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# SPECIAL COLLECTION

ORIGINAL ARTICLE PPH IN HUMANITARIAN SETTINGS

# Postpartum Hemorrhage in Humanitarian Settings: Implementation Insights from Using Heat-Stable Carbetocin and Tranexamic Acid

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#### **ABSTRACT**

Background and Objective: Maternal mortality, largely due to postpartum hemorrhage (PPH), remains high in resource-limited and crisis-affected settings, where heat-stable carbetocin (HSC) and tranexamic acid (TXA) offer promise for PPH prevention and treatment but lack evidence. This study, implemented in basic maternity facilities within humanitarian settings, explores healthcare providers' perspectives on an HSC and TXA-inclusive PPH intervention package and related operational challenges and facilitators.

Methods: Based on semi-structured interview guides and using thematic analysis, this qualitative research, through 13 focus group discussions and individual interviews, investigated the perspectives of 64 healthcare staff (mostly midwives) from eight basic emergency obstetric care facilities in South Sudanese and Ugandan settings hosting large numbers of forcibly displaced populations. The PPH intervention package comprised refresher training, an online provider community, PPH readiness kits, alarm bells, and displayed algorithms.

Results: Findings from both countries converged, highlighting providers' positive views on HSC and TXA. HSC effectiveness in preventing bleeding was acknowledged, bolstering staff's confidence in its use. TXA was perceived as effective although providers reported having less experience with it due to the limited number of PPH cases. Enabling factors included the ease of administration, practical training, endorsement by national and local authorities, and the absence of a cold chain requirement. Appreciation was given to the WhatsApp community of practice as it facilitated knowledge exchange, quality improvement projects that enhanced PPH diagnosis, and innovative tools like wall clocks to record the timing of clinical actions and bells to call for assistance. Challenges included confusion between new and existing medications and record systems that inadequately capture HSC, TXA, and other PPH indicators.

Conclusion and Global Health Implications: HSC and TXA integrated into a PPH intervention package were overall positively valued by providers in humanitarian settings. Continued education and support are crucial. Addressing challenges like medication confusion underscores the need for ongoing education and clear guidelines for the use of HSC, TXA, oxytocin, and other drugs for PPH prevention and treatment. Our findings stress the importance of a comprehensive strategy to overcome health system barriers in PPH management, potentially improving maternal health outcomes in resource-limited and fragile contexts, with broader global implications.

Keywords: Health Services Research, Postpartum Hemorrhage, Heat-Stable Carbetocin, Tranexamic Acid, Qualitative Research, Public Health Intervention Package, Humanitarian Settings, Fragile Settings

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#### INTRODUCTION

# Background of the Study

Characterized by excessive blood loss exceeding 500 mL after vaginal birth or 1000 mL after cesarean within 24 hours, PPH stands as a principal contributor to global maternal mortality rates (MMR), notably in low and middle-income countries grappling with fragility and humanitarian crises. [1,2] The active management of the third stage of labor (AMTSL) prevents PPH deaths.<sup>[3]</sup> It involves using prophylactic uterotonic agents, delayed cord clamping, and controlled cord traction (if skilled attendants are present). Oxytocin (10 IU, IM/IV) is the preferred uterotonic in settings with multiple options but requires cold-chain storage. Humanitarian settings face unique healthcare challenges, including the maintenance of cold chains, unreliable power supplies, and a scarcity of human resources, critically impeding PPH management. These gaps require bridging through innovative strategies. Notably, two temperature-stable medications hold promise for resourcelimited scenarios: heat-stable carbetocin (HSC), a long-acting oxytocin analog for PPH prevention, and tranexamic acid (TXA), an antifibrinolytic agent effective in managing PPH irrespective of the underlying cause. [4-9] Evidence is however essential for guiding the implementation of PPH interventions in humanitarian settings, as emphasized by recent scoping literature reviews.[10, 11] These reviews underscored the need for implementation research on PPH interventions, including HSC and TXA, in low-resource settings lacking cold chain infrastructure. Such research aligns with the World Health Organization's (WHO) Roadmap to combat PPH (2023 and 2030),[12] contributing to the global reduction of maternal mortality by 2030 (Sustainable Development Goal Target 3.1: MMR < 70 per 100,000 live births).[13]

