BALANCING THE SCALES
EXPANDING TREATMENT FOR PREGNANT WOMEN WITH LIFE-THREATENING HYPERTENSIVE CONDITIONS IN DEVELOPING COUNTRIES

A Report on Barriers and Solutions to Treat Pre-eclampsia & Eclampsia

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Many individuals from institutions across Africa, Asia, and Latin America generously shared their insights on pre-eclampsia and eclampsia for the purposes of this meeting and helped create a road map for the journey ahead. Although their names are too many to mention, we are indebted to them.

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EXECUTIVE SUMMARY

Giving birth should be a time for celebration, but for more than half a million women each year—or one woman every minute—pregnancy and childbirth end in death and mourning. Ninety-nine percent of these deaths occur in the developing world, and tragically, most of these deaths are preventable.

One of the most common, yet treatable, causes of maternal death worldwide is pre-eclampsia—the rapid elevation of blood pressure during pregnancy—which, if untreated, can lead to seizures (eclampsia), kidney and liver damage, and ultimately, death. The World Health Organization (WHO) estimates that at least 16% of maternal deaths in developing countries result from these conditions (UNDP/UNFPA/WHO/World Bank Special Programme, 2006). Thus, approximately 63,000 pregnant women die every year because of eclampsia and severe pre-eclampsia, which are also associated with a higher risk of newborn deaths.

Pre-eclampsia/eclampsia ranks second only to hemorrhage as a specific, direct cause of maternal death. In some countries, such as Mexico, pre-eclampsia and eclampsia is the number one killer. The risks that a woman faces vary greatly depending on where she lives: The risk that a woman in a developing country will die of pre-eclampsia/eclampsia is approximately 300 times higher than that for a woman in a developed country. While the use of magnesium sulfate has become the mainstay of treatment of pre-eclampsia and eclampsia in the vast majority of developed countries, medications such as diazepam and phenytoin (used in the treatment of other types of seizures, including epilepsy) have become more widely used in most other parts of the world.

Several research trials have identified magnesium sulfate as the most effective treatment for preventing the onset of deadly seizures. In fact, the maternal mortality rate was reduced by 55% in the 33-country Magpie Trial, which was conducted in 1995. Similarly, in the Collaborative Eclampsia Trial (2002), magnesium sulfate was proven to be more than twice as effective at preventing recurrent seizures as the two drugs (diazepam and phenytoin) that had been the drugs of choice for this problem in most countries. Treating mothers with magnesium sulfate improved outcomes not only for mothers, but for their babies as well.

While these findings are compelling, the research in itself has not translated into national health policies and clinical practices in many parts of the developing world. Mothers continue to die from the lack of magnesium sulfate—a safe, effective, and inexpensive drug. Today, magnesium sulfate is still not available in the hospitals of many countries, nor is it on the countries’ essential drug lists. In some nations, magnesium sulfate is not even licensed for sale.

Based on the scientific evidence, WHO identified magnesium sulfate as the most effective and low-cost medication for treatment of pre-eclampsia and eclampsia (WHO, 1994). Unfortunately, magnesium sulfate continues to be underutilized, especially in countries where pre-eclampsia and eclampsia remains one of the main causes of maternal mortality and morbidity.
In light of the above, EngenderHealth brought together international health experts to study and come to a consensus on the key barriers to the use of this life-saving tool and to develop a road map to improve access and implementation of magnesium sulfate treatment. The Workshop on Magnesium Sulfate for the Management of Pre-eclampsia and Eclampsia, held on June 26–27, 2007, in Oxford, England, was conducted in coordination with a Technical Advisory Group, which served as an advisory body overseeing the preparation and planning for the workshop. The Technical Advisory Group included representatives from the following agencies: Columbia University (The Averting Maternal Death and Disability Program), EngenderHealth, the London School of Hygiene and Tropical Medicine, UNICEF, the University of Leeds, the University of Oxford, and the World Health Organization. Workshop attendees included technical experts, country-level representatives from Ministries of Health and public health services, and representatives from universities and international organizations. Given the complexity of the issues, the Workshop required a multidisciplinary group of experts representing diverse experiences and countries. Participants represented the countries of Ghana, India, Malawi, Mexico, Nepal, Nigeria, Switzerland, Thailand, the United Kingdom, and the United States.

