What Women Want: meeting the global demand for medical abortion
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANMA</td>
<td>African Network for Medical Abortion</td>
</tr>
<tr>
<td>BPAS</td>
<td>British Pregnancy Advisory Service</td>
</tr>
<tr>
<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
</tr>
<tr>
<td>EDL</td>
<td>Essential Drugs List</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FDB</td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>FIGO</td>
<td>International Federation of Gynaecology and Obstetrics</td>
</tr>
<tr>
<td>FOGSI</td>
<td>Federation of Obstetrics and Gynaecology Societies of India</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>ICMA</td>
<td>International Consortium on Medical Abortion</td>
</tr>
<tr>
<td>IPPF</td>
<td>International Planned Parenthood Federation</td>
</tr>
<tr>
<td>MSI</td>
<td>Marie Stopes International</td>
</tr>
<tr>
<td>MVA</td>
<td>Manual Vacuum Aspiration</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>NGO</td>
<td>Non Government Organisation</td>
</tr>
<tr>
<td>PHS</td>
<td>Population Health Services</td>
</tr>
<tr>
<td>PPFA</td>
<td>Planned Parenthood Federation of America</td>
</tr>
<tr>
<td>PPH</td>
<td>Post-Partum Haemorrhage</td>
</tr>
<tr>
<td>SRH</td>
<td>Sexual and Reproductive Health</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually Transmitted Infection</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>VSI</td>
<td>Venture Strategies Innovations</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>

## Acknowledgements

We would like to thank the following organisations for their contributions: Gynuity Health Projects, Ipas, International Planned Parenthood Federation (IPPF), Pharm Access Africa Limited, Planned Parenthood Federation of America (PPFA), Population Services International (PSI) and Venture Strategies Innovations (VSI). In addition, we would like to thank Vicky Anning, Traci Baird, Luke Boddam-Whetham, Hilary Bracken, Fiona Carr, Jonathan Cooper, Bolormaa Dashdavaa, Mary Fjerstad, Faustina Fynn Nyame, Elizabeth Gardiner, Dana Hovig, Nathalie Likhite, Alexandra Lowell, Brad Lucas, Diane Luo, Vivek Malhotra, Lydia Morgan, Grethe Petersen, Nguyen Thi Bich Hang, Dhaival Patel, Anne Quesney, Heidi Quinn, Jenny Renju, Soumitro Ghosh, Chris Turner and Kate Worsley.

Contents

Acronyms inside front

Executive summary 5

Chapter 1: Medical abortion: a global phenomenon 8
  1.1 Introduction 8
  1.2 Unsafe abortion: a global problem 9
  1.3 Medical abortion and achieving MDG 5 9
  1.4 Medical abortion: a technological revolution 9
  1.5 The demand for medical abortion by women 10
  1.6 Service providers' views on medical abortion 11

Chapter 2: Meeting the global demand: registering and procuring medical abortion drugs 12
  2.1 Availability of medical abortion 12
  2.2 The Global status of Mifepristone and Misoprostol 13
  2.3 Registering medical abortion drugs 13
  2.4 Procurement 14

Chapter 3: Key components of medical abortion provision 15
  3.1 Training 15
  3.2 Counselling 16
  3.3 Referral systems 16
  3.4 Research 17
  3.5 Integrating medical abortion services within primary and reproductive health services 18
  3.6 Advocacy and education 18

Chapter 4: Meeting the global demand: promising innovations 21
  4.1 Demedicalisation as an approach for increasing access 21
    4.1.1 Home administration of medical abortion drugs
    4.1.2 Task-shifting
  4.2 Innovative models to increase access 24
    4.2.1 Network and accreditation
    4.2.2 Social marketing
    4.2.3 Telemedicine

Chapter 5: Conclusions and recommendations 27

References 29

Cont.
Figures

Figure 1: Gynuity map of countries that have currently registered Misoprostol in Africa and Asia  

Tables

Table 1: Summary of the main research questions related to medical abortion

Boxes

Box 1: Increasing access to Misoprostol and its impact on maternal health
Box 2: Registering Mifepristone in Ghana
Box 3: Overcoming procurement challenges
Box 4: Ipas training programmes
Box 5: Introducing medical abortion to an organisation: Planned Parenthood Federation of America’s whole-system approach
Box 6: Regional networks for medical abortion
Box 7: Ipas – using drama in India
Box 8: Self-administration of medical abortion drugs in Uruguay: overcoming legal restrictions
Box 9: Task-shifting in a remote rural area of Latin America
Box 10: Ipas – expanding access to medical abortion by partnering with pharmacists
Box 11: Social franchising in Viet Nam to provide high-quality medical abortion services
Box 12: India - achieving scale through social marketing
Executive summary

Globally, an estimated 19 to 20 million unsafe abortions take place every year and nearly 200 women die each day from abortion-related complications.

Medical abortion represents a revolution in women’s reproductive health. For centuries, women have resorted to ingesting a variety of pills, herbs, or mixtures in order to provoke abortion. It is only since the latter part of the twentieth century that reliable medications have been developed that can induce abortion with both high success rates and few side effects without the need for surgical intervention.

Not only is medical abortion a safe way to carry out abortions at minimal cost, it has significant potential to increase access to safe abortion massively in both developed and developing countries. This is particularly important in remote areas where health infrastructure may be weak and access to surgical procedures limited. Thus, medical abortion is critical to achieving Millennium Development Goal 5 (MDG 5), which pledges to reduce the maternal mortality ratio by three-quarters by 2015.

A number of organisations, including Ipas, Marie Stopes International (MSI) and Gynuity Health Projects, have made increasing access to medical abortion an organisational priority. This is in recognition of the clear evidence that supports the safety, efficacy and acceptability of medical abortion for the termination of pregnancies within the first nine weeks.

