

AFRICAN STRATEGIES FOR HEALTH



Misoprostol Policy and Scale-Up for the Prevention of Postpartum Hemorrhage in Nigeria

Country Report

August 2016

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MISOPROSTOL POLICY AND SCALE- UP FOR THE PREVENTION OF POSTPARTUM HEMORRHAGE IN NIGERIA

COUNTRY REPORT

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ACRONYMS

ACOG	American Congress of Obstetrics and Gynecologists
ASH	African Strategies for Health project
CHEW	community health extension worker
CSO	civil society organization
FIGO	International Federation of Gynecology and Obstetrics
HRH	human resources for health
ICM	International Confederation of Midwives
MDGs	Millennium Development Goals
MMR	maternal mortality ratio
MOH	Ministry of Health
MSH	Management Sciences for Health
MSS	Midwifery Service Scheme
NGO	nongovernmental organization
PAC	post-abortion care
PPH	postpartum hemorrhage
PRHP	Population and Reproductive Health Partnership
RCOG	Royal College of Obstetricians-Gynecologists
SOGON	Society of Obstetricians and Gynecologists of Nigeria
SSA	Sub-Saharan Africa
TBA	traditional birth attendant
TSHIP	USAID's Targeted States High Impact Project
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
VSI	Venture Strategies Innovation
WHO	World Health Organization

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I. EXECUTIVE SUMMARY

Introduction

Despite a 43 percent global decline in the maternal mortality ratio (MMR; maternal deaths per 100,000 live births) from 1990 to 2015, the number of annual maternal deaths remains unacceptably high, particularly in the low- and middle-income countries where 99 percent of these deaths occur.¹ Postpartum hemorrhage (PPH), or severe bleeding following childbirth, is the leading cause of maternal mortality in low-income countries and the primary cause of nearly one quarter of all maternal deaths globally each year.

The vast majority of deaths due to PPH can be effectively prevented or treated with uterotonics such as oxytocin and misoprostol, used to induce contractions or greater tonicity of the uterus.² Oxytocin is the most widely used uterotonic and is recommended by the World Health Organization (WHO) for use immediately after childbirth to reduce the risk of bleeding. However, oxytocin requires both refrigeration and administration via injection by a skilled provider, making it challenging to administer in resource-poor settings or in areas where the majority of women deliver at home. In a region where more than 50 percent of births occur without attendance by skilled health personnel, access to an alternative uterotonic or intervention for the prevention of PPH is critical to achieving maternal mortality reduction in Africa.³

Over the past decade, the use of misoprostol for PPH prevention has gained attention as an effective strategy in settings where skilled birth attendance is low. The findings of numerous studies, reviews, and evaluations of the distribution of misoprostol at the community level overwhelmingly support its use as safe, effective, and feasible in the absence of a skilled birth attendant.^{4 5} The intervention has since been included in various global clinical guidelines and, in 2012, WHO released a recommendation for the administration of misoprostol for PPH prevention by a lay health worker in the absence of a skilled birth attendant. Misoprostol is inexpensive, can be administered as a tablet, and does not require cold chain storage, making it an important intervention for the millions of women giving birth at home or in health facilities without reliable electricity, refrigeration, or qualified health providers. Despite this body of evidence and growing global consensus of the benefits of using misoprostol to prevent PPH, few countries in Africa have adopted national policies or service-delivery guidelines for the scale-up of this intervention.⁶

In an effort to enhance understanding of the processes behind the development and adoption of policies and subsequent implementation of guidelines around community-based distribution of misoprostol for PPH, the United States Agency for International Development's Africa Bureau (USAID/AFR) and its African Strategies for Health (ASH) project, implemented by Management Sciences for Health (MSH), conducted a review in three African countries. The *Review of National Policies for Community-Based*

¹ WHO. Trends in Maternal Mortality: 1990 to 2015: Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015.

² WHO and UNICEF. Countdown to 2015: Maternal, Newborn, & Child Survival, Decade Report (2000 – 2010).

³ UNICEF. *State of the World's Children 2015*.

⁴ Smith, JM et al. "Misoprostol for Postpartum Hemorrhage Prevention at Home Birth: An Integrative Review of Global Implementation Experience to Date." *BMC Pregnancy and Childbirth* 13 (2013):44.

⁵ Hundley V et al. "Should Oral Misoprostol Be Used to Prevent Postpartum Hemorrhage in Home-Birth Settings in Low-Resource Countries? A Systematic Review of the Evidence." *BJOG* 120 (2013):277-287.

⁶ WHO. WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage. Geneva (Switzerland): World Health Organization (WHO); 2012.

Distribution of Misoprostol for Prevention of Postpartum Hemorrhage and Subsequent Status of Scale-Up study explored the policy-making process and subsequent roll-out of the intervention in three countries which have national policies in development or in place: Madagascar, Mozambique, and Nigeria. This report details the study findings and recommendations from Nigeria.

Study Approach

Study Goal

The overall goal of this study was to identify common factors which influenced and enabled policy development for community-based distribution of misoprostol and to document the various successes and challenges related to implementation in an effort to develop recommendations for establishing a favorable policy and implementation environment in other African countries.

Methodology

Between April 2015 and April 2016, ASH conducted desk research and interviews with 12 key informants engaged in the policy development and/or implementation processes in Nigeria. The document review included policy documents, research and technical reports, program implementation reports, and training curricula. Key informant interviews were conducted with key stakeholders including the ministry of health (MOH), professional bodies, donors, civil society organizations (CSOs), and community leaders.

The study applied the policy triangle framework⁷ to analyze the key determinants of policy development and adoption, including policy content, context, actors, and processes, and the interaction between these components. The status of implementation and scale-up of community-based distribution of misoprostol was documented through key benchmark indicators representing each of the six WHO Health Systems Building Blocks. Each indicator addresses an issue(s) critical to achieving effective impact at scale in a sustainable manner.⁸

Key Findings and Recommendations

Policy Development Findings

In 2011, Nigeria adopted guidelines for the use of misoprostol for prevention of PPH at the community level. Study respondents described the process as long and difficult, with challenges seemingly unique to Nigeria including the government's three-tiered system and discordant objectives amongst several key stakeholders. Study respondents cited two factors as the most influential in the success of policy development and adoption. First, country-specific evidence of the intervention's effectiveness and feasibility even in the most challenging areas of Nigeria was critical to achieving buy-in from all stakeholders. Second, strong leadership within the federal MOH was key to enabling partnerships with various stakeholders for successful advocacy. The policy design phase was cited as being protracted and tedious due to the focus of certain stakeholders on advocating for the use of misoprostol for prevention of PPH, while others were solely focused on advocating for a policy on the use of misoprostol for post-abortion care (PAC). While the use of misoprostol for PAC seemed to increase controversy amongst concerned officials within the MOH, the final policy document approves the use of misoprostol for both PAC at health facilities and the prevention and treatment of PPH at the community level.

⁷ Walt G and Gibson L. "Reforming the Health Sector in Developing Countries: The Central Role of Policy Analysis." *Health Policy Planning* 9.4 (1994): 353-370.

⁸ WHO. *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes*. 2007.

Implementation and Scale-Up Findings

Nigeria's decentralized system of governance in which federal, state, and local governments have distinct enforcement abilities, has significantly impacted the implementation of the policy for community-based distribution of misoprostol for PPH prevention. Respondents cited a number of challenges including a lack of knowledge and resources at the local level to implement the policy, as well as a highly politicized process and lack of leadership for implementation. Since policy adoption, a few states have been successful in rolling-out this intervention, primarily through the support of programs and partners addressing advocacy and implementation issues at the local level. The USAID-funded Targeted States High Impact Project (TSHIP) successfully advocated for the introduction of integrated maternal and newborn health interventions and, in 2013, Sokoto and Bauchi became the first two Nigerian states to launch the use of misoprostol for the prevention of PPH coupled with a newborn intervention — chlorhexidine gel for umbilical cord care.⁹ The successes in these two states serve as a model across Nigeria and a number of visits from professional associations and other state governments have helped to inform future scale-up initiatives. However, at the conclusion of this study, no other states had replicated the misoprostol element of the project.

Table 1. Summary of Key Recommendations

Policy Development	Implementation and Scale-Up
<ul style="list-style-type: none"> ▪ Ensure local operations research is conducted with government and community support. <ul style="list-style-type: none"> ➤ Evidence that the intervention was feasible in the most remote areas of Nigeria was important for garnering broad-based support. ▪ Identify and engage national, state, and local champions who can effectively advocate for adequate resourcing and implementation. <ul style="list-style-type: none"> ➤ The leadership and persistence of the former minister of health was cited as a key factor in the policy development process. ▪ Engage various types of stakeholders from the very beginning of the process. <ul style="list-style-type: none"> ➤ The engagement of a range of stakeholders including national and local governments, NGOs and CSOs, donors, and professional associations, facilitated ownership and buy-in and ensured interests and concerns were heard and addressed throughout the process. 	<ul style="list-style-type: none"> ▪ Incorporate national and state-level implementation strategies ensuring regular reviews, assessment, and revision of implementation guidelines. <ul style="list-style-type: none"> ➤ With no operational plan, implementation and roll-out of Nigeria's policy on misoprostol has largely been weak and ineffective. ▪ Include a formal mechanism for monitoring and evaluation which facilitates accountability and allows for frequent and regular reviews of data. <ul style="list-style-type: none"> ➤ Since the policy was adopted, no indicators and related targets have been developed as part of the government's health information system. ▪ Use advocacy and community mobilization efforts, including engaging traditional and religious leaders, celebrities, and the media to increase knowledge and support for the intervention.

⁹ Cannon M, Charyeva Z, Oguntunde O, Sambisa W, Shoretire K and Orobato N. "A Case Study of Community-Based Distribution and Use of Misoprostol and Chlorhexidine in Sokoto State, Nigeria," Global Public Health, (2016). DOI: 10.1080/17441692.2016.1172102

2. BACKGROUND

Under the Millennium Development Goals (MDGs) adopted by the international community in 2000, countries committed to reducing maternal mortality by three quarters between 1990 and 2015. Despite tremendous progress towards reducing maternal deaths worldwide, every day an estimated 830 women continue to die from preventable causes related to pregnancy and childbirth. In 2015, the Sub-Saharan African region alone accounted for 66 percent of all maternal deaths and had the highest regional MMR at 546. An estimated 34 percent of maternal deaths in Sub-Saharan Africa (SSA) are due to PPH.¹⁰

In settings where the administration of oxytocin is not feasible, misoprostol provides a safe and effective alternative for the prevention and treatment of PPH. Misoprostol is included in the WHO Model List of Essential Medicines for the prevention of PPH as well as in various global clinical guidelines including guidelines from the International Federation of Gynecology and Obstetrics (FIGO), the International Confederation of Midwives (ICM), the American Congress of Obstetricians and Gynecologists (ACOG), and the Royal College of Obstetricians-Gynecologists (RCOG). Furthermore, WHO's 2012 recommendations include the administration of misoprostol for PPH by a lay health worker in the absence of a skilled birth attendant.¹¹ However, few countries in Africa have adopted national policies or service delivery guidelines for the scale-up of this intervention.

In 2011 and 2012, "A Global Survey on National Programs for the Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia" found that, of 20 African countries surveyed, misoprostol was on the essential medicines list for prevention of PPH in 16, 11 countries had conducted pilots on community-based distribution, but only four, including Nigeria, were beginning to scale-up the use of misoprostol at home births through the ratification of national policies.¹²

While several studies identify the challenges of and barriers to the transition from evidence to policy implementation for community-based distribution of misoprostol, there is presently no published literature reviewing the policy success stories.

