCUSSION

This study sought to identify WHO evidence-based recommendations for PPH prevention and treatment whose implementation are stalled and characterize some of the bottlenecks to implementation, using a combination of real-time direct observations of clinical practice and theory-derived surveys of global stakeholders' and local health care workers' perceptions. Among uterotonics, only oxytocin and misoprostol seemed to be readily available, but there are known quality concerns with oxytocin and

misoprostol in many low-resource settings (45–49). Health care workers' awareness of oxytocin quality concerns may have led them to compensate with additional oxytocin or simultaneous use of misoprostol, as observed in this study. However, it is unknown how much additional medication may be needed to compensate for poor quality, and such usages of PPH commodities may have other negative consequences. Recommended clinical maneuvers for PPH detection and treatment (uterine tone assessment and uterine massage) were observed to be widely used, likely due to the limited resources required (i.e., no commodities needed). Tranexamic acid for PPH treatment was found to be underutilized, likely due to the compounding effect of the multiple bottlenecks to implementation evidenced by this study. Some recommended interventions for treating refractory PPH were not available to health care workers, potentially contributing to underutilization and the desire to create improvised devices (50). Health system interventions like formal facility protocols for PPH management and referral and simulation training for preparedness were found to be substantially underutilized. Instituting these interventions is perhaps easier and faster to accomplish than ensuring other procurement-dependent interventions are consistently available to health care workers.

Global stakeholders and observed health care workers reported more challenges to implementation at lower-level steps in the conceptual framework (e.g., provider practice) than at higher-level steps (e.g., national policy) for all interventions. Interventions that stakeholders reported as facing substantial barriers at higher-level steps in the pathway had particularly low rates of utilization in direct observations. This suggests that higher-level challenges to implementation may create rate-limiting constraints that hinder implementation at lower levels, contributing to certain interventions being plagued by poor implementation across the pathway.

Findings from direct observations support the premise that implementation is context specific. These data show that observed facilities in Nigeria were less aligned with global evidence-based recommendations than those in Tanzania and Pakistan. Accordingly, there may be more bottlenecks to implementation in Nigeria or the bottlenecks may be more entrenched. These findings align with global literature suggesting that efforts to improve uptake of evidence-based interventions should begin with an exploration stage that encompasses local assessment of bottlenecks, barriers, and facilitators of/to implementation (implementation determinants) (21,51,52).

Strengths of this study include the use of a theory-derived approach to measuring bottlenecks to implementation, the use of data triangulation to allow for comparison of global stakeholder perceptions to facility-level practices, and the high response rate to the stakeholder survey. Further, the mixed-methods stakeholder survey illustrated the perils of relying solely on quantitative data to map barriers and bottlenecks to implementation. The open-ended stakeholder comments revealed qualitative differences between the implementation challenges facing ergometrine and heat-stable carbetocin, for example, which would have been obscured with a solely quantitative survey. In this way, the use of multiple, complementary data sources, theories, and analytical approaches strengthened the overall study and utility of the findings to the field.

However, the study also has limitations. First, it is possible that the implementation pathway is missing key steps, obfuscating understanding of potentially important barriers or bottlenecks to implementation. Second, although we used a 75% threshold aligned with the 'Agree' anchor to structure interpretation, this value is inherently interpretive. Importantly, all item-level aggregate scores are reported, allowing readers to assess how alternative thresholds would affect classification, particularly for items near the cutoff. As the study was not designed to support probabilistic inference, we did not

assess statistical significance of differences between interventions or countries; instead, credibility of findings rests on consistency of patterns across multiple data sources. Third, it is likely that these results understate the extent to which evidence-based PPH recommendations are underutilized in the field. Although direct observations were conducted in facilities not yet implementing an intervention, by nature of participating in a multi-country trial, these facilities were likely to have better than average implementation of evidence-based recommendations (given proximity to/involvement in global research networks and location and type of facility). In addition, direct observation of clinical care may have influenced provider behavior (Hawthorne effect), such that observed practices represent best-case scenarios even within these facilities. Together, these factors suggest that the true extent of implementation gaps in typical real-world settings may be greater than observed here. As the findings are intended to be illustrative rather than generalizable, this limitation does not diminish their value for identifying relative patterns of implementation bottlenecks. Finally, reflecting existing WHO PPH recommendations, this study focused primarily on interventions intended to be delivered within health facilities. These findings may have limited relevance for the many PPHs that occur in communities. More work may be needed to understand the kinds of community-level interventions that may be useful to prevent, detect, and treat PPH.