So far, there has been relatively little documentation about the changes that are taking place around the world in relation to demand for and access to medical abortion. This publication seeks to address this gap by highlighting best practice and lessons learnt in responding to this demand.

The lessons highlighted in this publication are based on:

- a literature review of existing documentation (both peer-reviewed articles as well as ‘grey’ literature)
- the experience of organisations, including Ipas and MSI, that are leading providers of medical abortion and
Demand for medical abortion both legally and illegally. Accessing medical abortion drugs — with more women demanding and dramatically over the last ten years, Safe abortion practice has changed.

Main findings
Safe abortion practice has changed dramatically over the last ten years, with more women demanding and accessing medical abortion drugs — both legally and illegally.

Demand for medical abortion

- Medical abortion is a safe, effective, low-cost and low-technology alternative to surgical abortion
- Given the choice, many women choose medical abortion over surgical procedures
- Medical abortion has become a global phenomenon. Throughout the world, women are learning about and demanding medical abortion. In some countries, the medication is already available ‘over the counter’. Where medical abortion drugs are not legally available, they can sometimes be purchased on the black market
- Misoprostol, one of the drugs used for medical abortion, is also registered for the management of post-partum haemorrhage (PPH) and has significant potential to reduce maternal-related deaths.

A growing number of governments are acknowledging the public health benefits of increasing access to safe abortion, and to medical abortion in particular. More and more countries are registering Mifepristone and Misoprostol, the two main drugs used for medical abortion.

Registering and procuring medical abortion drugs
Organisations such as Venture Strategies Innovations (VSI) and MSI are currently in the process of registering Misoprostol for the management of PPH or for medical abortion in more than 15 countries. However, the registration process is complex and time-consuming. Key factors facilitating registration include: the selection of a high-quality manufacturer that meets Current Good Manufacturing Practice (cGMP) international standards; preparation and submission of a strong dossier to the relevant food and drug authorities; the selection of agents with experience of the registration process; and the design of monitoring systems to ensure compliance. It is also important to undertake stakeholder analysis, advocacy and education in order to build stakeholder support and to negotiate potentially politically volatile issues.

A recent change to the World Health Organization (WHO) Essential Drugs List (EDL), which now includes Misoprostol as an essential drug for treatment of incomplete abortions, is welcome. Hopefully this will create a more enabling environment for countries that wish to register medical abortion drugs.

However, multiple challenges make the procurement of medical abortion drugs particularly complex. These include:

- The paucity of manufacturers of medical abortion drugs. This is particularly relevant in relation to Mifepristone. Since its sole use is in the context of medical abortion, pharmaceutical companies may perceive it to be too politically sensitive to justify investment. In contrast, Misoprostol has other indications apart from medical abortion e.g. gastric ulcers or the management of PPH.

- Unlike other products, such as male condoms, the WHO has not yet produced a harmonised procurement and prequalification list of manufacturers

- There is no international pharmacopoeia (i.e. authoritative documented directions for the identification of samples and preparation of compound medicines against which manufacturers can test their drugs)

- Producing good quality Misoprostol is a manufacturing and packaging challenge and there have been instances of ineffective products being released onto the market.

Increasing access to medical abortion: promising innovations
Ultimately, the safe and effective use of affordable, high-quality medical abortion depends upon ensuring that:

- Healthcare providers are trained
- Referral mechanisms and monitoring systems are in place
- Services are integrated within wider sexual and reproductive programmes, and
- Communities are educated about their reproductive health and related rights.

The global unmet need for safe abortion demands new and creative ways for expanding access. A particularly promising strategy lies in the
SUMMARY

‘demedicalisation’ of medical abortion through:

› task-shifting the provision of medical abortion from high-level healthcare providers to mid- or even low-level providers, such as pharmacists or community health workers.

› facilitating self-administration of either part or the entire medical abortion regime. This would have the additional benefits of offering women more choice and privacy, as well as reducing the burden on the healthcare system.

Promising models for expanding access to medical abortion include social franchising to mobilise the private healthcare sector and social marketing programmes. Telemedicine e.g. internet-based services or call centres offers the possibility of providing qualified diagnosis, prescriptions and follow-up directly to women.

In conclusion, increasing numbers of women are demanding medical abortion. Currently, governments and healthcare providers are failing to meet this demand, leading to the growth of a black market in the supply of medical abortion drugs. The key components of successful medical abortion programmes have been identified and creative and promising models for expanding access do exist. Most importantly of all, we know that women want access to safe medical abortion.

Recommendations

In order to accelerate progress on MDG 5, it is recommended that governments and development partners:

› ensure that the law supports women’s access to safe abortion services

› increase funding and prioritisation of family planning and safe abortion programmes

› register Misoprostol for the management of PPH, medical abortion and post-abortion care

› increase access to and awareness of medical abortion programmes.

For countries and partners that wish to register and procure medical abortion drugs, it is important to:

› ensure that existing manufacturers reach cGMP standards of good practice

› undertake complementary stakeholder analysis, education and advocacy campaigns to promote stakeholder buy-in and inclusion of these drugs on the EDL

› ensure a consistent supply of high-quality drugs

› encourage market competition to reduce prices and create incentives for improved quality

› develop harmonised procurement and prequalification lists.

Organisations setting up high-quality medical abortion programmes should consider the need to:

› train healthcare providers to offer safe and effective medical abortion

› provide counselling to women about the procedure, post-abortion family planning and follow-up

› develop monitoring and evaluation systems to ensure that the programme is achieving its intended impact and to track adverse outcomes

› provide referral mechanisms to women with complications or incomplete abortions. These could include a 24-hour helpline or dedicated internet site together with access to a clinic or surgical abortion provider

› undertake stakeholder, educational and advocacy activities in order to increase knowledge and acceptance of medical abortion.

