Overcoming barriers to integrating oxytocin into the immunization cold chain at health facilities

Practical Guidance for Policymakers

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Integrating cold chain pharmaceutical products into the Expanded Program on Immunization (EPI) supply chain has been a topic of interest for several years based on potential efficiencies from using the same cold storage and distribution system, and the availability of a growing number of temperature-sensitive pharmaceutical products. The integration of oxytocin into the cold chain has been noted as one product that could deliver notable public health benefits. Although endorsed by global bodies such as WHO and UNICEF,[i] the integration of oxytocin into vaccine cold chain at the facility level has not been taken up systematically.

This brief provides guidance to national level EPI and maternal health decision makers to help address the low-hanging fruit of including oxytocin in the CCE at the facility level[1] and provides evidence to address perceived barriers to integration, and highlights key considerations for successfully integrating oxytocin.

RATIONALE

OXYTOCIN IS A LIFE-SAVING MEDICINE

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality, particularly in low-income countries. It is estimated worldwide that hemorrhage accounts for 27% of maternal deaths; two-thirds of that is classified as PPH.[ii] The impact of maternal deaths goes well beyond that individual mother and causes severe financial, economic and social impact for families and their communities. One study in Ethiopia showed that 80% of infants whose mothers died during childbirth also died within a year.[iii] Additional research documents decreased nutrition and schooling for children throughout their lives.[iv] From a public health perspective, it is essential for mothers to survive childbirth to ensure children and families are safe and healthy.

Oxytocin is a life-saving medicine that is the first option for the prevention and treatment of post-partum hemorrhage. While most countries include oxytocin on their essential medicines list for prevention and treatment of PPH, many countries struggle with ensuring continuous availability of quality oxytocin at service delivery points.

INTRODUCING EFFICIENCIES TO THE SYSTEM

Oxytocin is a heat sensitive product which degrades when it is exposed to high temperatures. It should be maintained between 2˚ and 8˚ Celsius from manufacturer to the end-user at service delivery points. This often does not happen, however, as the supply chains of essential medicines, typically responsible for distributing oxytocin, do not have the equipment required for cold storage at each level of the system and transport throughout the supply chain. One study found that 64% of samples of oxytocin at central stores failed the quality test in ten countries, largely due to the lack of cold chain.[v]

By contrast, the immunization supply chain – often managed separately from the essential medicine supply chain – is designed around ensuring cold chain for vaccines from the point of manufacturer to the end user. Much investment has been made recently into improving the design and manufacturing of cold chain equipment (CCE) as well as ensuring optimal CCE availability in low-income countries through Gavi's Cold Chain Equipment Optimization Platform. Although immunization supply chains continue to have management challenges in terms of equipment maintenance, temperature monitoring, and distribution, among other areas,[vi] CCE that has been installed at a facility for vaccines are often the only CCE available, particularly at smaller facilities.

Integrating health cold chain products into the vaccine supply chain can leverage available equipment for a more efficient system. One analysis of potential products that could be integrated into vaccine storage and distribution determined that oxytocin "presents a particularly strong example" as it has the same cold chain requirements, the forecasting/needs estimation is somewhat predictable, and service delivery points are overlapping between the products at smaller facilities with only one piece of CCE, if managed appropriately, this integration can allow life-saving medicines to reach both mothers and children efficiently and effectively.[vii]

UNDERSTANDING THE ENVIRONMENT

ACKNOWLEDGING POLICY VERSUS PRACTICE

Globally, the WHO/UNICEF Joint Statement from 2014 (and updated in 2020) clarifies that temperature-sensitive products such as oxytocin can be included in the vaccine cold chain where feasible, cost-effective, and best management practices are adhered to.[i] Despite this clear guidance, there has been slow uptake by national immunization programs to adopt and institute this policy.

1 Although this brief only addresses facility-based CCE, oxytocin should be kept cold throughout the supply chain. Other aspects of integration (sub-national warehouses, transport, information management system, etc.) should also be considered when planning.

