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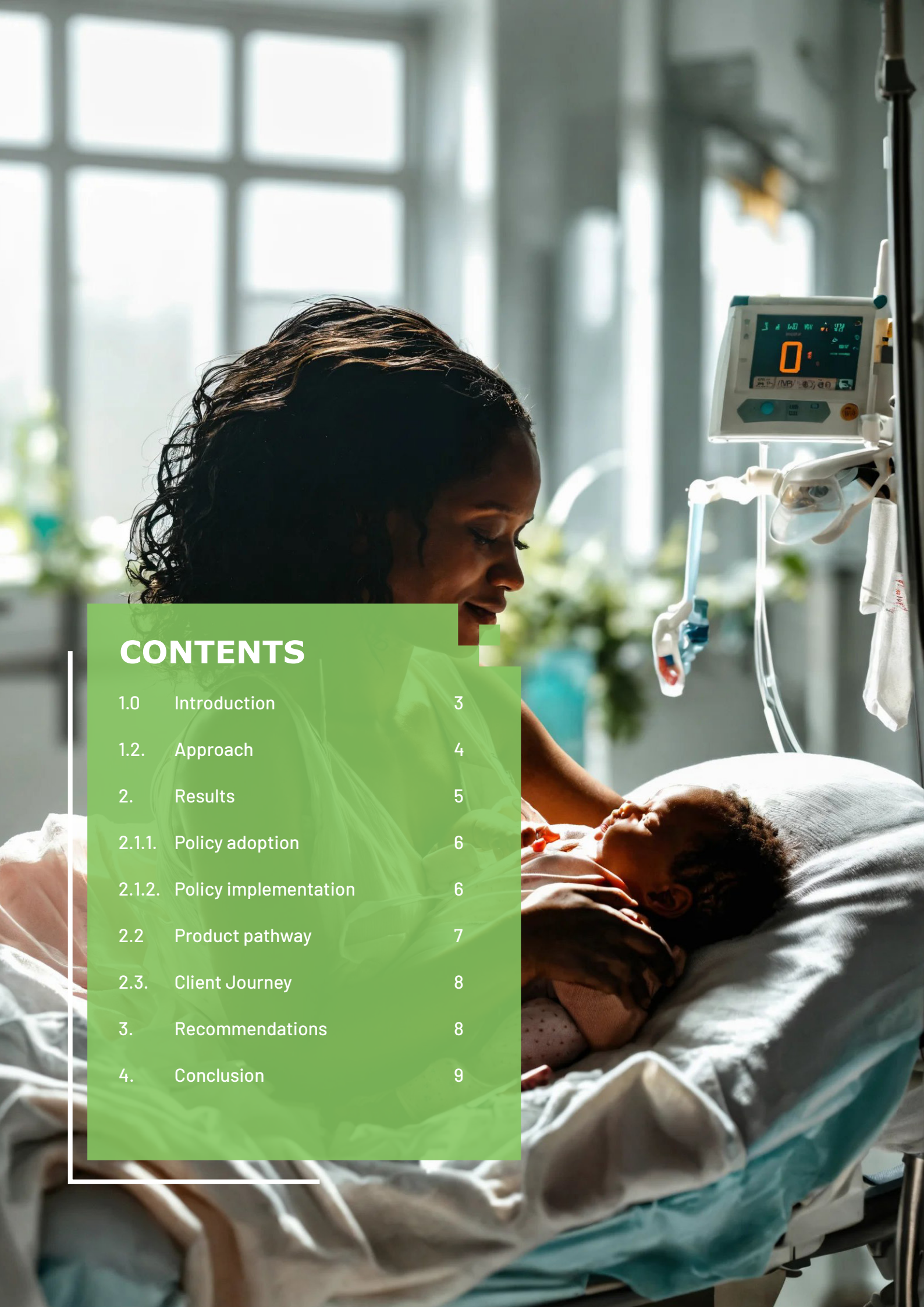
OPERATIONAL BARRIERS AND RECOMMENDATIONS TO ENHANCE TRANEXAMIC ACID ADOPTION AS AN ADJUNCT FOR POSTPARTUM HAEMORRHAGE TREATMENT IN NIGERIA



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INTRODUCTION

Nigeria, Africa's most populous country, faces a critical healthcare challenge with the third highest global maternal mortality rate. PPH which accounts for over 11.4%1 of maternal deaths in Nigeria is both preventable and treatable. Abundant evidence supports various interventions for addressing Postpartum Haemorrhage (PPH), with Tranexamic Acid standing out prominently for its effectiveness in alleviating excessive bleeding after childbirth, regardless of the underlying cause.

