

Ensuring Access to Safe Abortion Supplies

Landscaping of barriers and
opportunities

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Acronyms

CE	Conformité Européene
CLACAI	Latin American Consortium Against Unsafe Abortion
EML	Essential Medicine List
ERP	Expert Review Panel
FPP	Finished Pharmaceutical Product
HMIS	Health Management Information System
LMIS	Logistics Management Information Systems
MA	Medical Abortion
MVA	Manual Vacuum Aspiration
MOH	Ministry of Health
MSI	Marie Stopes International
NMRA	National Medicines Regulatory Authorities
PAC	Post-abortion care
PQ	Prequalification
QA	Quality Assurance
QC	Quality Control
SDGs	Sustainable Development Goals
SDP	Service Delivery Point
SCMS	Supply Chain Management System
SRA	Stringent Regulatory Approval
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

Access to safe abortion for women and girls is a critical public health and human rights imperative. Recognizing the health consequences women endure when undergoing an unsafe abortion, the International Conference on Population and Development in 1994 called for action to address this issue.¹ Subsequently, access to safe abortion remained a priority during the Millennium Development Goals (MDGs) era as well as currently, with the Sustainable Development Goals (SDGs).² With its focus on health and human rights, ensuring expanded access to safe abortion meets numerous targets under SDG goal #3 to ensure healthy lives and promote well-being for all at all ages.³

While nearly half of the 44 million abortions a year worldwide are unsafe resulting in high levels of maternal mortality and morbidity – nearly all occur in developing countries.⁴ Whether access is legally restricted or permitted under varying conditions, women face many challenges to accessing safe abortion. Unsafe abortions are however, entirely preventable.^{5,6} The technology to prevent unintended pregnancies and unsafe abortions exists, however, women face limited access for both indications. Family planning is now widely accepted but often poorly supplied. Mifepristone and misoprostol for medical abortion and manual vacuum aspiration are safe and effective medicines and technologies to provide safe abortions. From legal restrictions to drug quality and stock-outs of medicine, the challenges are vast. Much work has been done to better understand these barriers and to address them. This document aims to pull this work together to create a global picture of the many challenges that still exist for women and girls seeking safe and affordable abortion services. With funding from the Reproductive Health Supplies Coalition’s Innovation Fund, the Council reviewed literature and conducted stakeholder interviews to identify the gaps and challenges along the supply chain.



Photo credit: Ipas



Photo credit: safetochoose.org

Introduction

Unsafe abortion is a critical reproductive health issue that has major consequences for women's and girl's health, whenever unintended pregnancy interferes with women's right to decide on the number and timing of births. Recognizing it as a serious public health problem since 1967,⁷ the World Health Organization (WHO) defines unsafe abortion as "a procedure for terminating an unintended pregnancy whether by persons lacking the necessary skills or in an environment lacking the minimal medical standards, or both".⁸ Nearly half of all abortions worldwide are unsafe.⁹ Over 21 million women endure unsafe abortion worldwide with the vast majority - 18.5 million - occurring in developing countries.¹⁰ Despite the fact that the WHO has deemed unsafe abortion one of the easiest preventable causes of maternal mortality, complications from these procedures, including hemorrhage and infection, result in over 47,000 preventable deaths per year.¹¹ Deaths from unsafe abortions constitute 8-18% of all maternal deaths.¹² Of the women that survive, 5 million suffer long-term health complications arising from trauma to the cervix, vagina, uterus and abdomen. Alarming, these statistics are thought to be underestimated because unsafe abortions are often not documented due to their clandestine nature. Further, these numbers are likely to rise following the re-introduction of the Protecting Life in Global Health Assistance policy, commonly referred to as the Mexico City Policy, a U.S. policy that blocks U.S. funding to non-U.S. organizations that advocate or perform abortion with their own funding. The greatest mortality and morbidity burden is felt in developing countries where abortion is either restricted by law, is not accessible where legally permitted or where the knowledge of the legality of the services and appropriate supplies are limited both among providers and communities.

Unsafe abortion is one of the easiest preventable causes of maternal mortality.

-World Health Organization

Access to high-quality, safe abortion supplies and services can significantly reduce maternal mortality and is essential for addressing this as a public health priority. Misoprostol and mifepristone tablets (in combination or misoprostol alone if mifepristone is not available), and manual vacuum aspirationⁱ are WHO recommended medicines and technologies for safe abortion that are proven safe, effective and feasible to deliver in a variety of health settings.¹³ However, widespread availability of these safe abortion technologies is still a challenge and supply chains are generally weak. To better understand the supply chain issues facing these life-saving technologies, the Population Council conducted a global landscaping exercise of these products based on existing literature and stakeholder interviews. Using the four components of a customary reproductive health supply chain as identified by the World Health Organization as a guide - product selection, product procurement, product distribution and product use -

ⁱ Both manual vacuum aspiration and electric vacuum aspiration are WHO recommended procedures for safe abortion, however, this report focuses on manual vacuum aspiration since it is more conducive to lower-resource settings.

a range of issues were examined including where these supplies are available, how they are procured, and factors affecting quality. Innovative solutions to some of the challenges identified are featured. We hope this report can serve as a guide for global policy and decision-makers as well as future investment in safe abortion supplies as there are still many challenges to address before women can realize their right to a safe and legal abortion.

