



Guidance on Elements to Consider when Planning for the Integration of Oxytocin into the EPI Cold Chain



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The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Background

Post-partum hemorrhage (PPH) remains one of the major causes of maternal mortality and accounts for 35% of all maternal deaths.¹ The World Health Organization (WHO) has recommended oxytocin as the most effective medicine for the prevention and treatment of PPH, particularly for facility-based births.² In line with this recommendation, most countries list oxytocin as the medicine of choice for the prevention and treatment of PPH.

Despite this positive policy framework for oxytocin use, supply chain barriers that limit access to the medicine persist. Studies from many countries have shown that continuous availability of oxytocin at service delivery points is an issue, and more recent studies in individual countries have demonstrated that lack of availability is a major challenge.^{3,4,5,6} Inadequate forecasting of requirements, weak information systems, and poor distribution systems contribute to this challenge. Another major issue in ensuring access to quality oxytocin is maintaining cold storage of the product throughout the supply chain. Oxytocin must be stored between 2°C and 8°C, with possible excursions to room temperature for brief periods. In many countries, the distribution systems in place for essential medicines do not allow for cold storage. Likewise, in many settings, warehouses at lower levels of the system and service delivery points do not have the infrastructure or equipment to maintain cold storage. A recent systematic review of the literature showed the widespread availability of oxytocin of questionable quality in both the private and public sectors in many countries.⁷

In most countries, Expanded Program on Immunizations (EPI) cold chains are highly effective in reaching even the lowest levels of the system. However, they are managed vertically and separately from other essential commodities. One barrier to integrating other products into the EPI cold chain is the perception at the country level that this is not permitted. To address this perception, the Maternal Health Technical Resource Team of the UN Commission on Life-Saving Commodities, in close collaboration with WHO and the United Nations Children's Fund (UNICEF), developed a joint statement declaring that countries may choose to integrate other products, specifically oxytocin, into the EPI cold chain to ensure access to quality products.⁸ Integration is an option to consider, but operationalization within the country context is also needed.

Purpose

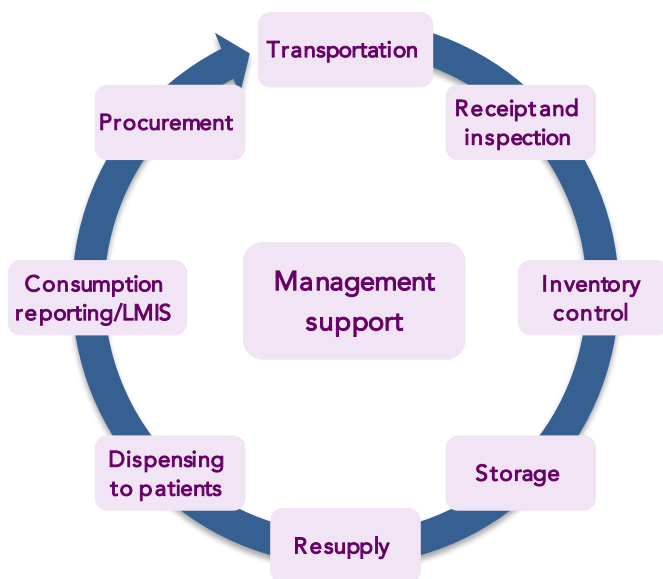
The purpose of this document is to provide guidance to national program managers who are considering integrating oxytocin into the EPI cold chain. It is intended for representatives from relevant offices of the Ministry of Health (MoH), such as

Pharmacy, Central Medical Stores, and Maternal and Child Health, as well as other policy makers, stakeholders, and implementing partners.

This guidance document introduces the pharmaceutical management elements that must be considered to successfully integrate oxytocin into the EPI cold chain and outlines the steps that will help national program managers plan the integration processes and strategies. Integrating oxytocin into the EPI cold chain may affect several elements within the pharmaceutical management cycle, from distribution systems, inventory management, and logistics management information systems and reporting procedures to roles and responsibilities, health facility infrastructure, and monitoring and evaluation. Some elements of the pharmaceutical system are afterthoughts that are only considered when challenges arise during implementation. Taking into account all elements that will be impacted by integrating oxytocin into a supply chain will not only help identify issues but also address needed changes in standard operating procedures and at the various stages of the supply chain. It is important to consider each element and address it in the strategy and implementation plan to ensure that oxytocin integration into the EPI cold chain is successful.