Tranexamic acid (TXA) is a synthetic antifibrinolytic agent that works by blocking the breakdown of blood clots formed by the body to stop bleeding. This action helps to prevent and control excessive bleeding, making TXA a valuable tool for managing PPH. TXA has been shown to reduce maternal mortality by up to 30% when used correctly.[2]

Globally, there is compelling evidence supporting the use of TXA for PPH treatment. The WOMAN trial in 2017, recommended the use of TXA for PPH treatment as an adjunct along with other interventions.3 In 2017, WHO updated its guidelines for PPH treatment to include TXA. Furthermore, the E-MOTIVE trial recommended the use of TXA as part of a comprehensive bundle which has the potential to significantly improve the continuum of care for PPH management by promoting early and timely intervention4. Especially in low-resource settings where access to skilled birth attendants and other specialized care may be limited and standardizing PPH management protocols across different levels of healthcare, leading to improved consistency and quality of care.

The Smiles for Mothers program, supported by MSD for Mothers, conducted a rapid assessment in Kano, Lagos, and Niger states to stimulate the use of TXA for PPH in these states by first understanding the barriers that hinders its use and developing recommendations to address these barriers. This technical brief outlines our findings and the recommendations developed for stakeholders and policymakers.

1.1 OBJECTIVES

The assessment aimed to:

- Identify policy and operational barriers to the adoption of TXA use for PPH treatment in the focus states
- Develop recommendations to address barriers to the adoption of TXA use for PPH treatment in the focus states
- Develop state plans for adoption of Tranexamic Acid for PPH treatment for inclusion in the 2024 health AOPs.

1.2. APPROACH

The assessment was conducted through a three-pronged framework examining policy, product, and client domains (fig. 2). By providing a clear understanding of barriers and recommendations, the assessment enabled states to define context specific recommendations and take ownership of feasible plans which would ultimately lead to the adoption of TXA use for PPH treatment across health facilities.

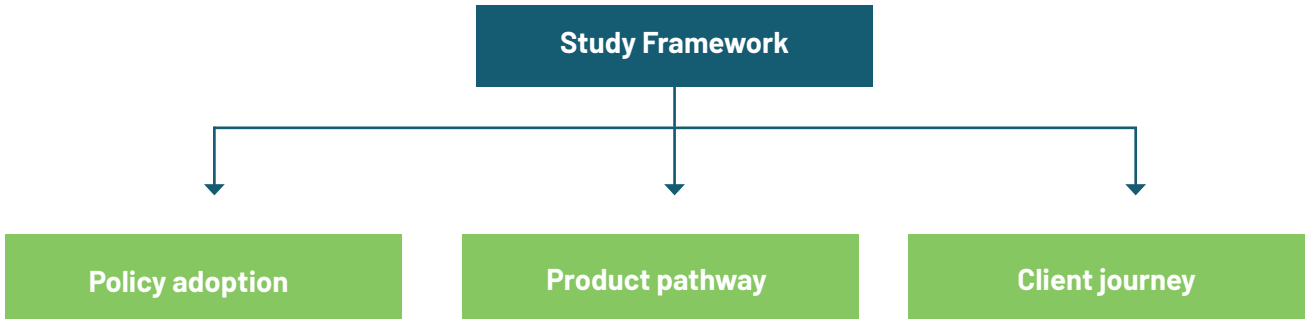

Figure 2: Three-pronged framework of the assessment

Policy adoption:

Encompasses the issues related to the awareness and implementation of existing policies, rules and regulations that govern the use of medical interventions like TXA

Product Pathway:

involves the processes and steps involved in the procurement, distribution and quality control of TXA, as well as its availability and accessibility in the Healthcare

Client Journey

addresses healthcare provider awareness of TXA's benefits for PPH treatment, the decision-making process related to its usage, and which healthcare providers are primarily responsible for its administration

The study employed a comprehensive approach, utilizing both qualitative and quantitative research methods:

Data was sourced from desk reviews, semi-structured questionnaires for 211 healthcare workers (doctors, nurses, midwives, and pharmacists) in obstetrics and gynaecology departments, along with interviews and literature reviews. We also engaged 25 policy makers, procurement staff, 4 TXA suppliers, 2 researchers, and 1 NAFDAC official. Data Analysis combined quantitative survey responses with qualitative insights from literature reviews and key informant interviews.