Methodology

This landscaping of safe abortion supplies was conducted at the global level with particular attention given to the 47 least developed countries as identified by the United Nations (see **Appendix A** for complete country list).¹⁴ Data was compiled from a desk review and stakeholder interviews.

Both peer reviewed and the gray literature was reviewed. The types of gray literature documents reviewed included unpublished reports, conference presentations, briefs, and country and global guidelines. Semi-structured in-depth interviews were conducted by phone (see **Appendix B** for a complete list of stakeholders interviewed). Data was gathered from these sources and key barriers and gaps were identified. Innovative approaches to addressing supply challenges in Nigeria and Nepal are featured.

Safe Abortion Supplies

Supply and commodity overview

The technical advancement in medical abortion has been revolutionary in reducing rates of abortion-related morbidity and mortality.¹⁵ Medical abortion (MA) is a nonsurgical procedure in which the drugs mifepristone and misoprostol or misoprostol-only are used to induce abortion. Mifepristone is an antiprogestin taken orally which blocks the action of progesterone causing the uterus to be unable to sustain an embryo. The drug also causes an increase in prostaglandin levels which softens the cervix, facilitating expulsion of the products of conception. Mifepristone may also be used for cervical ripening prior to labor induction in the third trimester.

Misoprostol is a synthetic prostaglandin E₁ analogue initially marketed for the prevention and treatment of gastric ulcers caused by long-term nonsteroidal anti-inflammatory drug use. It is also used for many reproductive health indications including labor induction, treatment of incomplete or missed abortion, treatment of intra-uterine fetal death, cervical priming prior to trans-cervical procedures, prevention and treatment of postpartum hemorrhage and elective termination of pregnancy.¹⁶ A regimen of 200 mg of mifepristone followed by 800 µg of misoprostol administered vaginally, buccally, or sublingually results in complete abortion in more than 98% of cases up to 9 weeks gestational age¹⁷. The drugs can be used throughout pregnancy at different dosing regimens and varying degrees of effectiveness to safely induce an abortion.

Where mifepristone is not available, the recommended method is 800 µg of misoprostol administered by vaginal or sub-lingual routes for pregnancies up to 12 weeks and 400 µg for gestational age over 12 weeks. For more information on regimens see the WHO's safe abortion technical and policy guidance: http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf. Complete abortion rates in early pregnancy with use of misoprostol-only range from 76 to 96%.^{18,19} While less effective than the combined drug regimen, misoprostol is currently more widely available and has been used safely for medical abortion globally.

Manual vacuum aspiration (MVA) is a safe and effective easy to use alternative to electronic vacuum aspiration for abortion of a first trimester pregnancy, management of incomplete or spontaneous abortion, and to perform endometrial biopsies. Over the last 40 years, clinical studies have demonstrated MVA to be 99% effective for early abortion.^{20,21} It allows for evacuation of the uterus using a hand-held plastic aspirator attached to a cannula (a thin tube). Unlike electric vacuum aspiration, MVA requires no electricity, is smaller in size, quieter, and less expensive, making it the preferred choice for uterine evacuation in low resource settings as recommended by the WHO.²² Although MVA and EVA are both outpatient procedures, MVA is less painful and requires less equipment.²³ Thus, MVA is more likely to be performed without anesthesia or use of an operating theater reducing time and cost required.

Legal framework

Since the 1950's there has been a global trend to liberalize abortion laws.²⁴ Nearly all countries (96%) allow women to terminate their pregnancies to save their lives and preserve their health.²⁵ Six countries prohibit abortions under any circumstances (Chile, the Dominican Republic, El Salvador, Nicaragua, Vatican City and Malta). All of the poorest 47 countries permit abortion to save a woman's life. Only 2 of these countries – Mozambique and Cambodia - allow termination for any reason. See The Center for Reproductive Rights' world map of abortion legal status updated in real time for more information (<http://worldabortionlaws.com/>).

Even in countries that permit abortion under certain circumstances, e.g., in cases of rape, incest, or presence of fetal anomalies, women face numerous challenges to obtaining a safe legal abortion. Some of these challenges include those related to the supply chain – and the focus of this report - include registration bottlenecks, stock-outs of medicine, poor quality of drugs, and lack of knowledge of abortion options or a woman's legal right to seek an abortion, limited or non-existent services, and stigma associated with accessing the services. Other challenges include mandatory waiting periods, biased counseling requirements, the requirement for parental permission, and conscientious objection, or the right to refuse to perform services because of moral or religious objections.²⁶

While abortion supplies are reproductive health supplies, one key differentiating factor is that whether legal or not, abortion remains highly stigmatized. While stigma within communities and the service delivery environment is well documented, barriers related to stigma along the supply chain are less understood. Nearly all stakeholders responded that stigma is pervasive along the supply chain either on a systems level or an individual level. For example, although MVA kits are registered in Kenya, there exist obstacles to adding it to annual work plans and securing funding for purchase due to personal objections within the Ministry of Health.²⁷ It is within this context of abortion being a legally restricted medical service which is highly stigmatized, that we examine issues along the abortion commodities supply chain below.