3. COUNTRY CONTEXT

Nigeria is the most populous nation in Africa and the second largest contributor to the global burden of maternal mortality. More than 58,000 maternal deaths occurred in Nigeria in 2015 and it is estimated that 145 women of childbearing age die from causes related to pregnancy and childbirth every day.¹³ PPH accounts for approximately 25 percent of these deaths, with other causes including eclampsia, sepsis, and indirect contributors such as malaria.

¹⁰ WHO. Trends in Maternal Mortality: 1990 to 2015: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015.

¹¹ WHO. WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage. Geneva (Switzerland): World Health Organization (WHO); 2012.

¹² Smith J, Currie S, Perri J, Bluestone J and Cannon T. "A Global Survey on National Programs for the Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia." *Maternal and Child Health Integrated Program*. http://www.mchip.net/sites/default/files/2012%20Progress%20Report_Short%20Report.pdf

¹³ UNICEF. 2014. State of the World's Children 2015. Geneva: UNICEF. <http://www.data.unicef.org/resources/the-state-of-the-world-s-children-report-2015-statistical-tables>

Wide geographic and socioeconomic disparities in health care access exist across the country. While institutional delivery remains low at 36 percent, women in Nigeria's northern regions are 77 percent more likely to deliver at home than their counterparts living in southern Nigeria.¹⁴ In a setting where most of the primary healthcare facilities lack the capacity and equipment necessary to provide basic emergency obstetric care services, and only 38 percent of deliveries are attended by skilled birth attendants, community-based distribution of misoprostol can help prevent thousands of deaths due to PPH and be a game changer for maternal mortality in the region.^{15, 16}

Essential services for maternal and newborn health are provided through a decentralized health system composed of three tiers: federal, state, and local. The federal government is in charge of tertiary health services provided at Federal Medical Centers and Teaching Hospitals, while the state manages the various general hospitals or secondary health services, and the local government focuses on dispensaries and primary health care. In addition, private providers of healthcare have a growing role to play in health care delivery.

4. STUDY OBJECTIVES & METHODOLOGY

Study Objectives

The *Review of National Policies for Community-Based Distribution of Misoprostol for Prevention of Postpartum Hemorrhage and Subsequent Status of Scale-Up* study explored the policy-making process and subsequent roll-out of the intervention in three African countries which have national policies in place for the use of misoprostol at home births for prevention of PPH: Madagascar, Mozambique, and Nigeria.

The purpose of this study was to identify the key determinants contributing to the development and adoption of policies, to determine the current status of implementation and scale-up of the intervention, and to identify successes and challenges in the subsequent national roll-out and scale-up of the intervention. The study findings provide practical recommendations for countries beginning policy development and adoption, and/or national roll-out of community-based distribution of misoprostol for PPH. Specific study objectives were to:

1. Analyze the policy-making process for national policies on community-based distribution of misoprostol for PPH prevention;
2. Identify key facilitators and enablers critical to policy development and adoption;
3. Ascertain progress towards scale-up of the intervention since policy adoption as measured by specific benchmark indicators; and
4. Identify successes and challenges to policy development and implementation.

¹⁴ UNICEF. 2014. State of the World's Children 2015. Geneva: UNICEF. <http://www.data.unicef.org/resources/the-state-of-the-world-s-children-report-2015-statistical-tables>

¹⁵ UNICEF. 2014. State of the World's Children 2015. Geneva: UNICEF.

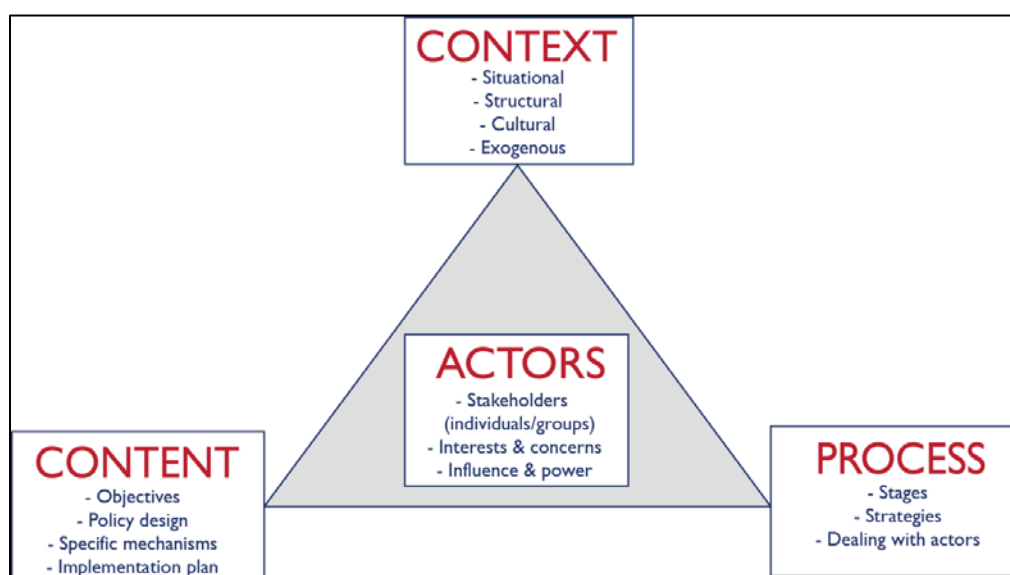
¹⁶ Erim DO, Kolapo UM, Resch SC (2012) A Rapid Assessment of the Availability and Use of Obstetric Care in Nigerian Healthcare Facilities. PLoS ONE 7(6): e39555. doi:10.1371/journal.pone.0039555

Conceptual Framework and Strategic Indicators

Policy Review

To analyze the policy-making process, the study applied the policy triangle conceptual framework (Figure 1). The framework theorizes that policy is influenced by a multitude of factors and the interactions between them. The study reviewed various components in Nigeria, including the situational and structural contexts around the policy, stakeholders' interests and influence, the content of the policy, its objectives and design, as well as the process by which the policy was developed.

Figure 1. Policy Triangle Conceptual Framework



Source: Walt, G and Gibson, L. *Reforming the health sector in developing countries: the central role of policy analysis*. *Health Policy Plan*. (1994) 9 (4): 353-370.

Status of Implementation and Scale-Up

The status of implementation and scale-up of community-based distribution of misoprostol was documented based on indicators representing each of the six WHO Health Systems Building Blocks (Table 2). Each indicator addresses an issue(s) critical to achieving effective impact in a sustainable manner.

Table 2. WHO Health Systems Building Blocks

Building Block	Indicator
Governance*	<ul style="list-style-type: none"> Is community-based distribution of misoprostol for the prevention of PPH included in current national strategies and practice guidelines? Is community-based distribution of misoprostol for the prevention of PPH included in both national and subnational implementation plans?
Finance	<ul style="list-style-type: none"> Is community-based distribution of misoprostol for the prevention of PPH included in MOH budgets?
Health Information	<ul style="list-style-type: none"> Does the MOH currently collect, report, and use appropriate indicators/information on community-based distribution of misoprostol for prevention of PPH?
Commodities & Supplies	<ul style="list-style-type: none"> Is misoprostol currently procured and distributed in sufficient quantities as part of the national logistics system?
Human Resources	<ul style="list-style-type: none"> Are the appropriate health worker cadres authorized to distribute misoprostol? Do the appropriate in-service and pre-service curricula include community-based distribution of misoprostol for prevention of PPH?
Service Delivery	<ul style="list-style-type: none"> Is community-based distribution of misoprostol for prevention of PPH included in MOH supervision schedules? Is misoprostol available for distribution at the community level?

*A national policy indicator is not included here given this is a criterion for inclusion in the study and thus all countries have a national policy in place.

Study Methodology

The study was conducted through the development of a qualitative retrospective case study developed through use of two methods: document review and key informant interviews.

Document Review

A document review provided an initial overview of policy development and current status of implementation. Documents included national policies, strategies, clinical guidelines, technical working group notes, training curricula, etc. The document review also included a brief stakeholder analysis in an effort to identify initial key informants, to understand their position/role with respect to the policy process, and to gain a clear understanding of stakeholder interests (i.e. what are the perceived drivers/facilitators for policy implementation success as it relates to each stakeholder).

Key Informant Interviews

Semi-structured interviews were conducted with 12 individuals from various stakeholders engaged in the policy development and implementation processes in each country. These stakeholders included respondents from government, multilateral organizations, donors, NGOs, and CSOs.

5. POLICY DEVELOPMENT: KEY FINDINGS

Nigeria's national guidelines and standards for the use of misoprostol for the prevention of PPH were approved in 2011 (Annex 2). The following sub-sections present findings from informant interviews and document reviews as they relate to each of the components associated with the policy development process: context, actors, processes, and content. It is evident that the process is not driven by one factor in isolation; rather, the relationship between the identified determinants is complex. Factors often interact with one another and discussion of them may overlap in certain areas of the following sections.

5.1 Context

Since 1990, the Nigerian government has intensified efforts to address maternal mortality. Despite a 40 percent decline in MMR from 1990 to 2015, Nigeria's MMR of 814 deaths per 100,000 live births remains the fourth highest MMR in Africa.¹⁷

In January 2006, the Nigerian National Agency for Food and Drug Administration and Control approved the distribution of misoprostol for the prevention of PPH, becoming the first country in the developing world to approve the registration of misoprostol for this lifesaving indication. In February of the same year, a policy meeting was convened in Abuja to discuss policy for misoprostol use, as well as to consider other strategies for reducing maternal mortality. While several meeting attendees advocated for the use of misoprostol at the community level, the government determined that misoprostol would be added to the national essential medicines list for the prevention and treatment of PPH and that immediate training of qualified health professionals for use at the facility level begin. It was also agreed that the potential role of less trained cadres of health providers and of patients in administering misoprostol would be reviewed as more country-specific information became available. In 2007, Nigeria's National Council on Health approved an Integrated Maternal, Newborn and Child Health Strategy, identifying community-based services as critical area of focus for the country.

In recognition of the high burden of maternal mortality in the country and the challenging context in which at least two-thirds of all women deliver at home without the presence of a skilled birth attendant, a range of stakeholders continued support for the development of a policy that would address PPH at the community level. In 2011, Nigeria approved the distribution of misoprostol at the community level for prevention of postpartum hemorrhage.

5.2 Actors

A number of actors, including key individuals, organizations, and the Nigerian government, contributed to the policy development process at various stages. Motivated by their specific interests and prevailing concerns, these organizations and individuals played varying roles in shaping the development and approval of Nigeria's first national policy for community-based distribution of misoprostol. In particular, the federal ministry of health, represented at the highest level by the federal minister and the directors of key departments, exerted considerable influence in developing the content and direction; respondents noted the policy could not have been successfully developed and approved at national level without their support. Other key actors included NGOs and civil society groups, donors, researchers and research organizations, health professional bodies including the Society of Obstetricians and Gynecologists

¹⁷ WHO. 2015. Levels and Trends for Maternal Mortality: 1990 to 2015. Geneva: World Health Organization. <http://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2015/en/>

(SOGON) and the Midwifery Society of Nigeria, communities, and the media. The roles, motivations, and concerns of these stakeholders are summarized in Table 3.