The reality in practice, however, can be different from the policy. Sub-national immunization staff, and particularly frontline healthcare workers (HCW,) report storing oxytocin in the vaccine cold chain, both at regional walk-in cold rooms, district cold stores, and at the facility level, even without the national directive to do so.[2] This practice is based on the necessity to keep oxytocin cold in order to maintain its potency, the availability of cold chain space in walk-in cold rooms and depots, and the reality that small facilities often only have one piece of cold chain equipment initially purchased for vaccines. It is a common sense practice responding to an immediate need that contributes to public health.[viii]

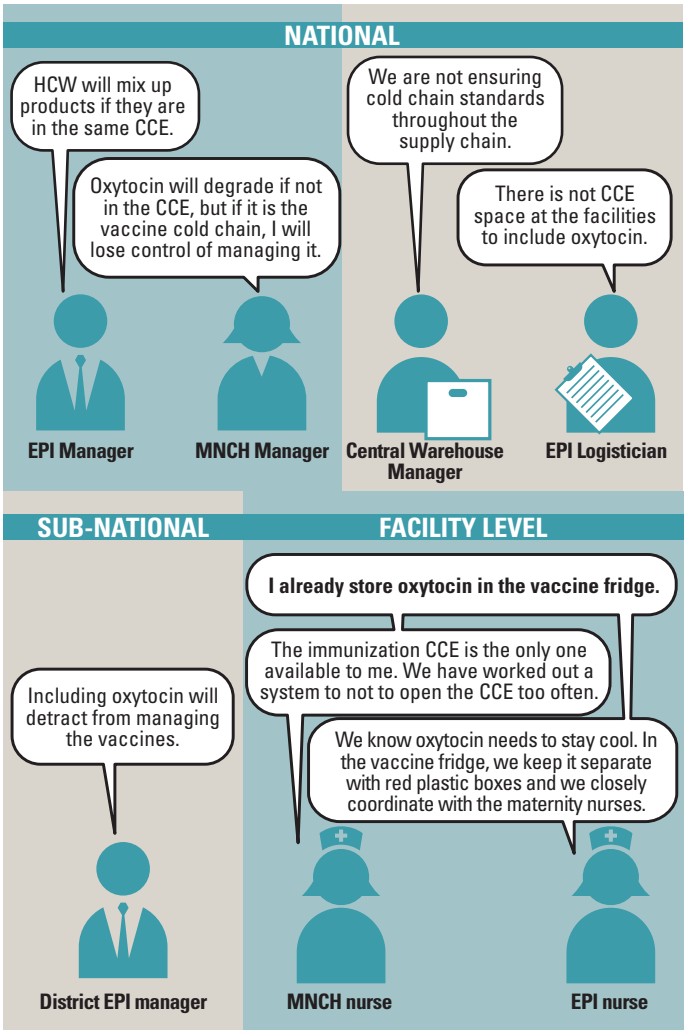
LESSONS FROM THE FIELD

A case study from Mali documented that some facilities have included oxytocin in the vaccine cold chain, even without having clear guidance. The decision was based on the fact that these facilities have only one piece of CCE available, and the directive from the Reproductive Maternal Health program was to keep oxytocin between 2° and 8° C, without explicitly saying to include it in the vaccine CCE.

ENGAGING STAKEHOLDERS

Anecdotally, two reasons are often stated for hesitancy to integrate: 1) concern that frontline healthcare workers (HCW) will mix up the products and accidentally inject a child with oxytocin; and 2) the perception of insufficient cold chain capacity (Figure 1).

Figure 1: Key stakeholder concerns and perspectives



Due to the various stakeholder perspectives and priorities across different programs within the health system, consensus and action to integrate oxytocin into the cold chain has not materialized in many countries to date.