Examining the safe abortion commodity supply chain

Manufacturers and distribution

Mifepristone and misoprostol are available from generic manufacturers sold as individual medicines and in combination packs (combipacks) made specifically for early medical abortion (MA). Two branded generics of mifepristone, Mifeprex® (Danco Laboratories, USA) and Mifegyne® (Laboratoire Exelgyne, France), and a non-branded generic (Linepharma, U.K.), are available in mostly high-income countries. Linepharma's product was registered in Kenya in 2012 and WCG Cares (formerly WomanCare Global) has been working to distribute it in additional countries in Africa. There are numerous pharmaceutical companies producing branded and generic mifepristone in China, India and Taiwan but their export capacity is low.

A strong reproductive health supply chain supported by an effective logistic management system ensures that the right quality product, in the right quantities, and in the right condition is delivered to the right place, at the right time, for a reasonable cost.

-World Health Organization

The misoprostol innovator product, Cytotec® (Pfizer), is the most widely available found in more than 80 countries (although not registered for obstetric indications). Now there are more than 50 branded and non-branded generic versions available inexpensively in high, middle and low-income countries including Argentina, Bangladesh, Brazil, Chile, China, Egypt, France, India, Mexico, Peru, South Korea, Russia and the United States.²⁸ The availability and use of generic misoprostol products has increased over the last decade.²⁹ Unfortunately, this increase was not met with adequate quality control or assurance as discussed below. There are close to 35 manufacturers in developing countries with varying regulatory standards.

Combination packs containing one tablet of mifepristone and four tablets of misoprostol are currently made by manufacturers in low and middle-income countries. Most of these products are manufactured in China and India for the local markets. Medabon® (Sun Pharmaceuticals, India) and a product made by Acme Formulations (India) are available for export to a limited number of markets in Africa and Asia including Cambodia, Ghana, and Kenya.

The original MVA device was developed in the 1970's by Ipas, an international organization that works to increase women's ability to exercise their sexual and reproductive rights and to reduce abortion-related deaths and injury. Today there are 9 brands of manual vacuum aspirators available worldwide; the devices developed by Ipas are by far the most widely available. They are validated for reprocessing 25 times. If handled well, they can be used effectively up to 100 times based on anecdotal evidence.³⁰ Marie Stopes International (MSI), a global nonprofit organization providing the full spectrum of reproductive health care in both developing and developed countries, has manufacturers in China, Malaysia and Taiwan that manufacturer single and double valve MVA. They

possess the CE mark which means “Conformité Européene” or conformity with health, safety and environmental protection standards for products sold within the European Economic Area, and thereby providing a quality certification.

From 2009 to 2017 WCG Cares was the licensee for the Ipas MVA kit providing over 1 million kits used for serving 32 million women³¹ In May 2017, Ipas and DKT International announced an exclusive partnership in which the Ipas MVA technology will be licensed to DKT for global distribution. DKT is one of the largest providers of family planning products and services in the developing world, providing safe and affordable options through social and commercial marketing in more than 35 countries. DKT will handle the manufacturing, distribution, marketing and regulatory oversight and Ipas will continue to provide training and education programs. Expanding registration of MVA, as well as mifepristone, in developing markets is planned. Narang Medical Limited in India also makes MVA kits but is not approved by a stringent regulatory authority (SRA). HPSRx Enterprises based in Virginia, U.S.A distributes only in the United States and sells the Ipas MVA Plus for \$65 per kit wholesale.

Registration

Mifepristone was developed in the 1980's in France and registered there in 1988 under the brand name Mifegyne®. It was first registered in 1988 with the USFDA under the brand name Mifeprex®, manufactured by Danco Laboratories, USA. It has since been registered in over 60 countries, however, availability is concentrated in largely high-income countries. This is due in part to restrictive abortion laws in low income countries. The originator product remains expensive although there are less expensive alternatives.³² Additional tradenames include Mifebort®, and Termipil®. Where abortion is illegal, and often severely sanctioned, the product is not being registered. One possible pathway to registration in these settings is to register for other indications such as treatment of incomplete abortion, post-abortion care (PAC), second trimester medically necessary abortions, intrauterine fetal death, or endometrial biopsy.³³ This could open the door to registration and eventual use by health providers in restricted legal settings. This approach is supported by a recent study conducted by the Latin American Consortium against Unsafe Abortion (CLACAI), which found that prior registration for obstetric use is a critical factor in securing national regulatory approval of misoprostol and mifepristone for medical abortion.³⁴ Once organizations such as the Concept Foundation or Marie Stopes International registers the product in a country they need to find a distributor which has also been a challenge due to the lack of anticipated volume, low margins, perceived risks of serving this market.