Elements to Consider When Integrating Oxytocin into the EPI Cold Chain

Integrating oxytocin into the EPI cold chain requires redefining the distribution system for the medicine from the central level to the client. The distribution cycle begins when a pharmaceutical is delivered by the manufacturer/supplier and ends when the medicine consumption is reported to the procurement unit.⁹ The distribution cycle



Distribution cycle of oxytocin

coincides with the procurement process after the medicines are cleared from the port (if internationally supplied), inspected, and available for delivery to service delivery points. The major activities of the distribution cycle include receipt and inspection; inventory control, including requisition of supplies; storage; delivery; dispensing to patients; and consumption reporting. Each activity needs to be considered when defining the flow of oxytocin from the central medical stores to the client, including how oxytocin will move from one level to the next in the distribution system and at which points in the system oxytocin should be integrated into the EPI cold chain.

Transportation

Policy makers and facility managers need to understand that effective and responsive health service depends on always having medicines available when and where they are needed, which requires the secure and proper transportation of pharmaceuticals and medical supplies. Transportation includes delivery of medicines to central medical stores and/or regional warehouses as well as delivery to service delivery points/health facilities. Good transport practice demands reliability, efficiency, safety, accountability, timeliness, affordability, and sustainability.¹⁰ Transportation must also take into account storage requirements, such as those needed for oxytocin.

Receipt and Inspection

Once medicines have been delivered by the manufacturer or supplier, central medical store staff must check the shipment for any damaged or missing items and verify

whether the contractual conditions have been met (i.e., drug type, quantity, storage conditions, packaging, labeling, or any other specifications indicated in the contract). This should be done at any point in the distribution cycle where medicines are delivered (e.g., central medical store, regional warehouses, service delivery points).

Inventory Control

The inventory control system is the backbone of the logistics system and is used for requisitioning and issuing medicines, financial accounting, and preparing consumption and stock balance reports to inform the procurement of medicines. The inventory control system also includes maintaining and managing all forms and procedures for medicine requisition. Maintaining accurate and current stock records and inventory management procedures is essential for coordinating the flow of health commodities through the distribution system.

Storage

Proper storage conditions must be maintained to ensure the physical integrity and safety of products and their packaging during transport, at the storage and health facilities, and until they are dispensed to patients. Storage conditions must be adequate to maintain the quality of products, and storage capacity must also be adequate to manage all products in the system. It is essential that facilities have the capacity, infrastructure, organization, and equipment to safeguard medicine quality and minimize theft and loss through damage.

Resupply

The schedule for resupplying medicines to health facilities will affect not only the availability of medicines but also the storage capacity at different points in the system, information flow, and transportation. Determining an optimal resupply interval (i.e., whether deliveries are made weekly, monthly, or quarterly) is key to ensuring continuous availability of quality medicines.

Consumption Reporting/Logistics Management Information System

Consumption reporting provides information on actual demand and stock balances to inform the quantification of medicine procurement needs. It is part of the overall logistics management information system (LMIS), which also includes inventory control, records and forms, and information flow related to pharmaceuticals. An LMIS focuses on commodity management and is the means through which information is gathered and communicated to enable managers to make decisions that ensure product availability and customer service.

Management Support

Management support is embedded in every step of the distribution cycle. At each point, it is a combination of determining roles and responsibilities for key health logistics personnel, identifying and meeting training needs, and continuously monitoring and evaluating the distribution system.

Roles, Responsibilities, and Guidelines

At each step of the distribution cycle it is imperative that roles and responsibilities are defined in the standard operating procedures (SOPs) or guidelines for that level of the health system. Integrating oxytocin will introduce changes in the distribution system that will need to be addressed in the SOPs for each step of the cycle. At each level, “what, where, when, and how to” needs to be defined for each role to ensure that all tasks that need to happen within the system and for oxytocin management occur.

