How can we increase global utilization of oxytocin for treatment of postpartum hemorrhage?

Challenge: Oxytocin, the Most Effective Treatment for Postpartum Hemorrhage, Remains Underutilized

Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the leading cause of maternal mortality in low- and middle-income countries, affecting more than 8 million women and claiming the lives of an estimated 69,000 women worldwide each year.[1] When a woman bleeds, she becomes anemic, goes into shock, and may eventually die of the condition if the bleeding does not stop or if she does not receive blood transfusions. Proper prevention and treatment for PPH can reduce maternal mortality.

Oxytocin is recognized by the World Health Organization (WHO) as the safest and most effective medication for preventing and treating PPH and is currently on WHO's Essential Medicines List and the United Nations Commission on Life-Saving Commodities (UNCoLSC) list of critical drugs.[2,3], Despite strong evidence that oxytocin is the most effective drug available for the treatment of PPH, it is underused in many low- and middle-income countries, where about 99% of PPH deaths occur.[4] Because oxytocin must be administered in a health facility, misoprostol is the recommended second-line drug for home deliveries and is included on the WHO's Essential Medicine List and the UNCoLSC list of critical drugs.

Accelovate is a five-year program United States Agency for International Development (USAID)-funded program to accelerate the availability and use of proven technologies and commodities to address global health challenges. In keeping with its mission, Accelovate aims to combat low utilization of quality maternal health drugs worldwide.

Oxytocin could prevent a majority of the 69,000 annual deaths caused by postpartum hemorrhage, but the relatively inexpensive commodity remains underutilized.

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Challenge Background: Barriers Limit the Use of Oxytocin

Oxytocin is widely available in developing countries and is fairly inexpensive, costing about $0.15 to $0.20 per 10 International Units (IU).[5] Although 10 IUs is enough to prevent PPH, 40 IUs are required for a treatment dose, costing $0.60 to $1.00. Despite this low cost, challenges in health sector infrastructure and health service delivery can create barriers to oxytocin use. Oxytocin must be manufactured in a sterile facility, and the manufacturer must test the finished pharmaceutical product for drug content and bioavailability (i.e., the rate and extent to which the active substance is absorbed from the pharmaceutical form), which can be challenging for manufacturers.[6] Additionally, oxytocin must be included in the cold chain (i.e., storage and transport equipment that enable medicines to be kept refrigerated from the point of manufacture to the point of use). The storage requirements for oxytocin are confusing because some labels state storage requirements of 2° to 8° Celsius, but others list ''controlled room temperature,'' which can be between 20° and 25° Celsius.[7]

Oxytocin must be transported and stored in the cold chain.

Because oxytocin is administered through intravenous or intramuscular injection, most countries require that trained health care workers administer the drug. Administration requires specialized skills, sterilized equipment, and proper disposal of medical waste.[8] This means that women delivering at home or with a traditional birth attendant probably will not have access to oxytocin. Furthermore, many health workers are unaware that oxytocin requires cold chain storage.[9]

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Although oxytocin is included in most national protocols for health services provision, recent studies in Ghana and Indonesia showed a large percentage of oxytocin tested did not meet quality standards. In Ghana, 65.5% of tested samples did not meet quality standards, and, in Indonesia, 11.5% of refrigerated samples failed assays for active pharmaceutical ingredient content and 15.8% of unrefrigerated samples failed.[10] To ensure quality, many international tenders require market authorization from a stringent regulatory authority[11] or prequalification by the WHO through a program that assesses medicines, active pharmaceutical ingredients, vaccines, diagnostics, injection devices, and quality control laboratories. As of September 2014, no oxytocin products are prequalified, although one is currently going through the prequalification process, and one is going through the expert review panel process. Because there are so many manufacturers of the drug, and there are no prequalified products, it can be difficult for procurement agencies to identify quality products.[12] Prequalifying manufacturers of oxytocin and clarifying labeling and storage requirements would reduce procurer confusion and ensure quality supplies of the drug.

Accelovate's Solution: Improve Postpartum Hemorrhage Screening, Diagnosis, and Clinician Capacity

In addition to increasing access to existing commodities, Accelovate partners with innovators to develop new solutions in critical areas. Bringing innovative solutions to low-resource settings is expected to translate into improvements in quality assurance of oxytocin throughout the supply chain and at the time of use. In 2015, Accelovate will continue its work documenting the screening landscape to aid donors, program implementers, host country governments, communities, and regulatory agencies in prioritizing areas of highest need and greatest impact.