In light of the evidence gaps detailing programmatic approaches to introduce HSC and TXA and enhance providers' capacity to do so in humanitarian settings, particularly in non-hospital environments, an implementation research study conducted within South Sudanese and Ugandan humanitarian settings investigated a capacity-enhancement PPH intervention package. The study was conducted in basic emergency obstetric and newborn care (BEmONC) services and aimed to assess the effect of the intervention package on the trends in uterotonic use, including HSC, for PPH prevention, the trends in PPH visual diagnosis, and the trends in both uterotonics and TXA for PPH treatment. The PPH package comprised three intervention components aimed at strengthening providers' competencies. First, a refresher training utilized a low-dose, high-frequency approach, incorporating introductory webinars, self-study, in-person workshop, and facility-based monthly mentorship and supportive supervision. Second, a community of practice established on the WhatsApp platform facilitated provider interaction and collaboration. Finally, PPH algorithm posters placed in delivery rooms assisted in adherence to established protocols. In South Sudan, additional interventions included the provision of wall clocks for appropriate medication timing and bells to call for emergency assistance. In Uganda, support in the implementation of PPH Quality Improvement (QI) projects was also part of the package. The study findings from both countries demonstrated the efficacy of the intervention packages in increasing HSC and TXA utilization, however, accompanied by a reduction in oxytocin use for PPH treatment upon HSC introduction.

# Objectives of the Study

Against this background and as part of the secondary outcomes of the overall research, this study aimed to gain qualitative insights into healthcare staff's perspectives and clinical experiences related to HSC and TXA use, as well as operational barriers and enablers linked to the implementation research in both countries. The decision to include both countries in a single study is based on their shared focus on humanitarian settings and the implementation of a similar intervention package.

# **Country Context**

In South Sudan, the maternal health situation is dire, marked by the highest recorded maternal mortality ratio globally (1223 deaths per 100,000 live births in 2020).<sup>[2]</sup> The challenges for maternal health include, among others, limited facility births (28%), high unmet family planning needs (30%), and low female literacy (29%).[14, 15] The nation, hosting internally displaced persons (IDPs) and refugees (9.1 million people in need of aid), faces numerous governance, conflict, and resource challenges affecting healthcare and service use. [16, <sup>17]</sup> Uganda, on the other hand, has made strides in maternal mortality reduction, decreasing from 461 deaths per 100,000 live births in 2010 to 284 in 2020.[2] However, studies reveal gaps in PPH incidence (9%) and proper obstetric care practices (only 34% receiving all the components of active management of the third stage of labor).[18, 19] Uganda also shelters refugees, including many from South Sudan and the Democratic Republic of Congo, particularly in the West Nile and Western regions.

#### **METHODS**

# Participants and Study Sites

Our qualitative study was designed around focus-group discussions (with midwives) and individual interviews (with in-charge staff) and consisted of 13 qualitative interviews, five in South Sudan and eight in Uganda. Sessions involved one to 11 participants each, totaling 57 in Uganda and only seven in South Sudan as participant availability was constrained by severe staffing limitations. Women constituted around 90% of all the participants combined and information about their age was not collected. Participants were directly or indirectly involved in labor and delivery and included maternity in-charge officers and midwives (the majority) as well as supply chain staff. Participants came from health facilities that were conveniently chosen to participate in the entire study. To be eligible, facilities had to have the following three characteristics: (a) they were defined as BEMONC only facilities, (b) had experienced disruption in cold storage over the past three months, and (c) were willing to participate. Facilities were excluded if they offered c-section and blood transfusion services, which are part of comprehensive emergency obstetric and newborn care (CEmONC) services. Each country featured discussions in at least three health facilities out of the six in the study. Sampling intentionally covered facilities with minimal and pronounced implementation challenges, facilitating comprehensive insights into operational barriers and facilitators. In South Sudan, participating facilities were in Bentiu, Malakal, and Wau; Uganda included Bidibidi Health Center (HC) III, Barakala HCIII, Uriama HCIII, Yinga HCIII, and Ucea HCIII.