ACTIONS FOR EFFECTIVE INTEGRATION

ENSURING SAFE INTEGRATION

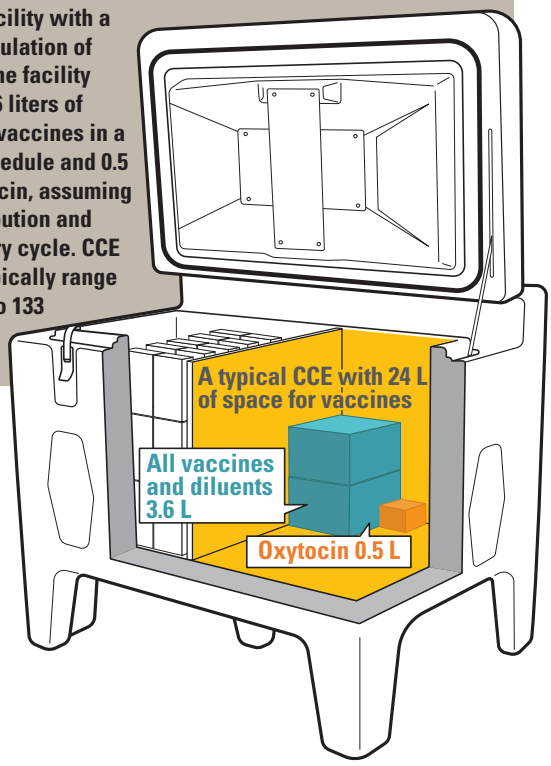
The concern that health workers will confuse oxytocin and vaccines is not unfounded. There have been a few reported cases of HCWs mixing up other cold chain products with vaccines with fatal results.[ix] To avoid dangerous mistakes, HCWs have created job aids and physical nudges to ensure oxytocin is clearly separated from vaccines, even if in the same piece of equipment. Some maternities report that they remove the oxytocin from the vaccine CCE and place it in a separate, small vaccine carrier to make it accessible for daytime and overnight use. This reduces the need to open the vaccine CCE multiple times and allows for access to the drug when and where it is necessary.

ASSESSING STORAGE CAPACITY FOR INTEGRATION

Assessing storage capacity is an important step to understanding the feasibility of integrating oxytocin into the EPI cold chain at facility level. There is often a perception that there may not be enough space in the CCE to accommodate adding oxytocin; however, this is often not the case.

Figure 2: Example of cold chain equipment with estimated storage

For a health facility with a catchment population of 9,800 people, the facility would need 3.6 liters of CCE space for vaccines in a typical EPI schedule and 0.5 liters for oxytocin, assuming monthly distribution and service delivery cycle. CCE in facilities typically range from 24 liters to 133 liters.



An analysis of the immunization supply chain in four African countries[3] showed that more than 75% of CCE at the facility level is using less than 10% of its storage capacity (Figure 3). The results were based on the current immunization schedule in each country and the policy of monthly vaccine deliveries to health facilities, and showed that space would still be available even when including expected population growth (i.e. additional vaccine needs) over the next few years.

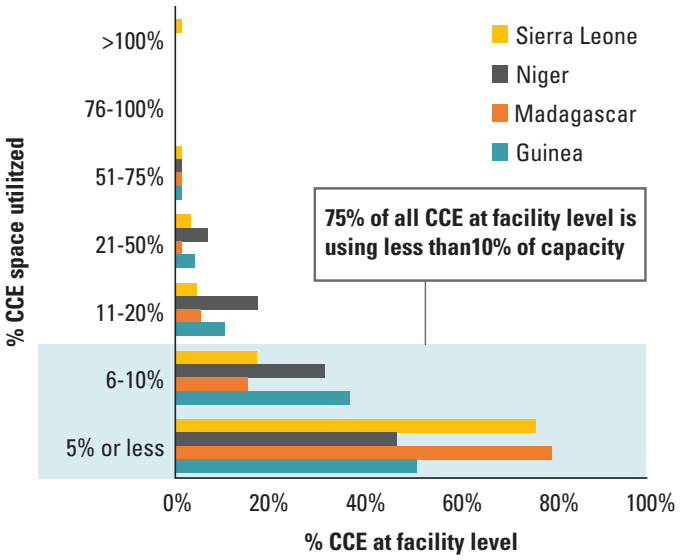
2 Seven out of nine countries surveyed where JSI is working indicated an informal practice of storing oxytocin with vaccines.