Table 3: Roles, Motivations, and Concerns of Stakeholders

Actor	Role(s) in Policy Development	Prevailing Concerns or Motivating Factors
The Federal Ministry of Health	<ul style="list-style-type: none"> Champions from the Ministry of Health provided leadership and overall support in initiating and guiding the policy development process. Their role was important for securing high-level support from the National Council on Health to ultimately approve the national policy. 	<ul style="list-style-type: none"> Potential use of misoprostol for abortion by young girls and women with an unwanted pregnancy. Respondents noted that government officials were resistant because of moral or religious reasons. Legal concerns were also noted because abortions are illegal in Nigeria except for unavoidable gynecological reasons. This led to deliberate delays in the approval process by some senior officials. Potential rupture of the uterus and other damage caused by incorrect use of misoprostol for other indications (e.g. labor induction) by midlevel health workers (midwives and nurses). Respondents cited cases of uterine rupture as a result of midwives incorrectly administering misoprostol in their private practice.
NGOs and civil society groups	<ul style="list-style-type: none"> Partner organizations supported advocacy efforts and the dissemination of research findings to a broad range of partners and stakeholders to garner support for community distribution of misoprostol for PPH. Partner organizations played a role in shaping content of the national policy and shepherded the process to ensure that the policy was finalized and approved. 	<ul style="list-style-type: none"> Different NGOs carried out advocacy to garner support for the inclusion of misoprostol for two indications: prevention and treatment of PPH and PAC, often at odds with each other.

Actor	Role(s) in Policy Development	Prevailing Concerns or Motivating Factors
Donors and international agencies	<ul style="list-style-type: none"> Donors provided financial support to conduct and disseminate findings from local operations research. They were influential in calling for federal ministry support for the national policy for community distribution of misoprostol. 	<ul style="list-style-type: none"> None identified.
Researchers and research organizations	<ul style="list-style-type: none"> Carried out the local, context specific operations research. Served as key spokespeople in communicating the findings of the operations research and generating support for a national policy based on local findings. 	<ul style="list-style-type: none"> Evidence generated at the local level supporting the safety and acceptability of misoprostol for PPH was critical motivation for a number of stakeholders throughout the process.
Professional health associations, in particular national associations of obstetricians and gynecologists and midwives	<ul style="list-style-type: none"> Provided review and input during ratification and finalization of the policy, specifically in clarifying the level of health provider to administer misoprostol. The Midwifery Council incorporated the updated protocols in the in-service training program for nurses and midwives. 	<ul style="list-style-type: none"> Correct administration of misoprostol by non-skilled health workers, such as traditional birth attendants (TBAs) and community health workers.
Communities	<ul style="list-style-type: none"> Communities were engaged as part of the local research study by taking part in community meetings and information sessions. Their contributions can inform the intervention beyond study sites. Community groups were also involved in donor-funded efforts led by researchers and civil society groups to persuade professional bodies, acting as spokespersons and participating in meetings. 	<ul style="list-style-type: none"> Community concerns included misinformation about misoprostol being used as a birth control method.
Media	<ul style="list-style-type: none"> As part of the operations research, community radio was used to generate awareness and build support for misoprostol's role in preventing PPH. 	<ul style="list-style-type: none"> None identified.

5.3 Process

This section discusses how the national community distribution policy in Nigeria was initiated, formulated, and ultimately finalized and ratified. According to key informants, the policy development process in Nigeria involved negotiation, compromise, and bargaining to accommodate potentially conflicting interests, with the ultimate aim of building a broad-based coalition of support for the use of misoprostol at community level. The development process can be described in five distinct stages: (1) prioritization by the MOH to address maternal deaths due to PPH and preliminary advocacy efforts to garner high-level support, (2) operations research, (3) engagement of varied stakeholders, (4) presentation of findings at the National Council on Health, and (5) actual policy design and approval.

Stage 1 - Prioritization by MOH and Preliminary Advocacy Efforts: Several drivers contributed to gains in advocacy and helped to create an enabling environment for community distribution of misoprostol. Early experiences with the country's Midwives Service Scheme (MSS), established by the National Primary Health Care Development Agency in 2009, showed that a public sector initiative and collaborative effort between the three tiers of government could provide an effective mechanism to reach rural areas and improve rates of skilled birth attendance.¹⁸ However, in recognition of the context of many rural communities, where at least two thirds of Nigerian women continued to deliver at home without a skilled birth attendant, the MOH understood the limitations of current strategies to address PPH and identified misoprostol's use in home births and in rural communities as a key intervention to address the high burden of maternal deaths.

A small group of stakeholders, including donors and NGOs, advocated with the then Minister of Health to support misoprostol as a key intervention to address the high rates of PPH, particularly in rural settings where most women give birth at home. Acting on its commitment to reduce the unacceptably high burden of maternal mortality and accelerate progress towards the 2015 MDG targets, but citing insufficient evidence supporting misoprostol's use by non-health professionals, the MOH requested that operations research be conducted to prove the safety and feasibility of community-based distribution of misoprostol for PPH prevention.

Stage 2 - Operations Research: Between January and December 2009, researchers from the Population and Reproductive Health Partnership (PRHP) of Ahmadu Bello University, Zaria, Nigeria, collaborated with the Bixby Center for Population, Health & Sustainability at the University of California, Berkeley and Venture Strategies Innovations (VSI) to conduct a research study in communities in Zaria, Kaduna State, in northwestern Nigeria. In these communities, nearly 95 percent of women deliver at home without skilled birth attendants. Using a community-based participatory approach, the research study trained TBAs on the use of misoprostol for PPH prevention and treatment and employed community drug keepers to dispense the medicine to TBAs or to pregnant women or their families. Findings indicated that community-based distribution of misoprostol is feasible. TBAs and community drug keepers were able to reach women who deliver at home with misoprostol; misoprostol was used correctly after home births for PPH prevention; and there was a high level of acceptability among men and women, with almost all women stating they would recommend misoprostol, take it again in a subsequent pregnancy, and be willing to purchase it. Misoprostol

¹⁸ National Primary Health Care Development Agency. Nigeria's Midwives Service Scheme (2011) <http://www.who.int/workforcealliance/forum/2011/hrhawardscs26/en/>

protected 83 percent of women who delivered in the home from PPH who otherwise would not have been protected.¹⁹

Stage 3 - Stakeholders' Engagement: The evidence from the Zaria research study provided the basis for extensive advocacy and engagement of key stakeholders to support community-based distribution of misoprostol and its scale-up throughout Nigeria. Through national and international dissemination meetings and the development of policy and advocacy briefs, the findings were widely disseminated to various partners including MOH officials, donors, and NGOs. As a consequence of these advocacy efforts, an MOH-led reproductive health technical working group was tasked with reviewing the operations research results and making recommendations to the National Council on Health.

Stage 4 - Presentation to the National Council of Health: The reproductive health technical working group, supported by individual directors and desk officers at the federal MOH, recommended that the National Council of Health—Nigeria's highest policy-making body on matters relating to health—consider community-level use of misoprostol for PPH prevention at its 53rd meeting held in Asaba, Nigeria in 2011. At this meeting, the National Council formally agreed that a policy be drafted to support community-level use of misoprostol for PPH prevention and treatment.

Stage 5 - Final Policy Development and Approval: During this stage, cited by respondents as overly protracted and tedious, a wider group of stakeholders, namely from the health professional associations, became involved in finalization of the policy document. A number of concerns were raised during this time. These included potential use of misoprostol for other indications such as abortion, use of misoprostol by unskilled health workers outside of health facilities, and the possible use of misoprostol as a birth control method. Stakeholders also represented different interests, with different NGOs advocating for its use for PPH and others for its use for PAC. Respondents noted the use of misoprostol for PAC seemed to increase controversy amongst concerned officials within the MOH. With significant amounts of time spent on agreeing on key aspects of the final policy document and addressing the main concerns, the new policy was approved and published in January 2011. The final policy approves both the use of misoprostol for PAC at health facilities and misoprostol for the prevention and treatment of PPH at the community level.

5.4 Content

Nigeria's policy, *Community Use of Misoprostol for Prevention and Treatment of Postpartum Hemorrhage in Nigeria (2011)*, contains two different sections. Section A focuses on the background information on maternal health in Nigeria, and sets the context for the use of misoprostol at community level, outside of health facilities. Section B develops the protocol for the use of misoprostol for PPH prevention at the health facility level and includes its use in PAC.

Section A provides summary guidance on the roll-out process at community level, detailing a step by step approach which includes visits with community leaders, assessment of numbers of home births, and others. Section A further discusses the process for training qualified personnel and provides recommendations for including misoprostol in the community revolving drug fund, a method for financing medicines in which, after an initial capital investment, drug supplies are replenished with monies

¹⁹ Ejembi C, Shittu O, Moran M, et al. "Community-level Distribution of Misoprostol to Prevent Postpartum Hemorrhage at Home Births in Northern Nigeria." *African Journal of Reproductive Health* 18.2 (2014):166.

collected from the sales of drugs.²⁰ The policy document identifies existing mechanisms for the roll-out of misoprostol for use at home births:

1. Inclusion in the MSS kits, along with oxytocin;
2. Social marketing through pharmacies and shops; and
3. Community health care providers and faith-based organizations.

A final section provides information on monitoring and support supervision, with instructions for data to be collected from communities and shared with the federal MOH. While the policy recognizes that misoprostol is appropriate for use at home births, the policy does not explicitly identify the cadre of health care worker authorized to administer the medication. The policy calls for “a new cadre of lay community health workers... be trained”, making it unclear as to whether TBAs can be included in this cadre of health workers.²¹

While this lack of specificity in authorizing TBAs to administer the medication was highlighted as one of the key failures of the current policy, other respondents have suggested that this ambiguity was deliberate, to allow for some flexibility in the implementation process. Respondents noted that community-based misoprostol distribution programs have utilized literate community leaders, community drug keepers, and other non-health workers to administer misoprostol. No project has thus far trained TBAs or supported pregnant women to self-administer misoprostol.

6. STATUS OF SCALE-UP: KEY FINDINGS

The status of implementation and scale-up of community-based distribution of misoprostol in Nigeria was assessed through eight indicators representing each of the six WHO Health Systems Building Blocks: governance, finance, health information, commodities and supplies, human resources, and service delivery. Each indicator addresses issues critical to achieving effective impact in a sustainable manner.

According to respondents, the implementation and roll-out of Nigeria’s policy on community distribution of misoprostol has largely been weak and ineffective. With no operational plan that accompanied the finalization of the policy, implementation has largely been limited to small-scale projects in initial operations research communities coordinated by community leaders with some support from PRHP researchers.

A few states have been successful in the scale-up and roll-out of community-based distribution of misoprostol; in 2013, USAID and TSHIP supported Sokoto state, with later expansion to Bauchi state, to make two life-saving drugs for women and their newborns widely available: misoprostol tablets for the prevention of PPH and chlorhexidine gluconate 7.1 percent gel for umbilical cord care.²² With support from TSHIP, Bauchi resourced a two-year supply of the commodity, representing a significant

²⁰ Management Sciences for Health & World Health Organization. *Managing Drug Supply: The Selection, Procurement, Distribution and Use of Pharmaceuticals*. 2nd ed. West Hartford, CT: Kumarian Press, 1997.

²¹ Federal Ministry of Health, Nigeria. *National Standards and Guidelines for the Use of Misoprostol in Nigeria in the Community and at the Health Facility*. 2011.

