ADVOCATING FOR IMPROVED ACCESS TO POSTPARTUM HEMORRHAGE MANAGEMENT: THE ROLE OF MISOPROSTOL

August 2018
Introduction

STATE OF GLOBAL MATERNAL HEALTH
The World Health Organization (WHO) estimated that in 2015, 303,000 women died from complications of pregnancy and childbirth, equivalent to 830 women dying every day. Almost all of these deaths occurred in low-resource settings, and most could have been prevented.

Sub-Saharan Africa remains the region with the highest ratio of maternal mortality, at 555 per 100,000 live births — almost triple that of the next highest region.¹ This demonstrates that, despite a worldwide decline of 44% in maternal deaths between 1990 – 2015, there is still a long way to go to meet the target for maternal health under Sustainable Development Goal (SDG) 3. The SDG target (2015–2030) is to reduce the global maternal mortality ratio to less than 70 per 100,000 live births, with no country having a maternal mortality rate of more than twice the global average.

POSTPARTUM HEMORRHAGE (PPH)
Hemorrhage is the leading direct cause of maternal mortality, accounting for 27.1% of maternal deaths worldwide. More than two thirds of reported hemorrhage deaths were classified as postpartum hemorrhage (PPH).² Most women who die from PPH have no known risk factors therefore all women should have immediate access to first line PPH management wherever they deliver. Options to manage PPH need to be made available in all settings, particularly given complexities and delays in referral.

IMPORTANCE OF MISOPROSTOL FOR THE PREVENTION AND TREATMENT OF PPH
Uterotonics play a central role in the prevention and treatment of PPH due to uterine atony, the most common cause of PPH. Oxytocin is the gold standard uterotonic*; however due to the route of administration it may not always be a viable option. If oxytocin is unavailable or unfeasible, misoprostol is a safe and effective alternative particularly in low-resource settings (where the highest numbers of maternal deaths occur) and is recommended by FIGO and the WHO.

FIGO and WHO recommendations on misoprostol are: 600 micrograms oral dose of misoprostol for the prevention of PPH and 800 micrograms sublingual dose of misoprostol for the treatment of PPH or secondary prevention. The chart below outlines the advantages of misoprostol in those settings where oxytocin use is not possible.

<table>
<thead>
<tr>
<th>OXYTOCIN</th>
<th>MISOPROSTOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administered intramuscularly/intravenously</td>
<td>Available in tablet form</td>
</tr>
<tr>
<td>Requires cold chain storage/refrigeration</td>
<td>Does not require refrigeration</td>
</tr>
<tr>
<td>Light stability and relative heat stability</td>
<td>Both heat and light stable</td>
</tr>
<tr>
<td>Requires sanitized equipment such as syringe</td>
<td>Does not require specialized equipment</td>
</tr>
<tr>
<td>Requires a skilled attendant to administer</td>
<td>Can be self-administered by women themselves if they have been adequately counselled on use</td>
</tr>
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</table>

* It should be noted that a number of uterotonics can play a role in prevention, including carbetocin. See study on Heat-Stable Carbetocin versus Oxytocin to Prevent Hemorrhage after Vaginal Birth by Widmer et al (2018) for the WHO CHAMPION Trial Group available in the New England Journal of Medicine.

FIGO Supports –

FIGO supports ongoing efforts to increase access to skilled health personnel, to promote facility-based births and to strengthen health systems. Equally, we support healthcare for all women and endorse strategies that extend the reach of proven PPH interventions to women who give birth in settings with few of these resources.

FIGO’s Call to Action

Leading global health organizations and professional associations — such as FIGO, WHO, the International Confederation of Midwives (ICM), and the United Nations Commission on Life-Saving Commodities for Women and Children (UNCoLSC)— support misoprostol use for PPH management. Further, the WHO’s Model List of Essential Medicines (WHO EML) includes misoprostol for both PPH prevention and treatment indications and recommends its use when oxytocin is not available or cannot be safely used.

To increase access to misoprostol for PPH, FIGO believes that it is important to establish clear and evidence-based policies and guidelines that emphasize misoprostol’s role in PPH management.

Member Associations are invited to call upon regulatory agencies and policy-makers to ensure that international guidance on misoprostol for PPH management is taken into account at a national level and that evidence-based regimens are adopted.

FIGO Member Association Survey

In 2016, FIGO circulated a survey to 130 Member Associations inviting them to answer a series of questions about country-level clinical guidelines on PPH management and their national essential medicines list. Our primary goal was to learn more about national recommendations on the use of misoprostol for PPH prevention and treatment. A total of 69 (53%) national societies responded to the survey.

KEY FINDINGS FROM SURVEY

• Many countries had outdated, non-evidence-based guidelines which do not include advice on international recommended regimens for misoprostol use in the prevention and treatment of PPH. 19% did not have national guidelines on PPH management in their country. Of those countries that do have national guidelines 41% did not include advice on misoprostol.

