

Translating Global Policy Into Country Action: MgSO₄ case study

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Our goal is increased access to *quality-assured* essential medicines



Our work is guided by three core truths *(cont'd)*

RMNCH ***product availability and access is essential*** to the uptake of essential clinical interventions

Barriers that threaten access to essential RMNCH supplies are systemic and also specific to each product

Starting point is ***developing global standards*** then translating them into country action through revised ***national policies***

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Specific **Barriers** to access of quality-assured MgSO₄

MgSO₄ specific barriers to access:

1. Lack of demand among health workers
2. Priority formulation not included in the national Essential Medicines List
3. Lengthy and complicated market authorization process
4. Unverified business case
5. No WHO pre-qualified product

(1) Addressed by health worker training, strong program implementation

(2,3) Addressed by global standards and national regulatory environments

(4,5) Addressed by market shaping **

Specific **Barriers** to access of quality-assured MgSO_4

MgSO₄ specific barriers to access:

1. Lack of demand among health workers
2. Priority formulation not included in the national Essential Medicines List
3. Lengthy and complicated market authorization process
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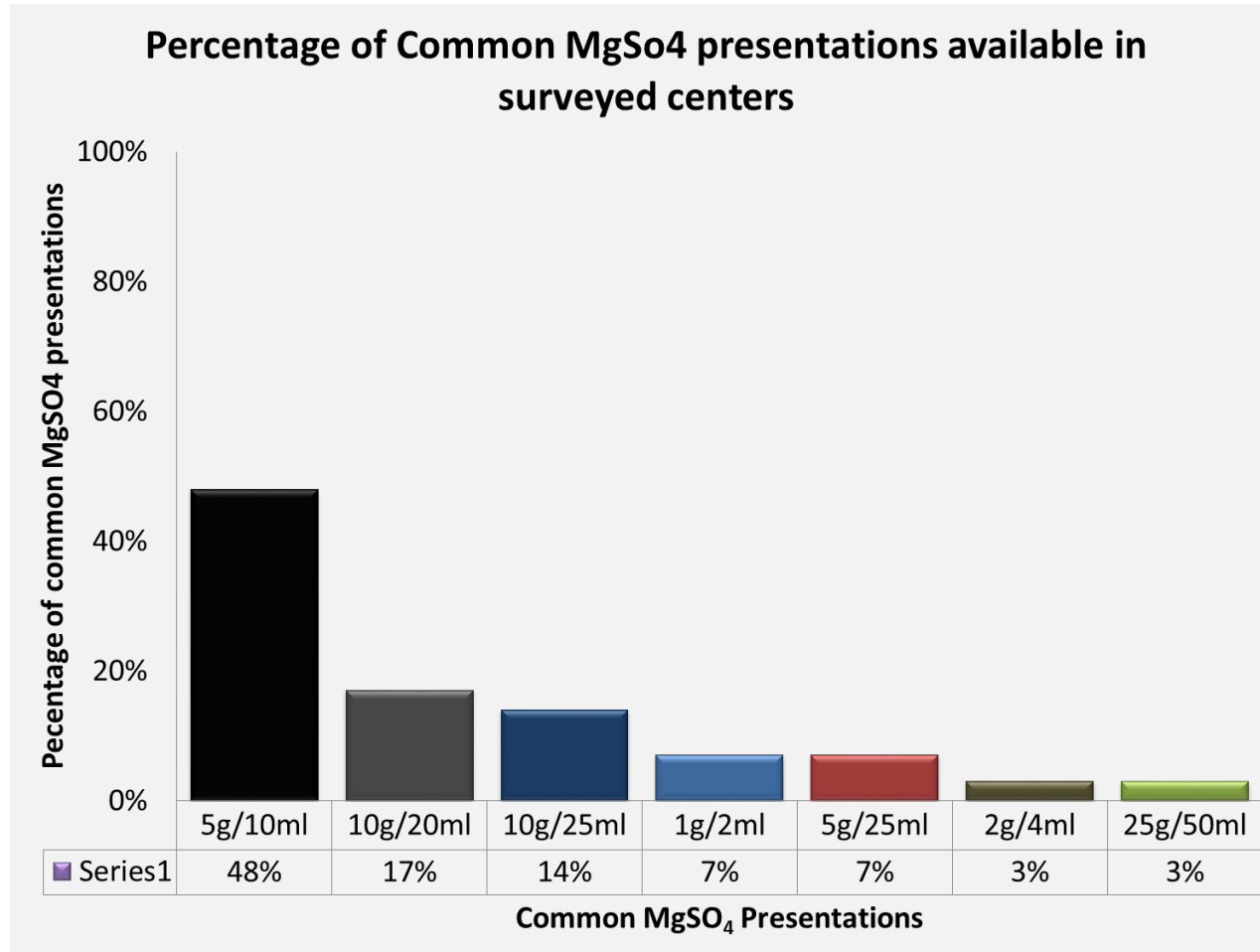
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(2,3) Addressed by global standards and national regulatory environments