#### Data Collection

The lead author developed the semi-structured interview guides in English, which were then locally validated and adapted by national researchers (KM, AWO) to ensure cultural and contextual relevance. Interviews were conducted in each country by a local team of researchers (in South Sudan: AWO and JS, male and female, respectively; in Uganda: KM and SM, female). They were trained to articulate technical terms clearly and appropriately and were proficient in English and, when needed, in the respective local languages (providers were fluent in English in both countries, with a few in South Sudan using a mix of English and Arabic to express their views). Privacy was ensured during interviews, which were audio-recorded after obtaining participants' consent. Nonconsenting individuals were excluded from the study. There was no one else present during the data collection process besides participants and researchers. Prior to the qualitative interviews, the interviewees were acquainted with the interviewers because contact had been established during the planning, implementation, and monitoring of the quantitative phase of the overall research study.

Queries centered on providers' clinical experiences with HSC and TXA, encompassing operational enablers and barriers, confidence levels, ease of use and challenges in administration, integration into routine practice, and suggestions for enhancing availability and utilization.

When viable, in-depth interviews prioritized in-charge personnel due to their hierarchical position. In Ugandan facilities, if participant numbers allowed, the research team divided cohorts into sub-groups of at least 3 individuals, encouraging thorough exploration and detailed feedback. Each subgroup was designated a note-taker and presenter. Following individual subgroup discussions lasting about 30-45 minutes, a plenary session gathered both subgroups for presentation and exchange. The team posed queries, sought clarifications, and prompted participants for specific illustrations to enrich insights. After presenting to the entire team, additional follow-up queries were posed by researchers to ensure data saturation and adequate understanding.

# Data Management and Analysis

When necessary, research aides translated the audio recordings into English and transcribed them using Microsoft Word. To ensure precision, word documents were cross-referenced against the audio files, but transcripts were not returned to participants for comment or correction. A thematic analysis was conducted, involving the manual identification of recurring themes by each country research team. Subsequently, the global research team (NTT, CSH) compiled and examined reports from both countries to identify shared insights. These shared findings underwent further validation through iterative discussions with the country teams, including during a national research workshop attended by select providers. The reporting follows the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist. Results are presented in four sections. First, HSC themes include "perceived HSC effectiveness bolsters confidence" (confidence defined as self-assuredness in using HSC), "ease of use and practicality" (referring to HSC's suitability for use in low-resource context), and "ingredients for successful integration" (components facilitating the incorporation of the new medications into routine service provision). Second, TXA themes include "perceived ease and effectiveness of TXA in PPH treatment" (referring to providers' experience of TXA's ease of use and success in controlling PPH) and "constraints in using TXA" (defined as limitations preventing its use). Third, under "crosscutting challenges" for both HSC and TXA implementation are "inadequate record system" (inappropriate capture of PPH prevention and treatment) and "confusion between HSC, oxytocin, and TXA" (difficulty in understanding the differences between the medications and applying them according to recommendations). Finally, as part of "other interventions" are "usefulness and practicality of wall clocks and bells" (perceived suitability of these items

in low-resource contexts) and "community of practice and quality of care" (WhatsApp group facilitating collaborative learning and knowledge sharing on quality of care experiences and tips).

#### **Ethical Approval**

Involvement in key informant interviews and focus group discussions was entirely voluntary, with no financial incentives, limited only to reimbursement of related expenditures. Participants' identifiable characteristics were removed during the transcription process, and their contributions were treated confidentially and anonymously.

## **RESULTS**

#### **HSC**

## Perceived HSC effectiveness bolsters confidence

The HSC effectiveness in reducing cases of bleeding after birth was noted by many providers. Its rapid and reliable action was praised in both countries and providers expressed good understanding and confidence in administering HSC for PPH prevention. Their positive experiences combined with the lack of observed adverse reactions galvanized their confidence in HSC's reliability as a uterotonic and in using it.

