

Buy Quality Oxytocin, Keep It Cold

**An Advocacy Messaging Framework for Oxytocin,
the First-Line Drug for the Prevention and
Treatment of Post-Partum Hemorrhage**

Acknowledgements

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Cover Photo: PATH/Evelyn Hockstein

Introduction

Postpartum hemorrhage (PPH)—or excessive bleeding after childbirth—is the leading cause of maternal mortality worldwide, and oxytocin is the first-line drug of choice for prevention and treatment. The World Health Organization (WHO) recommends oxytocin for PPH prevention and treatment, and it was included as one of the 13 priority, lifesaving health products under the UN Commission on Life-Saving Commodities for Women and Children. If used appropriately, universal access to oxytocin could save 1.4 million lives over the next 10 years. Countries around the world purchase and use oxytocin.

However, challenges exist to making high-quality oxytocin available to all women who need it. Government procurement agencies may prioritize lower prices over quality-assured products when purchasing the drug—even though investing in quality oxytocin can save lives and money over the long run. Critically, oxytocin is a heat-sensitive product that requires transport and storage in the cold chain—storing oxytocin at room temperature or higher can result in product degradation, especially in tropical climates. Despite general awareness of the threat to oxytocin quality if the cold chain is not maintained, many countries still do not transport and store oxytocin appropriately—with temperature maintenance failures occurring during shipment from the manufacturer, at the point of entry, in medical warehouses, and at the health center and facility levels.

The resulting impact of these storage and procurement challenges is that front-line health workers are often forced to use low-quality product and may not realize it. This compromises their ability to provide quality medical care and threatens many women whose lives could be saved by the drug.

1,400,000 LIVES

If used appropriately, universal access to oxytocin could save 1.4 million lives over the next ten years.



Why these messages are needed

In October 2017, a group of scientists, researchers, manufacturers and health experts from the public and private sectors came together in Geneva to review current evidence on oxytocin and identify a way forward for improving the quality of oxytocin in countries significantly impacted by PPH. It was clear from the meeting discussions that there is a wide diversity in product labelling and recommended storage practices, eliciting confusion among various country stakeholders. Among other outcomes, the group identified the need for technical consensus to overcome this confusion, as well as a common language to communicate challenges and solutions to key target

audiences – especially governments, multilateral organizations and donors – in a clear and compelling way that encourages specific action. The most pressing challenges and anticipated solutions focused on the changes necessary to improve oxytocin quality – in particular, procurement, distribution and storage. However, dialogue about oxytocin has traditionally remained the domain of technical experts; the group agreed that simple, concise messaging is needed to allow advocates and the public to demand changes in oxytocin procurement and storage practices.

Who and what these messages are intended for

This messaging framework is intended for use by maternal and child health advocates who are communicating with government policymakers, civil society, and other stakeholders pivotal to the decision-making process around oxytocin policy, procurement, and distribution. This may include health practitioners, technical experts, government leaders, and civil society and community representatives who are concerned about women's health and well-being.

A diverse group of oxytocin advocates and experts identified the target audiences and messages included in the framework. The resulting action-oriented messages should be part of strategic advocacy—including communications, outreach, and educational efforts—to:

- › Raise awareness of the lifesaving impact of widespread use of quality oxytocin, and the dangers of using low quality product.
- › Recommend specific actions that each target audience can take to improve the quality of oxytocin.

Limitations and constraints of these messages

This advocacy messaging framework serves a specific communications purpose and is not intended to function as a summary of the evidence on oxytocin, or a comprehensive review of the challenges in the field. The framework addresses a carefully selected set of core issues and actions

that can help drive progress on specific challenges that hinder use of quality-assured oxytocin in low-resource settings. They are meant to be clear, simple (but not simplistic) and action-oriented, serving as a tool for those who advocate to health policy- and decision-makers.

Core messages

These core messages provide overall framing for the issue of PPH and the potential and challenges for use of quality oxytocin. Core messages should be used to set the issue context, and ideally will be paired with the audience-specific messages in the sections that follow. They can inform one-on-one discussion, as well as a variety of communication channels and materials.

Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the leading cause of maternal mortality worldwide. PPH causes nearly one out of every five maternal deaths.

PPH can be prevented and treated using oxytocin—a highly effective, first-line drug. Access to oxytocin could save 1.4 million lives over the next 10 years.

- › Oxytocin is globally recommended by WHO and included in its Essential Medicines List.
- › Oxytocin was one of the 13 health products prioritized by the UN Commission on Life-Saving Commodities for Women and Children.