Results Achieved

Accelovate has also assessed efforts to drive new, existing, or emerging innovations in PPH management. Accelovate recommends improving clinic-level quality of oxytocin, creating visible markers of potency, developing portable, off-grid cold storage solutions, controlling drug distribution systems, establishing systematic and electronic tracking of quality and demand, and experimenting with new formulations and presentations of the drug. Accelovate also recommends creating tools and tests for quality assessment at the point of care and training providers to test quality. The continuation of this work is a priority for Accelovate in 2015; it is hoped that findings will become advocacy tools for donors, ministries of health, national policymakers, and clinical care providers.

Next Steps: Building on Accelovate's Achievements

Accelovate continues to work with strategic partners to promote the global availability of and access to high-quality maternal health commodities. These partners include but are not limited to: UNCoLSC, the Reproductive Health Supplies Coalition, WHO, various ministries of health, procurement agencies, commodity manufacturers, product developers, researchers, and implementing partners.

Accelovate's work builds on the excellent tools produced by partners and advocates in the field. Family Care International, with funding from the Reproductive Health Supplies Coalition, has produced briefs on Essential Medicines for Maternal Health, including oxytocin. The brief outlines the barriers to the use of oxytocin, strategies to ensure potency and quality with anecdotal evidence from the field, and examples of innovations in oxytocin delivery, as well as priority actions for ensuring quality and potency of oxytocin.

Bringing innovative solutions to low-resource settings is expected to translate into improvements in quality assurance across the supply chain.

[1] Jhpiego. Business Case: Investing in Production of High-Quality Oxytocin for Low-Resource Settings. 2015. Publication prepared by C. Schocken through the Reproductive Health Supplies Coalition. Available at http://reprolineplus.org/oxytocin-case Accessed 2 January 2015.
[2] UN Commission on Life-Saving Commodities. Life-Saving Commodities. UN Commission on Life-Saving Commodities: 2013. Available at http://www.lifesavingcommodities.org/about/lifesaving-commodities/. Accessed 25 November 2014.
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[4] Haeri S, Dildy III GA. Maternal Mortality From Hemorrhage. Seminars in Perinatology, 2012, 36(1):48–55.
[5] Jhpiego. Business Case: Investing in Production of High-Quality Oxytocin for Low-Resource Settings.
[6] *Ibid*
[7] Jhpiego. Business Case: Investing in Production of High-Quality Oxytocin for Low-Resource Settings. 2015.
[8] Family Care International. Oxytocin. Essential Medicines for Public Health. Reproductive Health Supplies Coalition: 2014. Available at http://www.rhsupplies.org/fileadmin/user_upload/Maternal_Health_Supplies/Essential_Medicines/Essential_Medicines_Maternal_Health.pdf. Accessed 2 January 2015.
[9] Jhpiego. Business Case: Investing in Production of High-Quality Oxytocin for Low Resource Settings. 2015.
[10] *Ibid*
[11] A stringent regulatory authority is a regulatory authority that is a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) or an ICH Observer and associated with an ICH member.
[12] Jhpiego. Business Case: Investing in Production of High-Quality Oxytocin for Low-Resource Settings. 2015.

Accelovate—a Partnership in Accelerated Global Health Innovation

Accelovate is a global program dedicated to increasing the availability and use of lifesaving innovations for low-resource settings. Led by Jhpiego, the Accelovate program began in 2011 as a five-year, United States Agency for International Development (USAID)-funded program under the Technologies for Health (T4H) grant.

Also Available from Accelovate:


Postpartum Hemorrhage


Rehabilitative Medicine


Pre-eclampsia & Eclampsia


Male Circumcision

Design Challenges promote the development of innovative solutions where appropriate technology is lacking

Solution Landscapes assess what solutions exist

Value Propositions assess the benefits and drawbacks of an array of solutions for our context

Business Cases assess manufacturability and commercial potential

Market Readiness Assessments evaluate a selected technology/solution for market-level readiness factors

Briefs describe technology access and utilization challenges in a topical area and outline Accelovate's approach

Excel Tools present raw data that implementers may develop for programming and advocacy purposes

Literature Reviews review secondary data, usually to understand a bottleneck

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Accelovate invites innovators, advocates, funders, and programmers addressing the procurement and use of maternal health drugs and technologies in low-resource settings to share our tools and join our efforts to ensure a market of standardized, high-quality oxytocin.