ESTIMATION OF UNMET MEDICAL NEED FOR ESSENTIAL MATERNAL HEALTH MEDICINES

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Estimation of Unmet Medical Need for Essential Maternal Health Medicines

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March 2014
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# ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
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<tbody>
<tr>
<td>DHS</td>
<td>Demographic Health Survey</td>
</tr>
<tr>
<td>EML</td>
<td>Essential medicine list</td>
</tr>
<tr>
<td>IM</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>IU</td>
<td>international unit</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>MCHIP</td>
<td>Maternal and Child Health Integrated Program</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
</tr>
<tr>
<td>PAC</td>
<td>Post-abortion care</td>
</tr>
<tr>
<td>PE/E</td>
<td>pre-eclampsia/eclampsia</td>
</tr>
<tr>
<td>PPH</td>
<td>postpartum hemorrhage</td>
</tr>
<tr>
<td>PO</td>
<td>per oral</td>
</tr>
<tr>
<td>RHCS</td>
<td>reproductive health commodity security</td>
</tr>
<tr>
<td>STG</td>
<td>standard treatment guideline</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>US Agency for International Development</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Estimation of Unmet Medical Need for Essential Maternal Health Medicines
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PURPOSE

Despite momentous efforts and investments made at both the global and national levels by international and local stakeholders to reduce maternal mortality, a substantial number of countries are not on target to meet Millennium Development Goal (MDG) 5. Increasing access to and use of essential commodities for maternal health have recently gained attention as key concerns of several international initiatives. The United Nations (UN) Commission on Life-Saving Commodities for Women and Children acknowledges supply and demand challenges as among the main barriers to access and use of these life-saving commodities. A basic step in improving access to these commodities is making sure they are available where and when women need them. To do so requires proper supply planning, which for various reasons has been a challenge for essential maternal medicines, such as their use for multiple indications and the lack of both morbidity and true consumption data on which to base quantification. At present, limited data are available to demonstrate whether countries are procuring enough medicines to cover all women who need these essential commodities. With less than three years left to meet the MDG goal, identifying the potential gaps, or unmet need, is critical as countries intensify efforts to scale up access and availability to these medicines in order to meet the goal. With these data, governments will be able to plan and spend more effectively and efficiently across the health sector.

The purpose of this document is to present an approach that will allow national program managers and other key stakeholders to assess a country’s theoretical need for the three overlooked life-saving maternal health commodities (i.e., oxytocin, magnesium sulfate, and misoprostol) and compare this with actual procurement data. The exercise will assist countries in rationalizing their efforts to implement Recommendation 6 of the UN Commission on Life-Saving Commodities for Women and Children of improving the supply of commodities—for the 3 out of the 13 overlooked life-saving commodities for maternal health. It will provide an indication of the extent to which needs are met and highlight the gaps that require attention. Countries will be able to tailor the tool based on their country’s need for these maternal health commodities for all obstetric indications for which the products are registered in the country. This information will then allow stakeholders to explore the reasons behind these gaps, reevaluate the assumptions on which procurement decisions are currently based, and stimulate further discussion and analysis, allowing stakeholders at the national level to work together to advocate for actions to increase access to these life-saving commodities. The inclusion of stakeholders from the private sector should also be considered in these discussions to assure that their role as providers of maternal health care is also contemplated. This effort can in turn complement the larger reproductive health commodity security work which is critical for increasing access to these medicines.
Assessing the Unmet Medical Need

The expression “unmet need” has been used for many years in reference to reproductive health. One of the earliest appearances of the expression in demographic literature dates to 1970, when Scheyer recommended increased federal involvement in subsiding family planning services. When used in reference to less-developed countries, unmet need for family planning has come to refer to potential users, or simply non-users, who do not wish to have more children but who are not using family planning methods.2

The overarching framework of commodity security—the ability of clients or end users to obtain the medicines as and when required—is also applicable to maternal health medicines, as here the notion is to guarantee availability of these medicines to service providers for use when a specific medical indication arises. The unmet need for these maternal health commodities unites women’s universal desire for and right to safe delivery outcomes for themselves and their newborns with availability and access to the essential medicines and services. Together, the two concepts provide a powerful humanitarian rationale for investing in any country’s current and future maternal health programs. A group-specific approach such as one described in this exercise to promote commodity security could prove an effective methodology for broadly diagnosing gaps in the accessibility of maternal health commodities and, consequently, in developing a road map to bridge the gap by designing specific interventions with ongoing monitoring of the supply planning to avoid stock-outs. In addition, important elements of advocacy that are core to the overall commodity security framework—such as partner coordination, financing requirements, enabling policy environments, updating the essential medicines list (EML), revising a country’s standard treatment guidelines (STGs), and allocating necessary resources (both financial and human) for supply chain functions—will be addressed through this exercise, thereby strengthening commodity security for this specific category of medicines.

It is increasingly important to develop a way of estimating needs for essential maternal health medicines—not only to enable an accurate forecast for procurement, but also as an advocacy tool. At present most countries do not quantify these needs. The country-specific data on maternal health indicators, such as incidence of postpartum hemorrhage or eclampsia, are not available, and forecasting and quantification are most often based on past annual procurement data. In many countries, historic consumption data are not even available, with distribution data being used instead. Estimating the need for maternal health medicines and then comparing this with actual procurement will highlight the potential inconsistencies between the two and instigate dialogue to identify strategies to address the gaps.
**BACKGROUND**

The UN Millennium Development Declaration, signed by 189 heads of state in 2000, committed world leaders to achieving MDG 5: to improve maternal health by reducing the maternal mortality ratio by three-quarters by 2015, and achieving universal access to reproductive health. Progress has indeed been made (figure 1). The maternal mortality ratio—the number of maternal deaths per 100,000 live births—decreased from 440 in 1990 to 210 in 2010. However, data indicates that only 9 of the 74 countdown countries with available data are on track to achieve MDG 5. Sub-Saharan Africa (with 56 percent of these deaths) and Southern Asia (29 percent) together accounted for 85 percent of the global burden in 2010.

**Figure 1. Country progress toward MDG 5 (adapted from ref. 26, p. 16)**

The major complications that account for 80 percent of all maternal deaths (figure 2) are severe bleeding, infections, high blood pressure during pregnancy (pre-eclampsia/eclampsia [PE/E]), obstructed labor, and unsafe abortion. Hemorrhage and hypertensive disorders account for the largest proportion of maternal deaths in developing countries.