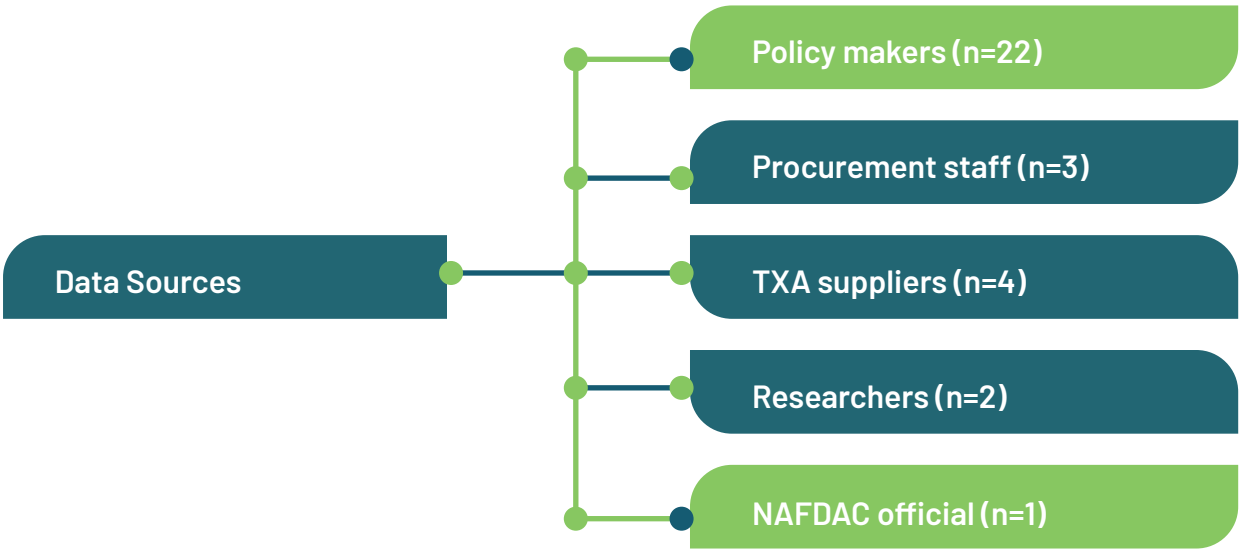

Table 1: Table showing the data sources

2. RESULTS

Policy formulation: There is currently no national policy for Postpartum Haemorrhage (PPH), and the existing local policies lack the latest globally recognized guidance on the recommended use of Tranexamic Acid (TXA) for PPH treatment.

The assessment identified significant challenges related to policy adoption and implementation of TXA for PPH treatment (fig. 3)