This study makes two primary contributions to the literature. The first is specific to PPH. By systematically mapping barriers to the implementation of evidence-based PPH recommendations, this study facilitates priority-setting within global maternal health. The global stakeholder survey identified four bottlenecks to implementation that were largely intervention-agnostic: availability/procurement of medicines and devices; affordability and quality of medicines and devices; presence of job aids in the facility; and availability of qualified staff. In addition, lack of supportive national policy (e.g., inclusion in national guidelines and Essential Medicines Lists) was identified as a key precipitating bottleneck – if

national policy was not supportive, it was very difficult for the intervention to be utilized. During the WHO-convened Global Summit on Postpartum Haemorrhage held in Dubai, United Arab Emirates in March 2023, stakeholders further underscored the importance of addressing these common bottlenecks across contexts. Consequently, these bottlenecks have been prioritized for global action within the Implementation strategic area of the *WHO Roadmap to Combat Postpartum Haemorrhage, 2023-2030* (41). Specifically, the first three categories of priority actions are: building clear national health policy and strengthening national and subnational leadership, improving availability and access to quality-assured and affordable PPH commodities at all levels of the health system, and ensuring availability of competent health care workers to deliver relevant good-quality facility-based services and commodities.

In addition to the topic-specific contribution, this study makes a methodological contribution to implementation science by demonstrating how theory can be used to organize and structure empiric studies of implementation. The theoretical landscape in implementation science is currently dominated by determinant frameworks and process models, with fewer explanatory theories (24,53,54). In recent years, there have been calls for developing more theory-based approaches to implementation, but little guidance on how to do so (17,55). This paper offers one approach, using theoretical *bricolage* (syncretic integration of theories from disparate academic traditions (56,57)) to develop a fit-for-purpose mid-range theory of pre-requisites to implementation that could then be used to identify barriers and bottlenecks. This mid-range theory intentionally linked different levels of the health system to illustrate one way in which the outer setting of implementation (e.g., policy and regulatory spaces) can shape the enabling environment for implementation within the inner setting (e.g., health facilities). This approach provides one example of how implementation-focused researchers might further integrate implementation science with health systems research and policy implementation to create more cohesive theorizing and research (58,59).

CONCLUSIONS

This study identified several critical implementation bottlenecks hindering further improvements in PPH-related morbidity and mortality. Notably, implementation bottlenecks occurring within the national policy space had far-reaching implications and contributed to compounding failure to implement evidence-based practices at lower-levels in the health system. In contexts where policy presents a barrier to implementation (for example, because midwives are not legally authorized to offer certain interventions), urgent actions to address outdated policies and create enabling environments for implementation are needed. Health care workers and facility leaders are important agents for change, but results will be underwhelming if efforts are limited to the implementation inner setting (e.g., health facilities) alone. Rather, systems approaches are needed.

As trusted professionals, health care workers are well-positioned to advocate with policymakers for the need for supportive policy environments that allow them to use evidence-based and life-saving interventions in their clinical practice. Securing high-level leadership from policymakers can set the stage for transformative change. Consequently, evidence on the most effective advocacy strategies for engaging these leaders is needed (60).

In addition, more research is needed on the most effective implementation strategies for affecting change at the nexus between inner and outer settings. Whole-of-system theorizing and approaches to implementation research could help to drive this dimension of the field and address the top-priority implementation-related research question generated by participants at the Global Summit on Postpartum Haemorrhage (60). Strategically embedding implementation research into future

implementation efforts could reap a double dividend of generating much-needed insights while reducing PPH-related death and disability.

LIST OF ABBREVIATIONS

CFIR	Consolidated Framework for Implementation Research
NASG	Non-pneumatic anti-shock garment
SDG	Sustainable Development Goal
PPH	Postpartum hemorrhage
UBT	Uterine balloon tamponade
WHO	World Health Organization

DECLARATIONS

Ethics approval and consent to participate

The survey was deemed exempt from Ethical Review. Survey respondents were informed prior to beginning the survey that their participation was voluntary and indicated their consent for their responses to be included in the study. The implementation trial in which the direct observation of clinical practice study was nested was approved by the University of Birmingham, the Ethics Review Committee of WHO (for the formative phase), and the relevant ethics and regulatory review committees in each country. Hospital leadership at each site provided hospital-level permission for the observations, and health care workers provided written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The survey datasets used and analyzed in the study are available from the corresponding author on reasonable request. The data that support findings from the clinical observations were provided for the purposes of this analysis by the authors of the E-MOTIVE Trial. Data requests for that dataset will be considered by the E-MOTIVE trial management group upon request to the Principal Investigator: a.coomarasamy@bham.ac.uk.