**Figure 2. Causes of maternal mortality (adapted from ref. 26, p. 20)**
Postpartum Hemorrhage

Primary postpartum hemorrhage (PPH), defined as blood loss equal to or greater than 500 mL within 24 hours after birth, is identified as a major killer of women during childbirth. Therefore, the 24-hour period after birth is the most dangerous for the mother and active management during this period is called for with every birth irrespective of where it happens. PPH has a prevalence rate of approximately 10.5 percent. It is difficult to predict who will have PPH based on risk factors; two-thirds of women who have PPH present no risk factors. Therefore, all women are considered at risk, and hemorrhage prevention must be incorporated into care provided at every birth. The World Health Organization (WHO) affirms that most deaths due to PPH can be avoided with proper diagnosis and use of essential medicines, such as oxytocin in every delivery and misoprostol in settings where oxytocin cannot be administered.

Pre-Eclampsia and Eclampsia

One of the most common, yet treatable, causes of maternal death and disability worldwide is pre-eclampsia—the rapid elevation of blood pressure during pregnancy. It is estimated that 2–8 percent of all pregnancies are complicated by pre-eclampsia; however, according to WHO, in Africa and Asia, nearly one-tenth of all maternal deaths are associated with hypertensive disorders of pregnancy, whereas one-quarter of maternal deaths in Latin America have been associated with those complications. Eclampsia can occur in the second half of pregnancy, during labor, or after the birth, and is more common in low- and middle-income countries than in high-income countries. The pathogenesis of eclampsia is partially understood: it is related to inflammation and endothelial damage, and to placentation. Approximately 5–8 percent of women with pre-eclampsia present this condition (eclampsia) in developing countries. For hypertensive disorders, the second-most-common cause of maternal death, greater use of magnesium sulfate is clearly called for.

Existing Data on Availability of Essential Maternal Health Medicines

As described earlier, the major causes of maternal mortality are known, as are interventions to prevent and treat these causes: the use of medicines such as oxytocin, magnesium sulfate, and misoprostol. The question is then whether women have access to the medicines required for the prevention and treatment of these conditions. While some data on availability of maternal health medicines have been collected, rarely is there a consideration of whether the amount available is sufficient to meet the needs of the population under study.
For example, a global survey undertaken by the USAID-funded Maternal and Child Health Integrated Program (MCHIP), first in 2011 and again in 2012, provides some information on the availability of oxytocin, misoprostol, and magnesium sulfate in more than 30 countries. The purpose of these surveys was to track the progress of implementation of national strategies for the prevention and management of PPH and pre-eclampsia/eclampsia (PE/E). The results are based on data collected mostly through interviews and document review at the national level. The recently presented results from the 2012 survey and their comparison with the findings from the 2011 survey indicate that a regular supply of oxytocin is still an issue at public health facilities in surveyed countries. Likewise, the survey indicates that little progress has been made in increasing the availability of misoprostol at public health facilities. An increase in the availability of magnesium sulfate, however, was reported in 2012.\(^9\)

While the MCHIP report offers a panoramic view of the global status, studies conducted recently in Rwanda and Kenya under the SIAPS Program provide country-specific information on the availability of these medicines in a select sample of facilities. In Kenya, oxytocin was present in most of the health facilities visited during the assessment, whereas many facilities did not have magnesium sulfate. Misoprostol, which according to the standard treatment guidelines (STGs) that applied at the time of the assessment should have been present only at the hospital level, was available at many lower-level facilities. In Rwanda, the situation was similar. Oxytocin was available in most health facilities, while magnesium sulfate was not. Misoprostol use for home-based maternal care had recently been introduced in pilot areas at the time of the assessment. It was available in the hospitals visited, but in very few lower-level facilities.

In summary, while these surveys, and others similar to them, provide some information on both reported and observed availability, they do not provide any indication as to whether the quantities available are sufficient to cover actual needs—for example, whether oxytocin is present in sufficient quantities so that every woman giving birth in a health facility receives oxytocin. In other words, few data are available to demonstrate the level of “unmet need” for these essential medicines.
METHODOLOGY

The methodology described is a participatory process in which national stakeholders undertake what is in essence a simplified pre-forecasting exercise that calculates theoretical need and then compares that need with the actual procurement data from their country. Forecasting involves obtaining an estimate of anticipated supply needs. If the forecasting had been done for procurement purposes (as the first step in quantification), it would then be checked against the available budget, and against the amount of medicine in the pipeline and in transit. (See the explanation of terms section.) In addition, proper supply planning would take into consideration the delivery of supplies by coordinating supply and demand, current procurement process and specification, assessment of warehouses/health centers to examine their capability for storage of these medicines, and the distribution strategy.

For this methodology, for a specific country a theoretical quantity will be calculated for universal coverage based on country demographic data, global epidemiological assumptions, and internationally accepted STGs (assuming no stocks are currently available in pipeline). These calculated quantities will then be compared with the country’s most recently available one-year procurement data to estimate the theoretical unmet need for each of the three essential maternal health medicines. This comparison will then be used to stimulate discussion among stakeholders to analyze current practices and inform decision making moving forward.

The process involves six steps:

**Step 1**
Collect demographic data

**Step 2**
Collect epidemiological data

**Step 3**
Calculate estimated need for each medicine for both the public and private sectors

**Step 4**
Collect procurement data

**Step 5**
Compare with procurement data to calculate unmet need

**Step 6**
Convene a meeting of stakeholders to discuss the results of the unmet need calculations and the underlying factors affecting the results and to develop an action plan to address gaps
Step 1: Collect Demographic Data

The specific data necessary for the calculation are as follows:

- Number of pregnant women who give birth per year (if this information is not available, the number of births per year can be used to calculate approximate number of pregnancies)
- Percentage of facility-based deliveries or deliveries attended by a skilled provider
- Percentage of deliveries occurring at home or unattended by a skilled provider
- Percentage of deliveries occurring at public sector and private sector facilities

Data from Demographic Health Surveys (DHSs) or Ministry of Health (MOH) service statistics can provide the information necessary for the exercise. Keep in mind that DHSs are not generally conducted annually and so data from these surveys may be two to three years old; therefore, some adjustments are likely to be needed. Likewise, MOH service statistics may not capture all women who give birth with a skilled birth attendant. Every effort should be made to use the most recent available data for these indicators.