Successful strategies to expand access in low-resource countries include:

› task-shifting the provision of medical abortion from high-level providers to lower-level providers, such as nurses, midwives, community health workers or pharmacists

› encouraging the demedicalisation of the medical abortion process, for example, by empowering women to administer the pills themselves

› mobilising all sectors of the health system (including private providers through social franchising and social marketing) and emphasise training and high-quality product and service.

---

Chapter One: Medical abortion: a global phenomenon

This chapter outlines the growing use of medical abortion and highlights its enormous potential to save lives.

1.1 Introduction

Medical abortion represents a revolution in women’s reproductive health and is critical to achieving Millennium Development Goal 5 (MDG 5), which aims to reduce maternal mortality by three-quarters by 2015. Medical abortion saves women’s lives and has enormous potential to increase access to safe abortion.

The term medical abortion refers to induced abortion through medication rather than surgical intervention. Historically, women have relied upon a variety of pills, herbs or mixtures to end an unplanned pregnancy. It is only in the latter part of the twentieth century that reliable and safe medications and regimens were developed to induce abortion with few side effects and high success rates.

Women who wish to terminate an unplanned pregnancy are increasingly familiar with, and are asking for, medical abortion drugs. Unmet demand has led to an increase in the number of professionals and non-professionals selling medical abortion drugs, including on the black market. In some countries, legal changes in relation to abortion are also occurring. An increasing number of countries are registering drugs that can be used for medical abortion such as Misoprostol, which is also indicated for the management of post-partum haemorrhage (PPH). Even in countries where access to abortion is limited, such as Uruguay, innovative programmes are being implemented in order to increase access to medical abortion.

To date, there has been relatively little documentation about the changes that are happening at country level in relation to demand for, and access to, medical abortion. This publication seeks to address this by highlighting best practice and lessons learnt in meeting the demand for medical abortion.

The lessons highlighted in this report are based on:

- a review of key literature (both peer-reviewed and ‘grey’ documentation)
experience of international organisations providing medical abortion

telephone and face-to-face interviews with more than 20 medical abortion providers in Ethiopia, Ghana, India, Mexico, Mongolia, Viet Nam, the United Kingdom and the United States of America (USA).

The report is structured as follows:

Chapter 1 provides a global overview of medical abortion, including clinical aspects, together with a summary of the evidence concerning demand by women and healthcare providers

Chapter 2 highlights key components of successful medical abortion programmes

Chapter 3 describes some promising approaches that are being used to meet demand for medical abortion

Chapter 4 identifies important lessons learnt in registering and procuring medical abortion drugs.

1.2 Unsafe abortion: a global problem

At the beginning of the twenty-first century, safe abortion is far from universally sanctioned or even provided in many countries. An estimated 364 million women of childbearing age live in countries with highly restrictive abortion laws. In these countries, induced abortion is either prohibited entirely or permitted only to save the life of a woman.

Each year, 80 million women have unintended pregnancies, more than half of which will end in abortion. Globally, an estimated 19 to 20 million unsafe abortions take place every year and nearly 200 women die each year from haemorrhage, infection or poisoning from substances used to induce abortion. Complications from unsafe abortion procedures account for an estimated 13% of maternal deaths worldwide. Globally, an estimated 220,000 children worldwide lose their mothers each year through abortion-related deaths.

Treating the complications of unsafe abortion overwhelms already hard-pressed health services and diverts limited resources from other critical healthcare programmes. In some low- and middle-income countries, up to 50% of hospital budgets for obstetrics and gynaecology are spent treating the complications of unsafe abortion. More than 97% of unsafe abortions take place in the world’s poorest countries, and women who resort to these services are frequently exploited both financially and sexually. If their action becomes known by others, they are also likely to be stigmatised.

1.3 Medical abortion and achieving MDG 5

Increasing access to safe abortion is a critical element of reducing maternal deaths. Safe surgical approaches to abortion (such as Manual Vacuum Aspiration – MVA) together with medical abortion make a crucial difference to the lives of women around the world.

The introduction of medical abortion regimens in countries with high abortion-related mortality is an important and feasible step towards achieving MDG 5, which aims to reduce maternal mortality by 75% before 2015.

With an estimated 14 million women experiencing pregnancy-related haemorrhage annually, PPH is the leading cause of maternal mortality worldwide (responsible for 25% of all maternal deaths). Misoprostol (indicated for both treatment of PPH and medical abortion) is cheap, easy to administer and stable in tropical climates, making it an ideal intervention for home births.

1.4 Medical abortion: a technological revolution

By the 1980s, medical abortion had become a safe and effective alternative for pregnancy termination in the first trimester. This was made possible with the availability of prostaglandins in the 1970s and of anti-progesterones in the 1980s. Various drugs and combinations have been used for first trimester abortion. The most widely researched drugs and

---


10 While Misoprostol is shelf stable and does not require a cold chain, its potency needs to be maintained by ensuring that it is kept cool. Any bottle that has been open for a while should be discarded if pills are not individually packaged.
According to WHO, the recommended regimen for medical abortion is 200mg of Mifepristone administered orally, followed 36–48 hours later by a prostaglandin (normally 0.8mg of Misoprostol) administered vaginally. Sublingual and buccal administration demonstrate similar efficacy and many programmes are using these routes of administration because they are more acceptable to women. This combination results in complete abortion in more than 96% of cases.13,14

While use of either Mifepristone or prostaglandins alone may lead to abortion, this can result in reduced effectiveness or an increased rate of side effects. Used in combination, they act synergistically. The challenge is in identifying a regimen that, in addition to being affordable and available, combines the lowest dose of both drugs that is highly effective and has least side effects. While in some countries divided doses of Mifepristone can be given over a period of days, a single dose is preferable in terms of both client convenience and service delivery. Work is ongoing to investigate the minimum effective dose of Mifepristone.