²² Cannon M, Charyeva Z, Oguntunde O, Sambisa W, Shoretire K and Orobato N. “A Case Study of Community-Based Distribution and Use of Misoprostol and Chlorhexidine in Sokoto State, Nigeria,” *Global Public Health*, (2016). DOI: 10.1080/17441692.2016.1172102

portion of the implementation budget. The successes in these two states serve as a model across Nigeria and a number of visits from professional associations and other state governments have helped to inform future scale-up initiatives. However, at the conclusion of this study, no other states had replicated the misoprostol element of the project.

To bring about health care system change, local, state, and federal policymakers need to collaborate more often and more effectively. According to respondents, the governance system and distinct enforcement abilities at federal, state, and local levels, has significantly impacted policy implementation. Study respondents cite a number of challenges including a lack of knowledge and resources at the local level to implement the policy, as well as a highly politicized process and lack of high-level leadership. Other implementation challenges as they relate to the WHO Health Systems Building Blocks are discussed in the section below.

6.1 Governance

Key governance indicators

- Is community-based distribution of misoprostol for the prevention of PPH included in current national strategies and practice guidelines?
- Is community-based distribution of misoprostol for the prevention of PPH included in both national and subnational implementation plans?

Successful implementation and scale-up of evidence-based health interventions depends upon effective stewardship, accountability, stakeholder engagement, and a shared strategic direction.²³ These key elements of effective governance have largely been missing from Nigeria's experience in rolling out the national policy on community-based distribution. The federal MOH, after championing the adoption of the national policy, appeared to abandon its commitment to ensuring the policy's effective implementation. There was no operational or implementation plan to guide policy roll-out, and no concrete steps were taken to disseminate and circulate the finalized policy to relevant partners, including state level government representatives.

According to respondents, Nigeria's decentralized system of governance, in which federal, state, and local governments have distinct enforcement abilities, also significantly impacted effective implementation of the policy. While the federal government developed and adopted the policy at the national level, enforcement is left to state and local governments. State and local governments can determine whether or not to execute national policies in their area of jurisdiction, and they may identify other priorities based on their local health needs.

²³ "Governance." *Leadership, Management, & Governance Project*. <http://www.lmgforhealth.org/expertise/governing>

6.2 Health Financing

Key financing indicator

- Is community-based distribution of misoprostol for the prevention of PPH included in MOH budgets?

In order for a policy to be effective, it needs to be adequately resourced and funded as part of national or subnational budgets. According to the WHO, health financing is the “mobilization, accumulation, and allocation of money to cover the health needs of the people, individually and collectively, in the health system ... the purpose of health financing is to make funding available, as well as to set the right financial incentives to providers, to ensure that all individuals have access to effective public health and personal health care”.²⁴

In the case of Nigeria’s policy for community distribution of misoprostol, respondents cited poor resourcing at the both the local and federal government levels as hindering progress in ensuring the procurement and availability of misoprostol for PPH. The reason behind the lack of funding was not entirely clear, perhaps due to a lack of domestic financial resources or the absence of political will to allocate resources to support the availability of oxytocin and misoprostol for the prevention of PPH.

According to respondents, community-based funding schemes helped support the financing of misoprostol in select communities in Zaria, Kaduna State where the local research study was conducted. Community leaders have continued to ensure the availability of misoprostol through community drug-revolving schemes where women purchase the medicine for use at home births directly or through TBAs. In contrast, financing for the TSHIP projects in Sokoto and Bauchi states have largely been supported by external donor funds, with purchase of the health commodities sourced by state governments themselves.

6.3 Health Information

Key health information indicator

- Does the MOH currently collect, report, and use appropriate indicators/information on community-based distribution of misoprostol for prevention of PPH?

The collection, processing, and use of health information—including process and outcome indicators—is critical for supporting evidence-based decision-making and is a cornerstone for ensuring both individual and public health outcomes.²⁵ Based on respondents’ feedback, there has been limited collection of data to monitor the availability and use of misoprostol for PPH. No indicators or related targets have been developed as part of the government’s health information system.

²⁴ WHO. “Health Systems Financing.” *World Health Organization*.

http://www.who.int/healthinfo/statistics/toolkit_hss/EN_PDF_Toolkit_HSS_Financing.pdf

²⁵ Adapted from Pacific Health Information Network. “Health Information Systems.” *PHIN*.

<http://www.phinnetwork.org/Resources/HIS.aspx>

In Sokoto and Bauchi States where the TSHIP project was being implemented, a well-structured data collection system was in place to collect and process project-specific data. This included key indicators related to use of misoprostol during childbirth, as well as other relevant maternal and newborn health information, such as postnatal monitoring for a six-week period.

6.4 Commodities & Supplies

Key health information indicator

- Is misoprostol currently procured and distributed in sufficient quantities as part of the national logistics system?

A consistent and reliable supply of misoprostol and other commodities depends on the following core functions: quantification (forecasting and supply planning to identify sufficient quantities), procurement (identification and purchasing of quality-assured and effective products), and distribution (storage, inventory management, and transport).²⁶ While misoprostol is included in Nigeria's Essential Medicines List, the federal MOH has not taken steps to quantify the amounts of misoprostol needed to ensure its roll-out at the community level and does not currently procure or distribute misoprostol for use by individual states or communities. Misoprostol is, however, available in many private sector pharmacies and patent medicine stores across the country under various brand names such as *Citotec*.

6.5 Human Resources

Key human resources indicators

- Are the appropriate health worker cadres authorized to distribute misoprostol?
- Do the appropriate in-service and pre-service curriculum include community-based distribution of misoprostol for prevention of PPH?

The Nigeria Health System Assessment 2008 indicates that the country has a good supply of human resources for health (HRH) compared with other countries in the region.²⁷ The main health care cadres within the Nigerian health system include medical doctors, midwives, and a lower cadre of medical officers called Community Health Extension Workers (CHEWs), who serve in the communities and support the primary health system. The policy does not specify whether misoprostol can be administered by CHEWs and some survey respondents indicated that misoprostol be administered only by skilled health workers such as doctors, nurses, and midwives. Respondents noted that the Nursing and Midwifery Council of Nigeria has included the use of misoprostol for the treatment of PPH as part of pre-service training at the facility level, but because misoprostol is not available in health facilities, nurses and midwives will not be able to administer it to women.

²⁶Reproductive Health Supplies Coalition. 2014. "Essential Medicines for Maternal Health: Ensuring Equitable Access for All." http://www.familycareintl.org/UserFiles/File/Essential_Medicines_Maternal_Health.pdf

²⁷ Kombe G, Fleisher L, Kariisa E, Arur A, Sanjana P, Paina L, Dare L, Abubakar A, Baba S, Ubok-Udom E, Unom S. Nigeria Health System Assessment 2008. <https://www.hfgproject.org/nigeria-health-system-assessment-2008/>

In the TSHIP implementation projects, volunteers were selected and trained to administer misoprostol. These volunteers were identified based on specific criteria, including completion of secondary school education and other literacy parameters. While these volunteers were not medical personnel and had no prior medical training, they were able to effectively administer the medication, identify and document side effects, and provide education to women on general maternal and infant health.²⁸

6.6 Service Delivery

Key service delivery indicators

- Is community-based distribution of misoprostol for prevention of PPH included in MOH supervision schedules?
- Is misoprostol available for distribution at the community level?

The effective delivery of health services combines various inputs (money, staff, supplies, equipment, and medicines) to ensure that specific health interventions are available and can be adequately provided at the facility and community level.²⁹

In Nigeria, the three-tier decentralized governance system presents a challenge for the effective delivery of health services since local governments, states, and the federal government are all expected to autonomously maintain their own health structures, facilities, and processes. For example, processes and systems implemented at the federal level in tertiary health institutions do not necessarily have to be replicated in facilities and communities at the state and local government levels. This autonomy implies that any level of government can decide not to prioritize the introduction or scale-up of a health intervention.

While misoprostol was available for distribution at the community level in states where implementation projects are ongoing, there is no evidence or information on any initiatives to continue the procurement, supply and distribution process in Nigeria. Key informants stated that no arrangements have been formalized in order to sustain supplies of the medication to the communities.

7. CONCLUSION & RECOMMENDATIONS

This study demonstrates that a number of facilitators, enablers, and challenges have contributed to Nigeria's support for community distribution of misoprostol for PPH and its subsequent implementation. While the policy development process was described as long and arduous, a strong facilitator for its adoption was the availability of local evidence highlighting the safety, feasibility, and acceptability of this intervention in the most challenging areas of Nigeria. The engagement of multiple stakeholders throughout the process was instrumental for gaining ownership and ensuring concerns and motivations were addressed. Advocacy for misoprostol's use for the prevention of PPH was often at odds with

²⁸ Cannon M, Charyeva Z, Oguntunde O, Sambisa W, Shoretire K and Orobato N. "A Case Study of Community-Based Distribution and Use of Misoprostol and Chlorhexidine in Sokoto State, Nigeria," *Global Public Health*, (2016). DOI: 10.1080/17441692.2016.1172102

²⁹ Adapted from: WHO. "Health Services." *Health Topics*. http://www.who.int/topics/health_services/en/

arguments related to its use for post-abortion care, creating delays in the design and approval process. Champions within the federal MOH were identified as key to generating broad-based support for community distribution of misoprostol and were instrumental in facilitating initial implementation in Nigeria.

The implementation and roll-out of Nigeria's policy on community-based distribution of misoprostol has largely been weak and ineffective. Without an implementation strategy, a monitoring plan, or a financing plan to ensure misoprostol's availability, implementation has largely been limited to small-scale or donor-funded projects in select states. A number of challenges have impacted the full implementation of the policy for community-based distribution of misoprostol for PPH including Nigeria's decentralized system of governance and a lack of high-level support and leadership to support its implementation. Relative ambiguity within the policy relating to the cadre authorized for the administration of the medication may allow for some flexibility in the implementation process, and should inform continued advocacy and subsequent scale up to ensure women are reached within their current contexts.

The following recommendations provide specific actions to support the effective scale-up and roll-out of misoprostol for PPH at the community level:

- **Ensure that local operations research** is conducted with government and community support to address concerns related to community distribution.
- **Identify and engage champions at federal, state, and local levels** tasked with leading and moving the process forward who can effectively advocate for adequate resourcing and implementation of the intervention.
- Incorporate **national and state-level implementation strategies** ensuring a phased approach whereby each state includes regular reviews, assessment, and revision of implementation guidelines.
- Include a **formal mechanism for monitoring and evaluation** which focuses on accountability and facilitates frequent and regular reviews of data for decision-making in the national and state-level implementation plans.
- Utilize **targeted, strategic advocacy**, including engaging traditional and religious leaders and celebrities, and traditional community-mobilization approaches to increase knowledge, understanding, and support of community-based distribution of misoprostol and address prevailing concerns and misconceptions.

In order to accelerate scale-up of community-based distribution of misoprostol and successfully address the leading cause of maternal mortality in Nigeria, attention must be paid to the effective functioning and capacity for advocacy and mobilization of resources at state level. The experience of Nigeria reveals an often complex policy development process, influenced by a range of factors requiring sustained commitment and action from various stakeholders. While government support at the highest levels was critical for the adoption of policy, it was not sufficient for the implementation across state and local contexts. Stakeholders and partners must play a role in supporting the adoption of the policy and the design of implementation plans at state and local levels, and hold government entities accountable to their commitments. The findings from this study offer recommendations for countries looking to adopt community-based distribution of misoprostol for PPH prevention, lessons for facilitating efficient and effective policy change, and inform future development and implementation design.

