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Challenges in updating national guidelines and essential medicines lists in Sub-Saharan African countries to include WHO-recommended postpartum hemorrhage medicines

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Abstract

Despite the 2017 WHO recommendations on tranexamic acid (TXA) for the treatment of postpartum hemorrhage (PPH), the 2018 uterotonic recommendations (which included heat-stable carbetocin (HSC) for the prevention of PPH) and their inclusion in the WHO Essential Medicines List (EML), both drugs are still underused or not used at all to manage PPH in many countries with a high burden. HSC is currently being registered in low- and middle-income countries and its policy inclusion is limited and slow. TXA (also heat stable) is available in many countries but is not registered for PPH treatment, which may have contributed to the delay in its inclusion in national guidelines and EMLs. For both drugs, national guidelines will need to be revised and updated for their optimal uptake. We implemented an advocacy initiative to accelerate the necessary normative policy change to ensure access to quality-assured and heat-stable medicines for the prevention and treatment of PPH in Sub-Saharan African countries. Our initiative aimed to raise awareness of the importance of recently recommended medicines for the prevention and treatment of PPH and support the process to update PPH guidelines and EMLs to include these drugs. We highlight the lessons learned during the initiative, including the challenges and opportunities identified in updating PPH policies at the national level.

KEYWORDS
essential medicines list, guidelines, heat-stable carbetocin, postpartum hemorrhage, Sub-Saharan Africa, tranexamic acid

1 | INTRODUCTION

There is general lack of awareness upstream about updated World Health Organization (WHO) guidelines to improve the initial translation of new evidence to key stakeholders before dissemination at country level. Consequently, the translation of these recommendations into policy and practice at country level is often delayed. Globally, postpartum hemorrhage (PPH) remains the largest cause of direct maternal deaths.[1] The situation is especially critical in Sub-Saharan Africa (SSA) due, among other health systems challenges, to frequent use of substandard or falsified products. Policymakers and practitioners need to remain up to date on WHO

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recommendations on PPH prevention and treatment[2,3] and subsequent revisions to the WHO Essential Medicines List (EML)[4] as a step toward ensuring access to quality uterotonics. WACI Health and Concept Foundation have been collaborating on an advocacy project since 2019, with the aim of closing the gap between global evidence-based recommendations and implementation of recommended heat-stable carbetocin (HSC) and tranexamic acid (TXA) in SSA countries by ensuring national norms and standards are in place and healthcare providers are trained in implementing these interventions at all levels of healthcare systems.

2 | MATERIALS AND METHODS

WACI Health and Concept Foundation engaged 14 SSA countries to support policy change toward inclusion of HSC and TXA for prevention and treatment of PPH, respectively, in national PPH guidelines and EMLs. WACI Health conducted key informant interviews to map out key stakeholders, and an analysis of national reproductive health policy guidelines for an evidence-informed selection of countries. The final selection was based on an assessment of willingness and capacity (through engagement with the ministries of health) to sustainably make progress beyond the timeline for the existing project. All countries have high PPH-related maternal mortality and morbidity. Other selection criteria depended on how the timeline fitted with the overall regulatory and HSC product introduction strategy, the presence or absence of local champions, and other contextual factors.

3 | RESULTS

From a total of 14 countries who were taken through the initiative, 10 countries showed willingness and commitment in making progress toward updating their PPH guidelines and EMLs. Figure 1

Country	Updated and validated EML 2019–2021	Updated and validated guidelines 2019–2021
Burkina Faso (2020)		
Ghana (2021)		
Ethiopia (2021)		
Ivory Coast (2021)		
Liberia (2021)		
Rwanda (2020)		
Senegal		
Sierra Leone (2021)		
South Sudan (2020)		
Uganda (2021)		

Red – Drafted documents but not yet completed

Yellow – Final signature pending MoH clearance

Green – Validated (final approval obtained) documents

FIGURE 1 Status of guideline and Essential Medicines List (EML) updates to include heat-stable carbetocin and tranexamic acid in the 10 project countries

shows the status of the national guideline and EML update in those 10 countries. The reasons behind the other four countries (Burundi, Mali, Tanzania, and Zanzibar) not progressing in revising their guideline and EML within the timeframe ranged from contextual factors, such as political instability, to lack of willingness and capacity to undertake the process for several reasons, including the recent update of the guidelines.

4 | DISCUSSION

WACI Health and Concept Foundation's role in this project was to support countries in the implementation of the most recent evidence-based WHO PPH recommendations by achieving national guideline and EML updates. We believe that our project accelerated the revision and update process in a significant proportion of countries with rich lessons learned and multiple challenges encountered including:

- Progress in updating national guidelines is possible, but the timing is unpredictable due to the interplay of many factors, including political and contextual issues.
- Lack of due diligent follow-through to disseminate so that the guidelines reach frontline workers effectively, which inadvertently impacted the timeframe for updating the guidelines and EML. The disconnect between healthcare providers and these guidelines demands strengthened linkages between civil societies, governments, and healthcare providers. We believe inclusion of HSC and TXA provides an opportunity to engage key national stakeholders on addressing maternal health system challenges.[5]
- Lack of substantive policy and programs (including training) to support the implementation of the guidelines.
- Some countries faced issues in reflecting new and current evidence because their national guidelines are not regularly updated.
- The COVID-19 pandemic made it difficult to keep PPH a key priority with government bodies.
- Local evidence of HSC use, availability, and pricing became a concern for many countries since the policy updates preceded the regulatory approval of HSC in the countries. This is in alignment with country-level considerations influencing the process of adapting global guidance which cannot occur in isolation from the broader pharmaceutical system.[6]

5 | CONCLUSION

WACI Health and Concept Foundation implemented the project with the aim of shortening the interval between getting global recommendations adopted and adapted within countries and bridging the gap between national policies and facility-level adoption of the clinical standards and guidelines. Despite the challenges, the project's successful approach of supporting the countries to update their recommendations on PPH prevention and treatment is warranted to be sustainable if countries can procure and efficiently supply the quality-assured medicines, and the policy implementation infrastructure is established.

AUTHOR CONTRIBUTIONS

JN, TC, SR, DN, and AMG wrote the draft manuscript. All authors approved the final version.

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CONFLICT OF INTEREST

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