Availability Case Study: Misoprostol in Tanzania

Background
As momentum builds toward achieving the United Nations’ (UN) Millennium Development Goal 5 of reducing maternal mortality by 75% by 2015, global health advocates are turning their attention to a consistently overlooked, but essential part of the solution to improving maternal health: the everyday availability of life-saving medicines and supplies. These simple and affordable commodities equip healthcare providers to save lives, yet they are often out of reach for those most in need. To address this inequity in access, the UN Commission on Life-Saving Commodities for Women and Children has called for collective efforts to identify strategies to improve the availability of 13 commodities, including the World Health Organization-approved essential medicine, misoprostol.

VSI connects women with life-saving medicines and services by engaging governments and partners to achieve regulatory approval of quality products and integrating them into national policies and practices. To date, VSI has facilitated the registration and introduction of misoprostol in 15 countries to address two major causes of maternal mortality: postpartum hemorrhage (PPH) and unsafe abortion. These important introductory activities lay the foundation for access, yet achieving equitable access to misoprostol and other essential medicines and supplies will depend upon the application of practical solutions, informed by country-specific data on availability and unmet need.

Goal and Objectives
In 2011, VSI initiated a comprehensive assessment of the current challenges to ensuring the everyday availability of misoprostol in Tanzania, with the goal of identifying opportunities to improve access over time. VSI defines “availability” to mean that any woman is able to request and receive a high-quality, affordable health product when and where she needs it. While achieving true availability of any essential medicine takes years, much can be done now to accelerate the process. This initiative has four key objectives:

1. Assess product availability across the total market (public, private and NGO sectors);
2. Identify barriers to product availability;
3. Make recommendations for improvement; and
4. In partnership, implement specific activities to increase women’s access to the product.

Availability Framework
Informed by two well known analytical and conceptual frameworks for access to health commodities,
VSI developed a framework based on five thematic areas or “pillars” that represent key factors influencing product availability. Each pillar includes a condition that needs to be satisfied to achieve everyday availability of misoprostol for women, and a set of indicators to gauge progress toward satisfying those conditions.

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<th>Availability Framework Pillars</th>
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<td><strong>Registration &amp; Quality Assurance</strong></td>
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<td>One or more high-quality products are registered for appropriate medical indications</td>
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<td><strong>Policy &amp; Financing</strong></td>
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<td>Product is included in key national policies; policy documents are disseminated and funds are allocated for purchase</td>
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<td><strong>Procurement &amp; Distribution</strong></td>
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<td>Total product procured and distributed by public, private and NGO sectors meets the national need for all approved indications</td>
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<td><strong>Provider Knowledge</strong></td>
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<td>All health providers know how to correctly use the product</td>
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<td><strong>End-user Knowledge</strong></td>
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<td>Individuals know the product’s uses and where to obtain it</td>
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**Assessment Methodology**

VSI developed and implemented tools to collect data on the framework pillars using a mix of qualitative and quantitative methods (see Figure below). The district-, regional- and national-level data VSI collected provide a snapshot of the current availability of misoprostol and a basis for comparing availability over time.

**Qualitative:** A policy review; interviews with stakeholders and district pharmacists; a review of supply chain research; and 3 regional rapid assessments of maternal health activities, partners and regional and district health offices.

**Quantitative:** A provider survey, end-user knowledge, attitudes and practices survey, and retail survey; and an analysis of public, NGO and private sector supply chain and sales data.

**Methodology to Assess Misoprostol Availability in Tanzania**

<table>
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<tr>
<th>Registration &amp; Quality Assurance</th>
<th>Policy &amp; Financing</th>
<th>Procurement &amp; Distribution</th>
<th>Provider Knowledge</th>
<th>End-user Knowledge</th>
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<tr>
<td>Policy Review: official documents, peer-reviewed literature</td>
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<td>3 Region Rapid Assessments: Morogoro, Shinyanga &amp; Tanga</td>
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<td>Key Stakeholder Interviews: 45 informants from 27 organizations</td>
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<td>Collection &amp; Mapping of Sales and Distribution Data: 18 months of public &amp; private sector information</td>
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<td>Provider Survey: 406 providers at 98 facilities in 3 districts (Morogoro, Shinyanga &amp; Tanga regions)</td>
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<tr>
<td>Retail Survey: 150 outlets in Arusha, Dar es Salaam, Iringa, Mbeya, Morogoro, Pwani &amp; Tanga</td>
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**Recommendations**

Several important milestones related to misoprostol availability have already been achieved in Tanzania, and ongoing government and partner activities are contributing to product availability. At the same time, VSI’s findings indicate that misoprostol tablets are currently in short supply, suffer from low demand and are underutilized. The following are VSI’s recommendations, key findings and sample activities to make rapid improvements and accelerate progress toward increased availability of this essential medicine in Tanzania.