8. ANNEX 1: KEY INFORMANT INTERVIEWS – CONSENT FORMS AND GUIDANCE

CONSENT FORM

Key Informant Consent Form

About this consent form

Please read this form carefully. This form provides important information about participating in this research study. If you decide to participate in this study you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Participation is voluntary

You are invited to take part in this research because you have been identified as an individual who is knowledgeable about community-based distribution of misoprostol in your country. It is your choice whether or not to participate. If you choose to participate, you may change your mind and terminate the interview at any time. There are no identified risks or benefits to participating in this study.

What is the purpose of this research?

Specifically the study seeks to identify the key determinants contributing to the development and adoption of national policy on community-based distribution of misoprostol for prevention of postpartum hemorrhage (PPH) at homebirths; to determine current status of implementation and scale-up of the intervention; and to identify successes and challenges in the subsequent national roll-out and scale-up of the intervention. The study findings will result in the development of practical recommendations for countries beginning policy development and adoption, and/or national roll-out of community-based distribution of misoprostol.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this study.

Name of Participant

Signature of Participant

Date

KEY INFORMANT INTERVIEW GUIDE FOR KEY POLICY DEVELOPMENT STAKEHOLDERS

Key Informant Interview Guide

Policy Development

1. Name and designation (Record interviewee's Name, organization, designation, email address, telephone number, and gender)

2. KII for _____ Duration of KII _____

Key Reminders to the Facilitator/Interviewer:

1. The key is to facilitate and lead rather than direct.
2. Begin the interview with a minute or two of general conversation.
3. The purpose is to get the person(s) engaged in a conversation.
4. Maintain a non-judgmental approach to the interviewee and his/her viewpoints.
5. Questions requiring opinions and judgments should follow factual questions, after some level of trust has been established and the atmosphere is more conducive to candid replies.
6. Questions should be simply worded, kept short, and phrased in the vernacular. Generally, they should be phrased to elicit detailed information, not just a simple 'yes' or 'no' answer.
7. Although we will have interviewer questions lined up and in a certain order, do not be afraid to deviate if the conversation takes you in a different order. It is entirely possible that a person may start talking and end up answering any number of questions without specifically being asked. It is also likely that someone may introduce a subject not included in the questions -- let him/her talk (within reason!). The whole point is to allow the person to tell his/her story, including their particular knowledge, opinions, and experiences. Give them the space to say what they need to say. If the person deviates completely from the topic, then do pull them back by referring to the questions.

Welcome

Thank you for accepting the invitation to take part in this meeting. You have been asked to participate as your knowledge, experience, and point of view are important. We realize you are busy and very much appreciate your time.

Introduction

My name is _____ and I am a consultant working for the African Strategies for Health (ASH) project funded by USAID's Africa Bureau. The ASH project is conducting a study in four countries in sub-Saharan Africa which have national policies in place for community-based distribution of misoprostol for prevention of postpartum hemorrhage. Specifically the study seeks to identify the key determinants contributing to the development and adoption of national policy on community-based distribution of misoprostol for prevention of postpartum hemorrhage (PPH) at homebirths; to determine current status of implementation and scale-up of the intervention; and to identify successes and challenges in the subsequent national roll-out and scale-up of the intervention. The study findings

will result in the development of practical recommendations for countries beginning policy development and adoption, and/or national roll-out of community-based distribution of misoprostol.

You have been identified as a key informant who was engaged, in some manner, in the development or approval process of the national misoprostol for prevention of postpartum hemorrhage policy. During this interview, you will be asked to answer some questions regarding your role in this process as well as your opinions and insights on the policy-making process. We are very interested in learning about your perception and experience in the policy development process. This discussion will take approximately 45 minutes to 1 hour.

Do you have any questions or concerns?

Anonymity

We would like to record the interview, if you are willing, to better enable data analysis. We will record the interview only with your consent, and will ask that no personal identifiers be used during the interview, to ensure your anonymity. Please feel free to say as much or as little as you want. You can decide not to answer any question, or to stop the interview any time you want. The tapes and transcripts will become the property of project.

If you so choose, the recordings and recording-transcripts (or copy of notes taken) will be kept anonymous, without any reference to your identity, and your identity will be concealed in any reports written from the interviews.

This interview was designed to be approximately 45 minutes to one hour in length. However, please feel free to expand on the topic or talk about related ideas. Participation in this study will involve no costs or payments to you.

If you agree to participate in this study, please provide your written consent (hand consent form to interviewee).

Leading Questions

Introductory	<ul style="list-style-type: none">• What do you believe first initiated the national discussion on establishing a policy for community-based distribution of misoprostol? (<i>ask for as much detail as possible</i>)• When was that?• Who was involved from the outset?
Content	<ul style="list-style-type: none">• What is the content of the policy?
Process	<ul style="list-style-type: none">• How would you describe the various stages of policy development for this particular policy?• How long did the overall process take from the very initial stage to final adoption?
Stakeholders	<ul style="list-style-type: none">• Who was engaged in these stages and in what capacities?
Process	<ul style="list-style-type: none">• What were some of the key challenges throughout the policy-making process and how were they addressed and overcome?• Who were the key players in addressing these challenges?

Stakeholders	<ul style="list-style-type: none"> • How would you describe the government's leadership of and advocacy for establishment of this policy? • Who were some of the key individuals or units engaged in this process from within the government? • Were there any particular bodies (such as a working group) that were specifically formed/tasked to support the policy process?
Stakeholders	<ul style="list-style-type: none"> • Who were some of the key external parties involved? (UN agencies, donor governments, NGOs, etc.)
Stakeholders	<p>Do you believe that there was one national "champion" (could be individual or organization) who helped to lead this process?</p> <p>If so, who?</p> <p>Why do you believe they were critical in the process?</p>
Context	<ul style="list-style-type: none"> • Do you believe the policy environment was conducive to the adoption of this policy at the start of the process? • If yes, why? • If not, what changed and how did it change?
Context	<ul style="list-style-type: none"> • In what ways did the structure/system of your national government influence the policy development process? (<i>probes: decentralization, legislature system, etc.</i>)
Context	<ul style="list-style-type: none"> • Describe some of the key contextual issues that you feel positively or negatively influenced the policy process? (<i>probes: cultural beliefs, financial issues, etc.</i>)
Content	<ul style="list-style-type: none"> • How important was the role of evidence-based data in the policy-making process? • What kind of data was available, what was requested, and what was presented? • To whom?
Content	<ul style="list-style-type: none"> • From your perspective, what are the expected outcomes of the policy on national level health outcomes, if implemented correctly/successfully?
Summary	<ul style="list-style-type: none"> • What do you believe were the key factors that lead to the adoption of the national misoprostol policy? • What do believe are the successes and failures of this particular policy? • If you had to make 2-3 key recommendations to a neighboring country seeking to develop and adopt a national community-based distribution of misoprostol policy, what would they be?

Conclusion

Thank you for participating. This has been a very useful discussion. Your opinions, knowledge, and insights will be a valuable asset to this study. I would like to remind you that any comments featuring in this report will be anonymous.

Do you have any final questions or concerns?

Thank you again and we will be in touch soon to invite you to a Stakeholders Validation Workshop to take place in the coming weeks.

KEY INFORMANT INTERVIEW GUIDE FOR KEY IMPLEMENTATION & SCALE-UP STAKEHOLDERS

Key Informant Interview Guide

Implementation & Scale -Up

1. Name and designation (Record interviewee's Name, organization, designation, email address, telephone number, and gender)

2. KII for _____ Duration of KII _____

Key Reminders to the Facilitator/Interviewer:

1. The key is to facilitate and lead rather than direct.
2. Begin the interview with a minute or two of general conversation.
3. The purpose is to get the person(s) engaged in a conversation.
4. Maintain a non-judgmental approach to the interviewee and his/her viewpoints.
5. Questions requiring opinions and judgments should follow factual questions, after some level of trust has been established and the atmosphere is more conducive to candid replies.
6. Questions should be simply worded, kept short, and phrased in the vernacular. Generally, they should be phrased to elicit detailed information, not just a simple 'yes' or 'no' answer.
7. Although we will have interviewer questions lined up and in a certain order, do not be afraid to deviate if the conversation takes you in a different order. It is entirely possible that a person may start talking and end up answering any number of questions without specifically being asked. It is also likely that someone may introduce a subject not included in the questions -- let him/her talk (within reason!). The whole point is to allow the person to tell his/her story, including their particular knowledge, opinions, and experiences. Give them the space to say what they need to say. If the person deviates completely from the topic, then do pull them back by referring to the questions.

Welcome

Thank you for accepting the invitation to take part in this meeting. You have been asked to participate as your knowledge, experience, and point of view are important. We realize you are busy and very much appreciate your time.

Introduction

My name is _____ and I am a consultant working for the African Strategies for Health (ASH) project funded by USAID's Africa Bureau. The ASH project is conducting a study in four countries in sub-Saharan Africa which have national policies in place for community-based distribution of misoprostol for prevention of postpartum hemorrhage. Specifically the study seeks to identify the key determinants contributing to the development and adoption of national policy on community-based distribution of misoprostol for prevention of postpartum hemorrhage (PPH) at homebirths; to determine current status of implementation and scale-up of the intervention; and to identify successes and challenges in the subsequent national roll-out and scale-up of the intervention. The study findings

will result in the development of practical recommendations for countries beginning policy development and adoption, and/or national roll-out of community-based distribution of misoprostol.

You have been identified as a key informant who can provide insights into the implementation and scale-up of the national misoprostol for prevention of postpartum hemorrhage policy following adoption. During this interview, you will be asked to answer some questions regarding your role in this process as well as your opinions and insights on the policy-making process. We are very interested in learning about your perception and experience in the policy development process. This discussion will take approximately 30 minutes to 1 hour.

Do you have any questions or concerns?

Consent/Anonymity

We would like to record the interview, if you are willing, to better enable data analysis. We will record the interview only with your consent, and will ask that no personal identifiers be used during the interview, to ensure your anonymity. Please feel free to say as much or as little as you want. You can decide not to answer any question, or to stop the interview any time you want. The tapes and transcripts will become the property of project.

If you so choose, the recordings and recording-transcripts (or copy of notes taken) will be kept anonymous, without any reference to your identity, and your identity will be concealed in any reports written from the interviews.

This interview was designed to be approximately 30 minutes to one hour in length. However, please feel free to expand on the topic or talk about related ideas. Participation in this study will involve no costs or payments to you.

If you agree to participate in this study, please provide your written consent (hand consent form to interviewee).