Absolute contraindications to medical abortion are rare. Medical abortion is considered to be a safe medical procedure, with a mortality rate indistinguishable from spontaneous abortion.15 Since its registration in the USA, seven deaths (from the estimated 560,000 medical procedures performed since 2001) have been reported to the Food and Drug Administration (FDA). Four of these deaths were related to Clostridium sordelli, a rare bacterium also implicated in deaths from spontaneous abortion.16 While evidence is inconclusive, it is thought that death from medical abortion is more likely to be related to the physiologic process rather than the drugs themselves. With the exception of seven women in North America who died from Clostridium sordelli-related toxic shock, there have been no other reported deaths from medical abortion anywhere in the world.

1.5 The demand for medical abortion by women

Despite a general dearth of documentation about medical abortion practices, there is increasing evidence that many women who have the choice of surgical or medical abortion often prefer the latter.5,17,18,19 In the UK, women presenting for a termination of pregnancy are offered a choice of surgical or medical abortion. Over the last five years, the proportion of women preferring a medical abortion has more than doubled.4 A similar trend is happening elsewhere in Europe and in other countries where access to legal safe abortion is high and women have a choice of procedures.20

In terms of less developed countries, research has focused on India where demand – and consequently supply – for medical abortion has increased dramatically over the last decade. Several researchers have studied this recent phenomenon.21, 22 In general, they found a high level of acceptance towards medical abortion by women and their male partners. Most studies focus on women, but some of the India studies also gauge the views of men.23 Clearly, it is not only women who know about and want a medical abortion. Men are very often a key part of the decision-making process and in India are often the procurers of medical abortion drugs. In some cases, they may have more liberal attitudes towards abortion than women.23

Many women find medical abortion less painful, easier, simpler and safer than the alternatives.17 Cheaper costs (in comparison with surgical abortion) also positively influenced women’s decisions.

The fact that it is not a surgical intervention, makes medical abortion preferable over surgical abortion for many women. For example, a MSI study of clients visiting its UK clinics for early medical abortion services found that the two most commonly cited reasons for choosing medical abortion were the fact that it is not a surgical procedure together with the ease and convenience it offered.24 The majority described themselves as being either “satisfied” or “very satisfied” with the process.

Even in areas where medical abortion was not yet widely available, researchers found women overwhelmingly supported the idea of medical abortion.25, 21 In Mexico, for example, focus groups revealed that women welcome the possibility of medical abortion as an option. However, these women also had an exaggerated perception of the associated risk and wanted an ‘expert’ to tell them what to do, suggesting a need for further research (A Lowell, Personal Communication, 2009).

Women find the way medical abortion works more acceptable because they perceive it to be consistent with the body’s natural processes (M Fjerstad, Personal Communication, 2009). In communal living settings, privacy can more easily be maintained following a medical abortion rather than a surgical procedure. Moreover, in settings where disclosure of a pregnancy could have potentially disastrous consequences for

women, the opportunity to ‘disguise’ an abortion as a heavy period could be life-saving.23

In India, perceived potential (but resolvable) barriers to increasing availability of medical abortion included the limited time-span within which medical abortion is permitted, time and opportunity costs involved in multiple doctor visits, and the problems of accessing specialist providers away from urban centres.21 Costs were also considered to be a barrier for poorer women. However, women’s support for medical abortion was influenced by its cheaper cost (in comparison to surgical abortion), the relative simplicity of the procedure and the avoidance of hospitalisation. Of the 45 women in one study who reported having a medical abortion, the majority (80%) were satisfied with their experience and more than half said that they would recommend medical abortion.21

When women learn about medical abortion, they are generally enthusiastic to have the choice of an alternative to surgical intervention. However, increasing the availability and take-up of medical abortion will be influenced not only by affected women and men but also by the wider community, and of course, by service providers.

1.6 Service providers’ views on medical abortion

“Service providers are happy with medical abortion because it’s less complicated and cheaper to deliver, but some gynaecologists are unhappy because of loss of business.”

Vivek Malhotra, Country Director, Population Health Services (PHS), India

Healthcare providers in many countries are positive about the introduction of medical abortion. For example, in Nepal providers were generally positive about the potential for introducing Mifepristone and Misoprostol, and pharmacists were willing to stock the drugs.26 Similarly, in South Africa both policy-makers and service providers were generally favourable towards medical abortion, explaining that it could provide an additional method that women would find less invasive and their ability to control the process would make it more appealing.25 There was also a perception that medical abortion might reduce the burden on health service personnel as well as being ‘easier from a conscience point of view’. As Hang Nguyen Thi Bich, Country Director of MSI Viet Nam points out:

“Attitudes among service providers in Viet Nam vary between rural and urban areas, and according to the level of knowledge and skills on the part of service providers who may lack confidence to counsel women about medical abortion. However, both public and private providers tend to prefer medical over surgical abortion because of the perceived lower risk of complications. Moreover, some Buddhist providers feel that medical abortion is more natural and as such more congruent with their spiritual beliefs.”

In the USA, Planned Parenthood clinics that are affiliates of the Planned Parenthood Federation of America (PPFA) have found that attitudes among US service providers appear to reflect, at least in part, the ability to empathise and identify with women. For example, in many centres, midwives have adapted most readily to providing medical abortion, as have advanced practice nurses who have performed approximately half of the 400,000 medical abortions provided by PPFA. On the other hand, some physicians find it difficult to understand why clients would choose medical over surgical abortion. This could reflect the physician’s preference for maintaining their role as gatekeepers to abortion services and therefore a reluctance to increase access through demedicalising the procedure. Many providers also show genuine concern about the safety and acceptability of a procedure with which they are as yet unfamiliar. In general, once these barriers have been overcome, service providers see medical abortion as less complicated to perform and cheaper to deliver (M Fjerstad, Personal Communication 2009). As Grethe Petersen, Country Director of Marie Stopes International Ethiopia, recalls:

“In MSI Ethiopia, initially there was considerable scepticism about the introduction of medical abortion services amongst providers. This was overcome through the suggestion made by a technical team member to identify a ‘medical abortion champion’ in each clinic. Some of our providers, who were initially quite sceptical about medical abortions, are now among the biggest advocates for offering this choice to women. They have been persuaded by witnessing firsthand how it helps the women we serve every day.’”