Competing interests

None declared.

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Disclaimer

This manuscript represents the views of the named authors only and not necessarily the views of HRP or WHO.

Author contributions

OTO and IDG conceptualized the study and provided oversight. OTO, IDG and MW developed the study protocol. OTO, IG, MW, and CRW developed the consolidated implementation framework. CRW, SR, and IDG developed the implementation bottlenecks survey, with input from AMG, LC, FA, MW, and OTO. KMM analyzed and interpreted the data from the direct observations of clinical practice, with input from AC and IDG. CRW managed the analysis of the survey data. AM and US provided input and country contextualization to help shape the interpretation of the data. CRW led the drafting of the manuscript, with input from all authors. IDG, AC, and OTO substantially revised the manuscript for intellectual content. All authors reviewed and provided input on the final manuscript. IG is responsible for the overall content as guarantor (accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish).

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REFERENCES

1. Cresswell JA, Alexander M, Chong MYC, Link HM, Pejchinovska M, Gazeley U, et al. Global and regional causes of maternal deaths 2009–20: a WHO systematic analysis. Lancet Glob Heal. 2025 Mar;
2. Zaat TR, van Steijn ME, de Haan-Jebbink JM, Olff M, Stramrood CAI, van Pampus MG. Posttraumatic stress disorder related to postpartum haemorrhage: A systematic review. Eur J Obstet Gynecol Reprod Biol [Internet]. 2018 Jun;225:214–20. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0301211518301702
3. Schoretsanitis G, Gastaldon C, Ochsenbein-Koelble N, Olbrich S, Barbui C, Seifritz E. Postpartum hemorrhage and postpartum depression: A systematic review and meta-analysis of observational studies. Acta Psychiatr Scand [Internet]. 2023 Jun 7; Available from: https://onlinelibrary.wiley.com/doi/10.1111/acps.13583
4. World Health Organization (WHO), World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization; 2012.
5. World Health Organization (WHO). WHO recommendations: Uterotonics for the prevention of postpartum haemorrhage. Geneva: World Health Organization; 2018.
6. World Health Organization, World Health Organization (WHO). WHO recommendation on routes of oxytocin administration for the prevention of postpartum haemorrhage after vaginal birth. Geneva: World Health Organization; 2020.
7. World Health Organization. WHO recommendation on umbilical vein injection of oxytocin for the treatment of retained placenta. Geneva; 2020.
8. World Health Organization (WHO), World Health Organization. WHO recommendation on

tranexamic acid for the treatment of postpartum haemorrhage. WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage. Geneva: World Health Organization; 2017.

9. World Health Organization (WHO). WHO recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage. Geneva: World Health Organization; 2021.

10. World Health Organization (WHO), World Health Organization. WHO recommendation on advance misoprostol distribution to pregnant women for prevention of postpartum haemorrhage. Geneva: World Health Organization; 2020.

11. World Health Organization. WHO recommendations on maternal and newborn care for a positive postnatal experience. Geneva; 2022.

12. World Health Organization. WHO recommendations on the assessment of postpartum blood loss and use of a treatment bundle for postpartum haemorrhage. Geneva: World Health Organization; 2023.

13. World Health Organization. Trends in maternal mortality 2000 to 2020: estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division. Geneva; 2023.

14. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander J a, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. Implement Sci. 2009;4(50):40–55.

15. Damschroder LJ, Reardon CM, Opra Widerquist MA, Lowery J. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. Implement Sci. 2022 Dec 22;17(1):7.

16. Lewis CC, Boyd MR, Walsh-Bailey C, Lyon AR, Beidas R, Mittman B, et al. A systematic review of empirical studies examining mechanisms of implementation in health. Implement Sci. 2020 Dec 16;15(1):21.

17. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10(53).

18. Tanahashi T. Health service coverage and its evaluation. Bull World Health Organ. 1978;56(2):295–303.

19. Baker U, Peterson S, Marchant T, Mbaruku G, Temu S, Manzi F, et al. Identifying implementation bottlenecks for maternal and newborn health interventions in rural districts of the United Republic of Tanzania. Bull World Health Organ. 2015 Jun 1;93(6):380–9.