Leading Questions

(Note: questions may be adapted/omitted dependent upon relevance to specific interviewee)

Introduction	<ul style="list-style-type: none">• Is community-based distribution of misoprostol for the prevention of post-partum hemorrhage currently being implemented in your country?• If yes, is it being implemented by the public health system?• Please describe the national strategy for roll-out/scale-up of this intervention?• In how many districts is community-based distribution of misoprostol currently being implemented?• Is implementation being supported by any external stakeholders (donors, NGOs, etc.)? If yes, who?
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Governance	<ul style="list-style-type: none"> • Is there are stand-alone implementation plan for community-based distribution of misoprostol for the prevention of PPH? • Is community-based distribution of misoprostol for the prevention of PPH included in current relevant national strategies? • If so, which ones? • Is community-based distribution of misoprostol for the prevention of PPH included in current relevant practice guidelines? • What specifically changed in these strategies/practice guidelines following the adoption of the national policy? • How long after the national policy was adopted were these changes made in national strategy and practice guideline documents? • Is community-based distribution of misoprostol for the prevention of PPH included in both national and subnational implementation plans? • Please describe what specifically is included in the implementation plans. • How long after the national policy was adopted were these changes made in national and subnational implementation plans?
Finance	<ul style="list-style-type: none"> • Is community-based distribution of misoprostol for the prevention of PPH included in the relevant MOH budgets at the national and subnational levels? • If yes, do you believe this policy is adequately financed for effective implementation? Explain. • If no, what have been the barriers/challenges to inclusion in the relevant budgets?
Health Information	<ul style="list-style-type: none"> • Does the MOH currently collect, report, and use appropriate indicators/information on community-based distribution of misoprostol for prevention of PPH? • If yes, at what levels? • What information is collected? • How is it currently being used and how is it intended to be used? • Has the program been assessed/evaluated by any stakeholder? • If yes, please describe (who, when, where, how, etc.)
Commodities & Supplies	<ul style="list-style-type: none"> • Is misoprostol currently procured and distributed as part of the national logistics system? • Is it procured in sufficient quantities? • Explain the supply-chain process for getting the misoprostol to the cadre of health worker distributing.
Human Resources	<ul style="list-style-type: none"> • Are the appropriate health worker cadres authorized to distribute misoprostol? • Do the appropriate in-service and pre-service curriculum include community-based distribution of misoprostol for prevention of PPH? • Please describe/explain. • If yes, how long after the national policy was adopted were the curriculum adapted?
Service Delivery	<ul style="list-style-type: none"> • Is community-based distribution of misoprostol for prevention of PPH included in MOH supervision schedules? • If yes, who is responsible for conducting supervision? • Is supervision happening on a regular basis?

Community Engagement	<ul style="list-style-type: none"> • Have local communities been engaged in the implementation/scale-up process? • If so, how? (<i>probes: community mobilization approaches, etc.</i>) • If not, why not? • Do you think community engagement is helpful for effective implementation and scale-up? • Why or why not?
Summary	<ul style="list-style-type: none"> • What do you believe have been the successes and challenges to effective implementation of community-based distribution of misoprostol in your country? • Do you believe community-based distribution of misoprostol is currently being implemented at scale? • If yes, is this sustainable? Why or why not? • If no, what do you believe it will take to achieve implementation at scale?

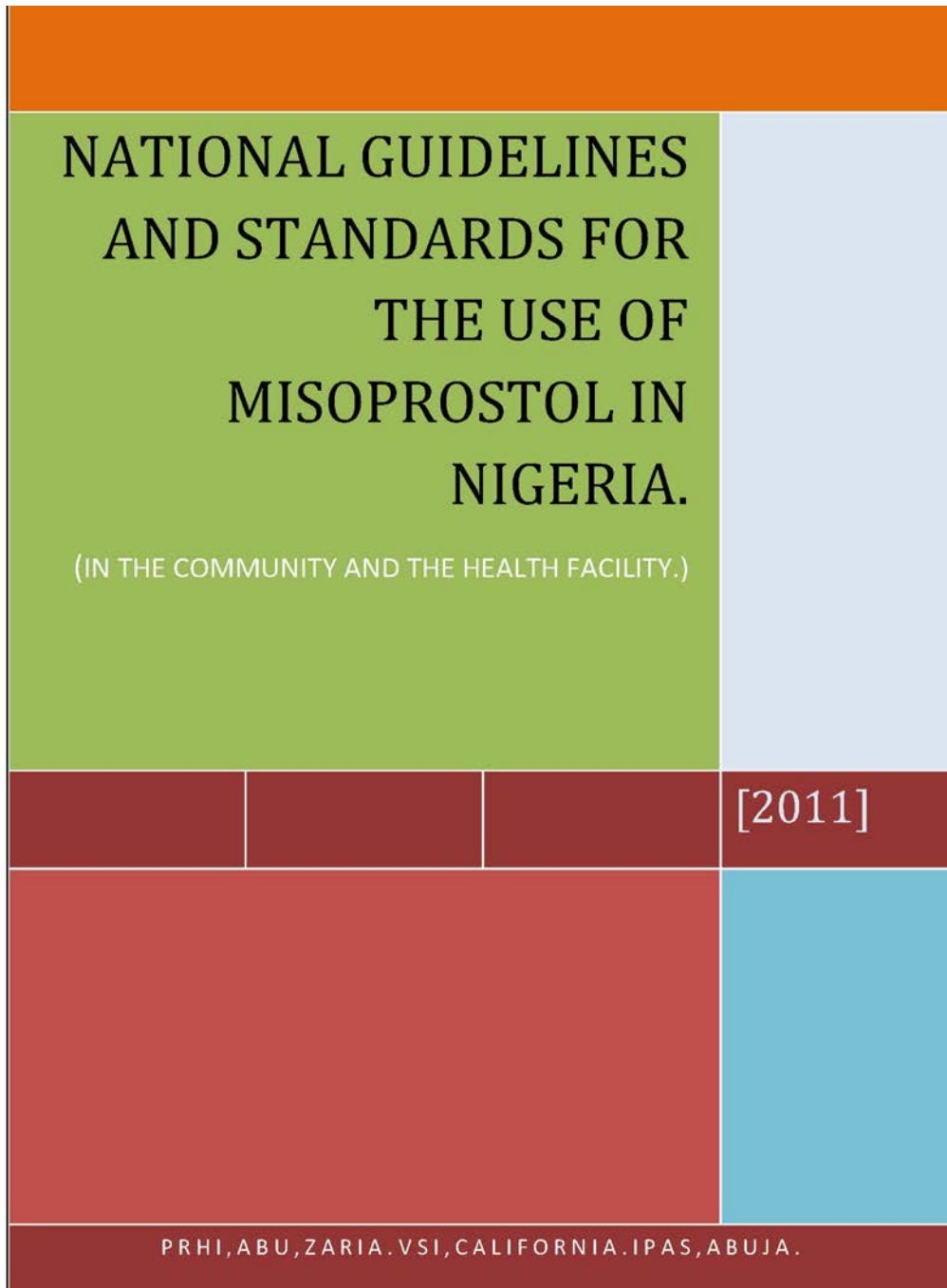
Conclusion

Thank you for participating. This has been a very useful discussion. Your opinions, knowledge, and insights will be a valuable asset to this study. I would like to remind you that any comments featuring in this report will be anonymous.

Do you have any final questions or concerns?

Thank you again and we will be in touch soon to invite you to a Stakeholders Validation Workshop to take place in the coming weeks.

9. ANNEX 2: NIGERIA'S POLICY ON COMMUNITY-BASED DISTRIBUTION OF MISOPROSTOL



FOREWORD

Nigeria has one of the highest maternal mortality ratios in the world, currently at 545 per 100,000 live births (NDHS, 2008). The major causes of maternal deaths are obstetric hemorrhage, eclampsia, infection, complications of unsafe abortion and prolonged obstructed labour. Obstetric hemorrhage, resulting mainly from uterine atony, contributes 23% of these deaths. The Government is committed to addressing the unacceptable mortality rates, and achieving the stated goals of the National Strategic Health Development Plan, the health sector blueprint for the national Vision 20:2020.

A groundbreaking study was conducted on the use of Misoprostol in the community by the Federal Ministry of Health (FMOH), Department of Community Medicine, Population and Reproductive Health Initiative (PRHI), Ahmadu Bello University, Zaria and Ventures Strategies Innovations (VSI). The findings of this study were presented at the 53rd National Health Council (NCH) meeting in 2010. Following this, Misoprostol was approved for use in the management of post partum haemorrhage by trained Healthcare workers at the community level, and has been included in the National Essential Drug List.

It is our belief that the use of Misoprostol at the Community and facility levels will address the challenge of Post Partum Haemorrhage from uterine atony and contribute to achieve remarkable reduction in maternal mortality. As part of her commitment, the FMOH in 2010 also trained selected health professionals from the 36 states and FCT, in the use of Misoprostol in reduction of Maternal Mortality due to PPH.

These guidelines have been developed to guide the doctors and nurse/midwives in the appropriate use of Misoprostol for the prevention and treatment of postpartum hemorrhage and other obstetric indications in the country.

I sincerely recommend the use of these guidelines at the community and facility levels of service delivery so as to contribute to the reduction of maternal mortality and morbidity in Nigeria.

Prof. C. O. Onyebuchi O Chukwu

Honourable Minister of Health

January 2011

ACKNOWLEDGEMENTS

The process of developing these guidelines have been challenging even though very important. It is obviously going to help reduce the very high maternal deaths and morbidity in Nigeria. We are glad that it is done.

Our sincere appreciation goes to the Honorable Minister of Health and officials of the FMOH, development partners, academic institutions, non-governmental organizations who contributed to the development of these guidelines.

Finally, we are grateful to Ipas, PRHI and Ventures Strategies Innovations for the technical and financial support throughout the process of development of these documents.

Dr P.N. Momah

Head, Family Health Department.

ACRONYMS.

1. AIDS- Acquired Immune Deficiency Syndrome.
2. AMTS- Active Management of Third Stage of Labour.
3. CORPS- Community Oriented Resource Persons.
4. FBOs- Faith Based Organizations.
5. FIGO- International Federation of Obstetrician and Gyneacologist.
6. FMOH- Federal Ministry of Health.
7. HIV- Human Immuno-deficiency Virus.
8. IEC- Information, Educational and Communication.
9. IUCD- Intra Uterine Contraceptive Device.
10. IUFD- Intra Uterine Foetal Death
11. IMNCH- Integrated Maternal Newborn and Child Health.
12. LGA- Local Government Area.
13. MCH- Maternal and Child Health.
14. MSS- Midwives Service Scheme.
15. NAFDAC-
16. NCH- National Council on Health.
17. NDHS- Nigeria Demographic and Health Survey.
18. NSHDP- National Strategic Health Development Plan.
19. PHC- Primary Health Care.
20. PPH- Post Partum Haemorrhage.
21. PRHI- Population and Reproductive Health Initiative.
22. RH- Reproductive Health.
23. TBA- Traditional Birth Attendant.
24. VSI- Venture Strategy Innovations.

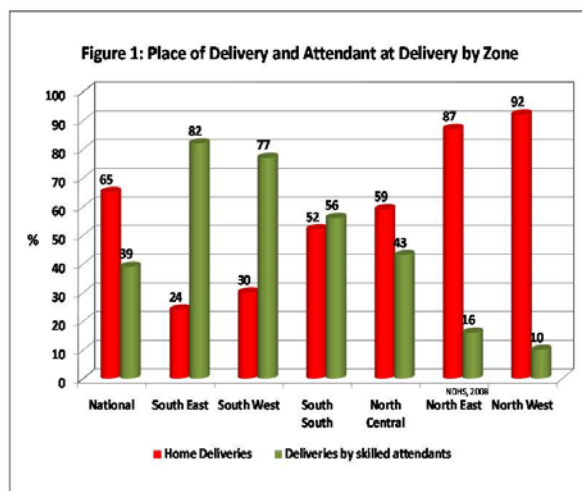
SECTION A.

Guideline on the Community Use of Misoprostol for the Prevention and Treatment of Postpartum Hemorrhage in Nigeria.