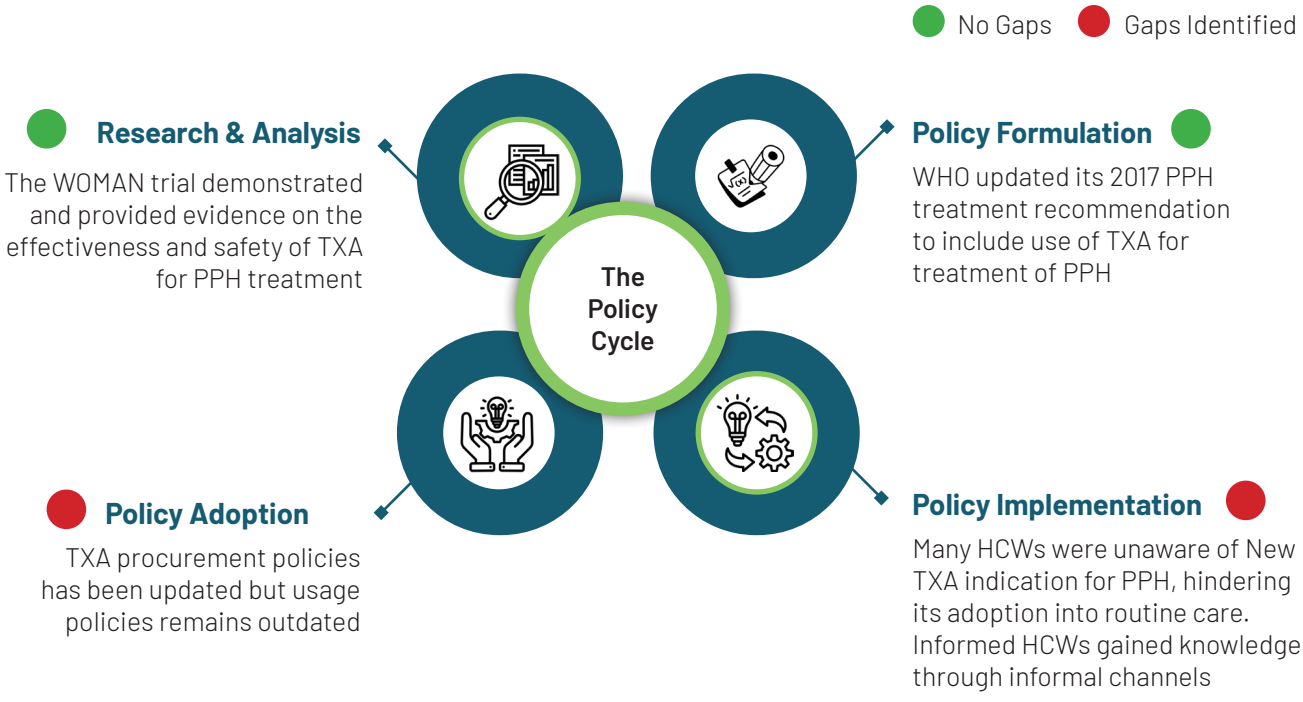

Figure 3: Policy cycle of the recommendation of TXA use for the treatment of PPH

2.1.1. POLICY ADOPTION

National and state EMLs capture TXA as part of their essential medicines, aligning with global standards. However, the outdated national PPH guideline and the LSS manual, which guides the practices of health workers, lists TXA as an alternative option for PPH treatment. This inconsistency with the latest evidence and guidelines could hinder the optimal use of TXA to prevent maternal mortality.

The Society of Gynaecology and Obstetrics of Nigeria (SOGON) has updated its guideline to recommend the use of TXA for PPH treatment, however, it suggests a sequential approach to TXA administration in line with the WOMAN trial. The more recent E-MOTIVE trial has demonstrated the superior efficacy of a bundled approach, and clinical practice guidelines should reflect this.

2.1.2. POLICY IMPLEMENTATION

There is a slow uptake of evidence-based recommendations on the use of TXA for PPH treatment due to poor knowledge of TXA, poor awareness of its recommendation and low use for PPH among different cadres of health care providers need them.

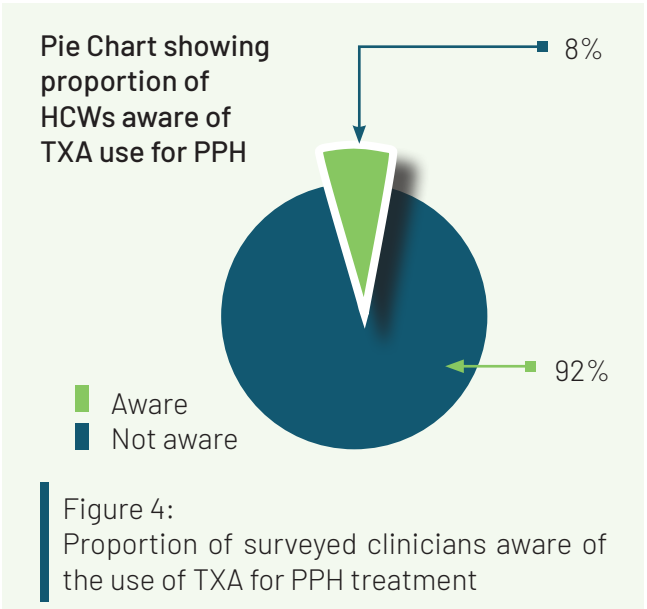

Figure 4:
Proportion of surveyed clinicians aware of the use of TXA for PPH treatment

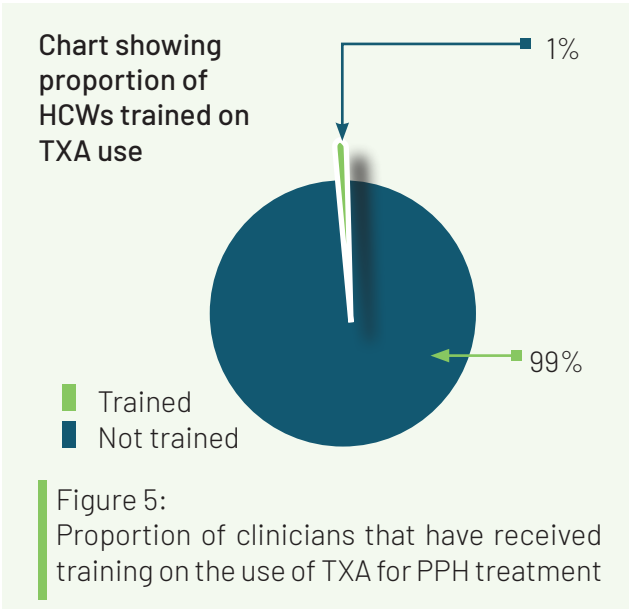

Figure 5:
Proportion of clinicians that have received training on the use of TXA for PPH treatment

Only 8% of health workers across the three states were aware of guidelines endorsing TXA use for PPH treatment.