Step 2: Collect Epidemiological Data

Ideally, to prepare an accurate forecast of medicines for obstetric complications, specific data on maternal morbidity (e.g., the number of pregnant women who experience or may develop PPH or PE/E) within a specific time period are needed. Unfortunately, very few countries regularly collect the information that could be helpful in calculating the actual incidence and prevalence of these maternal health conditions. In the absence of country-specific morbidity data, evidence present in published scientific literature has been used as proxy in this exercise. Table 1 presents the assumptions that can be used in the absence of country-specific data.
Table 1. Assumptions Related to Obstetric Conditions

<table>
<thead>
<tr>
<th>Assumption*</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of deliveries that require induction</td>
<td>9.6% of all deliveries Unpublished data from the WHO Global Survey on Maternal and Perinatal Health indicates that 9.6% of all deliveries require induction.</td>
</tr>
<tr>
<td>Percentage of deliveries that require augmentation</td>
<td>20% of all pregnancies According to the Cochrane Database of Systematic Reviews, caesarean section rates are above 20% in many developed countries and the high rate in nulliparous women is associated with dystocia, or prolonged labor. The unstratified analysis found early intervention with amniotomy and oxytocin to be associated with a modest reduction in the risk of caesarean section. In another meta-analysis of 9 trials with 1,983 women, early oxytocin was associated with an increase in the probability of spontaneous vaginal delivery (RR 1.09, 95% CI 1.03–1.17).</td>
</tr>
<tr>
<td>Percentage of deliveries that end up in PPH even when oxytocin is administered for prevention of PPH</td>
<td>2.85% of women who receive oxytocin for PPH prevention end up in PPH According to the WHO report Global Burden of Maternal Hemorrhage in the Year 2000, the incidence of PPH within 1 hour postpartum in those who were actively managed was estimated from the MISO trial (where PPH incidence, defined as &gt; 1000 mL of blood loss in the oxytocin arm of the trial), was 2.85%. A Cochrane review demonstrated that active management with oxytocin results in a relative risk of 0.33 for blood loss ≥ 1,000 mL within the first 24 hours compared to expectant management. Based on this evidence, it is assumed that the incidence of PPH in those who are managed expectantly by a skilled birth attendant would be twice as high, or 5.7% of births.</td>
</tr>
<tr>
<td>Percentage of pregnancies that end up in PPH even when misoprostol is administered for prevention of PPH</td>
<td>6% of pregnant women who receive misoprostol for prevention of PPH According to a randomized controlled trial of the use of oral misoprostol in resource-poor communities, of every 18 women given misoprostol for prevention of PPH, 1 case of PPH was averted. This represents roughly 6% of pregnant women who received misoprostol for prevention of PPH.</td>
</tr>
<tr>
<td>Percentage of pregnancies that are complicated by PE/E</td>
<td>2% of pregnancies require treatment with magnesium sulfate for severe PE/E The authors of the Magpie Trial estimated that PE/E complicates 2–8% of pregnancies. Since only a small percentage of patients will actually develop severe PE/E and need magnesium sulfate, 2% is used in the estimation.</td>
</tr>
<tr>
<td>Percentage of pregnancies that end in miscarriage and require treatment</td>
<td>28% of the miscarriage cases treated expectantly Cochrane Database Systematic Reviews mentions miscarriages occur in 10–15% of pregnancies, and about 28% of those managed with expectant care need treatment.</td>
</tr>
<tr>
<td>Post-abortion care cases that require treatment</td>
<td>1.4% of pregnancies end up in unsafe abortion It is estimated that, globally, 14 of 1,000 women aged 15–44 years had an unsafe abortion in 2008.</td>
</tr>
</tbody>
</table>

*Countries can use the most accurate range possible in reference to their country context.
Step 3: Calculate Estimated Need for Each Medicine

The assumptions used in this step are based on the most recent WHO recommendations for the management of PPH and PE/E and internationally accepted (International Federation of Gynecology and Obstetrics [FIGO], American Congress of Obstetricians and Gynecologists [ACOG]) STGs for post-abortion care (PAC), induction, and augmentation of labor. The quantity of medicines is estimated using the international guidelines for managing a given health problem, following specifications in the average treatment schedule. It is important to make this distinction of recommended use as per the guidelines, as it is possible that some medicines are in practice overused for specific conditions in certain settings. One such documented example of overuse is the use of oxytocin for induction of labor. The current recommendations for each medicine per indication are listed in tables 2–4.

Through this calculation the countries will arrive at the theoretical need only for any given year; however, countries should bear in mind that, between placing an order and the arrival of the required medicine at the central warehouse, there is a lead time that needs to be taken into account when actual forecasting is done. It is therefore suggested that when calculating the need for any specific year, at least three months’ worth of buffer stock should be included in the final calculated amount to avoid stock-outs.

A simple spreadsheet can be used for the calculations and to facilitate the later comparison between theoretical need and the quantities procured.
Oxytocin has several obstetric uses: induction and augmentation of labor, and prevention and treatment of postpartum hemorrhage. For calculation, it is assumed that oxytocin is used only by skilled birth attendants in facility-based deliveries.

Table 2. Recommended Uses of Oxytocin

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommendation</th>
<th>Dose required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction</td>
<td>According to current WHO guidelines: “When prostaglandins are not available, intravenous oxytocin alone should be used for induction of labor.”</td>
<td>Induction of labor, by IV infusion, adult and adolescent, initially 0.001–0.002 units/minute increased by 0.001–0.002 units/minute increments at intervals of 30 minutes until a maximum of 3–4 contractions occur every 10 minutes; maximum recommended rate is 0.02 units/minute; no more than 5 units should be administered in 24 hours.</td>
</tr>
<tr>
<td>Augmentation</td>
<td>According to a Cochrane systematic review of four studies involving 660 pregnant women. Three studies were randomized controlled trials and one trial was a quasi-randomized study. A higher dose of oxytocin was associated with a significant reduction in length of labor reported from one trial MD, 3.50 hours; 95% CI, -6.38 to -0.62; one trial, 40 women). There was a decrease in rate of caesarean section (risk ratio [RR] 0.53; 95% CI 0.38 to 0.75, four trials, 650 women) and an increase in the rate of spontaneous vaginal birth (RR 1.37; 95% CI 1.15 to 1.64; two trials, 350 women).</td>
<td>Higher dose of oxytocin starting and increment dose (4 mU/minute or more) was associated with a reduction in the length of labor and in caesarean section, and an increase in spontaneous vaginal birth.</td>
</tr>
<tr>
<td>Prevention of PPH</td>
<td>According to current WHO guidelines: &quot;Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug for the prevention of PPH.&quot;</td>
<td>Ideally, 100% of pregnant women delivering at the health facility would receive an injection of 10 IU oxytocin.</td>
</tr>
<tr>
<td>Treatment of PPH</td>
<td>According to current WHO guidelines: &quot;Intravenous oxytocin alone is the recommended uterotonic drug for the treatment of PPH.&quot;</td>
<td>WHO recommends, inserting IV line, 20–40 IU oxytocin is given in 1 L of IV fluids at 60 drops/minute, and that oxytocin infusion be continued at 20 IU/L of IV fluids at 40 drops/minute until hemorrhage stops.</td>
</tr>
</tbody>
</table>

MD, mean difference
To calculate the estimated need for oxytocin for all of the indications listed above, and considering the demographic data collected as part of step 1, the formulas in box 1 below should be used.