"I find HSC to be very effective because since I have personally been using it, as a drug or medication for PPH prevention, no case of PPH has occurred. Second to it, based on my experience also and based on what I have observed, HSC is very effective in placenta detachment and expulsion. Because when I administer HSC at the moment, I went and clamp and cut the cord, I found the placenta is already out." - Participant, South Sudan

# Ease of use and practicality

The HSC implementation was feasible reportedly due to the practical and relevant training provided to providers. Pocketbook and wallchart guidelines were supplied, ensuring adherence to PPH clinical sequences. The simple administration process and adherence to protocols further contributed to its feasibility. The absence of new and complex stocking and documentation procedures also supported its feasibility. Overall, HSC was preferred over oxytocin due to its ease of use and lack of a cold chain requirement. Providers, especially those working shifts alone, appreciated the convenience of not having to store it in refrigeration or change ice packs regularly.

"There is no fear by midwives because carbetocin doesn't need a fridge so that you might need to continue monitoring the temperature changes compared to oxytocin that when the temperature changes it becomes less effective... when it finds you on duty alone, we normally put it in the tray now, [while] oxytocin is kept in a vaccine carrier. In a situation like that,... it will need someone to open for you the vaccine carrier and remove it. But for carbetocin, you can put it on the table and just pick it very first and administer it. That's why I say, it's somehow easier to access and administer than the oxytocin. It doesn't require temperature monitoring, you just pick and administer" - Participant, Uganda

## Ingredients for successful integration

Participants reported that the successful integration of both HSC and TXA was facilitated among others by the endorsement of local authorities and collaboration with partner organizations. Specific to Uganda, the National Drug Authority conducted a cold chain assessment documenting its unreliability, upon which providers felt stimulated to opt for HSC use. Participants also underscored the essential role of teamwork in implementing the low-dose high-frequency approach to benefit other colleagues.

"The Ministry of health, district officials and other authorities in the area accepted the HSC study to be introduced in the facility. This smoothened the operational rollout of HSC...We had anticipated that the training would only focus on HSC and TXA but they went deep into midwifery (was broad and went into PPH in detail) and it was practical/hands-on, this was motivating to us as trainees... We came back and trained....and even mentored facility staff plus those who missed the previous training." – Participant, Uganda

Further detailed below, the community of practice established through WhatsApp and the QI projects were also perceived as key ingredients contributing to HSC and TXA integration into routine service provision.

## TXA

# Perceived ease and effectiveness of TXA in PPH treatment

Participants from both Uganda and South Sudan acknowledged TXA's ease of use, as reflected in the aspects reported for HSC and described above (i.e., job-aid and skills drills-backed training, no cold chain requirement, simple administration). They concurred on the effectiveness of TXA for PPH treatment and reported positive experiences with its use, including the lack of adverse events.

"Yes, we said this TXA can stop bleeding from whatever the cause, if someone is severely injured and bleeding, then we can give. When I gave the tranexamic acid, I gave the IV fluid plus oxytocin inside. The reason was that the uterus was relaxed because there were some clots, so first I gave the drug to stop the bleeding then I gave oxytocin to contract the uterus." -Participant, South Sudan

# Constraints in using TXA

Owing to the relatively low PPH incidence, participants indicated fewer opportunities for practical experience of using TXA compared to HSC, potentially contributing to their uncertainty during interviews concerning TXA's mechanisms of action and appropriate dosages. However, participants demonstrated a solid comprehension of TXA's potential effectiveness in managing bleeding from various etiologies. Participants recognized the necessity for ongoing training and skills drill sessions to uphold competence in the administration of TXA.