Preface (FMOH)

Introduction

The World Health Organization (WHO) identifies Nigeria as having the world's second highest number of maternal deaths, contributing 10% to the global burden of maternal deaths (UNFPA, 2005). Nigeria maintains a high maternal mortality ratio at 545 maternal deaths per 100,000 live births (NDHS, 2008) with wide regional variations between 210 and 1,500 deaths per 100,000 live births (UNFPA, 2005). An estimated 77% of these maternal deaths occur during or after childbirth (FMOH, 2008), and at home, as about two-thirds of women in Nigeria deliver at home (NDHS, 2008).



Presently, majority of Nigerian women 65% (with figures as high as 87% and 92% in some the North East and North West zones) still deliver at home without the presence of a skilled birth attendant (SBA). The use of supervision by SBAs is still as low as 10 percent in the North-West zone and 15 percent in the North-East zone (NDHS, 2008).

The Federal Ministry of Health has championed the efforts to increase national attention and policy change towards improving maternal and newborn health in Nigeria. The flagship of these efforts is the current Integrated Maternal, Newborn and Child Health Strategy (IMNCH) approved by the National Council on Health, November 2007. The IMNCH strategy is a holistic approach; it replaces the competing calls for mother or child. High coverage of the target group is one of the goals of MNCH, as well as integration of maternal, newborn and child health services with other key programmes such as HIV/AIDS, Malaria and Immunization.

Three of the seven strategic objectives of the IMNCH Strategy are:

- Improving access to health care;
- Adequate provision of medical supplies, RH commodities, drugs, and basic equipments;
and
- Strengthening community participation, a vital health system component.

One of the guiding principles of the IMNCH Strategy is the Continuum of Care, which ensures there is no gap in the health care delivery chain from the household/community to the facility.

The IMNCH Strategy has identified three healthcare service delivery modes namely:

- Family/community based service;
- population oriented services; and
- clinical based individual services.

Of these delivery modes, the community based service is best suited for institutionalizing preventive measures that will promote maternal, newborn, and child health.

The IMNCH Strategy is in consonance with the Service Delivery and Community Participation priority areas of the National Strategic Health Development Plan (NSHDP) 2010-2015, which is currently being implemented throughout the country.

The development of this guideline for the prevention and treatment of PPH outside health facilities in Nigeria is intended to strengthen the community response to these strategic documents and a response to the high rates of deliveries outside health facilities in the country.

Postpartum hemorrhage

Postpartum haemorrhage (PPH) is vaginal bleeding after delivery in excess of 500 ml, or any amount of bleeding that can endanger the life of a woman. There are two types:

- primary (bleeding within the first 24 hours of delivery), and
- secondary (bleeding after 24 hours).

Current Situation

Globally, postpartum hemorrhage is the leading cause of maternal mortality. Similarly, PPH is the leading cause of maternal deaths in Nigeria; official estimates attribute 23% of the maternal mortality burden in the country to PPH (FMOH, 2007). Even so, evidence of higher proportions of maternal mortality perceived to be due to PPH from national population-based surveys suggests that PPH is underreported and could be responsible for upwards of 44% of maternal deaths in 2005 and 38% in 2007 were attributed to PPH (FMOH, 2005; 2007).

Causes of PPH

Common causes of PPH include uterine atony, which is failure of the uterus to contract after delivery, retained placenta or membranes ruptured uterus, and genital tract lacerations (cervical, vaginal or perineal tears). However, **seven out of ten** cases of PPH result from uterine atony, making it the commonest cause.

Prevention and treatment of PPH

PPH is better prevented than treated and both of these are best undertaken when deliveries are conducted in health facilities or under the supervision of skilled birth attendants. PPH due to uterine atony can be prevented by Active Management of the Third Stage of Labour (AMTSL). This involves a set of interventions that is administered by a skilled birth attendant. (Please refer to AMTSL). AMTSL shortens the duration of the third stage of labour, thus decreasing blood loss after delivery. An essential component of this is the administration of a uterotonic. Uterotonics are drugs which contract the uterine muscles and prevent uterine atony when administered to women immediately after childbirth. For the prevention and treatment of PPH uterotonics drugs are commonly used throughout the world. The first line uterotonics commonly

used in Nigeria are Oxytocin and Ergometrine. Where these are not available a second-line uterotonic, Misoprostol can be used.

Limitations of current approaches to prevention of PPH

In Nigeria, the protection of women from PPH caused by uterine atony is limited by the following factors:

- High level of births outside health facilities,
- Low level of deliveries supervised by a skilled birth attendant,
- The first line uterotonics require refrigeration and protection from light, both of which are compromised when used outside health facilities. This is a huge challenge in rural settings.
- These preferred uterotonics require administration by injections and can therefore not be given by an unskilled birth attendant.
- Short shelf life of the conventional uterotonics.

Both Oxytocin and Ergometrine are effective when stored in a cool environment but lose potency when kept in hot weather. However both drugs require refrigeration, parenteral administration and have shorter shelf lives when compared to Misoprostol. Because they are parenteral, their use is limited to facility births to be administered by skilled birth attendants (Doctors, Nurses and midwives), trained in the administration of injections, as well as the availability of hypodermic syringes and needles. Misoprostol was added to Nigerian National and Clinical Service protocol for Obstetric use in 2007, for the prevention and treatment of postpartum haemorrhage. Misoprostol is a potent uterotonic in tablet form that is a good alternative for women delivering in the community or at home without a skilled birth attendant and facilities for refrigeration of medicines.

The current approach to prevention and treatment for PPH assumes that women will be delivering in a health facility and/ or be assisted by a skilled health professional that would be able to administer the uterotonic drugs as described in the clinical guidelines. However, many women still deliver at home without assistance from skilled birth attendants. It is in home births that the need for prevention and treatment of PPH is critical; most of women delivering at home have limited access to health facilities and skilled providers, and are in greater danger of death due to PPH. The advent of Misoprostol as a uterotonic has the potential to bridge these gaps.

Misoprostol

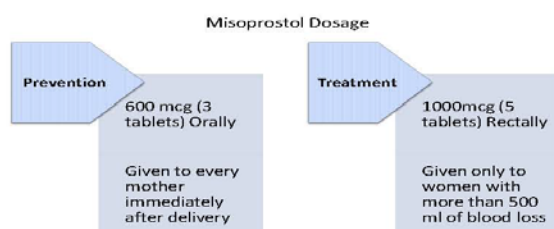
Misoprostol is an E1 prostaglandin analogue, registered by NAFDAC in 2006 (Reg. no: 04-8220) for use in prevention and management of postpartum hemorrhage and approved by the National Council of Health (NCH) in 2007 for health facility use. **In March 2010, the NCH approved the community use of Misoprostol as a step towards improvement of maternal health.**

Misoprostol is an effective, safe and easy to use intervention that is suitable for home births. It is in tablet form, stable in field conditions; administered in a single dose, and does not require a skilled provider. It is easy to administer through a variety of routes that include orally, rectally, vaginally and sublingually. Among the advantages for use at home births is the fact that its administration is easy to teach, women can self administer, and the side effects from its use are predictable, transient and self limiting.

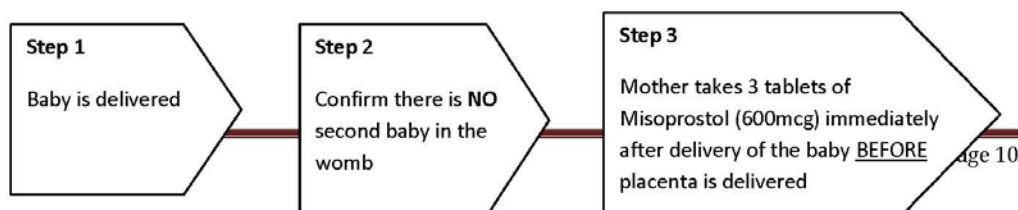
Dosages

Prevention: 600 mcg (3 tablets) swallowed (orally) immediately after delivery upon ensuring that there is no second twin. There is no need to wait for the placenta to be delivered.

Treatment: 1000 mcg (5 tablets) pushed into the anus (rectally), after blood loss equivalent to 500ml



Steps in Misoprostol Administration for Prevention of PPH



Side effects of Misoprostol

Many people using this drug do not have serious side effects. If they occur, they usually disappear within one hour without additional treatment. If necessary, they can be treated symptomatically.

Common side effects include:

- Shivering
- Transient increase in body temperature
- Nausea and vomiting, which are dose dependent
- Headaches
- Rashes
- Lower abdominal cramps due to contraction of the uterus

Contraindications for use of Misoprostol

It is not advisable for women with the following conditions to take Misoprostol:

1. Patients with previous history of cesarean section, as they are all expected to deliver in health facilities.
2. Patients with known bronchial asthma, or other chronic disease (e.g. cardiac diseases, diabetes)
3. Patients with a history of severe diarrheal illness (such as inflammatory bowel disease)

Evidence of distribution, acceptability and use in home births in Nigeria

Studies from countries around the world have demonstrated the effectiveness of Misoprostol in reducing PPH cases in community-based settings (insert references, FIGO statements etc). Similarly, in Nigeria a study to demonstrate the use of Misoprostol with providers in the prevention of PPH at the community-level was carried out in five communities (Shika Dam, Hayin Ojo, Dakace, Tsibiri, and Yakawada) around Zaria, Kaduna State, where home births is near universal and PPH was the leading cause of maternal death in 2009. The study was undertaken in response to the Federal Ministry of Health's (FMOH) desire to have an evidence-based research for policy review of existing guidelines in Nigeria. Of the 1800 post partum women interviewed in the study, almost all (95%) delivered at home, out of which (70%) reported delivery with a TBA whereas only (7%) delivered with a skilled attendant. Seventy nine percent of the women reported taking Misoprostol for the prevention of PPH; only 4% of the women indicated that they took an injection for PPH prevention. Thus Misoprostol use significantly increased protection from PPH from 4% to 83%. Of the 1421 women who received Misoprostol, only 16 (1.2%) developed bleeding with blood loss of 500ml or more, and of these only one received additional interventions (IV and blood). Among the much smaller number of 371 women who did not take Misoprostol, inclusive of 33 that took injectable uterotonics, 21 (6.4%) developed bleeding-related problems and were given Misoprostol at home for treatment of PPH. Less than a quarter of the women experienced side effects and they disappeared without treatment within an hour. Almost all the women (95%) indicated their willingness to use the drug again in subsequent deliveries, recommend to a friend and even purchase it.

Results of the study showed TBAs effectively administered the drug for the prevention of PPH; there was widespread acceptance and use of the drug, and side effects were minimal and self limiting. Also, PPH was effectively managed at home by appropriately trained community agents resulting in significantly reduced referrals and less need for blood transfusions for those who used Misoprostol. The study also observed: the prevention of PPH in women who had had PPH in preceding pregnancies; and a sharp reduction in maternal deaths in the study communities.

Strategies for the distribution of Misoprostol in community settings

The National Health Policy identifies primary health care as the main strategy for expansion of coverage with key health interventions to underserved populations in ways that are affordable and acceptable, using community participation and collaboration with traditional health care providers. It also seeks to enhance integration at all levels of the health care system. This is operationalized in the IMNCH strategy which has been incorporated into the NSHDP.

While it is recognized that the safest place to undergo childbirth is a health facility, where skilled birth attendants employ proven interventions like the AMTSL to preserve the lives and health of the mother and newborn, this is still not accessible to the vast majority of Nigerian women. These women who deliver outside health facilities do so in their homes, traditional birthing places, worship places and when in transit to health facilities. This category of women are consequently least protected against PPH and are thus the ones that need to be reached with Misoprostol.