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**** Translating global policies into country action**

Specific Barriers to access of quality-assured MgSO_4



*** Top 3 MgSO_4 Presentations Considered Most Practical**

5g in 10 mL (52%)

4g in 20 mL (28%)

10g in 25 mL (16%)

Developing **Global Standards** through the global EML

- Via the UN Commission's Maternal Health Technical Resource Team, suggested wording change for magnesium sulfate be changed to:

“Injection: 0.5 g/ml in 10-ml ampoule (5 g in 10 ml; 50% w/v)
0.5 g/ml in 2 ml ampoule (1 g in 2 ml; 50% w/v).”

- Argument: greater clarity and understanding about the contents of magnesium sulfate ampoules produced commercially, assist governments and procurers to make the correct decisions
- In **May 2015**, the World Health Organization accepted the UNCoLSC recommendations.

Translating global EML into National Policies

PART 7- SELECTION and RATIONAL USE OF MEDICINES

| 7.1 National Structures | | | | |
|--|------|--------|------|--------------------------------------|
| | Yes | Yes/No | YEAR | SOURCE |
| National standard treatment guidelines (STGs) for major conditions are produced by the MoH | Yes | Yes/No | 2007 | WHO Level I |
| -If yes, year of last update of national STGs | 2006 | Yes/No | 2008 | Ministry of Health and Child Welfare |
| National essential medicines list (EML) exists | Yes | Yes/No | 2007 | WHO Level I |
| -If yes, number of medicine formulations on the national EML | | number | | |
| -If yes, year of last update of EML | 2006 | Yes/No | 2007 | WHO Level I |
| -If yes, process for selecting medicines on the EML is publicly available | Yes | Yes/No | 2008 | National EML Committee |
| There is a committee for the selection of products on the national EML | Yes | Yes/No | 2007 | WHO Level I |
| -If yes, conflict of interest declarations are required from members on national EML committee | Yes | Yes/No | 2008 | National EML Committee |
| There are explicit criteria for selecting medicines for national EML | Yes | Yes/No | 2008 | Ministry of Health and Child Welfare |
| National medicines formulary manual exists | No | Yes/No | 2007 | WHO Level I |
| -If yes, national medicines formulary manual is limited to essential medicines | | Yes/No | | |
| -If yes, year of last update of national medicines formulary manual | | Yes/No | | |
| National STGs for paediatric conditions exist | Yes | Yes/No | 2007 | WHO Level I |
| -If yes, year of last update of national paediatric STGs | 2006 | Year | 2008 | Ministry of Health and Child Welfare |
| EML used in public insurance reimbursement | Yes | Yes/No | 2007 | WHO Level I |
| Rational use national audit done in the last two years | No | Yes/No | 2008 | Ministry of Health and Child Welfare |

- Next step, determining what national level policies are in place:
 - National Standard Treatment Guidelines (STGs)
 - National EML list (EML)
 - National EML Committee exists and selects has clear criteria for selecting/ updating EML
 - National Medicines Formulary Manual
 - National Health Insurance and medicines procurement policies
 - Market authorization and Registration protocols

Country profiles for essential medicines and health technologies exist on WHO website

Translating global EML into National Policies (*cont'd*)