Most of the healthcare workers surveyed perceived training as the primary method for effectively disseminating new policies across the three targeted states, However, 99% of healthcare workers had not received any training on the use of TXA for PPH treatment.

2.2 PRODUCT PATHWAY

Tranexamic Acid injection is accessible in Nigeria as a formulation and primarily available in the private health sector. Its availability, quality and supply to public health facilities is considerably limited

Challenges in the health commodities supply chain contribute to the limited availability of Tranexamic Acid:

Quantification:

States do not routinely quantify TXA due to low demand, alternative treatments, or limited medical conditions requiring its use.

Procurement:

Lagos is the only state procuring TXA for public health facilities, influenced by demand from health workers.

Financing:

Lagos includes TXA in its state-level insurance scheme, while other states have expressed interest in doing the same.

Suppliers

There are currently 4 NAFDAC approved suppliers of TXA in the country that supplies TXA in the IV formulation to both the public and private sectors

Price

The price of IV Tranexamic acid (TXA) ranges from N500 to N1000 per ampoule. These prices vary across the states and is influenced by economic factors.

Suboptimal quality:

Although most TXA samples met the acceptance criteria for active ingredient content, some deviations were observed, raising concerns about the overall quality of available products

Private sector demand

Tranexamic acid is widely available in the private sector, however its availability is limited in the public sector. Suppliers reported significant delays in recouping funds from the state central medical store and also facilities supplied directly as the reason for not supplying public facilities. Private and tertiary facilities get their commodities directly from suppliers and distributors due to a higher demand and unstable supply in the central medical store.

2.3 CLIENT JOURNEY

Healthcare workers are unaware of Tranexamic Acid's indication for treating Postpartum Haemorrhage (PPH) and consider training sessions the most effective way to increase awareness and encourage its use.

The limited awareness of TXA among healthcare professionals, combined with restricted access to the medication, serves as a barrier to its effective use

Awareness:

- Healthcare workers are largely unaware of the current evidence of TXA for PPH treatment as there were limited in-service training opportunities for healthcare providers. From our assessment, only 9% of surveyed health workers knew about the indication of TXA for PPH treatment.

Usage:

- Doctors, Midwives, and Nurses refrain from administering TXA to patients with PPH due to their lack of knowledge about the recent indication

Only 20 healthcare workers from 12 facilities used TXA routinely for PPH treatment, with doctors being the primary users.

3. RECOMMENDATION

Based on the assessment findings, the following evidence-based recommendations are provided:

Policy Formulation

The FMOH and states should partner with professional bodies like SOGON to update the unified protocol for PPH and maternal diseases, establishing a standardized guideline in Nigeria.

Policy Dissemination

Enhance the dissemination of guidelines endorsing TXA use for PPH treatment to improve policy implementation; Donors and development partners to support states adopt and implement activities to drive the utilization of Tranexamic Acid for PPH treatment

Product Pathway Pathway

SMoH should collaborate with the State DMA to conduct a forecast and include TXA in their procurement list and distribution plans for essential medicines

Client Journey

FMoH and states should develop and implement comprehensive training programs on the use of TXA for PPH treatment for healthcare workers across the three states using existing (BEMONC) and upcoming (E-MOTIVE) trainings

4. CONCLUSION

To effectively address the policy, supply chain, and client journey challenges that contribute to high PPH rates in Kano, Lagos, and Niger states, a comprehensive approach is crucial.

This approach should prioritize these key steps which includes; developing and effectively disseminating a comprehensive National PPH management protocol, establishing a robust public supply chain for TXA; preferably through drug revolving funds and other health insurance schemes, encouraging collaboration and knowledge-sharing between clinicians regarding TXA usage for PPH treatment and supporting adoption and integration by clinicians by creating easy access on trollies used in delivery rooms. By implementing these recommendations, stakeholders and policymakers can contribute to improved maternal healthcare and, potentially, the nationwide scale-up of TXA.

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