20. World Health Organization. Local Production and Technology Transfer to Increase Access to Medical Devices: Addressing the barriers and challenges in low- and middle-income countries. Geneva: World Health Organization; 2012.

21. Eboreime EA, Nxumalo N, Ramaswamy R, Ibisomi L, Ihebuzor N, Eyles J. Effectiveness of the Diagnose-Intervene- Verify-Adjust (DIVA) model for integrated primary healthcare planning and performance improvement: an embedded mixed methods evaluation in Kaduna state, Nigeria. BMJ Open. 2019 Mar 30;9(3):e026016.

22. Whitehorn A, Fu L, Porritt K, Lizarondo L, Stephenson M, Marin T, et al. Mapping clinical barriers and evidence-based implementation strategies in low-to-middle income countries (LMICs). Worldviews Evidence-Based Nurs. 2021 Jun 10;18(3):190–200.

23. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. Third. Los Angeles, CA: Sage Publications; 2018.

24. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res. 2019 Dec 25;19(1):189.

25. Bullock HL, Lavis JN, Wilson MG, Mulvale G, Miatello A. Understanding the implementation of evidence-informed policies and practices from a policy perspective: a critical interpretive

synthesis. Implement Sci. 2021;16(1):1–24.

26. Allen P, Pilar M, Walsh-Bailey C, Hooley C, Mazzucca S, Lewis CC, et al. Quantitative measures of health policy implementation determinants and outcomes: a systematic review. Implement Sci. 2020 Dec 19;15(1):47.

27. Stone D. Learning lessons, policy transfer and the international diffusion of policy ideas. Coventry: Centre for the Study of Globalisation and Regionalisation, University of Warwick; 2001.

28. Stone D. Transfer agents and global networks in the 'transnationalization' of policy. J Eur Public Policy. 2004;11(3):545–66.

29. Stone D, Porto de Oliveira O, Pal LA. Transnational policy transfer: The circulation of ideas, power and development models. Policy Soc. 2020 Jan 2;39(1):1–18.

30. Hill M, Hupe P. Implementing Public Policy: Governance in Theory and in Practice. Thousand Oaks, C.A.: Sage Publications Inc.; 2002.

31. Weiner BJ. A theory of organizational readiness for change. Implement Sci. 2009;4(1):1–9.

32. Glanz K, Rimer BK. Theory at a Glance: A Guide for Health Promotion Practice. Bethesda, MD: US Department of Health and Human Services, National Institutues of Health, National Cancer Institute; 2005.

33. O'Connell TS, Sharkey A. Reaching Universal Health Coverage through District Health System Strengthening: Using a modified Tanahashi model sub-nationally to attain equitable and effective coverage. New York; 2013.

34. Scaccia JP, Cook BS, Lamont A, Wandersman A, Castellow J, Katz J, et al. A practical implementation science heuristic for organizational readiness: R=MC2. J Community Psychol. 2015;43(4):484–501.

35. Adamou B, Curran J, Wilson L, Dagadu NA, Jennigs V, Lundgren R, et al. Guide for Monitoring Scale-up of Health Practices and Interventions. Chapel Hill, N.C.: USAID; MEASURE Evalution;

2014.

36. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011 Dec 23;6(1):42.

37. MSI, ExpandNet, WHO. 20 Questions for Developing a Scaling up Case Study. 2007.

38. World Health Organization. Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies. Geneva: World Health Organization; 2010.

39. Lokot M. Whose Voices? Whose Knowledge? A Feminist Analysis of the Value of Key Informant Interviews. Int J Qual Methods. 2021;20:1–8.

40. King G, Keohane RO, Verba S. Designing Social Inquiry: Scientific Inference in Qualitative Research, New Edition. Princeton: Princeton University Press; 2021.

41. World Health Organization. A roadmap to combat postpartum haemorrhage between 2023 and 2030. Geneva: World Health Organization; 2023 Oct 11. Available from: https://iris.who.int/handle/10665/373221

42. Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized trial of early detection and treatment of postpartum hemorrhage. N Engl J Med. 2023 Jul 9;389(1):11–21.