**Box 1. Estimation of Need for Oxytocin**

A = Oxytocin required for induction = 
\[(\text{# of births per year}) \times (\% \text{ of facility-based births}) \times (10\% \text{ of births induced}) \times (1-10 \text{ IU})\]

B = Oxytocin required for prevention of PPH = 
\[(\text{# of births per year}) \times (\% \text{ of facility-based births}) \times (100\% \text{ of births}) \times (1-10 \text{ IU})\]

C = Oxytocin required for treatment of PPH in those who received oxytocin for PPH prevention = 
\[(\text{# of births per year}) \times (\% \text{ of facility-based births}) \times (2.85\% \text{ of births with PPH}) \times (7-10 \text{ IU})\]

D = Oxytocin required for augmentation of labor = 
\[(\text{# of births per year}) \times (\% \text{ of facility-based births}) \times (20\% \text{ of facility-based births}) \times (1-10 \text{ IU})\]

E = Oxytocin required for treatment of PPH for those who received misoprostol for PPH prevention = 
\[(\text{# of births per year}) \times (\% \text{ of home-based births}) \times (6\% \text{ of births with PPH}) \times (7-10 \text{ IU})\]

Total oxytocin required for all conditions = A + B + C + D + E

**Misoprostol**

Misoprostol is currently recommended by WHO as an alternative where oxytocin is not available. Many studies and pilot experience of community distribution and use of misoprostol in home births are currently under way, and some countries have already revised their STGs to include use of misoprostol at lower-level facilities where appropriate storage of oxytocin in is not possible. In this exercise, however, we are calculating need for non-facility-based births for prevention of PPH and for PPH treatment, management of PAC cases, and treatment for unsafe abortions at facilities (see box 2).
### Table 3. Recommended Uses of Misoprostol

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommendation</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of PPH</td>
<td>Current WHO guidelines state: “In settings where skilled birth attendants are not present and oxytocin is unavailable, the administration of misoprostol (600 μg PO) by community health care workers and lay health workers is recommended for the prevention of PPH.”*6</td>
<td>600 μg orally</td>
</tr>
<tr>
<td>Treatment of PPH</td>
<td>Current WHO guidelines state: “If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, prostaglandin drug (including sublingual misoprostol, 800 μg) is recommended.”*6</td>
<td>800 μg sublingually</td>
</tr>
<tr>
<td>Induction of labor</td>
<td>There have been 25 trials with 3,074 participants to test the effectiveness of induction with misoprostol. In many of these studies, vaginal misoprostol appeared to be more effective than oxytocin for the induction of labor (10 trials, average RR for failure to achieve vaginal delivery within 24 hours 0.65, 95% CI 0.47–0.90). However, there is no conclusive evidence regarding the use of oral misoprostol for induction. Furthermore, at present only oxytocin is recommended for induction of labor in most countries’ STGs; therefore, this indication is not added in the calculation for estimating the need of misoprostol as shown in box 2 below.21</td>
<td>25 μg vaginally</td>
</tr>
<tr>
<td>Management of PAC</td>
<td>Misoprostol is the most common and thoroughly studied form of medical management and offers a highly effective alternative treatment for women wishing to avoid invasive surgery and anesthesia.22 Venture Strategies Innovations and IPAS recommend misoprostol use for PAC.23</td>
<td>• Per WHO guideline: for vaginal, buccal, or sublingual routes, recommended dose of misoprostol is 800 μg. • For oral administration, recommended dose of misoprostol is 400 μg.24</td>
</tr>
</tbody>
</table>

### Box 2. Estimation of Need for Misoprostol

- A = Misoprostol required for prevention of PPH=
  
  \[\text{(# of births per year)} \times (\% \text{ of home-based births}) \times (100\% \text{ of births}) \times (3-200 \mu g \text{ tablets})\]

- B = Misoprostol required for PAC/unsafe abortion* =
  
  \[\text{(92 \% of 23\% of cases PAC cases/year)} \times (2-4-200 \mu g \text{ tablets})\]

- C = Misoprostol for miscarriage =
  
  \[(28\% \text{ of miscarriage cases}) \times (3-200 \mu g \text{ tablets})\]

**Total misoprostol required for all conditions = A + B + C**

*Rate of unsafe abortion is 14 per 1000 women of reproductive age

**10-15 \% of pregnancies may end up in miscarriage**25
Magnesium Sulfate

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 percent in the 33-country Magpie Trial, which was conducted in 1995. Similarly, another study published in *Lancet* mentions that magnesium sulfate halves the risk of eclampsia and 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.

### Table 4. Recommended Uses of Magnesium Sulfate

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommendation</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of severe PE/E</td>
<td>WHO guidelines state: “Magnesium sulfate is recommended for the prevention of eclampsia in women with severe pre-eclampsia in preference to other anticonvulsants.”</td>
<td>There are currently two regimens:</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Pritchard regimen (IV/IM)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loading dose: 4 g in 20 mL (20% solution) administered IV over 15–20 minutes, followed by 5 g in 10 mL solution (50%) IM injection in each buttock</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance dose: 5 g in 10 mL (50% solution) IM injection every 4 hours in alternate buttocks</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Zuspan regimen (IV/IV)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loading dose: 4 g in 20 mL (20% solution) administered IV over 15–20 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance dose: 1 g per hour IV infusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For both regimens, the duration of treatment is 24 hours after last convulsion or delivery, whichever occurs later.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOTE: If convulsions occur after the loading dose is given, administer 2 g in 4 mL (50%) IV over 5 minutes.</td>
</tr>
</tbody>
</table>

### Box 3. Estimation of Need for Magnesium Sulfate

**Magnesium sulfate required** =  
(% of facility based births) x (2% of pregnancies) x (ampoules required for treatment of a single case) *  

*Because magnesium sulfate is available in different formulations and there are two different regimens, countries are advised to select the formulation procured along with the regimen in their individual STGs.*
Table 5 provides a summary of the product assumptions described above for oxytocin, misoprostol, and magnesium sulfate.