Commodity Specific

Very Weak
 Weak
 Mod

| | | Regulatory | | | | Supply | | | Performance | | |
|------------|---------------------------|--------------------------|-------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------------------|--|-------------------------------------|------------------------------------|
| | | National EML | National treatment guidelines | Registered in-country | Prescription authority | Tracked in eLMIS | National stock-outs | Percent of POS with stock available | Training Curriculum developed (National) | % facilities with trained personnel | Job-aid Check developed (National) |
| Productive | Female Condom | <div><div></div>5▲</div> | <div><div></div>1</div> | <div><div></div></div> | <div><div></div></div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>11%</div> | <div><div></div>3</div> | <div><div></div>49%</div> | <div><div></div>4</div> |
| | Implants | <div><div></div>5</div> | <div><div></div>3</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>29%</div> | <div><div></div>3</div> | <div><div></div>49%</div> | <div><div></div>4</div> |
| | Emergency Contra. | <div><div></div>5</div> | <div><div></div>3</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>64%</div> | <div><div></div>3</div> | <div><div></div>49%</div> | <div><div></div>4</div> |
| Maternal | Oxytocin | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>50%</div> | <div><div></div>4</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| | Misoprostol | <div><div></div>5</div> | <div><div></div>5▲</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>1</div> | <div><div></div>15%</div> | <div><div></div>4</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| | Magnesium sulfate | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>33%</div> | <div><div></div>4</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| | Injectable Antibiotics | <div><div></div>3</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>69%</div> | <div><div></div>3</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| Newborn | Antenatal corticosteroids | <div><div></div>5</div> | <div><div></div>3</div> | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>5</div> | <div><div></div>24%</div> | <div><div></div>3</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| | Chlorhexidine | <div><div></div>5</div> | <div><div></div>5</div> | <div><div></div></div> | <div><div></div>5</div> | <div><div></div></div> | <div><div></div></div> | <div><div></div>75%</div> | <div><div></div>3</div> | <div><div></div>44%</div> | <div><div></div>3</div> |
| | Neonatal resuscitation | <div><div></div></div> | <div><div></div>5</div> | <div><div></div></div> | <div><div></div>5</div> | <div><div></div>1</div> | <div><div></div>1</div> | <div><div></div>9%</div> | <div><div></div>3</div> | <div><div></div>44%</div> | <div><div></div>3</div> |

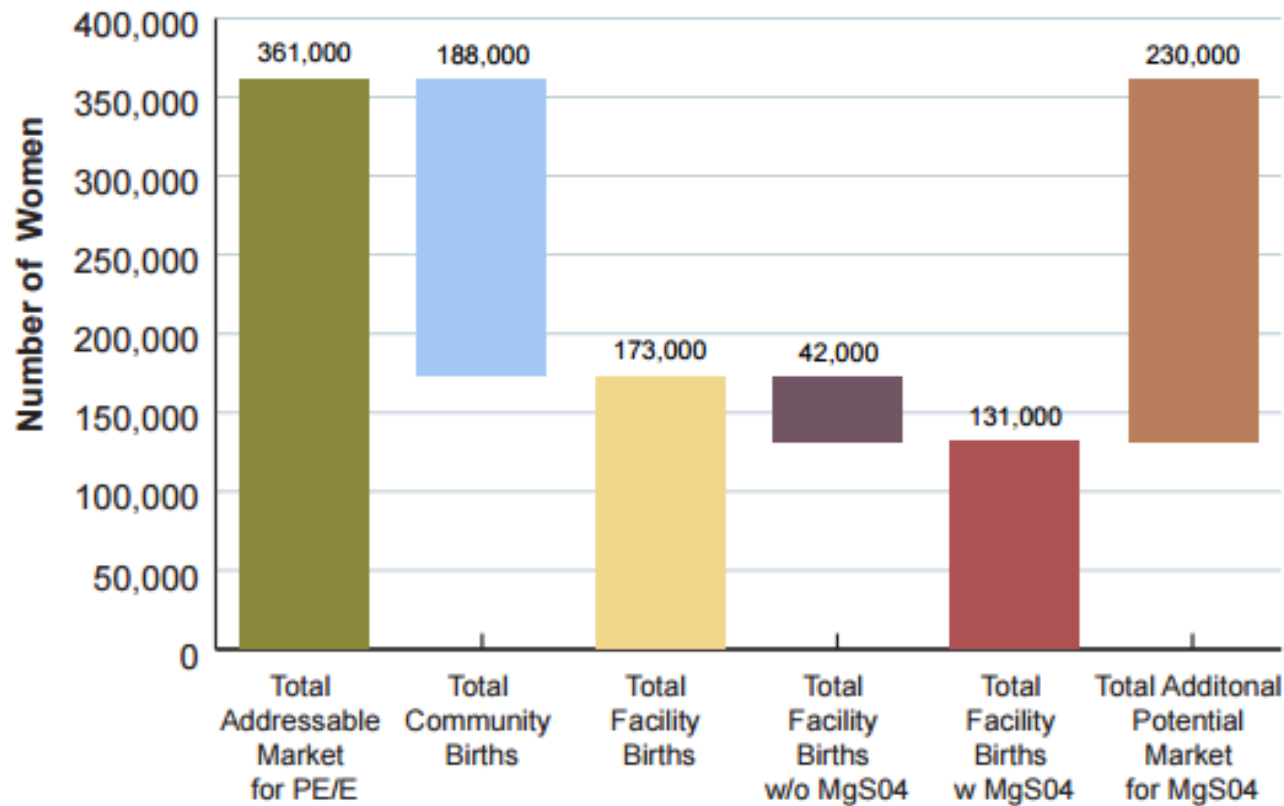
RMNCH Draft Indicator Report; preliminary data as of November 2014

