

Evidence based scaling-up to improve maternal and perinatal health

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Summary

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Second Meeting of the Technical Working Group on
Pre-eclampsia/Eclampsia
Maternal and Child Health Integrated Program
Washington DC, Nov 18-19, 2009

Meeting purpose

- to identify scaling-up strategies and evaluation frameworks that are both scientifically sound and acceptable for policy makers and research funders.
- Initial focus:
 - Magnesium sulfate for treating eclampsia.
 - Calcium supplementation for preventing PE/E

Participants

- WHO
 - Mario Merialdi
 - Eduardo Bergel
- NIH
 - Linda Wright
 - Marion Koso-Thomas
 - Jeanne Mcdermott
- CIHR (Canada)
 - Mike Kramer
 - Jeremy Grimshaw
 - Merrick Zwarenstein
 - Ellen Hodnett
 - Allan Donner
 - Pierre Turcotte
 - Nancy Edwards
- MacArthur Foundation
 - Erin Sines
- JHPIEGO
 - Patricia Gomez
- Consultants
 - Justus Hofmeyr
 - Tyler Hartwell
 - Simon Lewin
 - Laura Caulfield
 - Gabriela Cormick
 - Fernando Althabe
 - Jose Belizan

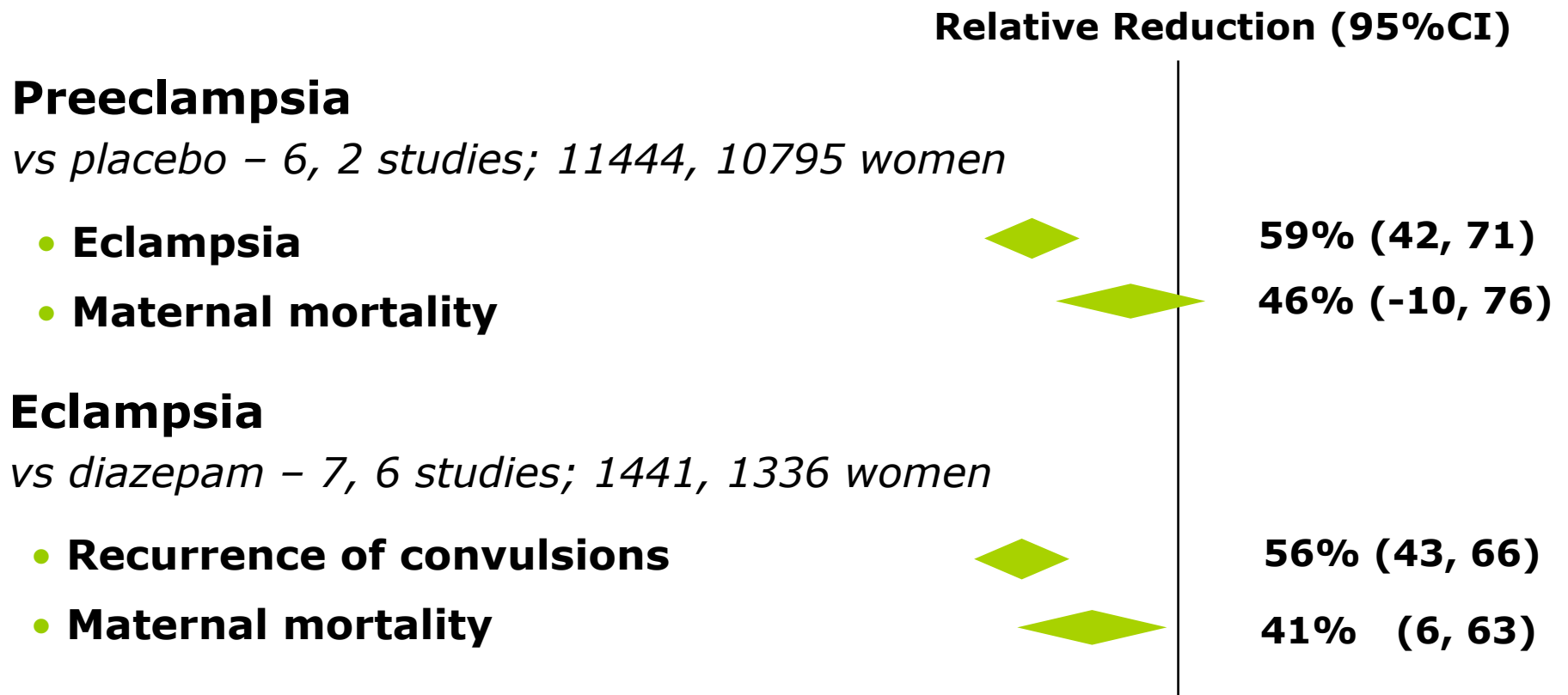
Maternal Mortality 2005 (WHO, UNICEF, UNFPA)

Related to Hypertensive disorders

	MMR (per 100,000)	Number of maternal deaths	maternal deaths hypertension	
			%	N
<i>Africa</i>	820	276,000	9%	25,000
<i>Asia</i>	330	241,000	9%	21,700
<i>Latin America</i>	130	15,000	26%	3,900

50,000 deaths per year

Magnesium Sulphate is effective to prevent and treat eclampsia.