# **Crosscutting Challenges**

#### Inadequate record system

Providers from both countries highlighted some systemrelated challenges, such as the need to update the Health Management Information System (HMIS) tools to include HSC and TXA data. For instance, participants in Uganda identified this gap as an opportunity to better document in the maternity registers the key interventions done for PPH treatment:

"Heat stable carbetocin is also missing in the maternity register...TXA is yet to be introduced. That's partially one of the reasons the management of PPH is still lacking." - Participant, Uganda

#### Confusion between HSC, oxytocin, and TXA

While most participants from both countries had a clear understanding of HSC, oxytocin, and TXA purpose and administration, others had doubts and confusion about their specific functions and applications. This was reflected in both countries in a significant and unexpected drop in oxytocin use for PPH treatment when HSC was introduced for PPH prevention. Through our reflective meetings and supportive supervision, we gained insights into the confusion encountered by practitioners. Notably, acknowledging the derivative origin of HSC from oxytocin, some reported their assumption that the use of oxytocin for treatment became unnecessary if HSC had already been used for prevention. As for the recommended systematic TXA administration in all PPH cases, a few reported that it was deemed unnecessary if PPH was controlled through other measures.

## Other Interventions

## Usefulness and practicality of wall clocks and bells

Health workers highlighted the importance of accurate time recording during deliveries, especially for administering TXA within three hours after PPH onset. They also reported the bells to be more practical than a wristwatch or a phone for assistance during emergencies, improving communication and timely response - "no shouting out anymore."

"So, getting a wall clock is even better than having a phone or having a watch in your hand...because also you do not need to take contamination to your newborns." - Participant, Sudan

## Community of Practice and Quality of Care

In both countries, providers valued the WhatsApp community of practice as a platform for sharing ideas, tips, and training materials related to the implementation of the PPH package intervention. For instance, in Uganda, facilities initiated QI projects, primarily focusing on blood loss measurement, leveraging pre-existing QI policies where already available. Initial challenges arose due to delays in acquiring calibrated measuring jars, with some facilities using their funds for procurement. Busier facilities faced reluctance due to post-delivery cleaning of the jars, which was addressed with additional jar procurement. The QI projects resulted in improved blood loss documentation accuracy and the inclusion of PPH cases in monthly maternity register summaries, a practice persisting beyond the study period. With gradual improvement, facilities gained confidence and continued sharing in the community of practice.

#### DISCUSSION

Qualitative research looking at the implementation of HSC and TXA in BEmONC facilities in Ugandan and South-Sudanese humanitarian settings converged to show healthcare staff's favorable opinions about both medications in terms of ease of use (no cold chain required) and perceived effectiveness with minimal side effects. Successful integration was attributed to local authority endorsement, interorganizational collaboration, and effective capacity building. Challenges included confusion between HSC, oxytocin, and TXA and the inadequacy of maternity registers to capture the use of the medications. The WhatsApp community was valued as a platform for facilitating knowledge and practices. In South Sudan, the usefulness and practicality of the wall clocks and bells were acknowledged, and in Uganda, quality improvement projects initiated and led by providers improved blood loss documentation and PPH diagnosis.

Overall, the quantitative and qualitative research studies aligned to show that HSC and TXA seemed to be acceptable to providers and feasible as part of a PPH management package in humanitarian BEmONC settings in both Uganda and South Sudan. The implementation was deemed feasible largely due to the practical skills-based training approach, which adopted a low-dose high-frequency strategy as highlighted in this journal supplement. Such a strategy appeared appropriate for resource-constrained settings as it allowed providers to learn and rehearse life-saving skills at their own pace while minimizing time away from clinical duties. The need for continued knowledge and skills drills is particularly relevant to TXA due to its infrequent usage.

The confusion, doubts, and uncertainties expressed by some participants highlight the importance of close monitoring and supportive supervision shortly following the introduction of HSC and TXA—impact on other established practices, such as oxytocin and other medications should also be monitored. This is essential to ensure the successful integration of these life-saving medications into maternal healthcare practices.

