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

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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)
### Kenya SWOT analysis

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Good and well-maintained vaccine cold chain infrastructure with efficient supply and information systems</td>
<td>- Inadequate/no fridges in maternity department in many facilities</td>
</tr>
<tr>
<td>- Experienced vaccine staff at all health facility levels</td>
<td>- Product specifications are not standardized across counties</td>
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<tr>
<td></td>
<td>- Not all counties/HFs aware of opportunity in policy</td>
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<td></td>
<td>- Frequent stock-outs of oxytocin</td>
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<tr>
<td></td>
<td>- Maternity staff need to coordinate with vaccine staff for out-of-hours supply</td>
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<tr>
<td></td>
<td>- Inadequate capacity of maternity staff to manage oxytocin cold chain</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Exception in vaccine policy allows for authorization in “disadvantaged” low-level facilities</td>
<td>- 2013 policy guideline document states no pharmaceutical products to be stored in EPI cold chain</td>
</tr>
<tr>
<td>- Some vaccine stores in subcounty depots already keep oxytocin in the fridge—plenty of available, separate fridge space</td>
<td>- High-level resistance to integrating the supply chain both at the national level and from the central medical stores (KEMSA)</td>
</tr>
<tr>
<td>- At lower levels, few staff handle medicines and vaccines, so integration is easier</td>
<td>- Maternity staff fear loss of control of oxytocin management</td>
</tr>
<tr>
<td>- Occasional use of the same cold chain infrastructure in health centers to store and transport oxytocin and vaccines</td>
<td>- Need to be able to distinguish between oxytocin and vaccines to avoid mix-ups and potential adverse events</td>
</tr>
<tr>
<td>- Capacity of cold-chain experienced vaccine staff to manage oxytocin</td>
<td>- High potential for confusion between vaccine diluent and oxytocin</td>
</tr>
<tr>
<td></td>
<td>- Parallel supply chains for essential medicines and vaccines</td>
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<tr>
<td></td>
<td>- Vaccines donor funded while oxytocin is purchased and sold to counties</td>
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</tbody>
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### Malawi SWOT Analysis

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Good vaccine cold chain infrastructure with efficient supply</td>
<td>• No fridges in maternity department and majority of health facilities in rural areas lack electricity for fridges</td>
</tr>
<tr>
<td>and information systems</td>
<td>• Product specifications are not standardized across districts</td>
</tr>
<tr>
<td>• Presence of the CMST, which can</td>
<td>• 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</td>
</tr>
<tr>
<td>play a coordination role to</td>
<td>• Procurement sources are different—vaccines through UNICEF and oxytocin procured through the CMST</td>
</tr>
<tr>
<td>harmonize the two supply chains for vaccines and medical supplies</td>
<td>• Frequent stock-outs of oxytocin</td>
</tr>
<tr>
<td>• CMST delivers medicines and</td>
<td>• Drug pilferage</td>
</tr>
<tr>
<td>supplies directly to facilities</td>
<td>• Lack of trust for vaccine staff to manage oxytocin</td>
</tr>
<tr>
<td></td>
<td>• Maternity staff need to coordinate with vaccine staff for out-of-hours supply</td>
</tr>
<tr>
<td></td>
<td>• Weak monitoring of oxytocin storage in facilities.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>• There is a plan to harmonize supply chains for vaccines and medical</td>
<td>• Policy taken to procure heat-stable oxytocin as solution to lack of fridges and power</td>
</tr>
<tr>
<td>supplies</td>
<td>• EPI policy states no other products to be stored in EPI cold chain.</td>
</tr>
<tr>
<td>• Occasional use of the same cold chain infrastructure in health</td>
<td>• High-level resistance at the national level, especially to integrating the supply chain from the central level at CMST</td>
</tr>
<tr>
<td>centers to store oxytocin and vaccines</td>
<td>• Maternity and EPI staff fear loss of control</td>
</tr>
<tr>
<td></td>
<td>• Confusion between vaccine diluent and vaccine with oxytocin</td>
</tr>
<tr>
<td></td>
<td>• Parallel supply chains for medicine and vaccines. Vaccines donor funded and oxytocin purchased and sold to districts</td>
</tr>
</tbody>
</table>
Malawi: Two Types of Oxytocin in the System

WW-OXY 10
Oxytocin injection 10IU/1ml

Composition:
Each 1ml ampoule contains Oxytocin 10IU

Dosage & indications:
As directed by the doctor refer to package insert.

Storage:
Store in a cool and dry place: below 25°C.

Reg No.: MW-PMPB/PL381/16
Batch No.: 170402
Mfg. Date: 04/2017
Exp. Date: 04/2020

Mfg for: Worldwide Pharmaceutical Distributor Malawi
Mfg by: Ningbo Pharma Biotech Co., Ltd. China
at Ningbo DHY Pharmaceutical Co., Ltd

PHARMACEUTICAL FORM AND CONTENTS
One ampoule of 1ml contains 10 IU oxytocin.

INSTRUCTIONS ON USE
Read the package leaflet before use.
Should be used undiluted or admixed as recommended in the package insert.

WARNING
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
For IV infusion after dilution only.

SPECIAL STORAGE CONDITIONS
Store in a refrigerator, between 2°C and 8°C.
Store in the original package in order to protect from light.

SPECIAL PRECAUTIONS
Any unused product or waste material should be disposed of in accordance with local requirements.
### 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

<table>
<thead>
<tr>
<th></th>
<th>Kenya</th>
<th>Malawi</th>
<th>Uganda</th>
</tr>
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<tbody>
<tr>
<td>Mean feasibility*</td>
<td>1.78</td>
<td>1.86</td>
<td>2</td>
</tr>
<tr>
<td>Mean acceptability*</td>
<td>1.76</td>
<td>1.53</td>
<td>2.5</td>
</tr>
<tr>
<td>Readiness of staff from partners **</td>
<td>N/A</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Availability of funding**</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Policy support**</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>3.54/7</td>
<td>4.39/9</td>
<td>5.5/7</td>
</tr>
</tbody>
</table>

(50%)

(48%)

(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