Highlights

- **Magnesium Sulphate is effective**
- **Safe for women and babies with eclampsia**
- **Relatively Safe for babies with pre-eclampsia**
- **Inexpensive**
- **Relatively easy to administer**
- **At hospital level**
- **Unclear at primary care level (health centers, home births)**

Barriers

- **Lack of Clinical Practice Guidelines**
- **Mag Sulph not included in Essential medicines list**
- **If CPGs exist, no appropriate dissemination**
- **Mag sulph only appropriate to use at hospitals**
- **Health workers not trained or not authorized to administer**
- **Market problems: few women affected, inexpensive drug**

Langer et al. Reducing eclampsia-related deaths—a call to action . Lancet 2008; 371:705-6.



Aaserud et al. Translating research into policy and practice in developing countries: a case study of magnesium sulphate for pre-eclampsia. BMC Health Serv Res 2005;5:68.

Potential impact in developing countries

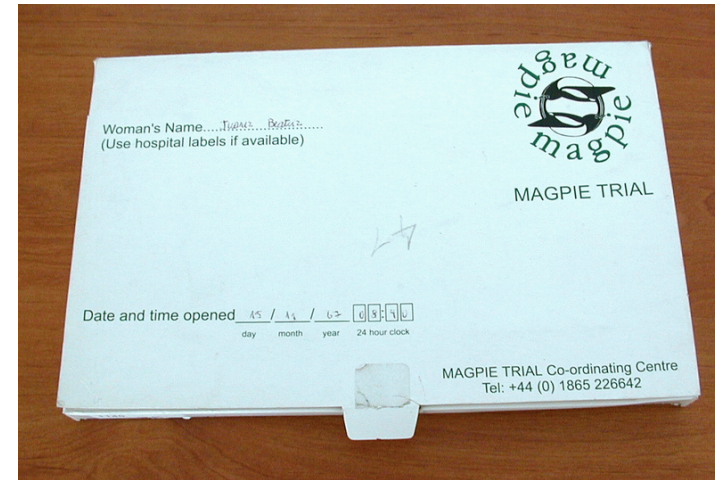
A 50% increase in the use of Magnesium Sulfate would prevent 10-15 maternal deaths per 100,000 live births

Hypothesis

A strategy including:

- Magnesium sulphate ready-to-use boxes
 - Guidelines
 - Training
 - Reminders
 - Health system support
-
- For treating women with eclampsia
 - At hospital level in LMIC
 - May increase the use of MgSO₄, and reduce eclampsia related maternal death or severe morbidity

Basis to support the hypothesis



Basis to support the boxes

Ready-to-use Boxes

- Pre-packaging of medications that simplify medication regimens, such as calendar blister or unit-of-use packaging,
 - modest improvement in increasing adherence to drug treatment regimens in adults,
 - effects on clinical outcomes have not been well evaluated. (Heneghan 2006; Haynes 2008; Connor 2004).
 - In LMIC, unit-of-use packaging has been effective to improve adherence to malaria treatment in Ghana (Yeboah 2001).
- We found no relevant trials of pre-packaging drugs treatments for emergency situations.

Basis to support the boxes

Ready-to-use Boxes

- *The treatment packs used in this study also have considerable practical implications, for both developed and developing countries. They are a simple, relatively cheap but effective way of ensuring that magnesium sulphate is always readily at hand when required....*
- *An additional advantage in all centres, and particularly those where individual clinicians rarely see a woman with eclampsia, is that the pack is self-explanatory and includes a quick and easy to follow protocol....*
- *Providing it in the context of treatment packs, as described here, would also help to promote safe and appropriate use.*
 - » Duley L 1996

Basis to support the boxes

Ready-to-use Boxes

- *...Other organisations could fund the provision and distribution of the treatment kits that proved so popular and effective in both of the controlled trials of magnesium sulphate.*
 - » Sheth & Chalmers 2002
- *Widespread availability and appropriate use of affordable, ready-to-use eclampsia treatment packs to give magnesium sulfate should be priorities...*
 - » Langer et al 2008
- Given the paucity of evidence to select appropriate strategies for implementation, research projects to evaluate innovative approaches to implement magnesium sulfate treatment are of high priority in LMIC.
 - » Lumbiganon et al 2007

EVALUATION AND DESIGN ISSUES

Settings and Population

- Countries with Mag Sulf licensed and available or committed to (3-4)
- Medium/Large Hospitals.
- High rates of eclampsia: 20 cases per year
- Low use of Mag Sulf: <20% use (WHO Global Survey 2010)

Intervention refinement

- Guidelines, training, boxes, reminders, health system support
- Final decision based on information collected during a preliminary phase
- Alternatives
 - Standard uniform across setting
 - Intermediate: prototype
 - Completely customized and tailored

Outcomes

- **Primary**
 - use of Mag Sulph in women with eclampsia
- **Secondary:**
 - Eclampsia related death or severe morbidity
 - Neonatal death or severe morbidity
- Health providers' perspectives?
- Economical evaluation?

Study design

- Cluster RCT
- Stratified design
 - By country
- Factorial design, and incomplete block design to be explored

Next steps

- Protocol development
 - WHO/IECS are working on a new version of the protocol
 - Protocol development group to be expanded
 - Other interested researchers/agencies are welcome
- Funding
 - WHO will provide funding,
 - But additional support will be required
- Next meeting
 - Protocol development team
 - Experts
 - Donors/Other interested Agencies.

Calcium

- No clear agreement on the need to scale up calcium supplementation
- More agreement in the need of research:
 - Methods to supplement populations including fortification
 - Pre-pregnancy and early pregnancy supplementation

Thank you!

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