### Table 5. Product Assumptions Using International Recommendations

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Indication</th>
<th>Recommended dose</th>
<th>Formulation</th>
<th>Units required per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oxytocin</strong></td>
<td>Induction/augmentation</td>
<td>10 IU</td>
<td>10 IU</td>
<td>1 vial</td>
</tr>
<tr>
<td></td>
<td>Prevention of PPH</td>
<td>10 IU</td>
<td>10 IU</td>
<td>1 vial</td>
</tr>
<tr>
<td></td>
<td>Treatment of PPH</td>
<td>Up to 70 IU</td>
<td>10 IU</td>
<td>7 vials</td>
</tr>
<tr>
<td><strong>Misoprostol</strong></td>
<td>Prevention of PPH</td>
<td>600 μg</td>
<td>200 μg</td>
<td>3 tablets</td>
</tr>
<tr>
<td></td>
<td>Treatment of PPH</td>
<td>800 μg</td>
<td>200 μg</td>
<td>4 tablets</td>
</tr>
<tr>
<td></td>
<td>PAC</td>
<td>400-800 μg</td>
<td>200 μg</td>
<td>2-4 tablets</td>
</tr>
<tr>
<td><strong>Magnesium sulfate</strong></td>
<td>PE/E</td>
<td>This will depend on the regimen most commonly used in the country.</td>
<td>The WHO-recommended presentation is a 50% solution, which is equivalent to 0.5 g/mL.(^3) Common presentations include 1 g/2 mL (50%) and 5 g in 10 mL (50%). However, several countries have other formulations, such as 15% solutions or 4 g/100 mL (4%) solutions. The presentation available in a country determines the regimen that can be administered.</td>
<td>Number of doses:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 g/2 mL:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pritchard = 39</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zuspan = 28</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5 g/10 mL:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pritchard = 8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zuspan = 6</td>
</tr>
</tbody>
</table>

### Assumptions

In calculating the theoretical unmet need using the methods mentioned above, some assumptions have been used such as:

- All PAC cases, inductions, and augmentations are managed at the facility level.
- All cases of induction and augmentation are managed using oxytocin.
- All cases of PE/E are managed at the facility level and every facility should have available stocks of magnesium sulfate to deal with emergency cases.
- All cases of PPH treatment are managed at the facility level using oxytocin.
• Misoprostol is registered in the country for indications such as PAC and PPH prevention.

If the team working on calculating unmet need has access to reliable evidence that suggests these assumptions are not valid in their local context, the assumptions can obviously be adapted.

*Management Flowcharts*

The flowcharts below represent the logic followed in steps 1, 2, and 3.
Management of miscarriage

- Number of women aged 15-44
- 14 unsafe abortions per 1,000 women aged 15-44 years
- Estimated 23% of unsafe abortions require hospitalization for complications
- Estimated 92% require treatment with misoprostol
  - Each case requires 400 μg misoprostol for oral administration; 800 μg misoprostol for vaginal, buccal, or sublingual routes

PAC with misoprostol

- Number of births
  - Number of births x 10-15% = Number of pregnancies
  - 10-15% of pregnancies end in miscarriages
  - 28% of miscarriages may require misoprostol
    - Each case requires 600 μg of misoprostol
**Step 4: Collect Procurement Data**

To estimate the *unmet* need, the theoretical need must be compared to the quantities of medicines that have been procured recently or are planned for procurement. For the purpose of this exercise, either can be used. However, it is important to ensure that the amounts compared are for the same period of time. The above calculations of estimated need are all annual estimates. If the procurement cycle in a given country is shorter or longer, the figures may need to be adjusted to come up with an annual figure.

In some countries, data on recent procurements may already be available online. In other countries, the agency responsible for conducting national public procurement will need to be consulted. In settings where subnational procurement of these medicines is also occurring, efforts should be made to take this information into account as well.

For the purpose of this exercise, it is important to know the following for each medicine:

- Formulation and presentation of each medicine (e.g., 10 IU/ampoule or 5 IU/ampoule of oxytocin); collecting this information is of prime importance, especially for calculating quantities of magnesium sulfate, which is currently available in multiple formulations
- Amount procured (e.g., 500,000 ampoules)
- The period that procurement is expected to cover (e.g., 12 months)
It is also important to collect as much information as possible about how decisions were made about the quantities of medicine to procure. This information will be discussed in detail when stakeholders come together to review the unmet need calculations.

**Step 5: Compare with Procurement Data to Calculate Unmet Need**

The preliminary calculations of medicines required to treat these conditions can be used to calculate the unmet need by comparing it with the actual procurement data. Once the unmet need is calculated, the next step for countries will be to develop an action plan at a stakeholders’ meeting to address the gap. This exercise will serve as a guidance tool when actual quantification is done, which will require additional information such as stock on order, stock on hand and supply pipeline, and buffer stock.

<table>
<thead>
<tr>
<th>Estimated yearly need</th>
<th>Country procurement plan</th>
<th>Percentage unmet need</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>[(A-B)/A] x 100</td>
</tr>
</tbody>
</table>

Despite its substantial infrastructure, the public sector health care system in most developing countries is often underused. The lack of qualified staff at public sector facilities, long traveling distances, and frequent stock-outs are major reasons for the underuse of this sector. As a result, large populations—even the poor—seek health care from a wide variety of private providers, ranging from private doctors, lower-cadre health workers, skilled birth attendants, and traditional birth attendants. Therefore it is necessary to involve the private sector in the national quantification process. If the estimated need for this sector is calculated, coverage for women expected to deliver at private sector facilities will be guaranteed. Most DHSs collect information on the percentage of facility-based deliveries occurring independently in both the public and private sectors. Thus the required amount calculated for facility-based delivery can be further divided to separately estimate needs for both public and private sectors from the percentage of facility-based births in each sector.

**Estimated need for public and private sector**

- **Total requirement of the medicine for all possible indications**
  - Facility-based births
  - Home births
  - Private sector
  - Public sector
Once the theoretical need calculations are made, the procurement data are collected, and unmet need is estimated, a consultative meeting of stakeholders can be convened to discuss the way forward.

**Proposed Participants**

Suggested participants include managers of the maternal health program/department within the MOH, representatives of the unit(s) responsible for procurement of maternal health medicines, representatives of nongovernmental organizations (NGOs) working on maternal health, representatives from international organizations, and donors. Where possible, private sector players, which could include health providers, manufacturers, importers, distributors, and retailers, should be invited, as this sector plays a key role in most developing countries in complementing public sector efforts to increase access to and deliver health services and are responsible for bringing maternal health medicines for the commercial/for-profit sector.

**Convening a Consultative Group Meeting**

A two-day meeting is proposed for the group; this will allow time to review the calculations and discussion regarding the way forward among the members, with the following objectives:

- To share the methodology developed for estimating the unmet need for essential maternal health commodities and to link the efforts to the overall UN Commission’s work

- To assist policy makers to identify next steps and a plan of action for quantification of the three overlooked maternal health commodities: oxytocin, misoprostol, and magnesium sulfate

- To identity and engage a group committed to the support of the ongoing planning and implementation of the quantification process and making necessary policy changes in the country, including, if necessary, revised STGs, and general advocacy efforts for ensuring safe delivery for every women expected to give birth

At least two days would be required to review the calculations and allow for ample discussion regarding the way forward.

