Getting Magnesium Sulphate to the Women Who Need It: Global, National, and Local Processes

Wednesday, March 29, 2017
9 a.m. EST
Ending Eclampsia seeks to expand access to proven, under-utilized interventions and commodities for the prevention, early detection, and treatment of pre-eclampsia and eclampsia and strengthen global partnerships.
CHALLENGES IN PROCUREMENT OF MAGNESIUM SULFATE

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March 29, 2017
STEPS IN THE PROCUREMENT CYCLE

Selection

Consumption data collection

Distribution

Procurement process

Quantification
Policy harmonization:
- Essential medicines list and standard treatment guidelines are aligned and products are registered

WHO recommended presentation is 50% weight/volume equivalent to 0.5 g in 1 mL
1. Determine the scope of the quantification
   What types of facilities are currently authorized to administer magnesium sulfate?
   How many of these facilities are to be supplied with the planned procurement?

2. Calculate the target population that will be given magnesium sulfate for the prevention and treatment of PE/E
   Depends on standard treatment guidelines
   Should be available in all facilities where women give birth
   In absence of data on number of cases, assumption must be made
3. Calculate the amount of magnesium sulfate needed for each case for the prevention and treatment of PE/E/establish standard or average treatment regimen

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<tr>
<th></th>
<th>Pritchard</th>
<th>Zuspan</th>
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<tbody>
<tr>
<td><strong>Dose required</strong></td>
<td>44 g</td>
<td>28 g</td>
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<tr>
<td><strong>Number of ampoules</strong></td>
<td>1 g / 2 mL</td>
<td>44</td>
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<tr>
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<td>5 g / 10 mL</td>
<td>9</td>
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4. Calculate the quantity of magnesium sulfate needed for prevention and treatment of PE/E for the forecast period
PROCUREMENT PROCESS

• Supply
  1 WHO prequalified product
  over 35 manufacturers worldwide

• Decentralized procurement
  Increased training needs
  Price implications?
  Quality assurance?
Need to ensure magnesium sulfate is available at every facility where women give birth at all times
  - Distinguish facilities that manage loading dose vs those that provide full treatment
  - Ensure minimum stock and prepare for potential wastage
DATA COLLECTION

Lack of data affects entire procurement cycle!

• No data on morbidity
  – Number cases of pre eclampsia/eclampsia typically not captured in health information systems

• No data on consumption of magnesium sulfate
  – Not included in many countries’ logistics management information systems
RESOURCES

http://www.lifesavingcommodities.org/

Supplies Information Database
THANK YOU!

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Toward WHO PreQualification of MgSO4 products

Alessandra Tomazzini & Fabienne Bochaton
MgSO4
An Essential Medicine – A Life-saving Commodity

- MgSO4 is part of WHO’s EML and is the recommended medicine for the prevention and treatment of pre-eclampsia and eclampsia. WHO also added it to the EOI invitation list of its PQ programme in 2006.

- It has been identified by the UNCoLSC as a life-saving commodity to be more widely spread to prevent avoidable maternal deaths.
Identification of Suitable Manufacturers

- Assessment of manufacturers’ technical ability to achieve WHO PQ:
  - Questionnaire
  - On-site visit

- Assessment of their willingness to go through WHO PQ process:
  - Showing there is a market
  - Interest in serving the public sector of Lower and Middle Income Countries
  - Commitment from management

- Assessment of the level of assistance to be provided
Support Toward WHO PQ

- WHO PQ program: Overview

- WHO PQ is a programme that was established in 2001 to make quality priority medicines available for the benefit of those in need.
- It provides a list of products (APIs and FPPs) that meet WHO-recommended norms and standards of quality, efficacy and safety.
- The list is used to guide UN agencies for procurement decisions or any organization involved in bulk purchasing of medicines (at country level, or at international level).
- PQ team also prequalifies quality control laboratories and provides technical assistance and training activities to regulators
  - manufacturers and quality control laboratories.
Support Toward WHO PQ (Cont’d)

- WHO PQ
- Process
- Guidance and instructions can be found on WHO website: https://extranet.who.int/prequal/

Support Toward WHO PQ (Cont’d)

• Stability testing

- The product should meet the recommendations as described in the guidelines for stability testing (long-term data at 30°C ± 2°C & 75% RH ± 5% RH – Climatic Zone IV b)
In Brief

- A WHO PQed MgSO4 product is:
  - A medicine that complies with **international standards of quality, safety and efficacy**
  - A medicine whose quality, safety and efficacy is **maintained over time** through regular assessments
  - A medicine that is **adapted** to the needs of LMICs
  - A medicine that can participate in **WHO CRP**
  - A medicine that can participate in **international tenders**
  - A medicine that, in addition to being quality-assured, is **affordable** for LMICs’ public health sector
WHO PQed and ERP Approved MgSO4 Products Currently Available

- 1 WHO PQed product:
  - Inresa Arzneimittel GmbH, Germany
  - Another 3 companies with dossier under assessment

- 2 ERP approved products:
  - JSC Kalceks, Latvia
  - Demo SA, Greece
THANK YOU!

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BARRIERS TO MANAGING PRE-ECLAMPSIA AND ECLAMPSIA IN PRIMARY FACILITIES: BANGLADESH, NIGERIA, & PAKISTAN

Gloria Adoyi
March 29, 2017
Background

- Pre-eclampsia and eclampsia (PE/E) is the second largest contributor to maternal mortality globally.
  - 1\textsuperscript{st} in Nigeria
  - 2\textsuperscript{nd} in Bangladesh
  - 3\textsuperscript{rd} in Pakistan

- For treatment and management, magnesium sulphate (MgSO\textsubscript{4}) is the gold standard.

- Low service utilization and improper use of MgSO\textsubscript{4} are major challenges to providing adequate PE/E services.
MgSO$_4$ availability, accessibility, and affordability

- Despite being on the essential medicines list, MgSO$_4$ is not always procured

- Inadequate knowledge of the procurement process

- MgSO$_4$ is not readily available at primary health centers (PHCs), though it is often in stock at hospitals
  - Especially in states without donor support

- Although inexpensive, cost was a reason for not keeping MgSO$_4$ in stock
Medical officers that know the correct loading dose:
- Pakistan: 54.5%
- Bangladesh: 35.4%
- Nigeria: 25.7%

Other health providers that know the correct loading dose:
- Pakistan: 20%
- Bangladesh: 1.4%
- Nigeria: 20%

Medical officers that know the correct maintenance dose:
- Pakistan: 54.5%
- Bangladesh: 36.7%
- Nigeria: 8.6%

Other health providers that know the correct maintenance dose:
- Pakistan: 20%
- Bangladesh: 0.5%
- Nigeria: 18.8%
Availability of MgSO$_4$ at facilities (%)
Other barriers to use (all countries)

- Dosage discrepancies
- Cost
- Lack of referral system
Conclusions

• Service providers lack knowledge of loading and maintenance dose of MgSO₄, and signs of toxicity

• PHC service providers are not confident to administer the loading dose of MgSO₄

• PHC facilities not equipped with essential equipment and commodities (MgSO₄)

• Low use of MgSO₄ at PHC level
Recommendations

• Review of service providers’ curricula at PHCs

• Trainings for task shifting to lower-level providers

• Strengthened referral systems

• Simple job aids for MgSO₄ use

• Simplified administration of MgSO₄ will build confidence in service providers to use the drug

• Simplified dosing and single dose packaging

• Engage national and state stakeholders to ensure quality MgSO₄ is procured and distributed

• Local manufacturing of MgSO₄
THANK YOU!