



Quality Assurance of Life-Saving Oxytocin through its Integration into the EPI Cold Chain: The Importance of Stakeholder Engagement

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RHSC Innovation Grant awarded to MSH



Background

- Oxytocin is heat sensitive
- It must be maintained at a temperature between 2 and 8° C throughout the supply chain, with only brief exposure to higher temperatures, to ensure its potency and effectiveness
- Cold chains for essential medicines are usually weak, and average ambient temperatures is higher than 25° C
- Doubts on quality of oxytocin
- Expanded Program of Immunization (EPI) has dedicated resources and functional cold chains reaching all facilities
- WHO and UNICEF agreement (May 2015): Temperature-sensitive health products in the EPI cold chain





Stakeholder Engagement

Tailor approach to address resistance and concerns to increase chance of acceptance and success

Stakeholders involved in:

- Initial mapping
- Developing options (small group)
- Validating and selecting options (wider group)
- Planning (select group)



Strengths

- Good and well-maintained vaccine cold chain infrastructure with efficient supply and information systems
- Experienced vaccine staff at all health facility levels

Weaknesses

- Inadequate/no fridges in maternity department in many facilities
- Product specifications are not standardized across counties
- Not all counties/HFs aware of opportunity in policy
- Frequent stock-outs of oxytocin
- Maternity staff need to coordinate with vaccine staff for out-of-hours supply
- Inadequate capacity of maternity staff to manage oxytocin cold chain

Opportunities

- Exception in vaccine policy allows for authorization in “disadvantaged” low-level facilities
- Some vaccine stores in subcounty depots already keep oxytocin in the fridge—plenty of available, separate fridge space
- At lower levels, few staff handle medicines and vaccines, so integration is easier
- Occasional use of the same cold chain infrastructure in health centers to store and transport oxytocin and vaccines
- Capacity of cold-chain experienced vaccine staff to manage oxytocin

Threats

- 2013 policy guideline document states no pharmaceutical products to be stored in EPI cold chain
- High-level resistance to integrating the supply chain both at the national level and from the central medical stores (KEMSA)
- Maternity staff fear loss of control of oxytocin management
- Need to be able to distinguish between oxytocin and vaccines to avoid mix-ups and potential adverse events
- High potential for confusion between vaccine diluent and oxytocin
- Parallel supply chains for essential medicines and vaccines
- Vaccines donor funded while oxytocin is purchased and sold to counties



Strengths

- Good vaccine cold chain infrastructure with efficient supply and information systems
- Presence of the CMST, which can play a coordination role to harmonize the two supply chains for vaccines and medical supplies
- **CMST delivers medicines and supplies directly to facilities**

Weaknesses

- No fridges in maternity department and majority of health facilities in rural areas lack electricity for fridges
- **Product specifications are not standardized across districts**
- **Inadequate knowledge at both the national and district levels on the storage of oxytocin. Many people think the oxytocin in use now does not need storage in a refrigerator**
- Procurement sources are different—vaccines through UNICEF and oxytocin procured through the CMST
- Frequent stock-outs of oxytocin
- Drug pilferage
- Lack of trust for vaccine staff to manage oxytocin
- Maternity staff need to coordinate with vaccine staff for out-of-hours supply
- **Weak monitoring of oxytocin storage in facilities.**

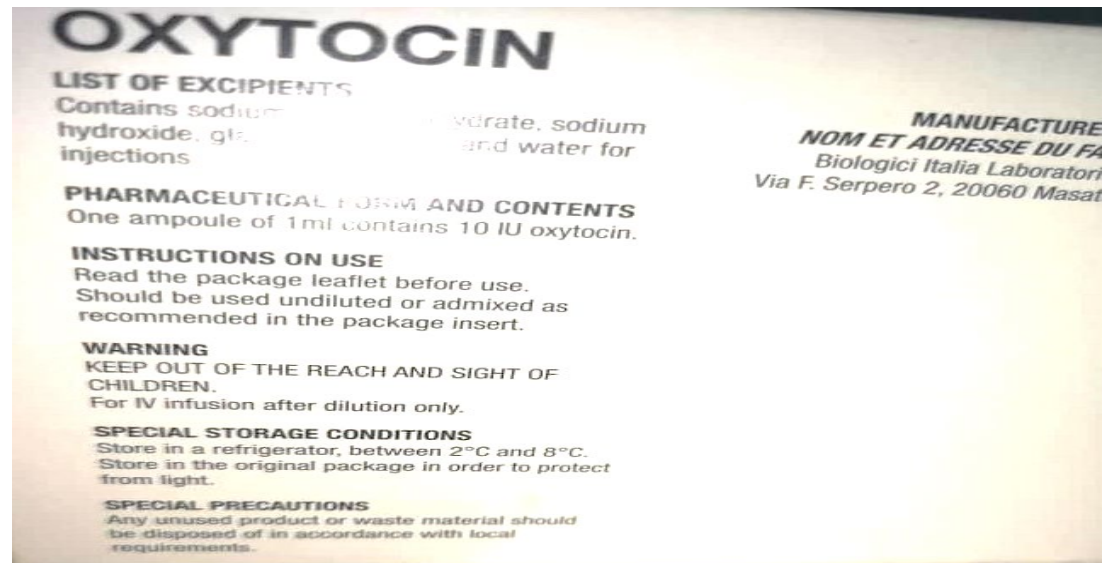
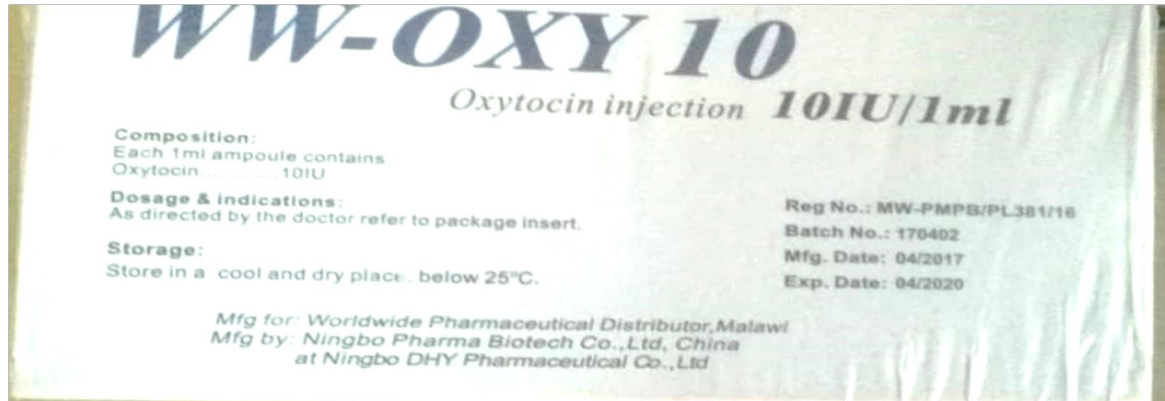
Opportunities