**Day 1:** On the first day of the meeting, the 6-step approach for estimating the unmet need is presented to the group. The assumptions used in step 3 are explained in detail so that all participants understand the basis for these calculations. During this discussion it is important to remember that the
Methodology

Estimations have been calculated to cover the universe of pregnant women in countries in a specific calendar year irrespective of the place they deliver.

The current procurement data would also be reviewed, giving participants an opportunity to include additional data that may not have been available at the time the calculations were prepared. For example, the procurement data used in the exercise may not have included contributions at the local level made through NGOs or donor-driven efforts. Likewise, the role of the private sector in provision of maternal health medicines should also be taken into account, as only public sector procurement may have been taken into account for the exercise.

Day 2: Once these data have been presented along with the estimated unmet need for each medicine, the rest of the meeting can be dedicated to discussion. During these discussions, decisions regarding assumptions used and a proposed action plan should all be recorded and agreed upon. For example, stakeholders may decide that it is realistic to aim only for a 20 percent reduction in unmet need for the following year. The second day is thus dedicated to group work. Suggested subgroups with tasks are:

Subgroup 1: Develop consensus on the assumptions for estimating medicines on the basis of needs at different levels of service delivery points.

- Analyze available data to identify gaps
- Consider whether, in the absence of country-specific morbidity data for these maternal health conditions, the assumptions presented in the methodology could be used?
- Consider what could be used in place of missing information/data
- Review reporting formats
- Review current STGs for all levels of service delivery (health center to hospital levels, and for home deliveries)
- Consider relevant changes in political/legal environment, such as agreement on community-based distribution of misoprostol for countries where misoprostol is registered for use in obstetric indication; for countries where misoprostol is not registered, the meeting could provide a good forum to start advocacy for introducing the product in the country

Subgroup 2: Consider improvements in future procurement practices. Certain products, such as oxytocin and misoprostol, are used for the same obstetric indication, and country programs could preferably opt to have both available for indications like induction, augmentation, and PPH prevention for facility-based births. Some important justifications for this approach are issues associated with the storage and transport of these commodities, especially oxytocin, and the presence of skilled personal at the time of delivery, even at facilities. Hence, while calculating the estimated need, an allocation between commodities for
their use in the same obstetrical indication should be made; for example some countries may consider availability of misoprostol for facilities births in addition to oxytocin. Suggested subgroups with tasks are:

- Determine percentage allocation between products used for the same obstetric indications
- Determine if there is a need for revision of reporting forms
- Determine the desired amount of buffer stock (in months)
- Standardize the formulations of the three commodities to ease future quantification and procurement; for example, reach agreement on which formulation of magnesium sulfate will be used in-country, or whether 5 IU or 10 IU ampoules of oxytocin will be procured for the country

**Meeting Outcomes**

The outcomes of this meeting would then be a mutual agreement among stakeholders to accept certain assumptions and conditions and recognize that gaps may still persist in the near future. This should be synthesized in an action plan with both short- and long-term strategies for addressing the identified gaps, with roles and responsibilities and time frames clearly defined. In countries where a reproductive health commodity security (RHCS) committee already exists, it could be appropriate to have a subgroup formulated under the broader RHCS committee with additional members as required. This will avoid duplication of efforts and inefficiencies and maintain a focus on MH commodities.

However, in settings where there is no existing RHCS, an individual maternal health commodity security working group or task force can be established to ensure collaboration in prioritizing and coordinating activities to address the identified gaps; ultimately the group can mutually reinforce related activities. The goal is to have a multi-sectoral representation with participation by (a) individuals who have technical knowledge on forecasting and quantification, (b) program managers and service providers who know the incidence of these maternal health conditions and the norms in country to manage these conditions, and (c) those that have the authority and influence to make necessary policy changes. As mentioned earlier, it is important that efforts are made to increase synergies to ensure commodity security in general for maternal health. To this end, the private sector should be represented in the group. This approach will increase the credibility of and productivity of these meetings, resulting in proposed suggestions and activities that are more appropriate and applicable to the local context.
VALIDATION OF THE METHODOLOGY IN TWO COUNTRIES

To validate the developed approach, SIAPS field-tested the methodology in the Democratic Republic of Congo and Bangladesh. In both cases, SIAPS assisted MoH in leading the process with participation from representatives of partner NGOs, service providers, and representatives from the pharmaceutical college. During the two-day workshops, the participants formed groups to estimate the unmet need in the country and identify reasons leading to this gap in procurement and actual need; these groups agreed to formulize the process and become working groups/task forces. The purpose of these working groups is to continue discussions to identify strategies to overcome the shortfalls documented during the workshops. A description of the results of these two workshops follows.

Estimating Unmet Need for Maternal Health Medicines in Bangladesh

Country Context

Bangladesh has made some remarkable progress in reducing maternal mortality in recent decades. According to the 2012 Countdown 2015 report, Bangladesh is on track to achieve MDG 5. The Bangladesh Maternal Mortality and Health Care Survey 2010 (http://www.cpc.unc.edu/measure/publications/tr-12-87) shows the maternal mortality ratio (MMR) declined significantly by about 40 percent from 322 to 194 between BMMS 2001 and BMMS 2010. The current policies in place demonstrate the Government of Bangladesh’s strong commitment to improving maternal health and making essential maternal medicines available to all women.

Approach

The SIAPS program in Bangladesh has the mandate to strengthen the overall supply chain management system of the Ministry of Health and Family Welfare (MoHFW), including building capacity for forecasting and supply planning. One of the specific areas SIAPS has been asked to support is quantification of essential reproductive, maternal, newborn, and child health medicines and supplies.

In this context, SIAPS facilitated a technical workshop to review the theoretical unmet medical need for three essential maternal health medicines (oxytocin, misoprostol, and magnesium sulfate) and to
discuss strategies to reduce this need among stakeholders working to improve maternal health. The two-day stakeholders’ workshop on “Assessing Medical Unmet Need for Essential Maternal Health Medicines” was held on April 28 and 29, 2013, at the SIAPS Bangladesh offices in Dhaka. In total, 16 participants representing over 6 different organizations, DGHS, and DGFP were present.

**Assumptions Used in Calculation of Need**

The methodology developed by SIAPS to estimate the theoretical unmet need for three essential maternal health medicines was presented to the participants who were then divided into three groups to review the assumptions and to define realistic coverage goals.

**Demographic Data Sources**

The participants agreed that it was appropriate to use the data from the last demographic health survey of Bangladesh conducted in 2011 on total population and number of births, both at facilities and at home. Some participants also suggested that the recent national census could also be consulted for population data.