Translating global EML into National Policies (*cont'd*)

- Initial review of countries (Zambia, Zimbabwe, Malawi, Uganda) show the following:
 - All countries have Lifesaving Commodities in Essential medicines list; globally few standouts exist
 - Countries don't have regularly updated EMLs: (1) diazepam, (2) recent EML change from 2015
 - Market authorization and enforcement is critical
 - Stakeholder engagement needs to be increased/ become more reflective of country based priorities

Noting the essential role of clarifying the **Business Case**

Sub-Saharan Market for Magnesium Sulfate (Low Estimate)



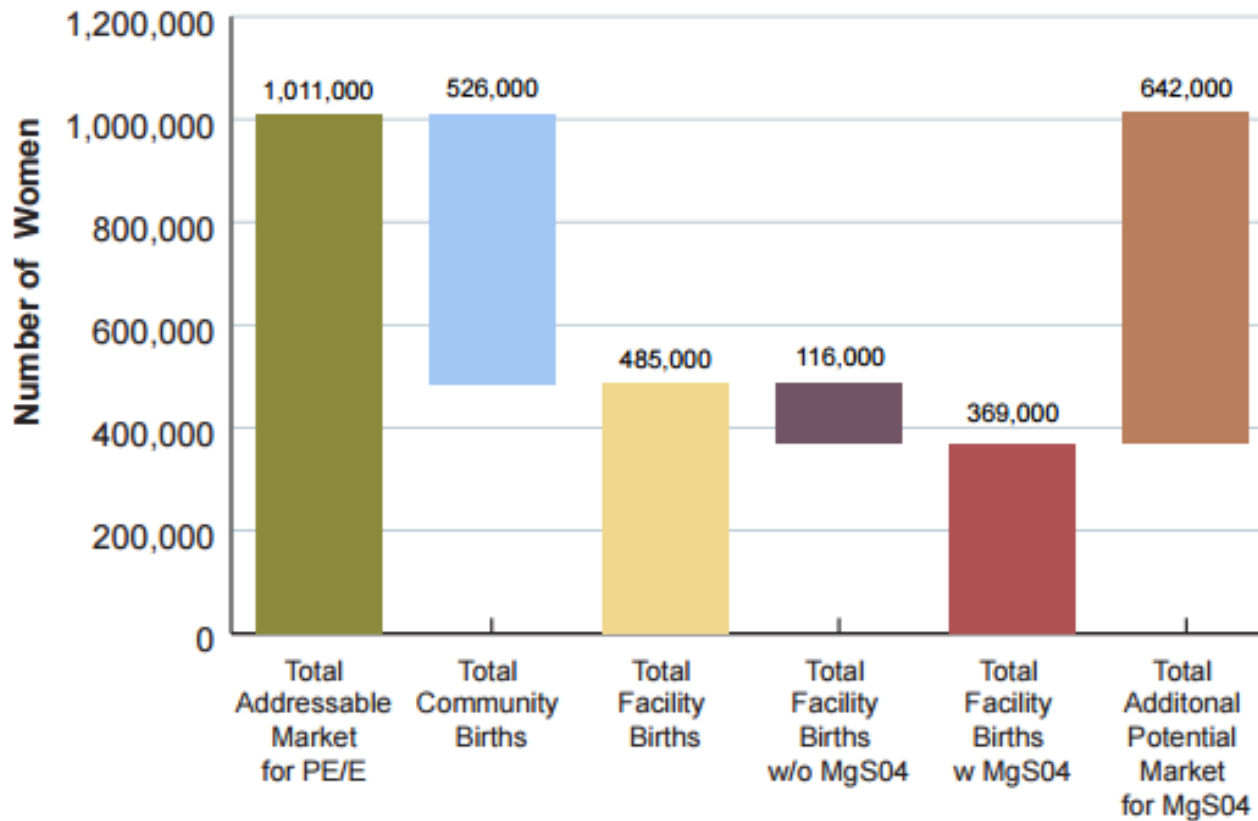
In the lower case scenario, wherein 1% of all pregnancies lead to severe pre-eclampsia and eclampsia, there are 361,000 cases per year with an unmet need for magnesium sulfate.