This historic gathering of global public health experts identified the primary barriers to expanding access to magnesium sulfate in developing countries, including:

- **Lack of National Priority and Guidelines.** In countries like Nigeria, Uganda, and Pakistan, guidelines mandating magnesium sulfate use do not exist, and only about half of the world’s countries include magnesium sulfate on their national list of “essential drugs.”

- **Lack of Education and Training.** Many clinicians remain unfamiliar with the safety and effectiveness of magnesium sulfate and continue to rely on other, less effective and riskier drugs. Education and training on the scientific validity and treatment protocols are needed.

- **Supply Shortage.** Relative to other health conditions, pre-eclampsia and eclampsia affect a small population. In addition, magnesium sulfate is relatively inexpensive. In combination, these factors leave little or no incentive for pharmaceutical companies to make magnesium sulfate more widely available.

Based on these conclusions, EngenderHealth and the University of Oxford have developed a “Call to Action” that calls on policy makers and ministers of health to make pre-eclampsia and eclampsia a higher priority and to set national guidelines for treatment and care, based on WHO guidelines. It also urges decision makers and international and national health organizations and agencies to help make magnesium sulfate more available and affordable, in part by empowering local clinicians with education and training.
I. INTRODUCTION

The Cost of Childbirth
For most women and their families, giving birth should be a time for celebration, but for more than half a million women each year—or one woman every minute—pregnancy and childbirth end in death and mourning (UNFPA, 2000). Ninety-nine percent of maternal deaths occur in the developing world, and most of these deaths are preventable. The risk of death and disability resulting from reproduction reflects the enormous disparities in maternal health care between industrialized and poor nations. Indeed, the risk of a woman’s dying as a result of pregnancy or childbirth during her lifetime is about one in seven in Afghanistan or Sierra Leone, while it is only one in 30,000 in Sweden (Lawn, Cousens, & Zupan, 2005).

Although the reduction of maternal mortality was adopted by the global development community as one of the Millennium Development Goals and is a stated target of many countries and international institutions, pregnancy-related deaths have fallen little in most low-resource countries over the past decades. The lack of success in improving pregnancy outcomes has been a result of failing health systems, as well as of insufficient political, financial, and social commitment to the issue.

What Are Pre-eclampsia and Eclampsia?
Pre-eclampsia is a rapidly progressive condition that can lead to stroke, kidney or liver damage, blood-clotting problems, and pulmonary edema (fluid in the lungs). The diagnosis of pre-eclampsia is based primarily on the presence of hypertension and protein in the urine during the latter stages of pregnancy. Eclampsia is defined as the development of convulsions or coma in a woman with pre-eclampsia. Pre-eclampsia and eclampsia occur much more commonly in first-time pregnancies and appear typically with minimal or no warning. The antenatal onset of pre-eclampsia and eclampsia is, by definition, after the 20th week of pregnancy. However, up to 25% of pre-eclampsia and eclampsia cases occur after delivery—usually within 48 hours postpartum. Some women with pre-eclampsia develop eclamptic seizures. Pre-eclampsia and eclampsia can also result in perinatal deaths. While many theories have been suggested to explain the etiology of pre-eclampsia and eclampsia, to date no single or unifying explanation of the cause exists. Unfortunately, pre-eclampsia is not preventable, nor is its onset accurately predictable.

Latest Data for Pre-eclampsia and Eclampsia
The World Health Organization (WHO) identifies the leading causes of maternal mortality worldwide as: hemorrhage (25%), indirect causes (20%), infections (15%), unsafe abortion (13%), pre-eclampsia/eclampsia (12%), obstructed labor (8%), and other direct causes (8%). Pre-eclampsia/eclampsia ranks second only to hemorrhage as a specific, direct cause of maternal mortality. However, these global averages hide important variations among countries. For instance, in Mexico, pre-eclampsia/eclampsia is the number one cause of maternal death (Lozano et al., 2005). In 2002, there were approximately 4,152,000 cases of pre-eclampsia and eclampsia that resulted in 63,000 deaths worldwide (WHO, 2005).
The Price of Pre-eclampsia and Eclampsia: How It Affects “Us” vs. “Them”

The cumulative risks from pre-eclampsia and eclampsia are many times higher for a woman in a developing country than for a woman in a developed country. A woman in a developing country is seven times more likely to develop pre-eclampsia. If she develops pre-eclampsia, she is three times more likely to progress to eclampsia. Should she develop eclampsia, she is up to 14 times more likely to die of eclampsia—even in hospital settings. Taken together, the risk of dying of pre-eclampsia and eclampsia is approximately 300 times higher for a woman in a developing country than for a woman in a developed country.