At the beginning of the twenty-first century, safe abortion is still far from universally sanctioned or available. Nonetheless, progress is being made. At the global level, medical abortion presents a potential strategy towards achieving MDG 5. At the individual level, medical abortion offers women increased choice and control over the process of terminating an unplanned pregnancy.
Chapter Two: Meeting the global demand: registering and procuring medical abortion drugs

2.1 Availability of medical abortion

The development of Misoprostol as a treatment for gastric ulcers, and its subsequent multiple gynaecological uses (i.e. for induction of labour, cervical priming and the prevention of PPH), means that it is widely available, even in countries where abortion itself is restricted. Latin America’s decline in maternal mortality over the last two decades has been attributed to extensive use of Misoprostol for the purpose of terminating pregnancies.27

In many countries (including the UK), Misoprostol is regularly used ‘off-label’ viii for abortion since it has not been re-registered specifically for this purpose. ‘Off-label’ use refers to differences in dose, population, or indication than those specified when the drug was originally registered in a particular country. The use of drugs for off-label indications is legal, common practice, and is not considered experimental, as long as it is based on sound scientific evidence. As long as a drug is registered in the country of its use, the physician can prescribe it off-label, provided they are well informed about the risks and benefits for their patient and are convinced of the medical grounds for its use.

Both Misoprostol and Mifepristone are believed to be widely available, even in countries where neither drug is actually registered. While this means that many women are

vi MSL is currently at different stages of the registration process in 15 countries.

viii Source: http://www.misoprostol.org/File/offlabeluse.php
theoretically able to access medical abortion in restrictive settings, this is likely to be neither safe nor equitable. When a drug is not registered, supply is likely to be poor and access restricted to women who have more money available. Furthermore, forcing women to access medical abortion through illegal channels renders them vulnerable to exploitation, lacking the benefit of a trained provider to assess their eligibility and treat any complications, should they occur.

2.2 The Global status of Mifepristone and Misoprostol

A study of worldwide legal availability reported that, of the Misoprostol sold worldwide, 91% was sold in North America and Western Europe. The most Misoprostol-only drugs were sold in Asia with dramatically increased sales in Bangladesh (by 128%) and India (by 646%), where various low-price brands are sold. Legal Misoprostol sales were found to have decreased in Latin America. However, legal sales increased in the Middle East, North Africa and sub-Saharan Africa, albeit with low amounts sold per head of population. The authors conclude that legal availability is improving in some low-income regions where Misoprostol could significantly reduce maternal deaths resulting from PPH and unsafe abortion. It is only recently that Misoprostol has become more widely available in some African countries with its registration for the prevention of PPH. Misoprostol is approved in many more countries than Mifepristone. The latter, with a single medical indication as an abortificant, has very limited availability. It remains unapproved in the vast majority of countries in Latin America. Neither drug is approved in most Middle Eastern countries.

Despite these limitations, both drugs are reportedly available on the black market in many countries.

While Mifepristone is more difficult to obtain (even on the black market) there are still reports of illegal cross-border sales in many countries. Several internet sites claim to provide Mifepristone by mail order, but some are selling drugs of poor quality or without any Mifepristone at all. Gynuity reported that, in some countries, falsified sugar or flour pills are passed off as Misoprostol, while some women are sold other drugs that do indeed induce vaginal bleeding but do not act as abortificants.

A Gynuity study exploring the availability of medical abortion drugs in four Latin American countries reported that the price of Misoprostol varied greatly between countries. Prices ranged from US$1 to $30 per pill, making the cost of Misoprostol-alone abortion costly in relation to average incomes. Indeed, it was found that the inflated price of Misoprostol in many situations was a response to the recognition of its potential value as an abortificant and the consequent price that pharmacists could demand.

Increasing legal supply and availability of medical abortion drugs will be facilitated by their inclusion on the WHO Essential Drugs List (EDL) in which drugs are identified by both name and indication. Misoprostol is included in the 2007 EDL and has recently been redefined as an essential medicine for incomplete abortion/miscarriage management. This decision was made by an expert committee, based on available evidence.

2.3 Registering medical abortion drugs

Without appropriate and approved products, massively expanding access to medical abortion is inherently limited. Product registration is therefore critical for the long-term sustainability of medical abortion programmes. Drug registration describes the national or state-level process through which drugs are submitted for formal approval in order for them to be marketed and distributed.

Increasing legal supply and availability of medical abortion drugs will be facilitated by their inclusion on the WHO Essential Drugs List (EDL) in which drugs are identified by both name and indication. Misoprostol is included in the 2007 EDL and has recently been redefined as an essential medicine for incomplete abortion/miscarriage management. This decision was made by an expert committee, based on available evidence.
This process is also required for drugs produced by a manufacturer under a new brand, even if the drug was previously registered by another company for example, when releasing a generic version of a branded drug. Registration can take between six months and three years. A comprehensive dossier, good product and good project management of the registration process can all significantly accelerate the process. Registration is often time-limited and can be revoked or renewal can be refused.

The culmination of the registration process is a legal document issued by the drug regulatory authorities that permit either the manufacturer, or their in-country agent, to market and distribute the product within the country. In turn, the manufacturer commits itself to producing the drug in accordance with the licence.

2.4 Procurement

Once a drug is registered, it is important to ensure a consistent supply. Procurement for medical abortion is complicated by the fact that there are so few manufacturers that produce Misoprostol or Mifepristone. Furthermore, there are very few standardised guidelines on good practice in procurement for medical abortion drugs. For example, for other products such as male condoms, the WHO has issued a harmonised procurement and prequalification list, which gives explicit guidelines on which manufacturers have been prequalified for procurement. To date, no suppliers of Mifepristone or Misoprostol have been granted WHO prequalification status. Nonetheless, the WHO, with support from the United Nations Population Fund (UNFPA), is in the process of undertaking a hormonal prequalification project. This will provide procurers with a definitive list of prequalified reproductive health suppliers and will eventually include manufacturers of Misoprostol and Mifepristone.