- **There is a plan to harmonize supply chains for vaccines and medical supplies**
- Occasional use of the same cold chain infrastructure in health centers to store oxytocin and vaccines

Threats

- **Policy taken to procure heat-stable oxytocin as solution to lack of fridges and power**
- **EPI policy states no other products to be stored in EPI cold chain.**
- High-level resistance at the national level, especially to integrating the supply chain from the central level at CMST
- Maternity and EPI staff fear loss of control
- Confusion between vaccine diluent and vaccine with oxytocin
- Parallel supply chains for medicine and vaccines. Vaccines donor funded and oxytocin purchased and sold to districts

Malawi: Two Types of Oxytocin in the System





Uganda SWOT Analysis

Strengths

- Adequate stakeholder engagement at national level within reproductive health stakeholders
- 2017 policy directive permits integration of oxytocin into vaccine cold chain
- Good vaccine cold chain infrastructure with efficient supply and information systems
- NMS distributes medicines to districts, and third-party providers distribute to health facilities
- Vaccines and oxytocin both tracked and reported on in the HMIS (DHIS2)
- EPI supervision guidelines revised to include co-storage of oxytocin and vaccines

Weaknesses

- Poor dissemination of policy directive
- Job aid developed to guide implementation at health facility level but not disseminated
- Where facilities lack fridges, oxytocin is stored at room temperature
- Fridges often lacking in labor wards, especially when health facility has no fridge
- Confusion caused by cold chain supervisors giving different messages about integration
- Third-party distributors to health facilities may lack cold chain capacity
- Oxytocin used only up to HC3, while vaccines go to lower-level facilities

Opportunities

- New positive, energetic EPI program manager supports integration
- NMS handles both medicines and vaccines and has adequate cold chain transportation facilities
- NMS willing to integrate distribution of oxytocin and vaccines pending MoH directive
- Pilot distribution of vaccines to health facilities from districts through third-party transporters contracted by NMS
- Some facilities already handle oxytocin with vaccines
- Procurement of 600 fridges with oxytocin chambers

Threats

- Limited stakeholder engagement and participation from EPI program managers and cold chain supervisors
- Resistance among cold chain assistants at district level
- Parallel supply chains for medicine and vaccines
- Health facilities order oxytocin off a credit line managed at NMS, while vaccines are free



Resource Considerations

Infrastructure

- Fridge capacity is adequate to add oxytocin? (keep in box - bulky)
- Transport using cold chain conditions (e.g., KEMSA-contracted third-party transporters with refrigerated vehicles)

Human

- Overload of staff managing the vaccines at the facility
- Oxytocin should be managed by qualified personnel
- Capacity building of cold chain management

Financial

- Using existing fridges if capacity is sufficient represents economies of scale
- Vaccines primarily donor funded and oxytocin purchased with government funds
- Need adequate funding for oxytocin

Information

- Solid information systems for vaccines
- Information systems for essential medicines are frequently fragmented and not fully functional



Feasibility and acceptability

	Kenya	Malawi	Uganda
Mean feasibility*	1.78	1.86	2
Mean acceptability*	1.76	1.53	2.5
Readiness of staff from partners **	N/A	1	N/A
Availability of funding**	N/A	0	N/A
Policy support**	0	0	1
Total	3.54/7 (50%)	4.39/9 (48%)	5.5/7 (78%)

* Scale of 3 to 0

** yes or no 1/0



Summary

- Kenya: Strong resistance at national level; strengthen existing cold chain for essential medicines
- Malawi: Has policy in place to procure non refrigerated product but no cold chain storage policy; evidence needed on oxytocin quality and effectiveness to determine if policy change is needed
- Uganda: Political will; guidance needed for implementation; support for implementation (e.g., procurement of fridges with oxytocin compartment)



Thank you