Misoprostol was first registered in 1998 by G.D Searle and Co, now Pfizer, under the brand Cytotec® for the prevention and treatment of gastric ulcers and is currently available in over 100 countries. With Nigeria leading the way as the first country to register the product for postpartum hemorrhage, it has since been registered in over 30 countries for obstetric use.³⁵ Of these countries, misoprostol is only registered in 11 for the treatment of incomplete abortion (i.e., Angola, Burundi, Kenya, Malawi, Mozambique, Niger, Nigeria, Rwanda, Tanzania, Senegal and Zambia). Where not registered for induced abortion, off-label use for this purpose, although often at a high price, is quite

common.³⁶ Unfortunately, the product is often not registered in countries with small populations of women of reproductive age because of the high registration costs posing a real challenge for equitable access. Manufactures find it challenging to enter these smaller markets and still be profitable.³⁷

Combination packs of mifepristone and misoprostol are also available. Medabon® is registered for medical abortion in 26 countries including Cambodia, India, Mozambique, Nepal, Ethiopia and Zambia. The Concept Foundation is working in partnership with IPPF, Ipas, PSI, WCG Cares and MSI to register and introduce the product in the public sector in as many countries as feasible.³⁸ Acme Formulations' product is also registered in Mozambique. In India, many brands of Indian-made combination packs are registered for medical abortion for use in India only. Efforts are under way to register combination packs from other manufactures in several countries in sub-Saharan Africa. Many of these efforts are difficult to track due to inadequate information systems on private distribution systems.

Manual vacuum aspiration supplies are registered in over 100 countries. Ipas's U.S. FDA approved MVA products are registered by WCG Cares and also have the CE mark. MSI's MVA products are mainly issued in MSI clinics but are available to external procurers as well. As the licensee of Ipas's MVA kit, DKT's goal is to expand market access to these kits in additional countries.

One challenge regarding registration of all these products is the rapidly changing regulatory environment.³⁹ For example, while manufactures were able to use a standard label for product import, the requirements now often vary by country. Each time there is a specific request from a country, it complicates both manufacturing and the entire the supply chain. These delays need to be factored into lead times planning a program including ordering product to supply the program.

Inclusion of these products as a class on the World Health Organization Model Essential Medicines (EML) Lists is a facilitating factor for country registration. As seen in **Table 1**, misoprostol is on the model EML for incomplete abortion, early abortion (with mifepristone), induction of labor, and prevention and treatment of post-partum hemorrhage.⁴⁰ Mifepristone was included on WHO's EML Complementary List in 2007 for induced abortion with misoprostol, where permitted under national law and where culturally acceptable. Inclusion on the complementary list (rather than on the main list) may not have a significant impact on whether a country decides to add the product to their country EML.⁴¹ However, ensuring these are included on country EMLs is an important step to securing country commitment for procurement and /or importation of these medicines. One ongoing effort (see **Appendix C**) aims to register mifepristone and support its addition to country EMLs.

Manual vacuum aspiration is listed on the WHO, UNFPA, USAID Interagency list of priority medical devices for essential interventions for reproductive, maternal, child and newborn health.⁴²

Table 1: WHO Model Lists of Essential Medicines	
misoprostol	<p>Tablet: 200 micrograms.</p> <ul style="list-style-type: none"> • Management of incomplete abortion and miscarriage; • Prevention and treatment of postpartum hemorrhage where oxytocin is not available or cannot be safely used. <p>Vaginal tablet: 25 micrograms.*</p> <p>*Only for use for induction of labor where appropriate facilities are available.</p>
mifepristone* – misoprostol* Where permitted under national law and where culturally acceptable.	<p>Tablet 200 mg – tablet 200 micrograms</p> <p>*Requires close medical supervision.</p>
Source: World Health Organization ⁴³	

Quality

Quality-assurance

The highest rated quality assured (QA) products are those that have met SRA approval or have been prequalified by the World Health Organization, as both processes require product quality verifications. An overview of prequalified mifepristone and misoprostol products is found in **Table 2**. There are currently three prequalified mifepristone products on the market: Linepharma’s generic, Zizhu Pharmaceutical’s Mifeprex® and Exelgyn’s Mifegyne®. Four misoprostol products are prequalified (see list below) and it is currently eligible for the WHO Prequalification of Medicines Program,⁴⁴ and for the United Nations Population Fund (UNFPA) Expert Review Panel (ERP) process, a mechanism to assess whether medicines submitted for prequalification (PQ) review could be recommended for use before they are prequalified.⁴⁵

Once determined to meet specific quality standards via the WHO-PQ process, products must still be approved for use by the national medicines regulatory authorities (NMRAs) of the countries for which market entry is sought. The WHO has designed a procedure that enables NMRAs to make use of work already conducted by the WHO and to strengthen their own regulatory processes. This Collaborative Procedure between the WHO Prequalification of Medicines Program and National Medicines Regulatory authorities in the Assessment and Accelerated National Registration of WHO-

prequalified Pharmaceutical Projects is open to MNRAs in WHO Member States and holders of prequalified finished pharmaceutical products (FPPs).