Box 2: Registering Mifepristone in Ghana

Marie Stopes International Ghana (MSI Ghana) has taken the lead in registering Mifepristone in Ghana and has provisional registration of Mifepristone (in the MSI brand name of Mediprist). The process was made easier by MSI selecting a strong supplier who was known to the national Food and Drugs Board (FOB). MSI Ghana also found a reputable and well-established local agent who could assist with the dossier submission, set up meetings with the FDB and ensured all requirements were clearly communicated to both MSI and the supplier. The agent was able to monitor the progress of the submission and ensure that questions raised by the FDB (particularly since this was the first time a medical abortion drug had been registered in Ghana) were responded to quickly.

Both prior to registration submission of the dossier and during the process, MSI Ghana was involved in stakeholder meetings and communication to push the process along.

As Tracey Brett, Head of Procurement at MSI, says:

“We’re often focused on service provision but we need to tap into the knowledge of the commercial agents who can help us with registrations. We also need to link with other agencies and key stakeholders and advocate for registration in country. We’re a NGO moving in commercial circles. This process needs someone to push it through and manage the necessary relationships.”

Box 3: Overcoming procurement challenges

A further potential difficulty in the procurement process lies in the fact that there is no international pharmacopoeia* “standard” for the finished (tablet form) of Mifepristone and Misoprostol. This is the reference standard to which a supplier manufactures, and against which organisations can test.

In order to overcome this challenge, MSI has worked with an independent testing laboratory to test against the manufacturer’s specification. MSI has also been working closely with MDA Global, a Chinese consulting and product sourcing firm, in order to test products according to the Chinese pharmacopoeia. This is comprehensive and provides adequate parameters for testing the supplier’s standard specifications and test methods.

Through independent consultants, MSI provides technical assistance on cGMP and product formulation development. Through their partnership with MSI, many manufacturers have made improvements to quality, for example, by undertaking bio-equivalence** of their product against the originator product. One manufacturer has upgraded its manufacturing facility, and is improving its dossier.

Monitoring is required to ensure that consistent supply is maintained. Random sampling and testing is conducted by MSI throughout the duration of the contract. In addition, the supply chain is carefully reviewed to ensure that products are transported from manufacturer to client without interference or damage.

---

* Pharmacopoeia is a published reference standard containing information on the drug, such as formulae, method for making the drug preparation, requirement and tests for the drugs strength and purity and other related information.

** Generic products need to conform to the same quality, safety and efficacy as the originator product (the original drug that was developed). Bio-equivalence is the testing, using a pharmokinetic study that demonstrates this equivalence.
Effective public health programmes depend for their success upon access, availability and affordability of high-quality products and services. There are a number of key elements that need to be addressed in relation to increasing the provision of medical abortion:

1) Training
2) Counselling
3) Referral mechanisms
4) Research
5) Integrated sexual and reproductive health (SRH) services and
6) Education and advocacy.

### 3.1 Training

Training ensures that providers have the knowledge and skills necessary to be able offer a high-quality service with confidence. Training also provides opportunities to introduce new technologies and to create and reinforce positive attitudes towards them. At an organisational level, training reinforces standardisation of services, making the monitoring and evaluation of these services streamlined and comparable. The content and methods of training must be designed to suit the specific needs of participants. Thus, while training for medical staff will include significant clinical detail, training for sales people in a social marketing programme will be less clinical and focused more upon the identification and dissemination of key messages. In the USA, provider concerns about delivering medical abortion stem, in large part, from exaggerated fears about possible complications and risks associated with medical abortion, and from misperceptions regarding the level of technical expertise it requires. Training is therefore critical, not only in terms of skill acquisition, but also in relation to clarifying misunderstandings.

Gynuity has developed a guide for countries that emphasises the importance of staff training in each of the following areas:

- protocols for medical abortion: staff should be knowledgeable
about Mifepristone and Misoprostol and the protocol(s) being used at the clinic.

- **counselling**: staff should receive comprehensive training on counselling for medical abortion.
- **dating gestational age**: staff should be able to assess gestational duration by review of pertinent history, symptoms and physical examination.
- **identifying rare pregnancy abnormalities**: staff should be knowledgeable about warning signs for rare pregnancy abnormalities, such as ectopic pregnancies and hydatiform mole.
- **determining success**: abortion status can be assessed at follow-up by clinical history and examination.
- **values clarification**: discussion with staff about values can be useful, especially when staff members may be ambivalent about providing abortion services.

### 3.2 Counselling

“Counselling is a critical component of high-quality abortion care. Fundamental principles of abortion counselling include the effective communication of information and respect for the client’s rights. The process of medical abortion offers an excellent opportunity to provide information and counselling to clients about the abortion itself, as well as about contraceptive methods and services.”

*Ipas 2003*

The success of medical abortion relies heavily upon the counselling a woman receives before taking the medication. Within a service delivery framework, counselling refers to the information and guidance imparted by the service provider that allows a client to make an informed decision about her treatment. As Hang Nguyen Thi Bich from MSI Viet Nam points out:

“Counselling is central because it inspires confidence in clients – if the client is not confident, medical abortion does not work. We had complaints in the early days and many returned, insisting on surgical abortion. There was a problem with the way service providers chose the time for women to take first tablet, for example, late afternoon, so clients went straight home and experienced heavy bleeding and got very scared to go through this alone at home. So we provide refresher training and prepare staff to help women anticipate the effects of medical abortion. It is essential to monitor the quality of client counselling.”