43. Mammoliti KM, Althabe F, Easter C, Devall A, Martin J, Funmi AL, Yusuf R, Abubakar F, Arigbede LC, Mugambi J, Oyoo P. When Is Postpartum Haemorrhage Treatment Initiated? A Nested Observational Study Within the E-MOTIVE Trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2025 Oct;132(11):1664-72.

44. Devall AJ, Nausheen S, Muhammad S, Soofi S, Karmaliani R, Lakhani A, Sajid K, Ahmed I, Raza A, Ashraf A, Shahid N. Early detection and bundled treatment of postpartum haemorrhage with the E-MOTIVE intervention: a prospective pre–post intervention study in Pakistan. The Lancet Obstetrics, Gynaecology, & Women's Health. 2025 Oct 1;1(2):e114-21.

45. Torloni M, Gomes Freitas C, Kartoglu U, Metin Gülmezoglu A, Widmer M. Quality of oxytocin available in low- and middle-income countries: A systematic review of the literature. BJOG An Int J Obstet Gynaecol. 2016 Dec 22;123(13):2076–86.

46. Lambert P, McIntosh MP, Widmer M, Evans L, Rauscher M, Kuwana R, et al. Oxytocin quality: Evidence to support updated global recommendations on oxytocin for postpartum hemorrhage. J Pharm Policy Pract. 2020 Dec 15;13(1):14.

47. Hall PE. Quality of medicines: Quality of misoprostol products. WHO Drug Inf. 2016;30(1):35–9.

48. Anyakora C, Oni Y, Ezedinachi U, Adekoya A, Ali I, Nwachukwu C, et al. Quality medicines in maternal health: Results of oxytocin, misoprostol, magnesium sulfate and calcium gluconate quality audits. BMC Pregnancy Childbirth. 2018 Dec 30;18(1):44.

49. Bower J, Chinery L, Fleurent A, Gülmezoglu AM, Im-Amornphong W, Kilfedder C, et al. Quality testing of mifepristone and misoprostol in 11 countries. Int J Gynecol Obstet. 2024 May 29;165(2):405–15.

50. Finlayson K, Vogel JP, Althabe F, Widmer M, Oladapo OT. Healthcare providers experiences of using uterine balloon tamponade (UBT) devices for the treatment of post-partum haemorrhage: A meta-synthesis of qualitative studies. Garzon S, editor. PLoS One. 2021 Mar 18;16(3):e0248656.

51. Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. Adm Policy Ment Heal Ment Heal Serv Res. 2011;38(1):4–23.

52. Northridge ME, Metcalf SS. Enhancing implementation science by applying best principles of systems science. Heal Res policy Syst. 2016 Oct;14(1):74.

53. Escoffery C, Sekar S, Allen CG, Madrigal L, Haardoerfer R, Mertens A. A scoping review of outer context constructs in dissemination and implementation science theories, models, and frameworks. Transl Behav Med. 2023 May 13;13(5):327–37.

54. Esmail R, Hanson HM, Holroyd-Leduc J, Brown S, Strifler L, Straus SE, et al. A scoping review of full-spectrum knowledge translation theories, models, and frameworks. Implement Sci. 2020 Feb 14;15(1):11.

55. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. Implement Sci. 2019 Dec 11;14(103).

56. Gilson L, editor. Health Policy and Systems Research: A Methodology Reader. Geneva: World Health Organization; 2017.

57. Jones CM, Gautier L, Ridde V. A scoping review of theories and conceptual frameworks used to analyse health financing policy processes in sub-Saharan Africa. Health Policy Plan. 2021;36(7):1197–214.

58. Sheikh K, Gilson L, Agyepong IA, Hanson K, Ssengooba F, Bennett S. Building the field of Health Policy and Systems Research: Framing the questions. PLoS Med. 2011 Aug 16;8(8):e1001073.

59. Nilsen P, Ståhl C, Roback K, Cairney P. Never the twain shall meet? - a comparison of implementation science and policy implementation research. Implement Sci. 2013;8(63):1–12.

60. Williams CR, Adnet G, Gallos ID, Coomarasamy A, Gülmezoglu AM, Islam MA, et al. Research agenda for ending preventable maternal deaths from postpartum haemorrhage: a WHO research prioritisation exercise. BMJ Glob Heal. 2024 Nov;9(11):e015342.