Possible focus of advocacy:
* Advocate for the development/revision of national guidelines on PPH management which incorporate misoprostol regimens in line with WHO and FIGO guidelines.
* Advocate for a regular review of guidelines to ensure that guidelines are up-to-date and reflect the latest evidence.

• Referencing documents used in the development of national guidelines did not always align with international guidance causing confusion amongst national OBGYN societies on correct regimens.

Possible focus of advocacy:
* Advocate for changes to national guidelines to ensure that they include internationally-recognized misoprostol regimens (i.e. correct dosage and route of administration) for PPH prevention and treatment.

• In many cases, misoprostol was not listed on national essential medicine lists for PPH. 39% of countries surveyed mentioned that misoprostol is not included in national EML.

Possible focus of advocacy:
* Advocate for the inclusion of misoprostol on national essential medicines list in line with international guidelines.

• Most common challenges for implementing guidelines that include use of misoprostol for PPH was the lack of supportive policy and programs, and misoprostol not widely and regularly available.

Possible focus of advocacy:
* Advocate for improvements in awareness of PPH mortalities and importance of management at all levels of care in national PPH, emergency obstetric care (EmoC) and Maternal Child and Health (MCH) guidelines.
* Advocate for increased availability of misoprostol in health facilities ensuring (more consistent) misoprostol stock throughout the health system.
* Partner with national midwifery and nurses associations to make sure guidelines are consistent and to acknowledge and support task sharing of PPH management as “first aid” by skilled health personnel.
THREE SIMPLE ADVOCACY DO’S

1) **Evidence**: present decision-makers with the latest evidence to support revisions to national guidelines in line with WHO and FIGO guidance. See *International Guidance on Misoprostol Use for PPH* and the *Extracts from international PPH guidelines on misoprostol* sections below. Additionally see the *Evidence and literature on misoprostol for PPH management and role of guidelines* document included as part of this pack, accessed from the *Other Useful Links and Further Reading* section.

2) **Collaboration**: partnering with other healthcare providers and professional associations such as midwives and nurses can help to develop a collective voice to motivate policymakers to act whilst ensuring greater consistency and understanding between the different organizations.

3) **Standardization**: Ask decision-makers to update both national guidelines and the national essential medicines lists so that there is consistency in the documents and no contradicting information which could cause confusion.

Further ideas for advocacy actions can be found in *Advocacy actions or Examples of successful advocacy on misoprostol for postpartum hemorrhage* document included as part of this pack, accessed in the *Other Useful Links and Further Reading* section.

Advocacy actions (quick and handy tips)

National Obstetrics and Gynecology Societies face different challenges in accessing misoprostol for PPH management ranging from a lack of up-to-date clinical guidelines on PPH that include evidence-based recommendations for misoprostol to a lack of knowledge of PPH and its management amongst frontline healthcare providers. This list provides useful advocacy suggestions for a spectrum of different challenges that can prevent PPH evidence from being adopted. What are the biggest challenges for your society? Which of these actions can you take to address them?

**Challenge: Lack of priority or political commitment given to PPH**
- Meet local, regional and national stakeholders or decision-makers to influence them with the national society PPH agenda; utilize informal relationships with key individuals to the same end
- Identify specialist maternal mortality champions given that women who die from PPH often present multiple complexities (sepsis, pre-eclampsia etc.)
- Establish, reinvigorate or get more involved in your national PPH Technical Advisory Group (TAG)
- Influence healthcare/public health professionals and/or decision-makers by holding workshops/symposium
- Get colleagues motivated to act through inserting sessions or presentations on PPH into national/regional obstetrics and gynecology or other public health meetings and conferences
- Collect facility, district or national data on incidence of PPH and outcomes to build your case
- Engage the media to build awareness of the issues

**Challenge: Lack of up-to-date national clinical guidelines on PPH that include recommendations for misoprostol for PPH management in line with international guidance**
- Contact government and ministry of health representatives and other relevant organizations about creating or revising guidelines
- Make sure your professional society is involved at all stages of guideline development
- Use the clinical evidence and international recommendations provided in this package of resources to support your case
- Consider developing a multi-stakeholder task force to support the government

**Challenge: Misoprostol not listed on national essential medicine and procurement lists / misoprostol is listed but not for PPH management in line with international recommendations such as the WHO Essential Medicines List**
- Contact government and ministry of health representatives insisting these medicines be on lists
- Submit letters of support to relevant bodies using FIGO advocacy materials which includes international recommendations, guidelines and the latest evidence
• Consider developing an official petition or a national call to action led by the national obstetrics and gynecology society
• Connect with other key organizations who can provide further technical expertise
• Anticipate opposition and resistance and plan how this will be managed and have a clear response