MH Commodity Business Cases available on Accelovate Website

<http://reprolineplus.org/oxytocin-case>

Noting the essential role of clarifying the **Business Case**

Sub-Saharan Market for Magnesium Sulfate (High Estimate)



In the higher case scenario, wherein 2.8% of all pregnancies lead to severe pre-eclampsia and eclampsia, there are 642,000 cases per year with an unmet need for magnesium sulfate.

MH Commodity Business Cases available on Accelovate Website

<http://reprolineplus.org/oxytocin-case>

Noting the essential role of clarifying the **Business Case**

Cost of Magnesium Sulfate for Treatment of Severe Pre-Eclampsia and Eclampsia

| | |
|--|---------------|
| Upper Cost for one 5g/10mL ampule | \$1.60 |
| Lower Cost for one 5g/10mL ampule | \$0.50 |
| Upper Cost to Treat One PE/E Case with MgSO4 (Pritchard) | \$12.80 |
| Lower Cost to Treat One PE/E Case with MgSO4 (Pritchard) | \$4.00 |
| Upper Cost to Treat One PE/E Case with MgSO4 (Zuspan) | \$9.60 |
| Lower Cost to Treat One PE/E Case with MgSO4 (Zuspan) | \$3.00 |

*Cost does not include the cost of peripherals (including intravenous and intramuscular injection equipment and IV solution) or the cost of calcium gluconate, the antidote to magnesium sulfate.

Noting the essential role of clarifying the Business Case

Cost of Magnesium Sulfate for Treatment of Severe Pre-Eclampsia and Eclampsia

| | PRITCHARD HIGH COST | PRITCHARD LOW COST | ZUSPAN HIGH COST | ZUSPAN LOW COST |
|------------------------|------------------------|-----------------------|---------------------|--------------------|
| Kenya high scenario | \$245,000 | \$77,000 | \$184,000 | \$58,000 |
| Kenya low scenario | \$88,000 | \$28,000 | \$66,000 | \$21,000 |
| Ethiopia high scenario | \$109,000 | \$34,000 | \$82,000 | \$26,000 |
| Ethiopia low scenario | \$38,000 | \$12,000 | \$29,000 | \$9,000 |
| Uganda high scenario | \$339,000 | \$106,000 | \$254,000 | \$80,000 |
| Uganda low scenario | \$122,000 | \$38,000 | \$91,000 | \$29,000 |
| Zambia high scenario | \$107,000 | \$34,000 | \$80,000 | \$25,000 |
| Zambia low scenario | \$38,000 | \$12,000 | \$29,000 | \$9,000 |
| Senegal high scenario | \$134,000 | \$42,000 | \$101,000 | \$32,000 |
| Senegal low scenario | \$48,000 | \$15,000 | \$35,000 | \$11,000 |

*Data sources used to create this table are available in the data set that accompanies this paper.

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4

The Continued Path Forward

Starting point is **developing global standards** then translating them into country action through revised **national policies** and **business cases**

3

4

Modify Regulatory Environment

Guide Manufacturers to Market

Accelovate's
Work