Figure 1: Conceptual model of barriers and bottlenecks to national implementation of WHO-recommended interventions to prevent, detect, and treat postpartum hemorrhage

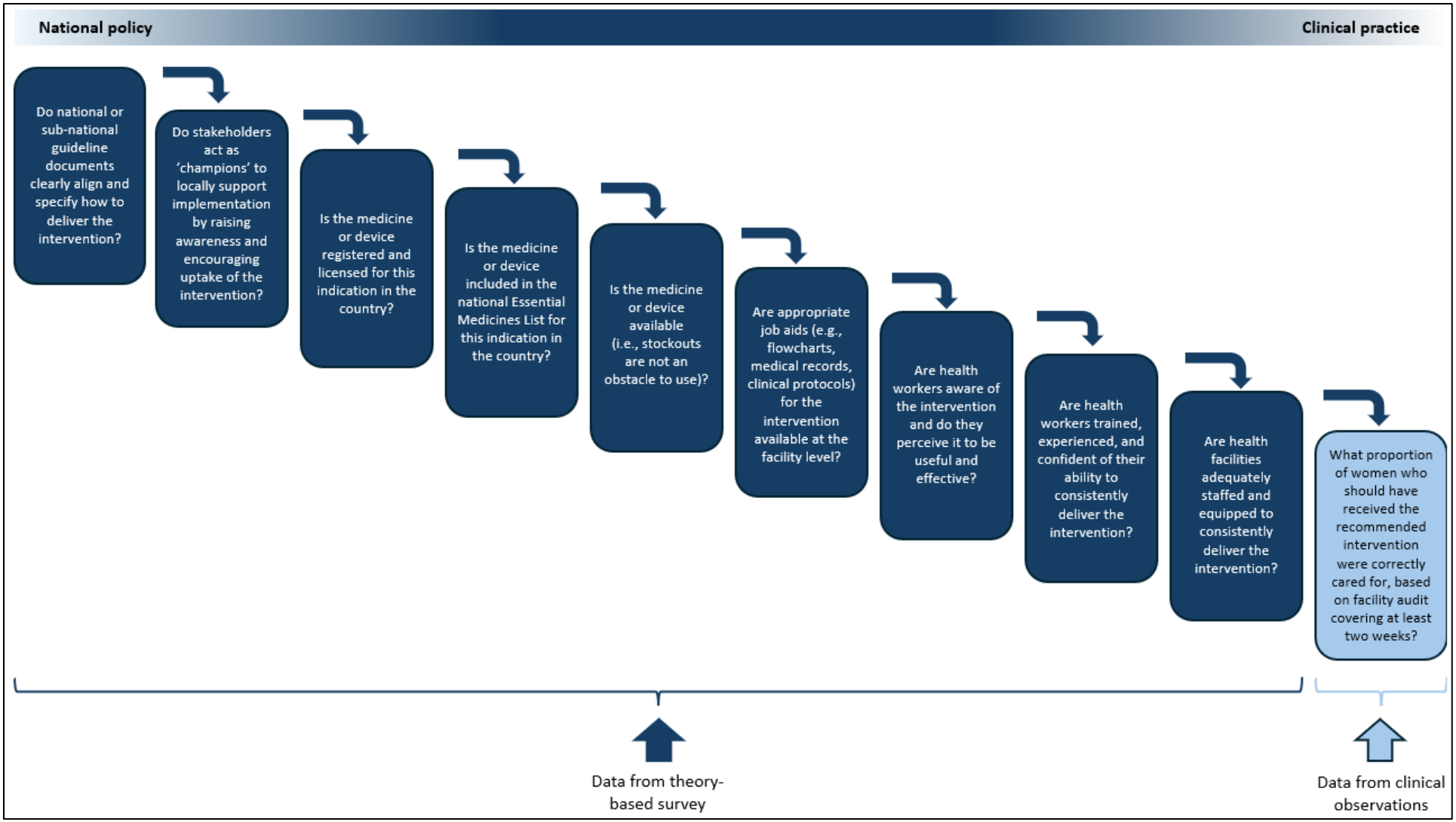

Figure 2: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the prevention and detection of postpartum hemorrhage

Recommended interventions for PPH prevention	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH prevention	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH prevention (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Heat-stable carbetocin injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	45%	50%	53%	47%	29%	37%	45%	48%	37%	37%
Oral misoprostol for PPH prevention (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Oxytocin in combination with controlled cord traction for retained placenta	71%	67%	78%	78%	63%	60%	69%	60%	62%	54%
Controlled cord traction is the recommended method for removal of the placenta in caesarean section	70%	70%				66%	70%		68%	67%
Recommended interventions for PPH detection										
Abdominal uterine tonus assessment for early identification of uterine atony for all women postpartum	71%	71%				67%	73%		69%	63%