3 This CCE analysis was completed for all equipment in 2020 for Sierra Leone, Madagascar, Guinea and Niger as part of a larger system design analysis.

Two of those countries also considered the addition of oxytocin into the existing CCE of facilities providing maternity services. Results showed that storing both vaccines and oxytocin would still use no more than 50% of the CCE storage capacity.

CCE capacity would need to be assessed based on each country's protocols for vaccine distribution and potential new vaccines to be introduced, which can be done through EPI and maternal health program analysis.

Figure 3. Analysis of CCE space utilization in four countries shows sufficient space for vaccines at the facility level



Source: Results of system design analysis

KEY CONSIDERATIONS FOR INTEGRATING OXYTOCIN AT HEALTH FACILITY LEVEL

Integrating oxytocin into the vaccine cold chain can be a multi-layered process that requires coordination across health programs, clarifying new lines of authority, and aligning priorities and even language across programs and supply chains. It also must be tailored must be tailored to the country's context.[x] As noted above, oxytocin is already being stored in CCE in facilities in an ad hoc way; formalizing this practice can ensure that best management practices are understood and adhered to.

KEY CONSIDERATIONS:

- Align priorities
- Manage changes in cold chain capacity needs
- Address safety through standardizing clear labeling and separation of products
- Develop standard management practices
- Monitor implementation
- Consider long-term planning

ALIGN PRIORITIES

Moving this conversation forward requires bringing together stakeholders who are not typically obligated to coordinate closely, particularly at national level. Decision makers and leaders from immunization, maternal health programs, and the medical supply chain agency must understand the rationale of integrating oxytocin into the vaccine cold chain and agree that the benefits are worth the effort to change. Sub-national level managers and frontline HCW should also be engaged in this discussion. Integration of various Maternal, Newborn and Child Health (MNCH) interventions, especially at the service delivery point, is one of the declared priorities in many countries. Integrating oxytocin and vaccines can become a great practical example.

While there are challenges to aligning priorities of various stakeholders across different programs and levels of the health system, it is a critical first step to successfully instituting policies and guidelines. With proper advocacy, analysis, planning, and leadership, stakeholders can can identify steps and procedures to reduce risks and address stakeholder concerns.

MANAGE CHANGES IN COLD CHAIN CAPACITY NEEDS

Even as the evidence suggests that smaller facilities have sufficient CCE space, needs and any potential gaps must be calculated for current equipment capacity if oxytocin is included. Stakeholders can use the CCE inventory or the CCE Gap Analysis tool to estimate the space required for oxytocin, coordinating with the maternal health department for forecasting and need estimation. Decision makers must consider expected population growth and any planned new vaccine introductions in the coming years. Vaccine campaigns also require special consideration for CCE as large quantities of vaccines are required for specific time periods.

Within facilities, it is often only the immunization nurse who has access to the vaccine CCE. This reduces accessibility to the maternity ward, particularly at night and on the weekends when immunization services are not provided. Vaccine carriers can be used for immediate use of oxytocin (as well as birth dose vaccination) to reduce the number of times the CCE would need to be opened during the day to access oxytocin. Clear standard operating procedures, roles and responsibilities can ensure best management practices and access to the CCE.

As this practice of including oxytocin into the vaccine cold chain often happens in an ad hoc manner already, the EPI and maternal health programs should seek input into CCE capacity issues and any best practices related to reducing any risks of mismanagement from sub-national level supply chain managers and HCW.