Table 2: WHO prequalified misoprostol and mifepristone	
Manufacturer	Date prequalified
MISOPROSTOL	
Linepharma International, England	n/a
Cipla Ltd, Cipla House, India	April 2014
Acme Formulation Pvt. Limited, India	April 2016
China Resources Zizhu Pharmaceutical Co Ltd, China	Nov 2016
MIFEPRISTONE	
Linepharma International, England	Oct 2014
China Resources Zizhu Pharmaceutical Co Ltd, China	Aug 2016
Laboratoire Exelgyn, France	May 2016
Source: WHO website (http://www.who.int/mediacentre/factsheets/fs278/en/)	

Quality control

Quality control is the process of identifying and fixing defects in the finished product. Sub-quality safe abortion medicines and instruments can lead to additional complications and cost to consumers and health systems. It is generally accepted that the quality of mifepristone meets international standards for the drug.^{46, 47} In 2013 Concept Foundation and its lab subsidiary Health Concepts tested eighteen different mifepristone-alone products and 14 different mifepristone-misoprostol combination packs manufactured in India, Vietnam, and China. The assessment of mifepristone quality reported that all samples were within the drug content requirements and had low levels of impurities.⁴⁸ The study concluded that there is no evidence of mifepristone quality issues.⁴⁹

The quality of misoprostol on the market, however, varies considerably. Quality control effort have not kept pace with the increased availability of generic products available worldwide. Misoprostol is a viscous oil which makes it susceptible to degradation. This is adjusted for by using a 1% dispersion of misoprostol in hydroxypropyl methyl cellulose (HPMC) which is more stable and allows for a shelf life of several years at room temperature. Exposure to water during any phase of manufacturing through storage has been found to be the primary factor contributing to degradation. Low-quality products are commonly found in countries such as Pakistan because of its weak regulatory

environment and proximity to India where there are many manufacturers that are not quality assured.⁵⁰

In a study of misoprostol quality conducted by the Concept Foundation, thirty-four out of 74 samples tested had less than 90% of labelled content; 8 had less than 20%. Thirty-one out of fifty-eight samples tested had impurities greater than the limits set by the European and US Pharmacopoeia. There was no evidence that 14 samples contained any misoprostol and 3 samples were falsely labeled as the innovator product. Products packaged in plastic/aluminum blister packs deteriorated rapidly and more so than products in aluminum/aluminum packs. The issues affecting quality included moisture in all stages of production and post distribution, manufacture and quality of APIs and FFPs, and packaging of tablets.

Results demonstrate the necessity of packaging in double aluminum blister packs to prevent moisture. Quality also degrades rapidly between 3 months and one year.⁵¹ This degradation would not have been detected by pre-shipment quality control (QC) processes. Appropriate environmental controls at all stages of manufacturing process and use of a double aluminum blister pack should prevent degradation of the finished product. Numerous recommendations were made based on this study including removal of substandard products by national authorities, and purchasing of quality-assured products packaged in aluminum/aluminum blister packs. The knowledge about misoprostol quality is clear and as recommended by one stakeholder, the focus can now shift to disseminating this information to the field so that programs know how to procure good quality products.⁵²

There are numerous challenges with assuring the quality of MVA products. In a 2003 comparative evaluation of 9 MVA devices, durability was compromised by high temperatures and quality by manufacturing defects⁵³. Many products did not meet minimum safety, functionality and durability standards. Boiling and steam sterilization techniques seemed to cause moderate to significant changes in quality and durability among all cannula tested. Further, the particular design of the instrument was key to ensuring safe reuse.⁵⁴ MVA kits are often used beyond their lifespan or incorrect sterilization procedures are used in-country, both of which lead to degradation of the instruments and loss of efficacy. Overuse stems from lack of knowledge about procurement or resupply, lack of funds to procure/order and not knowing how to order replacement cannula separate from the entire MVA kit.⁵⁵

While the lowest cost MVA instruments may appeal to procurers in many low-income countries, they may not be the safest or cost-effective in the long-term due to their sub-standard safety and effectiveness.⁵⁶ A practical guide for the selection of MVA instruments based on the above study provides information for procurers and decision-makers on MVA selection.⁵⁷