Training Needs

When introducing changes to the distribution cycle, SOPs and guidelines need to be updated and personnel need to be trained on the new procedures. Identifying training needs along the distribution cycle and at each level of the health system builds capacity for staff and facilities to manage all aspects of the distribution cycle, from inventory control, storage, and delivery to managing information systems.

Monitoring and Evaluation

Monitoring and evaluation can help identify the needs for program implementation and potential problems that require corrective action. It should be an integral part of the day-to-day management of pharmaceutical supply systems.



Methodology for Considering Integration

This methodology is a proposed approach to think through the points described above. National program managers and stakeholders can carry out an exercise to develop a sound planning process for oxytocin integration into the EPI cold chain. This exercise comprises six steps:

1. Form a core working group
2. Advocate to policy makers for the integration of oxytocin into the EPI cold chain
3. Assess the current level of integration of oxytocin into the EPI cold chain
4. Form a task force and organize stakeholder workshops
5. Develop and present a plan to stakeholders to reach consensus
6. Plan for integration based on the assessment results and workshop discussion



1.

Form a core working group

The purpose of the core working group is to lead, organize, and develop a strategy for the integration of oxytocin into the EPI cold chain. This core working group must include stakeholders, such as the drug regulatory authority; EPI program managers; maternal, newborn, and child health program managers; regional and local health authorities; nongovernmental organizations (NGOs); and implementing partners. The drug regulatory authority or the national health department within the MoH should lead the process. The primary responsibilities of the core working group are to advocate for and define the policy environment for oxytocin integration into the EPI cold chain; organize, prepare for, and conduct planning activities; and document each step in the process.



2.

Advocate to policy makers for the integration of oxytocin into the EPI cold chain

The core working group should advocate for the integration of oxytocin into the EPI cold chain based on WHO recommendations and expected benefits and generate political will within the MoH for this change.

Health program managers and other personnel dedicated to logistics can also influence these policies. Many country governments have established policies on the selection of medical products (usually based on essential medicine lists); how items are procured (for example, international competitive bidding or using prequalified manufacturers); when items are distributed; where and how items are stored; and the quantities customers receive (often called dispensing protocols). Involving such personnel in these functions is essential for influencing policy change related to logistics management.

3.

Assess the current level of integration of oxytocin into the EPI cold chain

Some countries may already be integrating oxytocin into the EPI cold chain, particularly at health facilities at the lower levels of the health system. It is important to assess the current state of oxytocin integration into the EPI cold chain within the country and to identify the need for integration and the challenges that facilities may face in storing oxytocin.

The assessment should be conducted at the central, regional, and district levels at randomly selected storage and health facilities. Outputs of the assessment may include:

- A current distribution map of oxytocin in the country from the central level to the point of service delivery
- Documentation on how the EPI cold chain is maintained for oxytocin throughout the health system
- Identification of points along the supply chain where oxytocin is currently integrated into the EPI cold chain, the steps taken to enable this integration, challenges encountered, and actions taken to address those challenges

The results of this assessment will serve as the foundation for developing and implementing a strategy for oxytocin integration into the EPI cold chain.

4.

Form a task force and organize stakeholder workshops

Once the assessment is completed, a task force within the group should be formed. This task force will facilitate stakeholder workshops to determine feasible options for integration based on the results of the assessment and define steps to operationalize these options. The task force should include members of the core working group and institutions within the MoH that are involved in the EPI cold chain, supply chain, and use of oxytocin as well as representatives of other groups, such as facility managers and consumer association members. These workshops will play a crucial role in planning oxytocin integration and developing a proposal that is agreed upon by stakeholders.

The objectives of the stakeholder workshop are to:

- Share and discuss the results of the assessment
- Discuss the implications of integrating oxytocin into the EPI cold chain for the distribution cycle
- Identify, analyze, and propose options for the integration of oxytocin into the EPI cold chain
- Propose a logical framework for the integration options discussed and selected

Discussion Questions that Can Help in Decision Making

Once the group has agreed on the integration of oxytocin and the levels at which it should be integrated, members should develop and propose an acceptable, achievable, and sustainable logical framework for the integration. Discussion questions should focus on the elements of the distribution cycle, such as transportation; receipt and inspection; inventory control, including requisition of supplies; storage; delivery; dispensing to patients; and consumption with management support. The task force should then agree on the system design elements that need to be revised and on all revised elements of the system design. The table below gives an overview of possible questions that need to be considered and discussed for each element of the distribution cycle.

