



# How can we increase access to and use of magnesium sulfate?

## Challenge: Magnesium sulfate saves lives, but is underutilized

The second leading cause of maternal mortality in low- and middle-income countries has a proven and effective treatment that costs around one US dollar an ampule. Still, this solution remains vastly under-utilized. When an affordable, lifesaving drug has demonstrated efficacy and supportive global policy, what can be done to increase its availability and use among women who need it the most?

Accelovate is a five-year, United States Agency for International Development (USAID)-funded program charged to increase availability of and access to lifesaving technologies and commodities in low-resource settings. In keeping with its mission, Accelovate addressed the challenge of increasing access to high-quality maternal health commodities such as magnesium sulfate, otherwise known as  $MgSO_4$ .

## Challenge Background: Critical barriers complicate widespread use of magnesium sulfate

Pre-eclampsia/eclampsia (PE/E) is a hypertensive disorder of pregnancy that threatens both mothers and their babies. Left untreated, it can lead to organ damage, seizures, and also death.<sup>1</sup> An estimated 52,000<sup>2</sup> women succumb to PE/E worldwide each year, making it the second leading cause of maternal mortality in low- and middle-income countries. Proper screening, prevention, and treatment for PE/E can reduce the global burden of maternal mortality.

$MgSO_4$  is the first-line treatment for PE/E, and is recognized by the World Health Organization (WHO) as the safest and most effective anticonvulsant for preventing the onset of deadly seizures caused by PE/E. Global policies recommend its use, and  $MgSO_4$  is listed on WHO's Essential Medicines List (EML) as well as the 13 priority commodities as defined by the UN Commission on Life-Saving Commodities for Women and Children.<sup>3,4</sup>

Despite strong evidence and usage recommendations,  $MgSO_4$  drug uptake remains slow in many low- and middle-income countries,

What will increase access to and use of drugs where price, evidence, and global policy pose no barrier?

Accelovate identified a critical bottleneck to low  $MgSO_4$  use: inconsistent product formulations.



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where women face a risk of dying from PE/E that is approximately 300 times<sup>5</sup> higher than that for a woman in a developed country.

To understand why, the Access to Quality Maternal Health Products (AQMHP) working group of the UN Commission's Maternal Health Technical Resource Team—led by Accelovate as a co-convener of the working group—produced a literature review on “Barriers to Use of Magnesium Sulfate for PE/E.” Critical barriers that complicate the widespread use of  $MgSO_4$  were noted in this report,<sup>6</sup> confirmed by independent program research, and summarized in a joint problem statement issued by both Accelovate and the USAID-funded Maternal and Child Health Integrated Program (MCHIP).<sup>7</sup>

Through this work, Accelovate identified a critical bottleneck to low  $MgSO_4$  use: inconsistent product formulations stemming from complicated procurement and leading to provider reluctance to use  $MgSO_4$ .

### **Accelovate's Solution: Promoting a priority formulation of magnesium sulfate**

To administer the drug effectively, facility-based health care providers rely on available products to be consistent with dosing regimens included in training and service delivery guidelines. They also rely on an efficient procurement system that lets them re-order the same products to prevent drug stock-outs. Put simply, they require product supply to match product demand. With multiple product formulations, health systems cannot guarantee that match.

In one example,<sup>8</sup> Accelovate found that one-third of providers cite a preferred  $MgSO_4$  presentation (4 g in 20 ml at 20% dilution) that was neither available in nor commonly procured by their facility. Instead they received alternative presentations (5 g in 10 ml, 10 g in 20 ml, and 10 g in 25 ml) that required an adaptation of the dilution process during dosage preparation. The additional burden of re-calculation is time-consuming and can introduce potential errors, tempting providers to substitute  $MgSO_4$  with diazepam, a more straightforward but less effective anticonvulsant.

Accelovate decided on a solution: promoting a priority formulation of  $MgSO_4$  by developing clear product guidance and ensuring that available product presentations reflect the standardized formulation.

### **Results Achieved**

At a global symposium held at the 2013 Women Deliver Conference in Kuala Lumpur, Malaysia, Accelovate joined a panel of global experts and identified a priority formulation to be

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Promoting a priority formulation of  $MgSO_4$  addresses the critical challenge of low use.

translated into clear product guidance for global and country-based EMLs. The following consensus was reached:

- Priority presentation of MgSO<sub>4</sub> is 5 g in 10 ml (50% w/v) for use in both Pritchard (IV/IM) and Zuspan (IV/IV) dosing regimens
- Standard product labeling should state: “Magnesium Sulfate, MgSO<sub>4</sub>, 50%, 5 gr in 10 ml”
- An additional relevant presentation consistent with national context can be considered, based on country-level recommendations as applicable

This consensus was translated into a proposal for revised language on MgSO<sub>4</sub> on the WHO Model List of Essential Medicines, submitted via the AQMHP working group of the UN Commission in May 2014. Accelovate continues to build on this work in selected countries, determining country-level EML changes to follow proposed global revisions, as applicable.

For the priority formulation to translate into product availability, global and national procurement agencies must focus on procurement of the 5 g in 10 ml (50% w/v) presentation. This is complemented by developing market assessments and the business case to compel MgSO<sub>4</sub> manufacturers to improve existing product presentations and invest in high-quality production.