Forecasting, procurement and price

Inaccurate forecasting for safe abortion supplies is a major barrier to access. Facilities are unsure of how much stock to have on hand to accommodate the volume of clients they serve. Ipas developed a mobile (mHealth) app to address this barrier. Even with a supportive legal and policy framework, maintaining adequate stock remain a challenge. In one analysis conducted by Ipas of their facilities in 13 countries, only Ethiopia had an adequate supply of MA in 2015.⁵⁸ While fewer sites had stock-outs of MVA supplies, the percent of sites stocking supplies at the recommended level per Ipas ranged from zero to 87%.⁵⁹

As with many reproductive health supplies, procurement of medical abortion supplies tends to be fragmented.⁶⁰ In Nepal and Ghana for example, the government purchases product with its own funds while in many other countries, supplies are procured with donor funds or some combination of the two. While some have an annual tender like Bangladesh, in general national governments need to invest more to improving forecasting. International partners can provide assistance, but there is a need for fundamental improvement in many of the systems. The private sector often does a better job of ordering and monitoring supplies, but they are not exempt from some of the same challenges.⁶¹ Procurement of MA over the internet from organizations such as Women on Waves, Women Helping Women and safe2choose is also available.

In countries where abortion is restricted mifepristone is not readily available in the market and black market misoprostol prices are high. A physician may prescribe the drug for ulcers at a low price, however, the price increases on the black market where there is suspicion that it will be used for abortion. Mifepristone is expensive due to the relatively complex synthetic pathways of the API and there are only a few commercial manufacturers.

Quality misoprostol is available at a price premium, in part due to the limited number of quality assured products on the market. The price premium is challenging for governments and smaller procurers to absorb which often results in the purchase of lower price products of lower quality.⁶² It is difficult to estimate the volumes procured because many of these drugs are procured by national governments and private sector in developing countries which do not report centrally. There is a wide range of reported costs of misoprostol for the PPH indication versus the abortion indication.⁶³

UNFPA procures MA combination packs for \$11.75 USD and mifepristone tablets for \$8.00 USD and IPAS plus MVA kit for approximately \$10.52 USD (\$8.70 aspirator, \$1.13 cannula, \$0.69 accessories).⁶⁴ The purchase of MVA kits at this time is largely driven by international donors.

Mobile technology for better forecasting in Nigeria

A new and innovative mobile health (mHealth) application has been developed by Ipas to help facilities plan for continuous availability of safe abortion commodities. The app is designed to estimate a facility's required inventory levels and consumption of MA and MVA and determine minimum and maximum inventory levels. The app was recently piloted with public and private healthcare providers in Nigeria. Providers found the app easy to use and the calculators were found to provide faster and more accurate estimation of supply needs preventing commodity stock-outs. Based on positive results of the pilot, widespread dissemination is planned.

The MA and MVA calculators can be found on Ipas's website.

Approximately 200k units of the Ipas kit are sold per year⁶⁵. In some countries there is concern that pharmacists are increasing the price of mifepristone and misoprostol as demand increases, hindering access to those that cannot afford it.⁶⁶ With a pharmaceutical partner, the Concept Foundation has negotiated a preferential price for Medabon® combipacks globally. DKT suggests the UNFPA price and the distributors add a mark up to cover costs and overhead.⁶⁷

Product Use

In-person training is critical to safe and effective use of safe abortion supplies. Linking MVA kit availability with training opportunities can ensure MVA supplies that have been ordered are not sitting on a shelf due to lack of training.⁶⁸ Instructions for providers on proper dispensation of MA and use of MVA equipment are often misunderstood potentially decreasing the efficacy of these technologies. Dose requirements for MA change depending on gestational age; further complications arise due to the multiple indications of misoprostol with different dosages. With MVA, use beyond the lifespan of the equipment is common.⁶⁹ Provider training and instructions are key to ensuring women have access to the safest and most effective methods possible for their needs and circumstances.

Generating demand

Generating demand for safe abortion supplies is dependent on a supportive policy environment and women's knowledge of their legal right to obtain an abortion. Government support was cited as one of the most important facilitating factors to ensuring access to safe abortion supplies.⁷⁰ Even with government support, individuals in decision-making positions can pose a barrier to access. Women often are not aware of their legal right to obtain an abortion, nor where qualified providers might be accessible. Increasing awareness of their right to do so can help generate demand. See the success of Nepal's unique and comprehensive approach below.

One of the main challenges facing MVA is that it is marketed as an abortion product.⁷¹ Marketing efforts could focus on additional uses for the product such as management of spontaneous abortion or miscarriage says one stakeholder.⁷² In Bangladesh, for example, menstrual regulation is the indication.

Finally, a major challenge for improving access to safe abortion supplies as cited by 5 stakeholders is the lack of donor funding for supplies issues. Most U.S. donors, including the U.S. Government and several large foundations will fund Post-abortion Care but do not fund procurement or research on safe abortion supplies. International funding for supplies issues is limited.