Elements to Consider When Planning for Integration

General Considerations

- Should the integration of oxytocin into the EPI cold chain be considered?
 - If yes, at which level(s)?
 - If no, why? Propose other alternatives for the cold storage of oxytocin.
 - Is there some level of integration already being done at certain levels of the health system? If so, what levels? How is it being done? What have been the challenges? How are the medicines being tracked? Who are the responsible personnel?
 - Is distribution through a push system, a pull system, or a combination?
 - Which levels of the supply system order oxytocin from suppliers?
 - How does oxytocin flow through the health system (i.e., from the central level to the patient)?
 - Map out the distribution system for oxytocin/EPI.
 - How will oxytocin be distributed through each level in the distribution system?
 - At what point in the distribution system should oxytocin be integrated into the EPI cold chain?
 - Who or what facilities will be responsible for ensuring this integration?
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Transportation

- How is oxytocin transported from the central level to other levels of the health system? How does this compare with vaccines in the EPI cold chain?
 - Who is responsible for providing transport of medicines from the warehouses to the health facilities? How is this done within the EPI supply chain?
 - What mode of transport is used? What is the capacity of the transport vehicles?
 - What is the capacity of the cold chain for EPI?
 - Prior to integration, how will cold chain storage conditions for oxytocin during transport be addressed?
 - Is partnering with private-sector transportation companies an option?
 - At each level of the system, what is the average quantity of oxytocin ordered? How will this impact transportation along with EPI commodities (i.e., capacity levels, resupply)?
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Receipt and Inspection

- If oxytocin and vaccines are supplied by international suppliers, who is responsible for clearing and inspecting the medicines at the port?
- Once the medicines arrive from the port or local supplier, who must inspect the supplies?
- What are the procedures for dealing with damaged or missing items and for ensuring that contract conditions, such as dosage, labeling, packaging, quantity, and storage, are met?
- At the storage and health facilities, who is responsible for receipt and inspection of the products?
- At the point of the health system that integration should happen, who is responsible for ensuring this integration?

Inventory Control and Information Systems

Integration may involve two inventory control or information systems—the one used to track EPI products and the one used to track oxytocin.

- At each level of the health system, who will be responsible for maintaining the stock records for oxytocin?
- At each level of the health system, who will receive reports on stock status of oxytocin? Will the existing reporting and feedback structures need to be modified?
- Will oxytocin be included in EPI stock records and reporting forms, or will it remain separate?
- If any changes in recording and reporting are planned (e.g., inclusion of oxytocin in EPI information systems), will SOPs need to be revised?
- Will EPI SOPs for storage and inventory management cover oxytocin products?
- Will the SOPs need to be revised?

Storage

- Do existing storage facilities have the capacity to include oxytocin?
 - Do the EPI local offices and health facilities have the storage capacity to incorporate oxytocin? If not, what changes to facilities and transport vehicles are needed?
 - What equipment is needed to ensure proper integration of oxytocin into the EPI cold chain at each level of the system (i.e., homologated refrigerators, thermometers, icepacks, and vaccine carriers)?
 - Do facilities at all relevant levels have the proper equipment to integrate oxytocin into the EPI cold chain?
 - If necessary, how will facilities be updated prior to integration (e.g., taking inventory of equipment for the cold chain)?
 - Will the central level provide facilities with homologated refrigerators and temperature control accessories?
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- Will facilities that do not have electricity be provided with solar refrigerators? What else can be done at the lower levels of the system that may not have electricity?
 - What equipment is necessary for distributing oxytocin during transport?
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Delivery/Resupply