Accelovate developed an interactive resource entitled “[Maternal Health Drug Business Assessments: Excel Tool and User's Guide](#)” that contains global market data pertaining to three maternal health products, including MgSO<sub>4</sub>. This tool allows users to manipulate assumptions to generate tailored market projections. National health organizations, donors, and manufacturers wanting to explore the impact of investing in MgSO<sub>4</sub>, as well as advocates attempting to assess the business case for the drug in their countries, may use this tool to explore scenarios to support their decision-making.

These market assessments led to the development of business cases with additional funding from partners, including the Reproductive Health Supplies Coalition. “[Business Case: Investing in Production of High-Quality Magnesium Sulfate for Low-Resource Settings](#)” demonstrates that market sizes are sufficiently large to incentivize manufacturers to produce this product. The business case maps manufacturers of MgSO<sub>4</sub>, approximates market sizes for the drug, and characterizes market dynamics. The case is a resource for country-level manufacturers, ministries of health, national policymakers, and donors wanting to demonstrate the economic and business value of investing in high-quality MgSO<sub>4</sub> and advocates attempting to prequalify MgSO<sub>4</sub>.

## **Next Steps: Building on Accelovate's achievements**

Accelovate continues to work with strategic partners to promote the priority formulation of MgSO<sub>4</sub> and advocate for the production of high-quality MgSO<sub>4</sub>. These partners include but are not limited to: the UN Commission on Life-Saving Commodities for Women and Children, the Reproductive Health Supplies Coalition, WHO, ministries of health, procurement agencies, commodity manufacturers, and implementing partners.

Meanwhile, the program continues to explore additional innovations to improve MgSO<sub>4</sub> access and use, which include improvements in:

- Product labeling: Creating systems to align products with the WHO-recommended regimen and facilitate dosage preparation by providers (i.e., color-coding)
- Dosage preparation and administration: developing affordable technologies to simplify accurate dosage calculation and administration (i.e., syringe technology and ready-to-use packs)
- Distribution models for increased access to MgSO<sub>4</sub> and related necessary supplies

<sup>1</sup> Magnesium Sulfate. UN Commission on Life-Saving Commodities. 2013. Available at <http://www.lifesavingcommodities.org/about/lifesaving-commodities/magnesium-sulfate/>. Accessed 25 November 2014.

<sup>2</sup> Jhpiego. 2014. *Business Case: Investing in Production of High-Quality Oxytocin for Low-Resource Settings*. Publication prepared by C. Schocken through the Reproductive Health Supplies Coalition. Available at <http://reprolineplus.org/oxytocin-case>. Accessed 2 January 2015.

<sup>3</sup> Life-Saving Commodities. UN Commission on Life-Saving Commodities. 2013. Available at <http://www.lifesavingcommodities.org/about/lifesaving-commodities/>. Accessed 25 November 2014.

<sup>4</sup> WHO Model Lists of Essential Medicines. World Health Organization. 2013. (April). Available at [http://apps.who.int/iris/bitstream/10665/93142/1/EML\\_18\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/93142/1/EML_18_eng.pdf?ua=1). Accessed 25 November 2014.

<sup>5</sup> Magnesium Sulfate. UN Commission on Life-Saving Commodities. 2013. Available at <http://www.lifesavingcommodities.org/about/lifesaving-commodities/magnesium-sulfate/>. Accessed 25 November 2014.

<sup>6</sup> Please contact [accelovate@jhpigo.org](mailto:accelovate@jhpigo.org) for a copy of the literature review.

<sup>7</sup> Jhpiego. 2014. Problem Statement: Increasing the Use of Magnesium Sulphate for Prevention and Treatment of Severe Pre-Eclampsia and Eclampsia. Written by USAID-funded programs Accelovate and MCHIP.

<sup>8</sup> Jhpiego. 2014. Survey on Current and Preferred Future MgSO<sub>4</sub> Use and Receptiveness to Ready-to-Use Packs in Low-Income Countries (unpublished). Written by the USAID-funded Accelovate program.

## Accelovate—a Partnership in Accelerated Global Health Innovation

Accelovate is a global program dedicated to increasing the availability and use of lifesaving innovations for low-resource settings. Led by Jhpiego, the Accelovate program began in 2011 as a five-year, United States Agency for International Development (USAID)-funded program under the Technologies for Health (T4H) grant.

### Also available from Accelovate:

**Design Challenges** promote the development of innovative solutions where appropriate technology is lacking

**Solution Landscapes** assess what solutions exist

**Value Propositions** assess the benefits and drawbacks of an array of solutions for our context

**Business Cases** assess manufacturability and commercial potential

**Market Readiness Assessments** evaluate a selected technology/solution for market-level readiness factors

**Briefs** describe technology access and utilization challenges in a topical area and outline Accelovate's approach

**Excel Tools** present raw data that implementers may develop for programming and advocacy purposes

**Literature Reviews** review secondary data, usually to understand a bottleneck

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Accelovate invites innovators, advocates, funders, and programmers addressing the procurement and use of maternal health drugs and technologies in low-resource settings to share our tools and join our efforts to ensure a market of standardized, high-quality MgSO<sub>4</sub>.

To discuss **partnership opportunities around new solutions**, contact us at [accelovate@jhpigo.org](mailto:accelovate@jhpigo.org)