Nepal: a model for safe abortion scale-up

Nepal's implementation of liberalized abortion law can be viewed as a model for rapid scale-up. Transitioning from a restrictive legal code instituted in 1854 (final version passed in 1963) prohibiting abortion except if a woman's life was at risk to 2002 legal reform that permits abortion: a) on request up to 12 weeks of pregnancy; b) up to 18 weeks if the pregnancy is the result of rape or incest; and c) at any time during the pregnancy if the life, physical or mental health of the woman is at risk or if the fetus is deformed, occurred in record time. The Abortion Task Force (ATF) and later the Technical Committee for Implementation of Comprehensive Abortion Care (TCIC) and a Safe Abortion Advisory Committee (SAAC) were convened to ensure safe and widespread access to abortion. Most abortion care supplies and services are made available for free. The products are on the national EMLs and there are policies in place for forecasting, procurement, quality checks, and storage. The Family Health Division in the Ministry of Health procures mifepristone/misoprostol combination packs from multiple distributors and makes them available through the public sector. Signs painted on government facility walls read "Have safe abortions here." The TCIC developed a safe abortion logo widely recognized as the symbol of safe abortion in Nepal and viewed as a key innovation to expanding access.⁷³ MVA kits are procured by the MOH from Atlas directly to LMD, FPAN, MSI and Ipas. Abortion services are provided for a modest fee while contraception and post abortion care is free. The private sector, including MSI and the Family Planning Association of Nepal provide an important role in urban areas.⁷⁴

By 2011, the MMR in Nepal had declined from 539 in 1996 to 229 per 100,000 live births in 2009 and abortion complications decreased from 41% in 1998 to 26% in 2008.⁷⁵ The success in expanding safe abortion services can be attributed to strong government leadership and commitment; applying evidence-based policies and protocols and permitting trained mid-level health care providers to provide abortion care, major donor support active involvement of NGOs and women's health advocacy groups.⁷⁶ Despite this progress, unsafe abortion still occurs. Access in remote areas remains a challenge, stigma is still a challenge and awareness of legal provision of abortion is poor among many women (38%).⁷⁷



Figure 1: Nepal's safe abortion logo

Conclusion and Recommendations

While considerable progress has been made in the effort to make safe abortion supplies available to women and girls most in need, it is clear that numerous gaps and challenges remain. This review of the extensive work already completed in this area, and insights from experts in the field, has revealed areas that require additional focus and provides concrete suggestions. There are also ongoing projects with rigorous research and evaluations, the results of which are anticipated in the future and therefore could not be included in this document. They should however, be considered when strategies to operationalize the following recommendations are considered. Key ongoing projects can be found in **Appendix C**.

The following are overarching recommendations for future activities to expand access to safe abortion supplies. Some recommendations will need to be addressed at the global level through international agreements or policies, while others will need be addressed at the country level and adapted to specific country contexts and some may benefit from a two-pronged approach (as seen in **Table 3**).

1. Increase the number of high quality (SRA or WHO-PQ'd) products registered at country level and remove substandard products from market
Substandard misoprostol quality continues to be a barrier to providing safe abortion services. Technical assistance to generic manufacturers to improve quality is needed. In addition, sharing the knowledge regarding quality of products already available with procurers and Ministries of Health can help ensure appropriate procurement and the supply of safe products.
2. Better understand the regulatory environment to accelerate product registration
The ever-changing regulatory environment poses challenges to registering medical abortion supplies in-country in a timely fashion. Countries often add requirements for registration that contribute to delays in getting a product into the country. Further, the high cost to register a product in a small country with a poorly developed market is often not a viable option as there is the expectation of little or no return on investment for manufacturers. Strategies to overcome the high cost to register and deliver supplies in these settings needs to be developed. The WHO's collaborative registration procedure can help expedite the registration process, however, not all countries are eligible to participate.
3. Provide guidance on usage of supplies in lower-resource settings
Best practice for manual vacuum aspiration instruments requires accompaniment by effective training. Linking MVA kit availability with training opportunities can ensure MVA supplies that have been ordered are not sitting on a shelf due to a lack of training; and that they are maintained well when in use. Instructions for appropriate use of mifepristone and misoprostol can also be improved.
4. Strengthen country level inventory and forecasting mechanisms
Often MVA kits are not in use because a very inexpensive part such as the cannula is missing or there are stock-outs of mifepristone and misoprostol. Strategies to integrate inventory and

ordering into existing mechanisms for other reproductive health supplies can be developed. Sharing of inventory within service delivery networks is one way of addressing this short-term problem.