- Who will be responsible for calculating the resupply quantities at each level?
 - Who will be responsible for requisitioning oxytocin?
 - Who should receive requisition forms and receipt confirmations?
 - How often should oxytocin be resupplied to health facilities at the different levels (i.e., weekly, monthly, quarterly)? What is the resupply interval for vaccines? Are expiration dates considered when determining optimal resupply levels?
 - What is the storage capacity at each level of the system?
 - What are the cost implications for the resupply intervals (i.e., shorter resupply intervals can increase transport costs while longer intervals may affect storage costs)?
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Dispensing to Patients

- If oxytocin is stored for daily use in the delivery room, who will be responsible for returning unused oxytocin to cold storage?
 - How will the removal of oxytocin from the delivery room be accounted for in stock registers?
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Management Support

Roles and Responsibilities

- Are there SOPs/guidelines for each element of the distribution cycle?
- Do the SOPs/guidelines need to be updated for the facilities, particularly those for EPI, to incorporate oxytocin?
- Are roles and responsibilities clearly defined in the guidelines and SOPs?
- For each step in the distribution cycle, who will be responsible for carrying out the procedures?
- Is the current staffing sufficient to carry out these responsibilities, or will more staff be needed?

Training Needs

- What changes should be made to the roles and responsibilities of relevant personnel?
 - Will these personnel need to be trained?
 - Will training materials need to be developed?
 - Steps that can be taken to address training needs include:
 - Reviewing and updating the training modules
 - Developing the training roll out strategy, including a train the trainer program
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- Training staff and stakeholders involved in the integration of oxytocin into the EPI cold chain
 - Following up with trained staff in the field (through formative supervision) and providing training and refreshers to maintainers of the cold chain

Monitoring and Evaluation

- What indicators need to be tracked? What are the sources of data for each indicator?
 - How will the data/results be used for decision making? Define SMART (specific, measurable, achievable, relevant, and time-bound) indicators; sources of data; and how the data/results will be used.
 - How often will the indicators be reported and data collected? How often will the data be reviewed?
 - Who will be responsible for collecting and submitting the data and to whom?
 - How will the strategy be monitored to ensure that it is functioning properly?
 - How will the strategy be evaluated and when (e.g., at the mid-point of implementation? at the end of implementation)?
 - How will internal monitoring of the integration at facility level be conducted? By whom?
 - How frequently will implementation be supervised or monitored through site visits?
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Remaining Issues

The task force should identify and propose resolutions to any remaining issues that need to be addressed before the integration can begin.

Discussion questions may include:

- Is there anything participants heard that contradicts with what had already been discussed during the workshop?
- Were there any contradictory recommendations made by the different groups?
- Are there other relevant questions based on the content of the group presentations?
- Do any remaining issues need to be resolved before integration?
- How can each issue be resolved? Option include:
 - Discuss it now and agree on a resolution.
 - Assign another group to resolve the issue by a set deadline.

5. **Develop and present a plan to stakeholders to reach consensus**

Based on the discussions and outputs of the workshops, the task force should develop an implementation plan to integrate oxytocin into the EPI cold chain. The implementation plan will include all activities, resources, roles and responsibilities, structures, indicators and means of verification, and costs and an implementation timeline.

The task force should also identify recommendations from past assessments/group work that are relevant to the design of the integration of oxytocin into the EPI cold chain. Members should consider how past recommendations, observations, and discussions may influence the integration of oxytocin into the EPI cold chain and identify additional input for design decisions, needs, and outstanding issues. They should identify any issues that may need to be resolved to finalize the integration design, keeping in mind that the system should be easy to implement to avoid mistakes and work overload.

Once the implementation plan has been developed, it should be presented again to the stakeholders of the working group for any feedback, discussion, suggestions, and approval. This will ensure that all stakeholders agree to the plan and take ownership.

6. **Plan for integration based on the assessment results and workshop discussion**

A broader stakeholders' workshop should be held to present options for integration, achieve consensus on the most feasible recommended options, and develop an action plan for operationalizing recommendations. The stakeholders' workshop should include representatives of the different levels of the health pyramid and NGOs in addition to participants of the task force work sessions.

During the workshop, the results of the oxytocin integration assessment should be shared. Participants should analyze and validate the different options selected by the task force for oxytocin integration into the EPI cold chain and validate the conceptual framework and implementation plan of the selected options for operationalizing this integration.

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