Challenge: Essential medicines such as oxytocin, misoprostol and carbetocin are included in national guidelines and essential medicine lists but are not widely available in facilities
• Collect facility, district or national data on availability of essential medicines to support your case
• Identify opportunities for joint public private funding of essential medicines for scale up of provision

Challenge: Lack of knowledge of PPH and its management amongst frontline healthcare providers
• Support measures to increase knowledge of PPH warning signs (with the public and healthcare professionals)
• Connect with other key organizations who can assist with training provision
• Provide training materials and sessions in your own facility using publically available tools
• Advocate to government and ministry of health representatives to fund and organize roll-out of trainings
• Conduct community outreach
• Mobilize youth by engaging the International Federation of Medical Student Associations (IFMSA) or the World Association of Trainee Obstetrician and Gynaecologists (WATOG)

Challenge: Lack of a cohesive, collaborative approach between various cadres of healthcare providers
• Ensure your facility or district has policy and programs in place that facilitate a collaborative approach to PPH management
• Join with nursing and midwifery colleagues to advocate for change to national policy to enable the delivery of essential interventions at all points of care and by all types of skilled health personnel through task-sharing
• Include a role for women and their families where availability of skilled birth attendants is still low or irregular

International Guidance on Misoprostol Use for PPH


Extracts from 1, 2 and 7 are included in the next section for ease of reference.
WHO RECOMMENDATIONS FOR THE PREVENTION AND TREATMENT OF POSTPARTUM HAEMORRHAGE (2012)

Recommendations for Prevention of PPH

- The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births. (Strong recommendation, moderate-quality evidence)
- Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug for the prevention of PPH. (Strong recommendation, moderate-quality evidence)
- In settings where oxytocin is unavailable, the use of other injectable uterotonics (if appropriate ergometrine/methylergometrine or the fixed drug combination of oxytocin and ergometrine) or oral misoprostol (600 μg) is recommended. (Strong recommendation, moderate quality evidence)
- In settings where skilled health personnel 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.

Recommendations for Treatment of PPH

- Intravenous oxytocin alone is the recommended uterotonic drug for the treatment of PPH. (Strong recommendation, moderate-quality evidence)
- If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 μg) is recommended. (Strong recommendation, low-quality evidence)

The full recommendations can be found at the 1st link in the previous section (International Guidance on Misoprostol Use for PPH).

WHO MODEL LIST OF ESSENTIAL MEDICINES (20TH LIST) (2017)

22. OXYTOCICS AND ANTIOXYTOCICS

22.1 OXYTOCICS

<table>
<thead>
<tr>
<th>Drug</th>
<th>Form</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ergometrine</td>
<td>Injection</td>
<td>200 micrograms (hydrogen maleate) in 1-mL ampoule</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>Tablet</td>
<td>200 micrograms, Management of incomplete abortion and miscarriage; Prevention and treatment of postpartum haemorrhage where oxytocin is not available or cannot be safely used</td>
</tr>
<tr>
<td></td>
<td>Vaginal tablet</td>
<td>25 micrograms.* Only for use for induction of labour where appropriate facilities are available.</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>Injection</td>
<td>10 IU in 1-mL</td>
</tr>
</tbody>
</table>

The full recommendations can be found at the 7th link in the previous section (International Guidance on Misoprostol Use for PPH).
FIGO GUIDELINES: PREVENTION AND TREATMENT OF POSTPARTUM HAEMORRHAGE IN LOW-RESOURCE SETTINGS (2012)

Recommendations for Prevention of PPH

- Within 1 minute of delivery of the infant, palpate the abdomen to rule out the presence of an additional infant(s) and give oxytocin 10 IU intramuscularly (IM). Oxytocin is preferred over other uterotonic drugs

- A single dose of misoprostol 600μg orally is indicated for prevention of PPH in settings where oxytocin is not available.

Recommendations for Treatment of PPH

- One dose of misoprostol 800μg sublingually is indicated for treatment of PPH when 40 IU IV oxytocin is not immediately available (irrespective of the prophylactic measures).

The full recommendations can be found at the 2nd link in the previous section (International Guidance on Misoprostol Use for PPH)

FIGO MISOPROSTOL ONLY RECOMMENDED DOSAGE CHART (2017)

**POSTPARTUM USE**

Postpartum hemorrhage (PPH) prophylaxis

- 600 μg po

Or PPH secondary prevention

(approx. ≥ 350ml blood loss) 800 μg sl

PPH Treatment

- 800 μg sl

The full recommendations can be found at the 6th link in the previous section (International Guidance on Misoprostol Use for PPH)

Other Useful Links and Further Reading

a. Maternal mortality: a global tragedy (Infographic)
c. List of resources and tools for successful global health advocacy
d. Examples of successful advocacy on misoprostol for postpartum hemorrhage

Available at [www.figo.org/pph](http://www.figo.org/pph)

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