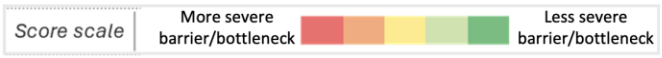

Figure 3: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the first-response treatment of postpartum hemorrhage

Recommended interventions for PPH treatment (first-response)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Oxytocin injection for PPH treatment	82%	76%	89%	91%	57%	64%	83%	52%	71%	52%
Ergometrine injection for PPH treatment (if oxytocin is unavailable)	72%	57%	78%	74%	50%	53%	65%	56%	58%	48%
Fixed-dose oxytocin and ergometrine combination injection for PPH treatment (if oxytocin is unavailable)	51%	44%	52%	48%	33%	40%	46%	37%	45%	36%
Oral misoprostol for PPH treatment (if oxytocin is unavailable or did not stop the bleeding)	74%	68%	68%	71%	55%	61%	68%	63%	64%	55%
Isotonic crystalloids for fluid resuscitation of women with PPH	76%	75%	80%	79%	66%	69%	76%	75%	74%	63%
Tranexamic acid (TXA) injection plus standard care for PPH treatment	66%	65%	66%	63%	48%	51%	57%	59%	48%	50%
Uterine massage for conservative treatment of PPH	81%	81%				77%	82%		79%	73%

Figure 4: Global stakeholder perspectives on barriers and bottlenecks to national implementation of WHO recommendations for the treatment of refractory postpartum hemorrhage and health system interventions

Recommended interventions for PPH treatment (refractory)	National guidelines align and specify how to deliver the intervention	Stakeholders act as 'champions' to locally support implementation in countries by raising awareness and encouraging uptake	Medicine/Device is registered and licensed for this indication	Medicine / Device included in national Essential Medicines Lists or national equivalents for this indication	Medicine/Device is available and stock-outs are not an obstacle to use	Appropriate job aids (e.g. clinical protocols) are available at facility level	Healthcare workers are aware of the intervention and perceive it as useful and effective	Available products in the markets are perceived as affordable and of good quality	Health workers are trained, experienced, and confident to consistently deliver the intervention	Healthcare facilities are adequately staffed and equipped to consistently deliver the intervention
Uterine balloon tamponade (UBT) for refractory PPH treatment	54%	59%	52%	46%	39%	45%	55%	43%	39%	37%
Non-pneumatic anti-shock garment (NASG) as temporizing measure for definitive PPH care	50%	54%	47%	44%	33%	37%	43%	43%	34%	35%
Uterine artery embolization for refractory PPH treatment	43%	43%				34%	41%		26%	25%
Bimanual uterine compression as temporizing measure before definitive PPH care	74%	69%				61%	71%		56%	54%
External aortic compression as temporizing measure for definitive PPH care	56%	48%				43%	46%		38%	45%
Surgical interventions (laparotomy with vessel ligation or compressive sutures or hysterectomy) for refractory PPH treatment	72%	69%				61%	76%		51%	46%
Health system interventions										
Formal protocols at health facilities for prevention and treatment of PPH	72%	70%				64%	72%		59%	51%
Formal protocols for referral of women to a higher level of care for treatment of PPH	64%	64%				52%	69%		56%	45%
Simulations of PPH treatment for pre-service and in-service training programs	53%	62%				48%	61%		45%	39%

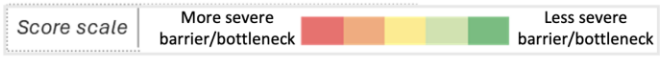

Table 1: Administration of recommended interventions for PPH prevention, detection, and treatment during direct observations in Nigeria, Pakistan, and Tanzania