In the consultation, the provider can ensure that the woman’s pregnancy within the limits of the regimen they are offering. They can also provide information about how to take the medications and what to expect, as well as giving the woman a chance to ask any questions she may have. Every woman who receives a medical abortion should be aware of the expected effects of the medications and the side effects that may occur, together with any warning signs that indicate a need for further medical assistance. The emphasis when communicating this information to women should be on providing clear and simple instructions and advice in ways that women can easily understand. Counsellors must be confident in the information they are imparting and ensure that the woman feels comfortable with the procedure before she leaves.

### 3.3 Referral systems

While complications resulting from medical abortion are rare, nonetheless, medical abortion can fail. It is therefore important to establish a referral system. This should ensure that, where the original service delivery point cannot provide appropriate treatment to those
experiencing adverse affects from the medications, incomplete or unsuccessful treatments, they can receive the help they need at another facility.

In the event of a failed medical abortion, the procedure can be repeated or else the client can be referred for a surgical abortion. Similarly, if the termination is incomplete, a woman can be given either a repeat dose of Misoprostol (600mcg orally), or referred for a surgical procedure in order to empty the uterus of the retained products of conception.

From their initial consultation, women should already be aware of the warning signs for potential complications and incomplete and continuing pregnancy. It is important that women know where they should go if they believe they are experiencing any of the warning signs. Depending on the resources available and the urgency indicated by their symptoms, women can potentially contact a range of people and sites for advice and treatment:

- 24-hour toll free advice line
- a local medical abortion provider
- a local surgical abortion provider
- a local healthcare facility or hospital.

In Ethiopia, MSI has a number of referral and follow-up mechanisms. As Grethe Petersen, Country Director for MSI Ethiopia, describes:

"Women come into our clinic and get one tablet. They come back after 36 hours for the second set of tablets. They have the option to stay until the abortion occurs and most choose to do so, largely because the majority of people have no toilet facilities at home. Everyone is given our telephone number in case of any complications. For those who don’t abort after six hours of taking the second set of tablets, we follow up by providing a free surgical abortion."

In any situation, it is important that a local healthcare facility has trained personnel, equipped to deal with such cases. Providing free training on post-abortion care to private and government providers in the region can be a useful way of increasing the capacity of the healthcare infrastructure to deal with abortion-related complications. It can also be critical in establishing a good working relationship between medical abortion providers and local clinics and hospitals.

### 3.4 Research

Monitoring, evaluation and research are essential at all stages of designing, delivering and evaluating a medical abortion programme. Before starting the provision of medical abortion services, it is useful to undertake a needs assessment that maps out current knowledge, beliefs and practices related to abortion. Once programmes are initiated, monitoring systems are crucial in order to track

<table>
<thead>
<tr>
<th>Research objective</th>
<th>Approach and data collection methodology</th>
<th>Outputs</th>
<th>Programme planning and implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To understand current knowledge and attitudes towards medical abortion</td>
<td>Secondary research and key informant interviews</td>
<td>Data on abortion practices and its impact</td>
<td>Identifies research needs, Assists with programme planning</td>
</tr>
<tr>
<td>2. To understand current provision of medical abortion in public and private sectors and factors that influence it</td>
<td>Mystery client survey</td>
<td>Information on the market availability of medical abortion and how the products are currently provided</td>
<td>Assists with positioning the programme within the market and ensuring that the programme meets unmet need</td>
</tr>
<tr>
<td>3. To understand socio-behavioural factors that influence whether or not women use medical abortion</td>
<td>Formative, qualitative research using focus group discussion and in-depth interviews, Quantitative surveys to establish baseline findings</td>
<td>Motivators and barriers to medical abortion, behavioural triggers, communication strategies, willingness to pay</td>
<td>Key to quality programming and development of an effective communications strategy</td>
</tr>
<tr>
<td>4. To understand clinical and behavioural outcomes related to using medical abortion drugs</td>
<td>Randomised controlled trials, Observational studies, Acceptability studies and longitudinal studies, Routine tracking of clinical information</td>
<td>Data to assess complication and success rates, Information on post-abortion reproductive behaviour (e.g. post-abortion family planning), Client profile</td>
<td>Allows assessment of whether or not the service provision is of high quality and tracks any potentially adverse events</td>
</tr>
</tbody>
</table>
clinical outcomes in relation to new drugs and regimens. Finally, research is important to assess which service delivery mechanisms (see Chapter 4) are the most cost-effective and equitable. Table 1 on page 17 shows the main research questions to be asked in relation to the provision of medical abortion.

### Box 5: Introducing medical abortion to an organisation: Planned Parenthood Federation of America’s whole-system approach

The experience of the Planned Parenthood Federation of America (PPFA) in introducing and establishing medical abortion in its clinics highlights a number of important lessons. Three hundred PPFA clinics are now providing medical abortion throughout the USA, with approximately 50% of all eligible patients now opting for medical abortion.

This success is attributed to a number of factors. First, an overarching organisational commitment to the provision of medical abortion existed and a whole system approach (i.e. working with all staff) was adopted. Second, collecting and using local data has been important, not just in relation to the ability to respond to concerns about adverse events (which is mandatory for medical abortion drugs), but also in relation to helping the organisation to understand its progress in terms of providing medical abortion. For example, in 2006, concern about the Clostridium bacterium led to a US Congressional sub-committee hearing and to a day-long session of the Centers for Disease Control. In light of these concerns, PPFA, in collaboration with its committee of experts, reviewed its existing procedures and decided to switch from the vaginal to buccal route of administration of Misoprostol. At the same time, PPFA clinics were required to test every patient for chlamydia or provide patients with a week-long course of Doxycycline. In this way, the organisation was able to track a decline in the rate of serious infection.33 Having its own local data was critical to this success.