Oxytocin is used widely, and governments have adopted WHO recommendations for its use to manage PPH. However, there is a high prevalence of low-quality product resulting from poor manufacturing practices, limited regulatory oversight, and/or inadequate transport and storage conditions—posing dangers to lives and health systems.

- › In a recent systematic literature review, over one-third of the 559 samples tested in eight studies contained less than the stated amount of oxytocin¹.

The prevalence of low-quality oxytocin in the supply chain costs lives and money, and compromises health systems.

- › Low-quality oxytocin threatens women's lives. When health workers unknowingly administer ineffective doses of poor quality product, and when backup interventions are not available, women die needlessly.
- › Product that has not been stored correctly can become ineffective causing critical delays in lifesaving care as health workers administer additional, increasingly larger doses of oxytocin, hoping for success while incurring unnecessary cost.

Procuring only quality oxytocin is an effective strategy for saving lives, and—like other successful maternal and child health initiatives—may result in cost savings.

- › Quality oxytocin administered just after birth has a high probability of preventing PPH, avoiding additional maternal and fetal risk, and minimizing costs—benefits similar to the value gained from vaccination programs.

1. Quality of oxytocin available in low- and middle-income countries: a systematic review of the literature <https://www.ncbi.nlm.nih.gov/pubmed/27006180>

Country governments should commit to only purchasing and distributing quality oxytocin.

- › Oxytocin should be quality-assured [for example, approved by a stringent regulatory authority (SRA), prequalified by WHO, or recommended by an Expert Review Panel (ERP)].
- › Oxytocin that is procured should always be labeled for storage at 2-8° C.
- › Oxytocin should be procured in 10 IU ampoules—many countries instead procure 5 IU ampoules, doubling the cost and risking potential misuse of the product.

Because oxytocin degrades when exposed to prolonged heat, to ensure quality it must remain in the cold chain consistently from the manufacturer to the end user.

- › WHO and UNICEF recommend that oxytocin-based products stay refrigerated.
- › To ensure the quality of oxytocin is maintained throughout the supply chain, it must be stored at 2-8° C. Refrigeration is especially important in tropical climates.

Everyone has a role to play in making sure that deaths from PPH are prevented. Coordination and commitment are needed across Ministries of Health and Finance and civil society to make the changes that will improve the quality of oxytocin supply.

Country governments can save lives and money by:

- › Improving financing, policies, oversight and programming that support the procurement and management of quality oxytocin through the supply chain.
- › Registering and purchasing only quality-assured oxytocin (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP).
- › Registering and purchasing only quality oxytocin that is labeled for storage at 2-8° C, and in 10 IU ampoules.
- › Ensuring that oxytocin remains cold (2-8° C) throughout the public health supply chain—from the manufacturer to the point of entry and during distribution to, and storage at, health facilities.

Donors and multilateral organizations can support distribution of quality products by:

- › Endorsing the WHO/UNICEF joint statement on integrating temperature-sensitive health products into the Expanded Programme on Immunization health supply chains.²
- › Financing programs and initiatives that support procurement and provision of quality oxytocin.
- › For those that purchase oxytocin and donate to countries, procuring only quality-assured oxytocin, labeled for storage at 2-8° C and in 10 IU ampoules.

Media and civil society can use their voices to:

- › Highlight the consequences of low-quality oxytocin and call for quality oxytocin products.
- › Demand that quality oxytocin is available in their local facility and kept in the cold chain.

2. Temperature-sensitive health products in the Expanded Programme on Immunization cold chain: [https://www.unicef.org/health/files/EPI_cold_chain_WHO_UNICEF_joint_statement_A4_rev2_5-14-15_\(3\).pdf](https://www.unicef.org/health/files/EPI_cold_chain_WHO_UNICEF_joint_statement_A4_rev2_5-14-15_(3).pdf)

Audience-specific messages

Maternal, Newborn and Child Health (MNCH) Program Leaders

Public-sector MNCH program leaders play a pivotal role in ensuring the use of quality oxytocin because they identify program priorities, set training for frontline health workers, and identify the types of medicines that should be used throughout a country's public health programs. They may have influence with high-level policymakers (such as Ministers of Health) and can influence the technical specifications for oxytocin procurement and distribution and storage practices.

Public-sector MNCH leaders have a unique opportunity to prevent deaths from PPH by making quality oxytocin widely available.