	Nigeria		Pakistan		Tanzania	
Recommended interventions for PPH prevention	**%**	**n** (N=1352 observations in 19 facilities)	**%**	**n** (N=38 observations in 2 facilities)	**%**	**n** (N=649 observations in 6 facilities)
Oxytocin injection for PPH prevention	99.7%	1348	100.0%	38	100.0%	649
Oxytocin infusion also administered	*3.4%*	*46*	*0.0%*	*0*	*5.5%*	*36*
Ergometrine injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.4%	6	0.0%	0	0.0%	0
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0
Heat-stable carbetocin injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.7%	9	0.0%	0	0.0%	0
Misoprostol for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	61.5%	832	78.9%	30	2.0%	13
Oral or sublingual	*13.8%*	*186*	*2.6*	*1*	*0.2%*	*1*
Per Rectal	*51.8%*	*700*	*78.9%*	*30*	*1.8%*	*12*
Both Oral or Sublingual and Per Rectal	*4.0%*	*54*	*2.6%*	*1*	*0.0%*	*0*
Recommended interventions for PPH detection	**%**	**n** (N=1352 observations in 19 facilities)	**%**	**n** (N=38 observations in 2 facilities)	**%**	**n** (N=649 observations in 6 facilities)
Abdominal uterine tonus assessment for early identification of uterine atony for all women postpartum during direct observations*	64.4%	898	100.0% %	38	73.0%	474
* Numerator: number of times uterine tone checked for 1st direct observation; Denominator: number of discrete HCP observations (women)						
Recommended interventions for PPH treatment (first-response)	**%**	**n** (N=77 PPHs diagnosed)	**%**	**n** (N=7 PPHs diagnosed)	**%**	**n** (N=72 PPHs diagnosed)
Oxytocin injection for PPH treatment	70.1%	54	100.0%	7	98.6%	71
Ergometrine injection for PPH treatment (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0
Fixed-dose oxytocin and ergometrine combination injection for PPH prevention (if oxytocin is unavailable or quality cannot be guaranteed)	0.0%	0	0.0%	0	0.0%	0

Misoprostol for PPH treatment (if oxytocin is unavailable, quality cannot be guaranteed or did not stop the bleeding)	41.6%	32	28.6%	2	36.1%	26
Oral or sublingual	*15.6%*	*12*	*0.0%*	*0*	*1.4%*	*1*
Per Rectal	*29.9%*	*23*	*28.6%*	*2*	*34.7%*	*25*
Both Oral or Sublingual and Per Rectal	*3.9%*	*3*	*0.0%*	*0*	*0.0%*	*0*
Tranexamic acid (TXA) injection for PPH treatment	27.3%‡	21‡	100.0%‡	7‡	48.6%‡	35‡
Isotonic crystalloids for fluid resuscitation of women with PPH	62.3%	48	100.0%	7	79.2%	57
Oxytocin in combination with controlled cord traction for retained placenta	-	1	-	None occurred	-	3
Uterine massage for conservative treatment of PPH	92.2%	71/77	100.0%	7/7	91.7%	66
‡ Variations occur in standard care						
Recommended interventions for PPH treatment (refractory)	**%**	**n**	**%**	**n**	**%**	**n**
Uterine balloon tamponade (UBT) for refractory PPH treatment	-	None occurred	-	None occurred	-	2
Non-pneumatic anti-shock garment (NASG) as temporizing measure for definitive PPH care	-	1	-	None occurred	-	None occurred
Uterine artery embolization for refractory PPH treatment	-	None occurred	-	None occurred	-	None occurred
Bimanual uterine compression as temporizing measure	-	4	-	None occurred	-	26
External aortic compression as temporizing measure for definitive PPH care	-	None occurred	-	None occurred	-	None occurred
Surgical interventions (laparotomy with vessel ligation or compressive sutures or hysterectomy) for refractory PPH treatment	-	1	-	None occurred	-	None occurred
Health system interventions	**%**	**n** (N=19 facilities)	**%**	**n** (N=2 facilities)	**%**	**n** (N=6 facilities)
Formal protocols at health facilities for prevention and treatment of PPH	Yes: 42.1% No: 47.4% Unknown: 10.5%	8 9 2	Yes:100.0% No: 0.0 % Unknown: 0.0%	2 0 0	Yes: 83.3 % No: 16.7 % Unknown: 0.0%	5 1 0
Formal protocols for referral of women to a higher level of care for treatment of PPH	Yes: 0.0% No: 100.0%	0 19	Yes: 50.0% No: 50.0%	1 1	Yes: 0.0% No: 100.0%	0 6
Simulations of PPH treatment for pre-service and in-service training programs	Yes: 5.3% No: 94.7%	1 18	Yes: 100.0% No: 0.0%	2 0	Yes: 83.3% No: 16.7%	5 6

Response to reviewer comments

Supplemental file S2