Innovations to Improve the Quality of Oxytocin and Other MH Drugs

Maternal Health Supplies Caucus Meeting
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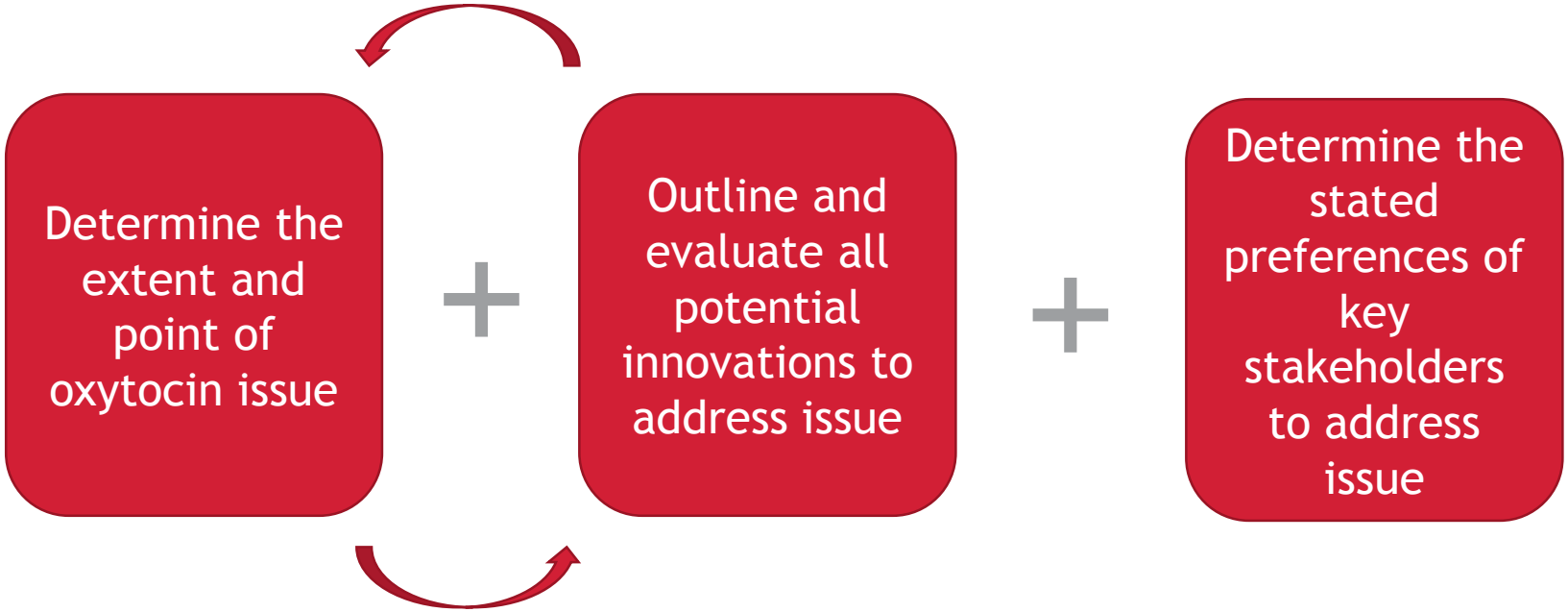
The fundamental challenge to improving the quality of Oxytocin and other MH Drugs

Given today's landscape of existing and emerging solutions to address oxytocin quality - how do we choose an appropriate solution?