ADDRESS SAFETY THROUGH STANDARDIZING CLEAR LABELING AND SEPARATION OF PRODUCTS

Oxytocin vials look very similar to vaccine vials, which fuels the concern of potentially mixing up the products. To avoid this confusion, some facilities use separate colored plastic containers for oxytocin in the CCE to clearly create a separation of products. Job aids and reminders should be developed with the facility level staff to make it more meaningful to them.

DEVELOP STANDARD MANAGEMENT PRACTICES

With this change, all personnel working in a facility or sub-national warehouse using an integrated cold chain approach should be trained on the new product and best supply chain management practices for it. General Standard Operating Procedures (SOPs) should be developed by immunization and maternal health stakeholders, and then adapted at the facility level. All aspects of the management of both vaccines and oxytocin should be considered and updated. There is no one-size fits all approach; it must be tailored to the specific country and even sub-national level context.

Some questions can guide the planning process:

Storage management	• At national and sub-regional storage sites, who is responsible for tracking stock of oxytocin? • Will this role shift if it is integrated? • How will the two programs coordinate?
Distribution coordination	• Who plans distribution of vaccines from national to sub-national levels? • Who will coordinate with the transport team and both immunization and maternal health teams? • When going from the facility to collect vaccines from the district/sub-national level, will the HCW also collect oxytocin at the same time?
Access to the CCE at the facility level	• Does any role and responsibility need to be changed to allow for access to oxytocin even at night and the weekends? • Are there other job aids needed that can be put in place to facilitate this, such as using cold boxes for immediate use of oxytocin in the maternities?
Monthly reports and stock requests	• Does keeping oxytocin in the vaccine CCE change any tracking or changing of monthly reports and stock requests? • Who ensures there is no stockout of oxytocin?
Supervision and training	• Which supervision checklists may need revision? • Which program is responsible for supervision, such as ensuring safe separation/labeling of EPI vs oxytocin products? • Which standard trainings may need revision? What is the plan for training HCWs? • What job aids may need to be developed and distributed to facility level? • What peer-to-peer learning opportunities can be used to reinforce proper practices?

MONITOR IMPLEMENTATION

As with any changes, special attention should be provided to monitor the implementation and adherence to this new policy, and particularly to prevent any impact or negative consequences due to this change. Consider complementing on-going monitoring with a more in-depth evaluation after three months of implementation.

Specific metrics to track for monitoring:

- Doses of oxytocin administered
- Stockouts of vaccines and oxytocin
- Maternal deaths
- Vaccine coverage
- Reported adverse events following immunization (AEFI)
- Any reports of mixing up oxytocin and vaccines

Plan for follow-up training or peer-to-peer learning to strengthen adherence to the new policy and share lessons learned of how to reduce the risk and ensure best management practices. During supervision visits and on-going monitoring, note where there may be gaps in performance, understanding or adherence to the policy.

CONSIDER LONG-TERM PLANNING

The health system is a constantly evolving entity. As new vaccines are developed and introduced, as populations grow and shift geographically, and as expanded cold chain pharmaceutical products are developed, cold chains will have to adjust, shift and expand in different ways. Many of the current best practices related to the vaccine cold chain will be paramount to ensuring quality cold chain pharmaceutical products. Best practices include regularly updating the country's cold chain inventory, developing a budgeted CCE maintenance plan, and training capable technicians who have access to spare parts and other required resources for CCE maintenance. Countries may also consider expanding the availability of CCE if funds permit, optimizing the CCE use and placement through supply chain system design, and strengthening the collaboration across health areas, recognizing that cold chain needs may grow.

FINAL CONSIDERATION

The Immunization Agenda 2030 highlights the importance of integration and collaboration with stakeholders across health areas.[xi] This provides an opportune moment for decision makers to systematize the integration of oxytocin into CCE at health facilities and provide clear guidance and procedures in order to reduce the risks associated with having non-vaccine products in the vaccine cold chain and significantly increase health benefits from the vaccine cold chain.

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