**Epidemiological Data Source**

The epidemiological assumptions used as the basis for calculation of need sparked much discussion.

**Prevention of PPH**

While the assumption regarding oxytocin for prevention of PPH was agreed on by all, the assumption for misoprostol was not. The current recommendation in Bangladesh is for women to take two 200 mcg tablets for prevention for a total dose of 400 mcg, rather than the internationally recommended 600 mcg. Participants suggested that 40 percent of home births are not attended by anyone associated with the health system and therefore would not be receiving misoprostol supplied by MoHFW.

**Treatment of PPH**

Participants were not convinced that the assumption used in the calculation (that only 2.85 percent of women who have received a uterotonic for prevention will go on to develop PPH) can be used as a proxy for Bangladesh. They felt that the percentage was too low, given potential deficiencies in quality or efficacy of the product used for prevention. However, they admitted that there was no hard evidence for this supposition. Another concern was the referral rate of home births presenting PPH to facilities. In this case as well, there was no firm evidence to cite.
Use of Uterotonics for Induction and Augmentation
No firm conclusions were reached on the assumptions for use of uterotonics for this indication.

Management of Miscarriage/Post-Abortion Care
There was little agreement reached in terms of the assumptions used for these indications.

Prevention and Treatment of PE/E
Participants acknowledged the lack of national data, but agreed that the assumptions seemed reasonable.

Calculation of Unmet Need
The procurement for these essential maternal health medicines in Bangladesh is done at both the national and sub-national levels.

Procurement Data Sources
The SIAPS Bangladesh team contacted DGHS and DGFP offices to collect available data on procurement of these essential maternal health medicines at national level.

The collected data was presented to the group at the workshop; the participants commented that the most recent procurement plans needed to be consulted to ensure that the actual updated procurement data was captured. The estimations had been based on information taken from the operational plans. However, operational plans do not necessarily reflect the total amount that is ultimately procured. Participants recognized that while information on sub-national procurement of maternal health commodities is not readily available at the central level (especially relevant to oxytocin), it needs to be taken into account during procurement planning, as should stock on hand.

Using the agreed epidemiologic and demographic data the group calculated the unmet as follows.

Table 6. Unmet Need, Public Sector

<table>
<thead>
<tr>
<th>Product</th>
<th>Theoretical need</th>
<th>Quantity procured</th>
<th>Unmet need %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin</td>
<td>1,015,905</td>
<td>136,875</td>
<td>86</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>7,392,677*</td>
<td>4,700,000</td>
<td>36</td>
</tr>
<tr>
<td>Magnesium sulfate</td>
<td>249,848</td>
<td>265,000</td>
<td>(-6.1)</td>
</tr>
</tbody>
</table>

*The quantity of misoprostol required for home births is also being procured and distributed by MoH, hence the total need is referenced under the public sector data.

The unmet need for oxytocin, misoprostol, and magnesium sulfate was found to be 86 percent, 36 percent, and -6.1 percent, respectively.
Discussion

The participants discussed reasons behind this gap in procurement and came up with the following list of issues that initiated a lot of debate and discussion within the groups.

- Funding commitments often do not match what is actually received for procurement and is often much lower than the amount requested or initially planned for procurement.
- Poor/insufficient information is available to accurately estimate need; information on MCH commodities does not flow back up through the system to inform decision making.
- Lack of coordination in planning.
- Provider behavior affects use of all three medicines, especially magnesium sulfate; participants mentioned the confusion among providers because of the large variety of formulations available.
- Lack of skilled manpower for forecasting.
- Participants questioned the quality of oxytocin in use at lower levels of the health system and the capacity of facilities to adequately store it.

Conclusions

The main conclusions reached during the discussion of plans were:

- There is very limited information available for the epidemiological assumptions and, as such, data from comparison countries (e.g., India) need to be reviewed and considered.
- A small committee or working group should be formed comprised of NGOs working on MNCH and representatives of both the DGHS and DGFP to review quantification of maternal health medicines.
- A consolidated action plan based on the group work should be prepared and presented to the various existing technical working groups (e.g., the Maternal Health Taskforce, the National Technical Committee, the PPH Prevention Taskforce) to reach consensus and plan the way forward.
- The relevant departments within MoHFW and other government agencies need to be informed about the importance of these medicines and supplies and the need to ensure adequate access to them. In other words, MoHFW needs to ensure that the quantities proposed in the operational plans are actually procured.
Validation of the Methodology in Two Countries

Estimating Unmet Need for Maternal Health Medicines in the Democratic Republic of the Congo

Country Context

Although the Democratic Republic of the Congo (DRC) has shown improvements in maternal health over the past decade, with a decrease in the MMR from 930 in 1990 to 540 in 2010, more intensified efforts are required to bring the MMR to 233 per 100,000 live births and achieve MDG 5. In sub-Saharan Africa, hemorrhage, hypertensive disorders, and unsafe abortions account for 34 percent, 19 percent, and 9 percent of maternal deaths respectively. Identifying gaps or unmet need is critical as DRC intensifies its efforts to scale up access in pursuit of achieving the MDG 5 goal. Representatives from the DRC MoH emphasized the importance of conducting the unmet needs workshop as they recognize that the current amount of maternal and infant health products procured in DRC is not sufficient, evident from the fact that each hour 2 women, 13 newborns, 29 children less than 1 year, and 232 children less than 5 years die of preventable causes (EDS 2007).

This exercise engaged policy makers and program implementers in a dialogue to consider strategies to increase access to these medicines and thereby reduce maternal deaths.

Approach

The DRC MoH, with technical and financial support from SIAPS, organized the workshop to validate the methodology and stimulate a dialogue to improve future quantification and procurement for the three essential maternal health medicines. The problem is analyzing the significant gap between procurement and actual needs. A total of 41 representatives from MoH, service providers, implementing partners, donors and international NGOs participated in the two-day workshop held in September 2013.

Assumptions Used in Calculation of Need

The methodology developed by SIAPS to estimate the theoretical unmet need for three essential maternal health medicines was presented to the participants and the floor was then opened to suggestions.

Demographic Data Sources

Participants agreed that required demographic data available in the last demographic health survey conducted in 2007 and the Multiple Indicator Cluster Survey Report 2010 will be used for calculating the
theoretical need during the workshop. However, they proposed that some adjustments should be done to get updated and as accurate possible number of population using annual rate of increase of the population so as to have an accurate estimation of number of births when doing actual quantification.

**Epidemiological Data Source**

Since the incidence rate for these maternal health conditions is not available in most countries, SIAPS gathered information published in internationally recognized scientific literature and research papers to come up with a set of global assumptions that could be used by countries in the absence of country-specific morbidity data. The assumptions were presented to the group, and, in general, the group agrees that in the absence of DRC-specific data, global assumptions could safely be used for morbidity incidence. However, the group recommended that MoH conduct studies to collect specific morbidity data/incidence rates in DRC.