Our findings align with those from various Sub-Saharan African countries (see journal supplement), underscoring similar challenges and opportunities in implementing HSC and TXA across diverse low-resource settings. Recent studies by Smiles for Mothers in Kenya and Nigeria, which focused solely on HSC, reported a high level of acceptance among healthcare providers. This was attributed to HSC's perceived effectiveness and ease of use compared to oxytocin or misoprostol. Additionally, in Burkina Faso, Ethiopia, Ghana, Sierra Leone, and Uganda, providers generally embraced the use of both HSC and TXA, as indicated by their high utilization rates and reported in this journal supplement. Healthcare providers also emphasized the importance of refresher training with supportive supervision as part of a comprehensive training approach for preventing and managing PPH using HSC and TXA.

# Strengths and Limitations of the Study

Our qualitative inquiry occurred during the rollout of HSC and TXA as well as after the study ended, allowing the research team to swiftly address providers' misconceptions and inappropriate practices while reinforcing good knowledge and services.

The study has several limitations. First, due to financial and time limitations, it focused solely on providers' perspectives and did not engage with women to gauge their level of acceptability and satisfaction with the PPH management strategy as end users. However, we selected providers from facilities that reported the most and least implementation challenges to gain insights into a spectrum of implementation barriers and enablers. Second, qualitative analysis was done manually in both countries, potentially leading to missing important data and themes. However, both countries used the same interview guide to explore common aspects (including feasibility, barriers, enablers, and quality of care). Additionally, regular discussions across country teams with the global team allowed repeated comparison of results to ensure information saturation. The qualitative results were eventually validated

with the broader community of providers and policy-makers during national review workshops.

# CONCLUSION AND GLOBAL HEALTH **IMPLICATIONS**

The implementation of a PPH intervention package in humanitarian settings, featuring HSC and TXA, was overall well-received by healthcare providers in South Sudan and Uganda in terms of ease of use, suitability for the context, and challenges that can be mitigated to ensure success and sustainability. They utilized WhatsApp-based communities of practice to exchange clinical insights, enhancing obstetric service quality. The recognized effectiveness, safety, and userfriendliness of HSC and TXA underscore their potential as cornerstone interventions in PPH management. However, the confusions, doubts, and uncertainties expressed by participants highlight the importance of ongoing education and clear guidelines for the use of HSC, TXA, oxytocin, and other drugs in PPH prevention and treatment. Therefore, further researching and addressing challenges in training, monitoring, and documentation is crucial for scalability. Robust data systems integrating HSC and TXA play a pivotal role in evaluating interventions and shaping evidence-based policies and should be established. Our findings emphasize the necessity of a comprehensive strategy to address health system barriers in PPH management. Such an approach would foster the widespread adoption of the PPH intervention package and could improve PPH prevention and treatment in humanitarian and fragile settings characterized by high maternal mortality rates.

## Key Messages

- Integrating heat-stable carbetocin (HSC) and tranexamic acid (TXA) in humanitarian obstetric care facilities is backed by providers' confidence in their efficacy and userfriendliness.
- Clear guidelines, continuous training, and supervision are vital to address medication confusion and ensure proper use of HSC, TXA, oxytocin, and other existing medications.
- Establishing WhatsApp-based communities of practice for knowledge exchange and postpartum hemorrhage (PPH) quality improvement projects, alongside improving health information systems, could play a pivotal role in successfully integrating HSC and TXA.

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#### COMPLIANCE WITH ETHICAL STANDARDS

#### **Conflicts of Interest**

The authors declare no competing interests.

#### Financial Disclosure

Nothing to declare.

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## **Ethics Approval**

The study strictly adhered to the ethical principles outlined in the Declaration of Helsinki and received approval from South Sudan (RERB NO: 32/21/07/2022 - MOH/RERB/29/2022) and Uganda (National Council for Science and Technology HS2456ES - Mak-SOMREC-2022-428).

#### **Declaration of Patient Consent**

The authors certify that they have obtained all appropriate patient consent.

# Use of Artificial Intelligence (AI)-Assisted Technology for **Manuscript Preparation**

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

# Disclaimer

Opinions are those of the authors and not of UNFPA.

#### **Special Collection**

This article is published as part of the special collection on prevention and treatment of postpartum hemorrhage in high-burden low- and middle-income countries: building cross-national evidence through implementation research.

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