5. Develop advocacy campaigns/tools for women to know their right to legal abortion
Demand for these life-saving abortion supplies will also help to ensure their availability. Often women do not know that they are legally permitted to obtain an abortion or they are not aware of what safe abortion options exist, and where to access them. When women and communities know their rights, the demand for both effective contraceptive and safe abortion supplies will increase and unsafe abortions will decrease.
6. Address stigma and supplies availability
There has been much research conducted on stigma among providers and families causing barriers to accessing safe and legal abortions. But stigma exists along other points in the supply chain such as in the Ministry of Health or procurement office that needs to be examined and addressed. Further, guidance on better integrating abortion supplies into the package of family planning and reproductive health services would help overcome some of the barriers to access related to stigma. Changing social norms around acceptable health interventions is also required so that staff understand the impact of this service on the health of women and girls and their families.
7. Conduct research on price and devise price reduction strategies where needed
The cost of safe medical abortion services varies significantly by country. In some countries in which mifepristone is registered, medical abortion services with the mifepristone and misoprostol regimen is provided through the public sector and is highly subsidized. In other countries, women may have to pay out-of-pocket for their medical abortion care, with a wide variation in prices by sector and type of provider. In some countries, misoprostol is available directly from pharmacies and is relatively inexpensive. In other countries, misoprostol may be considerably more expensive. A global review of price, perceived value, ability to pay, and strategies for price reductions would be beneficial.
8. Update Essential Medicines Lists (WHO and country level EMLs)
Mifepristone and misoprostol for medical abortion are currently on the WHO's model Essential Medicines Complementary List (for contexts where abortion is permitted by law). With countries putting more value into the Essential Medicines Lists (EML), ensuring mifepristone/misoprostol is on country EMLs could help ensure these supplies are integrated into country programs. Additionally, misoprostol is on the model EML for the management of incomplete abortion and miscarriage only (abortion indications). The literature demonstrates misoprostol-only to be safe and effective for pregnancy termination, with clinical backup for post-abortion care if needed. Adding the indication of abortion to the model EML could broaden safe access to this important medicine for women seeking an abortion.
9. Communicate with the larger reproductive health and rights community regarding safe abortion supplies issues
Limited funding for safe abortion supplies was viewed as a major barrier to addressing challenges along the MVA and MA supply chains. More work needs to be done to reach national and local governments, NGO service organizations, private sector partners, civil society groups and the donor community to brief them on the supplies related barriers to accessing safe abortions.

Table 3: Implementation of key recommendations at the global and national level

Recommendation	Global	National
1. Increase the number of high quality products registered at country level and remove substandard products from market	✓	✓
2. Better understand the regulatory environment to accelerate product registration	✓	
3. Provide guidance on usage of supplies in low resource settings	✓	
4. Strengthen country level inventory and forecasting mechanisms		✓
5. Address stigma and supplies availability	✓	✓
6. Conduct research on price and value, and devise price reduction strategies where needed	✓	
7. Update Essential Medicines Lists (WHO and country level EMLs)	✓	✓
8. Develop advocacy campaigns/tools for women to know their right to legal abortion and their right to health		✓
9. Communicate with the larger reproductive health and rights community regarding safe abortion supplies issues	✓	

Appendices

Appendix A. United Nations list of least developed countries⁷⁸

Afghanistan	Guinea	
Angola	Guinea-Bissau	+Sao Tome and Principe
Bangladesh	Haiti	Senegal
Benin	Kiribati	Sierra Leone
Bhutan	Lao People's Democratic Republic	Solomon Islands
Burkina Faso	Lesotho	Somalia
Burundi	Liberia	South Sudan
Cambodia	Madagascar	Sudan
Central African Republic	Malawi	Timor-Leste
Chad	Mali	Togo
Comoros	Mauritania	Tuvalu
Democratic Republic of the Congo	Mozambique	Uganda
Djibouti	Myanmar	United Republic of Tanzania
Eritrea	Nepal	Vanuatu
Ethiopia	Niger	Yemen
Gambia	Rwanda	Zambia

Appendix B. List of stakeholders contacted

Stakeholder	Role / area of expertise
DKT International	Manufacturing, distribution, social marketing
Gynuity Health Projects	Research and technical assistance
Independent Consultant	Consultant
HPSRx Enterprises	Distribution
HPSRx Enterprises Consultant	Marketing consultant to distributor
Ipas	Research and technical assistance
Linepharma International	Manufacturer
Peaches Health	Consultant
PATH	Research and technical assistance
Population Council	Research and technical assistance
Swedish International Development Agency	Donor
Woman Care Global	Distribution

Appendix C. Key ongoing safe abortion supplies efforts

Project	Organization	Contact
Misoprostol quality landscaping	IPAS	Nathalie Kapp Email: KappN@ipas.org
Creation of mifepristone global coalition to increase access	IPAS	Nathalie Kapp Email: KappN@ipas.org
Quantification guide for abortion commodities	IPAS	Nathalie Kapp Email: KappN@ipas.org
Research on access to safe abortion: a review of the external landscape (IPPF program accomplishments, best practices in programming, and future programming recommendations).	IPPF	Katie Lau Email: klau@ippf.org
Creation of searchable database on medical abortion commodities (Misoprostol, Mifepristone and the Combi-packs of Mifepristone and Misoprostol).	IPPF	Rebecca Wilkins Email: rwilkins@ippf.org

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