The following observations were made by the participants, in addition to the epidemiologic assumptions:

- Oxytocin should be the primary medicine used to treat PPH in facility-based births, but a small percentage of misoprostol should also be allocated.
- Research studies need to be found that indicate misoprostol should be used for PPH treatment until women are transferred to the hospital
- Misoprostol should be used to induce labor
- If regional data is found, it should replace global assumptions on unsafe abortion, miscarriage, and PAC

**Calculation of Unmet Need**

The system for procurement in DRC is not centralized; partners have been assigned districts and they are responsible for procuring all medicines for those districts. SIAPS/DRC staff along with the staff of DPM (Direction de la Pharmacie et du Médicament, D3)/MoPH collected available national procurement data for 2012 to compare it with the calculated theoretical need to determine unmet need for these commodities. However, multiple partners are involved in procurement and each has a different procurement cycle within the same calendar year; therefore, data from all partners could not be collected and consolidated for the same period (January-December 2012).

**Procurement Data Sources**
The team contacted the United Nations Population Fund (UNFPA), Bureau Diocésain des Oeuvres Médicales (BDOM), the International Rescue Committee (IRC), Association régionale d’approvisionnement en médicaments essentiels (ASRAMES), and the Integrated Health Project (IHP), implemented by Management Sciences for Health, and was able to collect the data on procurement to calculate the unmet need. Using the agreed epidemiologic and demographic data, the group calculated the unmet need in the following table.

Table 7. Unmet Need, Public Sector

<table>
<thead>
<tr>
<th>Product</th>
<th>Theoretical need</th>
<th>Quantity procured</th>
<th>Unmet need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin</td>
<td>2,319,094</td>
<td>537,912</td>
<td>71%</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>2,736,093</td>
<td>None</td>
<td>100%</td>
</tr>
<tr>
<td>Magnesium sulfate</td>
<td>340,704</td>
<td>14,740</td>
<td>96%</td>
</tr>
</tbody>
</table>

As misoprostol is not currently procured for the public sector, the unmet need for misoprostol is 100 percent. However, the unmet needs for oxytocin and magnesium sulfate were found to be 85 percent and 96 percent, respectively.

Discussion

The calculation exercise initiated a lot of debate and discussion within the groups to evaluate reasons behind this huge gap in procurement, with special emphasis on:

- Current practices for quantification and procurement of these medicines and making the following changes:
  - Revise reporting formats
  - Compile data on procurement and distribution at the national level
  - Use the SIAPS-developed approach for quantification of next year’s procurement of misoprostol, oxytocin, and magnesium sulfate

- STGs
  - Include use of misoprostol for PPH prevention for home births
  - Recommend magnesium sulfate for managing severe PE/E cases as first-line drug management

- Revision of the essential medicine list for DRC
  - Include all three products under respective categories and indications in the EML
  - Align the STGs and EML to ensure all partners procure the same formulations
Conclusions

The participants agreed to have a technical working group with participation from Direction de la santé de la famille et des groupes spécifiques (D10), D3, and partner NGOs involved in procurement of maternal health commodities. The group will reconvene semi-annually and design strategy to reduce the identified unmet need. The technical working group will be involved in the national quantification for 2014-15.

At the close of the workshop, the participants developed recommendations regarding policy changes, follow-up actions that MoH should take, and how donors could support addressing unmet need.

Recommendations for MoH

- Accelerate the implementation of a logistic information system so that data can be available for review every six months to avoid both overstocking and shortages
- Review the norms for MNCH and include the three products as first-line treatment for PPH and PE/E for facility and home births
- Gather research studies and data that have already been completed in the DRC to have a factual basis for writing norms and directives on management of pregnant women with hemorrhages by using oxytocin and misoprostol
- To the General Secretariat for Public Health: Ensure that standard care protocols including indications for each product are affixed in delivery rooms and maternity wards throughout the country
- Update the D10 protocols for use of oxytocin and misoprostol for management of PPH and make them available at all levels of service
- The technical working group will advocate to update the NEML to include misoprostol for use in management of PPH, especially for home births
- Have DPM, PNAM, Cellule d’Appui à la Gestion (CAG), Programme National de la Santé de Reproduction (PNAM), and other specialized programs prepare a harmonized procurement plan after the quantification exercise to align all the suppliers of lifesaving medicines for women and children
- Conduct a workshop on the use of misoprostol for obstetric indications

Recommendation for Donors

- Commit to strengthening the Government’s leadership to implement a procurement plan, bringing to light the supply of each of the three products that save mothers’ lives
**EXPLANATION OF TERMS**

**Forecasting:** Forecasting answers the question, “How much is needed, in quantities and cost, to meet the health demand of the population?” It is the process of estimating the expected consumption of commodities based on historical consumption, service statistics, morbidity and/or demographic data or assumptions when data are unavailable, in order to calculate the quantities of commodities needed to meet demand during a particular timeframe.

**Quantification:** Quantification answers the question “How much will be procured and when will it be delivered?” It includes both forecasting and supply planning. It is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to ensure an uninterrupted supply for the program. It takes into account the expected demand for commodities, unit costs, existing stocks, stock already on order, expiries, freight, logistics and other costs, lead times, and buffer stocks. Using this information, the total commodity requirements and costs are calculated and compared with the available financial resources to determine the final quantities to procure.

**Needs estimation:** Similar to forecasting, in this document the term is used to refer to an estimation based on theoretical assumptions.

**Procurement data:** Information on amounts of products procured in the recent past by the national government, NGOs, or amounts planned for upcoming procurement.

**Consumption data:** Information on amounts of products used within the health system; often this information is not available and data on the amount of product distributed within the system is used as a proxy.

**Supply pipeline:** The number of supply points at each level and the stock level at each point required to avoid stock-outs.

**Procurement lead time:** The time between placement of an order for supplies and receipt of the supplies at the medical store (or dispensary, depending on the level).

**Procurement period:** The number of months between orders.

**Stock on order:** Any stocks that have been ordered but have not yet arrived.

**Safety stock:** An amount of stock that is kept in reserve, calculated as the average amount needed to cover a lead time period to ensure against stock-outs in the case of sudden changes in demand or supplier performance problems (also known as buffer stock).
Stock at hand: The amount of stock available for distribution.

Supply planning: The supply plan is the final output of quantification, and details the quantities required to fill the supply pipeline, costs, lead times, and arrival dates of shipments, in order to ensure optimal procurement and delivery schedules.
REFERENCES