Making only quality oxytocin available is critical to saving the lives of those suffering from PPH. When low-quality products circulate in the supply chain, many women's lives are put at risk.

MNCH leaders must take responsibility for ensuring that government policies and practices prioritize quality oxytocin products, and that health professionals are trained correctly in procurement, use, and storage.

Suggested Actions

MNCH managers and directors should:

- › Advocate for government registration and purchase of quality-assured oxytocin only (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP). Publicly procured oxytocin should be labeled for storage at 2-8° C, and purchased in 10 IU ampoules.
- › Issue a high-level policy statement that directs procurement agencies to purchase quality product with proper labeling; supply chain managers to distribute oxytocin in the cold chain; and health care workers to keep oxytocin cold in health facilities.
- › Raise awareness of the prevalence of low-quality oxytocin and the potential impacts, including lives lost and increased spending.
- › Coordinate/work with the local Expanded Programme on Immunization to ensure oxytocin is integrated into the cold chain.

National Regulatory Authorities (NRA)

National Regulatory Authorities (NRA) ensure that only quality oxytocin enters the national market, and that quality is safeguarded once the drug is circulating within country. They set guidelines for registration of products and can influence manufacturers' decisions on labeling and quality.

As the creator and enforcer of health product regulations, the NRA has the authority to ensure that only quality-assured oxytocin products (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP) are approved for sale and distribution in their country.

The NRA is obligated to ensure that only quality oxytocin is registered, and that only quality-assured products labeled for cold storage are available throughout the country. Low-quality product threatens women's lives and costs the government money.

Suggested Actions

The NRA should:

- › Only register oxytocin products that are quality-assured (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP), labeled for storage at 2-8° C and packaged in 10 IU ampoules, for purchase and distribution.
- › Require manufacturers to label oxytocin products for storage at 2-8° C.
- › Work with MNCH and EPI program directors to communicate changes and requirements to procurement agents.
- › Support post-marketing surveillance of oxytocin to ensure only registered quality products are available in country.

Public-Sector Procurement Agents

Public-sector procurement agents seek to purchase high-quality oxytocin at the lowest possible price, maximizing government investment. They make decisions about which product to buy and are responsible for assessing a product's availability and affordability for the local market.

Public-sector procurement agents are uniquely positioned to ensure that only high-quality lifesaving drugs, including oxytocin, are purchased and circulated throughout the country's public health system. Low-quality oxytocin threatens women's lives, undermines the credibility of the procurement system, and can waste public funds.

Procurement agents have a responsibility to purchase only oxytocin products that have been approved by the country's NRA, and are quality-assured (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP) and labeled for distribution and storage within the country's cold chain.

Purchasing product of low or unknown quality, even if it is less expensive, costs the government more in the end.

Suggested Actions

Public-sector procurement agents should:

- › Only purchase oxytocin that meets the following critical criteria:
 - › Quality-assured (for example, approved by a SRA, prequalified by WHO, or recommended by an ERP).
 - › Approved by the NRA.
 - › Labeled for storage at 2-8° C.
 - › Packaged in 10 IU ampoules.
- › Prioritize quality when weighing product options, as purchase and distribution of lower cost oxytocin that is of poor or unknown quality can cost lives and money.

Supply Chain Managers

Supply chain managers oversee the movement and distribution of oxytocin from point-of-entry into the country to point-of-use. They often have the authority to ensure that oxytocin is included in the cold chain during distribution and specified for cold storage at the point-of-use.

Supply chain managers have a responsibility to ensure that lifesaving drugs, including oxytocin, reach those who need them most.

Low-quality oxytocin, common in the supply chains of many countries, threatens the integrity of the entire health system and puts women's lives at risk.

To ensure quality, oxytocin must be included and maintained in the cold chain.

Suggested Actions

Supply chain managers should:

- › Determine options for inclusion of oxytocin in the country's cold chain.
- › Advocate for the financial and structural investments necessary to include oxytocin in the cold chain.
- › Communicate the importance of keeping oxytocin cold to pharmacists, logisticians, and health providers throughout the national supply chain.



The Reproductive Health Supplies Coalition

The Coalition is a global partnership of public, private, and non-governmental organizations dedicated to ensuring that everyone in low- and middle-income countries can access and use affordable, high-quality supplies for their better reproductive health. It brings together agencies and groups with critical roles in providing contraceptives and other reproductive health supplies. These include multilateral and bilateral organizations, private foundations, governments, civil society, and private sector representatives.