Incidence of Pre-eclampsia

The incidence of pre-eclampsia, the precursor to eclampsia, varies greatly worldwide. WHO estimates the incidence (or number of new cases) of pre-eclampsia to be seven times higher in developing countries (2.8% of live births) than in developed countries (0.4%) (Dolea et al., 2003).

Progression of Pre-eclampsia to Eclampsia

Only a relatively small proportion of all women with pre-eclampsia progress to the more potentially deadly eclampsia. However, once again, a pre-eclamptic woman in a developing country is three times more likely to progress to eclampsia than a woman in a developed country. The WHO estimates that eclampsia develops in 2.3% of pre-eclamptic women in the developing world, compared with 0.8% of pre-eclampsia cases in developed countries.

Challenges to Defining the Problem: Variations in Death Rates from Eclampsia

Reliable statistics about women dying due to eclampsia are difficult to obtain because of the poor quality of vital statistics registration systems and hospital records in many developing countries. In addition, a sizable number of deliveries take place at home, and thus there are no records at all for these births. Therefore, data on women who die from eclampsia are only available from a limited number of countries (see Table 1, below). Nevertheless, it is clear that the case fatality rates for eclampsia vary greatly across countries, with the risk of death from eclampsia being much higher in developing countries than in developed ones.

Table 1: Case Fatality Rates for Eclampsia in Select Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Case Fatality Rate</th>
<th>Year(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkina Faso</td>
<td>15.7%</td>
<td>1992–1995</td>
</tr>
<tr>
<td>Niger</td>
<td>5.9%</td>
<td>1997</td>
</tr>
<tr>
<td>South Africa</td>
<td>21.2%</td>
<td>1994–1995</td>
</tr>
<tr>
<td>South Africa</td>
<td>26.3%</td>
<td>1996–1997</td>
</tr>
<tr>
<td>Peru</td>
<td>8.0%</td>
<td>1991–1997</td>
</tr>
<tr>
<td>Thailand</td>
<td>3.3%</td>
<td>1988–1997</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1.8%</td>
<td>1992</td>
</tr>
</tbody>
</table>

Magnesium Sulfate: The Evidence-Based Solution

While there is no cure for pre-eclampsia and eclampsia, treatment measures can prevent and/or reduce maternal and perinatal death and disability. The currently prescribed management of pre-eclampsia and eclampsia originated in the early 1900s. In 1925, Lazard published a preliminary report in the American Journal of Obstetrics and Gynecology describing the effectiveness of magnesium sulfate for treating pre-eclampsia and eclampsia (Lazard, 1925). The use of magnesium sulfate went on to become the standard treatment of pre-eclampsia and eclampsia in the United States. The results did not translate globally, and other, less-effective medications, such as diazepam and phenytoin (used in the treatment of other types of seizures, including epilepsy), were more widely used in other countries to treat pre-eclampsia/eclampsia.

Evidence of Effectiveness Treating Eclampsia

In 1995, more research confirmed the superiority of magnesium sulfate for the treatment of eclamptic seizures compared to other medications. The Collaborative Eclampsia Trial compared the relative effectiveness of the three most popular treatments (magnesium sulfate, diazepam, and phenytoin) for the treatment of eclampsia (Eclampsia Trial Collaborative Group, 1995). Women treated with magnesium sulfate had a 52% and 67% lower recurrence of convulsions than those treated with diazepam and phenytoin, respectively.

During the Collaborative Eclampsia Trial, treatment packs were prepared for the clinicians to treat women participating in the study. The packs contained magnesium sulfate (prepackaged for recommended standard dosing), calcium gluconate (an antidote for toxicity from magnesium sulfate), supplies for intravenous and intramuscular administration, record sheets to record clinical monitoring findings, and a protocol sheet that also included guidelines for other aspects of relevant care.