1. Activities to Date
2. Research in Process
3. The Path Forward

3 The Path Forward



1

Activities to Date

Oxytocin Quality Stakeholders Meeting Objectives *April 8th, 2015 in Washington DC*

1. Achieve a shared, comprehensive understanding among global stakeholders of completed, ongoing, or planned work within oxytocin quality
2. Identify and summarize current gaps in research efforts
3. Map direction and next steps

Source: April 8th Oxytocin Quality Stakeholders Meeting, USAID-Accelovate

1

Activities to Date

Measuring Oxytocin Quality

In-country studies: Ghana and Indonesia (USP-PQM)	• Assess quality and storage conditions across levels of the health system • Measurement of: Market Authorization, Assays for API, Storage Practice, Sterility
Oxytocin Injection: Thermal Stability Studies (SCMS)	• Oxytocin stability test using HLPC over 4 months for (a) room temperature and (b) 40C conditions from 3 manufacturers
Oxytocin Stability Data (Path)	• Oxytocin stability from 2 manufacturers • Formal stability study that measured potency and also pH, impurities, sterility, endotoxins

Source: April 8th Oxytocin Quality Stakeholders Meeting, USAID-Accelovate

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Activities to Date

Measuring Oxytocin Quality

Stability of Oxytocin along Supply Chain (WHO)	• Evaluate temperature variations across the supply chain and see if temp/storage affects the potency of active ingredient in
Systematic Revie of Oxytocin Quality (WHO)	• Extracted information from 7 studies/reports to assess relationship between quality of oxytocin and supply chain
Oxytocin Stability Study (Merck for Mothers)	• Compliment other studies by generating forced stress results on the same product in the field; degradation kinetics

Source: April 8th Oxytocin Quality Stakeholders Meeting, USAID-Accelovate

1

Activities to Date

Systems Approaches to Improved Oxytocin Quality

Oxytocin and Misoprostol Quality (Concept)	• Quality study in Nepal • Complemented by work to establish Prequalification of Oxytocin (n=2)
Randomized Cluster Trial Comparing Approaches (Gynuity)	• Randomized cluster trial comparing use of 2 prophylactic approaches (oral misoprostol vs. oxytocin in Unject) in community-level births in Senegal
Integrating Oxytocin into the EPI Cold Chain (MSH)	• Map distribution of Oxytocin in Mali from central to service delivery and document cold chain, possible points of integration, challenges

Source: April 8th Oxytocin Quality Stakeholders Meeting, USAID-Accelovate

1

Activities to Date

Innovations for Improved Oxytocin Quality

PharmaChk (Boston University)	• Portable tool to quality of oxytocin in field-level conditions
Carbetocin (Merck for Mothers)	• Heat-stable oxytocin analog that can be used for PPH management and treatment
Other Innovations	• Sub-lingual oxytocin (Path) • Inhalable oxytocin (Monash University) • Heat-resistant and non-invasive oxytocin (Mintaka Foundation for Medical Research)

Additionally, Accelovate landscape found 36 innovations across 7 different categories – constantly being updated

Source: April 8th Oxytocin Quality Stakeholders Meeting, USAID-Accelovate

Recommendations for Oxytocin stakeholders

- Incentivizing **procurement and manufacturing of quality-assured oxytocin**, including pre-qualified formulations
- Reviewing **oxytocin labeling** issues
- Address interrupted **cold chain** during supply/storage
- Invest in **health systems strengthening** and training of health workers
- Consider **feasibility/ acceptability** of oxytocin quality solutions and innovations

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Research in Process

Choose the appropriate solution by identifying priorities of key stakeholders in charge of implementation – **stated preference methodology**

1. Assess key attributes and levels for various oxytocin quality interventions along supply chain
2. Get both qualitative and quantitative data
3. Achieve an empirical way to quantify the preferences of MH stakeholders, using targeted exercises and research tools
4. Compare preferences across different sub-groups
5. Determine preferred allocation of resources to intervention areas

2

Research in Process

Three phases of evaluation

1. Data collection: Qualitative Interviews
2. Quantitative Instrument Development and Consultation
3. Data collection: Stated Preference Exercise + Resource Allocation Game

3 The Path Forward

Determine the extent and point of oxytocin issue

+

Outline and evaluate all potential innovations to address issue

+

Determine the stated preference of key stakeholders to address issue

???

Advocacy
Information Sharing
Coordination
Introducing Products
Market Dynamics
ETC

Questions?

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