Existing opportunities for the use of Misoprostol for births outside health facilities:

- The MSS provides an opportunity for the midwives to use Misoprostol in the communities they serve. Misoprostol should be included in the kit in addition to oxytocin.
- Some drugs and RH commodities such as family planning commodities, mama kits, antimalarial drugs etc are currently being distributed through social marketing. This strategy could be used for distribution of Misoprostol. Sales outlets include community pharmacies, shops etc.
- Community-based health care providers and faith-based organizations (FBOs) can use community organization structure and institutions to promote the use of safe and simple reproductive health technologies such as misoprostol.

Linkages to existing strategies in health care system

Linkages between community-based systems and other actors/arms of the health care system are important for the following reasons: training of Community Based Health Care Providers; sustainable drug supply; patient referrals; quality assurance; and monitoring, supportive supervision and evaluation.

Create community linkages

- a. Determine roles and responsibilities of different personnel involved in the program
- b. Link with religious leaders, traditional leaders, and other existing community organizations (especially women's groups)
- c. Establish appropriate response channels among community agents
- d. Establish clear lines of communication and reporting between community agents and facility level supervisors.

- e. Link the CORPS to the PHC service providers for support

Roll-out of Misoprostol at community level

The following steps provide information to help State and Local governments and health system planners to establish and sustain Misoprostol use at community level.

A. Roll-out Preparation

1. Community entry and sensitization
 - a. Conduct advocacy visits to community leaders - traditional and religious leaders
 - b. Conduct rapid assessment of the situation of maternal health in the community, including prevalence of home births, types of attendants at delivery, the magnitude of the problems of PPH and maternal mortality
 - c. Explore interest of community in acceptance, distribution and use of Misoprostol
 - d. Conduct community dialogues to sensitize men and women in community to the key issues and clarify concepts and issues
2. Prepare to introduce community-level use of Misoprostol
 - a. Assess the level of home births in the community
 - b. Assess the number and reach of health workers in the community by categories in the area.
 - c. Assess best way to reach women during pregnancy or just prior to delivery
 - d. Assess best way to reach women and the community with information, education, communication (IEC) about birth preparedness and Misoprostol for PPH prevention
 - e. Estimate Misoprostol supply needs.
 - f. Profile clients and CORPS agents.

B. Demand Creation

1. Use rapid assessment and environmental scanning to develop key IEC messages
2. Determine best channel of communication of messages (e.g., promotion of ANC and health facility delivery, prevention of PPH, appropriate use of Misoprostol among others)
3. Produce and disseminate IEC materials
4. Train and use CORPS to reinforce messages to pregnant women
5. Use interpersonal communication channels like community dialogues to reinforce messages
6. Reinforce health education messages in ANC clinics

C. Training

FMOH

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1. Determine training needs of the different categories of people to work on program
2. Train community pharmacists on drug storage, dispensing, stock monitoring and record keeping
3. Conduct health worker sensitization workshops for care providers in PHCs and referral outlets used by the women in the community on AMSTL and use of Misoprostol
4. Train Community-Oriented Resource Persons (CORPS) on interpersonal communication, counseling on ANC and birth preparedness.

D. Supply

1. Establish a commodity logistic management system for the sustainable supply of Misoprostol. To do that, all levels of government should be able to:
 - Forecast needs
 - Procure the drug
 - Store and distribute the drugs
 - Distribution to community level depends on the strategy being used.
2. Where drug revolving funds are operational, Misoprostol should be included in the DRF. Where free drugs are provided under the free MNCH services, adequate budgetary provisions should be made to ensure regular availability of the drugs
3. Establish linkage with PHC health care providers and community pharmacists and use them for the distribution, replenishing and monitoring of drug use at community level.
4. A system for monitoring distribution and use of the drugs should be put in place

Monitoring and supportive supervision

- a. Develop a monitoring plan to track progress
- b. Develop/adapt monitoring and supervisory tools to capture vital statistics and outcome of Misoprostol use
- c. Assign PHC workers to defined communities for supervision and monitoring
- d. PHC workers should be supervised to ensure adherence to standards maintenance of quality of care.
- e. PHC workers to conduct monthly review meetings with CORPs and village development committees
- f. Forward data collected from the communities to LGA MCH coordinator who will collate information and provide appropriate feedback.
- g. Report adverse events.

SECTION B.

Guidelines and Protocol s for the clinical use of Misoprostol in Obstetrics and Gynaecology at the Facility Level

Background: Background:

Nigeria has one of the highest maternal mortality ratios in the world, currently at 545 per 100,000 live births (NDHS, 2008). Approximately 59,000 maternal deaths occur annually representing 10% of the world's total. The deaths are disproportionately distributed among the five direct causes of maternal mortality which includes obstetric hemorrhage, eclampsia, infection, unsafe abortion and prolonged obstructed labour. Obstetric hemorrhage contributes 23% of these deaths most of which are due to post partum hemorrhage as a result uterine atony. (upto 70%). Eclampsia accounts for x% of maternal deaths and the resort to early delivery as part of management often requires a hysterotomy. X% of maternal deaths are caused by infections while x% are as a result of prolonged obstructed labour Combating these causes of maternal mortality often requires much training, availability of equipments and consumables which are very costly to the health system.

Misoprostol however, is an effective technology for preventing or managing most of these causes of maternal deaths. It is a synthetic analogue of prostaglandin E1 which was originally developed for the treatment of peptic ulcer. In comparison to other prostaglandin analogues, misoprostol has the advantage of being cheap, widely available, and stable at room temperature and has few side-effects.

Misoprostol has become an important drug in obstetrics and gynecological practice because of its uterotonic and cervical priming actions. Its potential is specifically promising in the developing world where maternal mortality is high and where an effective, low cost and stable technology is needed. Its clinical applications include prevention and treatment of post partum hemorrhage, treatment of complications of unsafe abortion and use in therapeutic abortion such as evacuating the uterus in early eclampsia thus eliminating the need for hysterotomy. Other uses of misoprostol in the prevention of maternal morbidity and mortality include uterine evacuation in missed abortion and intrauterine fetal death and cervical priming when labour induction is indicated.

Appropriate guidelines are essential for optimum use of misoprostol at health care facilities to prevent misuse which may lead to untoward effects like uterine rupture.

Recommended Service Providers at Facility Level

- ❖ Doctors and Nurse/Midwives

Indications

- PPH
- Induction of Labor
- Incomplete abortion
- Missed abortion
- Therapeutic Abortion
- Cervical ripening
- Intra uterine fetal death

Routes of Administration

- Oral
- Sublingual
- Buccal
- Vagina
- Rectal

Clients' assessment:

Appropriate history and physical examination are necessary and laboratory investigations to establish diagnosis in each client.

Counseling of the client on what to expect and treatment options and outcome are very important.

Ability /willingness for appropriate follow-up of the client should be done depending on the indication for the use of misoprostol.

Dosages and Routes of Administration

- The dosage depend on the route of administration and indication for use

Indication	Clinical Features	Dosage	Follow-up
Incomplete Abortion	Amenorrhoea, vaginal bleeding, lower abdominal pain, cervical os may or may not be dilated. Features of infection may be present e.g. fever, foul smelling discharge	600mcg orally or 400 mcg sublingually	Prophylactic antibiotics should be given concurrently, e.g. Ampiclox and Metronidazole. Follow-up visit should be on day 7. The uterus is expected to be empty by 14days.If bleeding continues after 14 days re-evaluate.
Missed abortion 0-12 weeks	Amenorrhoea, uterine size smaller than expected for gestational age, loss of symptoms of pregnancy, may or may not present with occasional spotting	800 mcg vaginally 3 hourly (max x2) Or 600mcg sublingually (Max x2)	Follow-up visit on day 7. Uterus is expected to be empty by 14days.If bleeding continues after 14 days re-evaluate.
Therapeutic abortion 1st trimester 0-9 weeks	Medical indications for termination of pregnancy are present e.g. severe pre-eclampsia/eclampsia	800mcg sublingually every 3or 4hrs for a total of 3 doses	Follow-up visit on day 7. Uterus is expected to be empty by 14days. If bleeding continues after 14 days re-evaluate
9-12weeks		800mcg administered vaginally every 6hrs-12hrs x3	The vaginal route is recommended but the sublingual route may be used if the woman so prefer
2nd trimester 13-15 weeks 16 -20weeks		400mcg given vaginally 200 mcg given vaginally	Repeat the dose 6-12hours if there are no signs of induction. Induction should be conducted

			within a health facility
Induction with a live fetus from 28 weeks:		Initial dose: *25mcg given vaginally	Dose intervals should not be shorter than 6 h (vaginally) or every 4hrs (orally or sublingually) for a max of 3 doses a day.
Termination of pregnancy with IUD		200mcg given vaginally	Induction should be conducted within a health facility. Retained placenta is a possibility, prepare for manual removal of placenta.
13-17 weeks		100 mcg given vaginally	
18-26 weeks			
Above 28 weeks		*25 or *50 mcg given vaginally repeat 12hrly	Induction should be conducted within a health facility Do not use more than *50 mcg each time and do not use more than 4 doses a day. Induction should be conducted within a health facility
NB: Misoprostol should not be used for continuous induction of Labor			

*To obtain doses less than 100mcg, dissolve a 200 mcg tablet of misoprostol in 20mls of water, thus each ml contain 10mcg of misoprostol for oral administration.

PPH

Misoprostol is a second line drug in the management of post partum hemorrhage. Oxytocin still remains the first line drug for the prevention and treatment of PPH.

Prevention-600mcg orally or sublingually **AFTER DELIVERY OF THE BABY**

Treatment- 1000mcg rectally or 600mcg sublingually

Notes: If bleeding persists after administration of drug, re-evaluate to rule out retained products of placenta, cervical tears or uterine rupture.

Cervical Ripening

Misoprostol can be used to soften the non- pregnant cervix prior to instrumentation or hysteroscopy

Dosage: 400mcg vaginally 3hrs before procedure

Side Effects:

Many people using this drug do not have serious side effects, most are self limiting and also respond to symptomatic treatment. However, they may experience:

- Diarrhoea
- Nausea and vomiting
- Headache, fever and chills
- Unpleasant taste with sublingual and buccal route
- Sense of numbness in the mouth or throat with the sublingual route
- Prolonged vaginal spotting

Others are:

- ❖ Rashes
- ❖ Lower abdominal pains due to uterine cramps
- ❖ Thrombocytopenia
- ❖ Fetal malformation in case pregnancy continues
- ❖ Immunosuppression when administered vaginally in combination with mifepristone.

Complications:

Life threatening complications include:

- Uterine rupture – stabilize with intravenous fluids, blood, and conduct appropriate surgery
- Fetal distress – deliver the baby by the fastest possible route
- Intrauterine fetal death – grief counseling, deliver as appropriate
- Asthmatic attacks - bronchodilators
- Abruptio placentae - stabilize with intravenous fluids, blood, and deliver by appropriate route

Contraindications:

- Known allergy to misoprostol or other prostaglandins
- Confined or suspected ectopic pregnancy
- Hemorrhagic disorder or concurrent anticoagulant therapy
- Inherited porphyria

Relative contraindications:

- Scarred uterus
- Heart Disease

Precautions:

Where there is IUCD in- situ, it should be removed before use of Misoprostol

Chronic adrenal failure or concurrent long term systemic corticosteroid use

Recommendation

- Training
- Monitoring (record keeping, RH commodity security logistics)
- Evaluation (Continuous)

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