Evidence of Effectiveness Treating Pre-eclampsia

Although the Collaborative Eclampsia Trial provided compelling evidence about the superiority of magnesium sulfate for treatment of eclamptic seizures, questions remained about the effectiveness of magnesium sulfate for the treatment of pre-eclampsia.

In 2002, a randomized, placebo-controlled study enrolled more than 10,000 women from 33 countries to address this issue (Altman et al., 2002). Known as the Magpie Trial, the landmark study enrolled 12 times more women than any previous pre-eclampsia study to compare the efficacy of magnesium sulfate to placebo. The Magpie Trial determined that when magnesium sulfate was given to women with pre-eclampsia, it lowered the chance of seizure by 58%. Following the Magpie Trial, magnesium sulfate was placed on the WHO essential drugs list, and as a result, many countries began full use of the drug, such as the United Kingdom.
**Improving Neonatal Outcomes**

Perinatal outcomes for women treated with magnesium sulfate for pre-eclampsia and eclampsia have been studied in recent years. Cochrane Review articles reported better outcomes for babies of mothers who received magnesium sulfate for eclampsia than for those who received diazepam or phenytoin. Specifically, the vigor of the babies (five minutes after birth) was greater and the chances of a long hospital stay in an intensive care unit were lower in the magnesium sulphate–treated group than in the diazepam–treated group. Similarly, maternal magnesium sulfate treatment was associated with fewer neonatal admissions to a special care unit, a shorter duration of stay (in days) in the neonatal care unit, and fewer neonatal deaths when compared with maternal treatment with phenytoin (Duley et al., 2003a; Duley et al., 2003b).

**Current Clinical Guidelines**

The positive research data from the Magpie Trial led institutions including the WHO, the American College of Obstetricians and Gynecologists (ACOG), and the Royal College of Obstetricians and Gynaecologists (RCOG) to recommend the use of magnesium sulfate as the first-line treatment for pre-eclampsia and eclampsia. Their recommendations specify correct dosing and administration and also emphasize the importance of monitoring to ensure safety.

Recommendations for the care of a woman with pre-eclampsia/eclampsia extend beyond simply the proper administration of magnesium sulfate. Current guidelines address appropriate laboratory tests for blood count and liver and kidney function. RCOG and ACOG also specify the need for treatment of severely elevated blood pressure with an antihypertensive medication to prevent nonseizure complications. For more specific guidelines on the management of pre-eclampsia and eclampsia, visit WHO at www.who.int/, ACOG at www.acog.org, or RCOG at www.rcog.org.uk.
II. BARRIERS TO COMPLIANCE WITH INTERNATIONAL STANDARDS OF CARE

Transforming Evidence to Practice

The presence of magnesium sulfate within a country and distribution of the drug to facilities are basic prerequisites for complying with international guidelines for pre-eclampsia and eclampsia care. Despite compelling data about magnesium sulfate as the first choice for treatment, the drug remains inaccessible to millions of women in developing countries. For example, in the United Kingdom, since 1991, the use of magnesium sulfate in cases of pre-eclampsia rose from 2% to 100%. By contrast, in many developing countries, magnesium sulfate is still unavailable or underutilized, and other anti-seizure medications continue to be used preferentially over magnesium sulfate. These facts indicate that although research findings are essential to improve clinical practices, they are not sufficient to change health policies and routine clinical care.

Although some studies have attempted to understand why this evidence has not translated into changes in practice, there had never been a specific forum to address this issue head on. The Workshop on Magnesium Sulfate for the Management of Pre-eclampsia and Eclampsia, held in June 2007 in Oxford, was conducted to identify the key barriers to expanding access to magnesium sulfate, including country-specific barriers, and to develop solutions to address them. The experts attending the meeting identified the following key barriers to translating knowledge about magnesium sulfate into policies and practice.

Key Barriers

Lack of National Priority and Guidelines

In countries such as Nigeria and Pakistan, national guidelines mandating magnesium sulfate use do not exist. And only about half of all countries in the world include magnesium sulfate on their national list of “essential drugs.” Where national guidelines do exist, facilities and clinicians are sometimes under no obligation to follow them. In many cases, each facility develops and follows its own policies.