1. **Increase the number of misoprostol products registered for obstetric indications**
   - Misotac®, registered for PPH (2007) and treatment of incomplete abortion (2011), was recalled in late 2011 due to poor product quality; subsequent suspension of its registration caused nationwide stockouts
   - Only one misoprostol product (Misoprost®) is currently registered and in the market in Tanzania
   - Amount women are willing to pay for 3 tablets of misoprostol for PPH prevention (approximately $1.47) is 42% less than the average market price ($2.53) as reported by retail pharmacies

   **Sample Activity:**
   Facilitate the registration of additional misoprostol products for obstetric indications to improve market competition and address the vulnerability of supply

2. **Champion the expansion of postabortion care policies and services**
   - National guidelines for postabortion care (PAC) services do not include misoprostol
   - Only 59% of health facilities provide PAC services
   - 33% of providers surveyed identified lack of training as a barrier to using misoprostol in PAC services

   **Sample Activity:**
   Establish a technical working group to develop a strategic plan to expand PAC services
Strengthen forecasting and quantification of misoprostol in the public health system

- In 2010, the unmet need for misoprostol for PPH and treatment of incomplete abortion and miscarriage was at least 73%, approximately 2.2 million tablets\textsuperscript{iii}
- From 2009 to 2010, forecasting was not completed for misoprostol; consequently, the Medical Stores Department central warehouse suffered severe stockouts of its limited procurement of tablets
- 60% of health centers and 20% of dispensaries that regularly procure misoprostol experienced a stock-out in the 3 months preceding the survey

**SAMPLE ACTIVITY:**
Strengthen national and regional quantification tools for forecasting and procurement of misoprostol

Clarify policies and procedures for ordering misoprostol in the public sector

- As reported by providers, only 32% of health facilities had ever ordered misoprostol
- Of those that had not ordered misoprostol, 70% cited lack of knowledge of misoprostol as an ordering barrier
- District pharmacists cited the exclusion of misoprostol on standard ordering forms as a barrier to procurement
- Less than half of facilities reported having a copy of national guidelines or job aids referring to the correct use of misoprostol for management of PPH or treatment of incomplete abortion

**SAMPLE ACTIVITY:**
Engage stakeholders to draft an ordering toolkit for maternal health commodities targeting district health management teams

Champion Ministry policy to allow for community-level distribution of misoprostol for PPH

- 74% of the population lives in rural and peri-urban communities\textsuperscript{iv}
- 60% of providers report that direct distribution of misoprostol to women for PPH prevention could work in their district, but a formal policy is not yet in place
- 56% of providers send women to purchase a uterotonic drug from retail outlets when a facility is stocked out
- 70% of women surveyed reported purchasing supplies for their last delivery

**SAMPLE ACTIVITY:**
Establish a technical working group to review evidence for distribution strategies enabling use of misoprostol for PPH prevention at home births

Generate demand for misoprostol among health providers and pharmacists

- Nationally, an estimated 6% of providers have been trained on misoprostol for PPH or PAC services
- In 3 districts, just over half (54%) of maternal health providers knew that misoprostol can be used for PPH prevention and only 15% knew that misoprostol can be used in PAC services
- Only 12% of pharmacy employees who knew about misoprostol could report the correct dose and route for PPH prevention, only 4% for abortion and just 2% for incomplete abortion

**SAMPLE ACTIVITY:**
Conduct pre-service lectures and support lecturers in 25 medical, nursing and pharmacy schools

Increase knowledge of misoprostol amongst women of reproductive age

- Only 4% of women in control districts had heard of misoprostol compared to 35% of women in former project districts
- Women who had heard messages about misoprostol were more likely (87%) to believe misoprostol can prevent or stop excessive bleeding than women who had not heard messages (37%)

**SAMPLE ACTIVITY:**
Engage partners and complement existing Information, Education & Communication (IEC) programs, using multiple channels to deliver messages on PPH and PAC services
CONCLUSIONS AND NEXT STEPS

When stocked on shelves and in the hands of healthcare providers, a simple maternal health medicine like misoprostol can dramatically change the outcome of pregnancy and childbirth for a woman and her family. Acting upon the insights from this analysis will have a ripple effect on families and communities for decades to come.

While current availability of misoprostol falls short of the goal that any Tanzanian woman can request and receive a high-quality, affordable product when and where she needs it, there are immediate actions that can be taken to accelerate access to this essential medicine. In collaboration with key partners and stakeholders, VSI is actively coordinating efforts to apply practical solutions and improve product availability today.

VSI looks forward to applying this model to other maternal health medicines and supplies and in other countries where the needs are great.

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3 VSI’s unmet need analysis is the estimated number of misoprostol tablets to be procured to meet the forecasted need for prevention and treatment of PPH, including home births, and treatment of incomplete abortion for women aged 15-44 in Tanzania.