Lack of Education and Training

Many clinicians are unfamiliar with the safety and effectiveness of magnesium sulfate and continue to rely on other, less-effective and riskier drugs. Health care providers and administrators may be reluctant to adopt a practice with which they have had little experience or one that requires intensive monitoring for a condition that is relatively infrequent. In addition, few clinicians or policy makers in developing countries are aware of the concept of evidence-based medicine or know about the findings from the Magpie Trial. In some countries, experts report that the utilization of magnesium sulfate is viewed as being appropriate only at highest functional facilities (such as facilities with an intensive care unit) because of the misperception that women receiving magnesium sulfate require very complex monitoring.

Supply Shortage

Relative to other health conditions, pre-eclampsia and eclampsia affect a small population. In addition, the drug itself is relatively inexpensive. In combination, these factors leave little or no incentive for pharmaceutical companies to make magnesium sulfate more widely available.
Lack of Comprehensive, Country-by-Country Data
Solid data about the availability of magnesium sulfate are generally lacking in many countries, and the data that do exist often present a challenging picture. For example, 2003 national surveys in Ghana and Rwanda reported that only 7% and 25% of facilities offering delivery services stocked magnesium sulfate (respectively). In 2005, the drug was entirely absent from a teaching hospital in Nigeria. Sevene et al. (2005) conducted a case study in Mozambique and Zimbabwe to examine the reasons why magnesium sulfate continues to be unavailable in these countries. The factors identified included: insufficient demand for the drug by physicians; poor communication between clinicians and pharmacists; complex mechanisms of drug approval, acquisition, and distribution; priority given to drugs used at all levels of the health system; and limited drug budgets.

Financial Cost
The cost of magnesium sulfate and the hospital care involved with providing it were seen as an impediment to its use in some countries. The problem of cost was reflected in the discrepancies between private and public facilities in their ability to stock magnesium sulfate. The cost of magnesium sulfate also differs depending on the country. While generally inexpensive across most countries, it is more expensive in places such as in Nigeria, than other, less favorable drugs.

Weak Health Systems
Without a stable health system, any intervention, including one that is relatively easy to administer with clinical training, will not succeed. It is critical to ensure that any training or program with magnesium sulfate is offered in the context of a functional health system, where providers are able to participate in job training and adopt new practices, where the procurement and distribution systems are effective, where norms and institutional quality protocols are in place, and where facilities are reasonably well-equipped. It is also important that interventions like magnesium sulfate are provided as part of a package of emergency obstetric care and in the context of a comprehensive reproductive health approach that addresses women's inextricably linked needs, including family planning.

<table>
<thead>
<tr>
<th>OVERCOMING HARMFUL PRACTICES IN NIGERIA</th>
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<tbody>
<tr>
<td>Dr. Bissallah Ahmed Ekele, Professor and Chair of the Department of Obstetrics and Gynecology at Usmanu Danfodiyo University, recounted that when he graduated from medical school, he knew far more about the so-called “lytic cocktail”—a potentially deadly treatment—than about magnesium sulfate for the management of pre-eclampsia and eclampsia. In his clinical textbooks, where magnesium sulfate was mentioned, providers were advised to use the drug with discouragingly great caution, due to the various myths associated with its use. The drug diazepam has also been very popular in the management of pre-eclampsia and eclampsia in Nigeria, despite the proven high recurrence of eclamptic fits associated with the drug. Similar to other countries, provider knowledge of and training about magnesium sulfate is very limited. And the cost is prohibitively high compared with other, less favorable drugs. Also, in many communities, the culture demands that women deliver at home or at their parents’ house, which prohibits women from accessing life-saving medical care in a timely manner.</td>
</tr>
</tbody>
</table>
III. THE WAY FORWARD: SOLUTIONS TO EXPANDING UTILIZATION OF MAGNESIUM SULFATE

Based on these conclusions, EngenderHealth and the University of Oxford developed a “Call to Action” that calls on policy makers and ministers of health to make pre-eclampsia and eclampsia a higher priority and to set national guidelines for treatment and care based on WHO guidelines. It also urges decision makers and international and national health organizations and agencies to help make magnesium sulfate more available and affordable, in part by empowering local clinicians with education and training. The recommendations for interventions to expand the use of magnesium sulfate are:

**Ensure Widespread Availability of Eclampsia Treatment Packs**
One specific and urgently needed step is to promote the use of “eclampsia treatment packs” (such as those used in the Eclampsia Collaborative Trial) to ensure ready access and appropriate utilization of the drug in all facilities offering delivery services and to increase the likelihood of the drug’s correct and safe use. The introduction of emergency packs could serve as a training aid to update key health professionals about current clinical guidelines for management of pre-eclampsia and eclampsia.

**Expand Training and Education to All Health Professionals**
All health professionals (including family and emergency room physicians, anesthetists, nurses, midwives, medical officers, and pharmacists) need to be appropriately trained in the care of women with eclampsia and severe pre-eclampsia, including the use of magnesium sulfate.

**Increase Political Commitment to Address Pre-eclampsia/Eclampsia, in Country and Globally**
All stakeholders concerned about women’s health are urged to take measures to prevent deaths due to pre-eclampsia and eclampsia. This would include working to:

- Add magnesium sulfate to essential drug lists and ensure registration, universal availability, and appropriate use in all countries.
- Develop country-specific standards of care drawing from WHO’s guidelines and best practices to share with national and international colleagues and organizations.
- Obtain local support and identify local champions, such as health care providers and politicians.

**Disseminate Research to Advocate for Increased Utilization and Access**
Various champions for the issue, such as researchers or professional organizations, can bring the results of their research to a wider audience, such as publishing articles that call for updating clinical practices in national or regional journals. The information could then be used to convince central health authorities and hospital administrators to make changes in clinical practices. Estimating the cost savings from the use of magnesium sulfate resulting in shorter maternal and newborn hospital stays would represent a powerful advocacy tool to influence local and national policy makers.
Conduct Country-Specific Research

Each country’s pharmaceutical situation, political environment, and health care system are unique. Data collected about a country in one region often cannot be generalized to other contexts. For the purposes of planning specific interventions, data must be obtained on a country-by-country basis in order to develop context-appropriate strategies for expanding magnesium sulfate availability and utilization. The types of local information that are needed include: maternal morbidity and mortality resulting from pre-eclampsia/eclampsia, legal status of magnesium sulfate and presence on essential drug list, potential for political support for health policy change, and current practices in management of pre-eclampsia and eclampsia. The desire for a complete data set for each country must be weighed against the costs, length of time needed, and reliability of the data collection.

The opportunities for reducing maternal and perinatal morbidity and mortality from pre-eclampsia and eclampsia are extraordinary. Magnesium sulfate is a solution with proven effectiveness and safety, and yet it still eludes thousands of women who die needlessly each year. Although the use of magnesium sulfate has lagged in many developing countries, resources to expand its availability and use also exist: Actions by international organizations, championing by highly regarded local clinicians, and the support of local policy makers can all help make magnesium sulfate the leading treatment to save women’s lives.

Mainstream the Use of Magnesium Sulfate in Mexico

Dr. Ricardo David Muñoz Soto, from the Ministry of Health, and Dr. Sandra García, from the Population Council, Mexico, shared the situation of magnesium sulfate in Mexico. Pre-eclampsia and eclampsia is the leading cause of maternal death in Mexico, with magnesium sulfate officially listed as the recommended standard of care for this problem. The drug is inexpensive, costing less than $5 per patient, and it is widely available, with very few reported side effects. Despite these factors, magnesium sulfate is not widely used in the country. Key barriers include: insufficient medical curricula about pre-eclampsia and eclampsia; difficult packaging of magnesium sulfate (i.e., magnesium sulfate coming in 1,000 and 500 ml packs, when the needed amount is 250ml); less-effective drugs, such as phenytoin, coming prepackaged and thus being easier to administer; and insufficient medical training, with providers failing to detect the symptoms of mild pre-eclampsia and lacking confidence to administer magnesium sulfate.

In response, the Ministry of Health has pledged its commitment to making magnesium sulfate more widely utilized for the treatment of pre-eclampsia and eclampsia. In 2005, intensive emergency obstetric care workshops held in 12 states included pre-eclampsia and eclampsia and its management with magnesium sulfate. The Ministry of Health and the Population Council are partnering to address the barriers to use of magnesium sulfate and to test interventions aimed at increasing utilization.
REFERENCES


%20Lozano%20%20Misclassification%20of%20Maternal%20Deaths%20in%20Mexico.pdf.