Third, also critical to success in terms of institutionalising the new service was having a person with designated responsibility and suitable resources (for example, budget for travel, training etc.), mandated to establish medical abortion throughout the organisation, keeping a watching brief and troubleshooting. Thus, when a perception emerged among staff that medical abortion was costing more to provide than its surgical equivalent, it was possible to organise the collection of six months of financial data (using Medicaid formulae ascribing costs) for two clinics, together with some complementary research. The study demonstrated that medical abortion actually costs less to provide than first-trimester surgical abortion.

Finally, having a dedicated individual responsible for the institutionalisation of medical abortion also meant that unanticipated successes could be identified and documented. For example, within the PPFA it has been possible to introduce medical abortion to clinics that do not have surgical facilities, such as the 130 PPFA clinics in remote settings that were previously only providing contraceptive services. A further unanticipated success was the realisation that approximately half of the 400,000 medical abortions provided by the PPFA were provided by advanced practice nurses.

### 3.5 Integrating medical abortion services within primary and reproductive health services

The potential of medical abortion to contribute to women’s reproductive health and rights can be further realised by expanding women’s access to it. In some clinics in the USA, medical abortion is being ‘normalised’ by making it available alongside standard SRH services such as family planning and pap smears. The medical abortion consultation also provides a key point of contact with a trained individual to explore other SRH concerns, including choice and provision of contraceptive methods, and screening and prevention advice in relation to HIV and sexually transmitted infections (STIs). Most importantly, counselling about and access to contraceptives can help to increase uptake of post-abortion family planning and reduce the need for repeat abortion (M Fjerstad, Personal Communication 2009).

### 3.6 Advocacy and education

The introduction of medical abortion into a community or country will require concerted efforts to educate and advocate for a change in attitudes. Abortion remains a sensitive issue that is politically contentious for most governments. Successful introduction of medical abortion often depends upon being able to overcome high levels of resistance among faith-based leaders, communities, government officials and healthcare providers.

Advocacy is the process by which larger-scale changes take place in terms of attitudes and policies towards women’s reproductive health and rights, including safe abortion (including medical abortion). It is, therefore, a key component to creating an enabling operational environment and improving access for women. To be effective, advocacy (i.e. political mobilisation and lobbying) needs to be supplemented by education and targeted communication about behaviour change. For medical abortion, advocacy needs to dispel myths about abortion and promote a pro-choice agenda, highlighting international treaties and instruments that support women’s right to abortion.

The International Planned Parenthood Federation (IPPF) works closely with governments...
to develop joint advocacy programmes that complement the introduction of medical abortion in a country. In the Democratic People’s Republic of Korea, the IPPF partner organisation, the Korean Family Planning and Maternal and Child Health Association, undertook a multi-pronged advocacy strategy. The first stage was to lobby the government to approve the introduction of medical abortion services in addition to the provision of surgical services. This advocacy included hosting multiple discussions and providing evidence to demonstrate the safety and acceptability of medical abortion.

This evidence was sufficiently convincing for the government to sign a Memorandum of Understanding with the Association, thereby granting legal legitimacy to the project and ensuring continuous government support. The second stage of the advocacy programme was to build stakeholder buy-in by hosting discussions with a range of groups such as community leaders, media professionals and medical personnel in both public and private hospitals.

The advocacy programme was complemented with training and the provision of medical equipment and supplies.

In parallel to building capacity, the Association continued lobbying the government to integrate medical abortion within the national SRH strategy, with the result that one in three terminations in Korea is now a medical abortion.xii

Knowledge of medical abortion amongst the general public is generally low.23 Therefore, educational activities are crucial for raising awareness of this important aspect of women’s SRH and rights, among women themselves, as well as among male partners, young people, health service providers and decision-makers.

Box 6: Regional networks for medical abortion

The new African Network for Medical Abortion (ANMA) was formed in March 2009 in Johannesburg, South Africa following a meeting sponsored by the International Consortium on Medical Abortion (ICMA) and Ipas. Sixty-two participants from 20 African countries were present at the conference where the ICMA African Network on Medical Abortion was formally launched. The initial goals of the ICMA Africa Network are:

- to facilitate the provision of safe and effective medical abortion by registering the drugs in more countries
- to develop the capacity of local partners to educate others about medical abortion
- to increase access to medical abortion where it is not well implemented
- to create an overview of the Africa region in order facilitate the identification of networks and coalitions.

A Latin American Consortium against Unsafe Abortion was launched in Lima, Peru in May 2006. The network, modelled on ICMA and with similar aims, reflects the unique situation in that region, where abortion is almost universally restricted in law, but where clandestine use of Misoprostol alone for medical abortion is widespread. The first meeting in 2006 was attended by 49 participants from 13 countries. The regional Consortium established five working groups on research, advocacy, clinical services, information, education and communication and strategies to maintain access to drugs used for inducing abortion.

Box 7: Ipas – using drama in India

In communities where few can read, street drama is an engaging way to spread information, raise awareness and get individuals involved. Ipas India has been working with Contact Base, a local organisation, to develop street drama that highlights where and how safe abortion services can be obtained and introduces the concept of medical abortion. Street drama scripts are developed to be as culturally relevant as possible and incorporate the local dialects and practices of a particular village. They are pre-tested in the community for feedback before Contact Base hires and trains young local talent to present the work to the public, thereby increasing community ownership and sustainability.

One actress described her excitement at being part of the street drama: “This is my first drama performance. I am acting as a lady doctor. I really feel good when [the] audience asks me several questions on their unwanted pregnancy [imagining] that I am a real doctor. I feel proud to contribute something for the wellness of my community.”

Before the show, there is dancing and singing as the actors declare that they have come to perform a drama about women’s reproductive health and that people should sit down to watch. They also announce that there will be a quiz after the show and that people who answer correctly will be presented with small gifts. Through their vivid and descriptive scripts, the actors are able to deliver life-saving information to women who would otherwise remain unaware of the rights and services available to them.

Another advantage of street drama is that it attracts community members of all genders, age and caste. Furthermore, it creates a space for men and women to access information and talk together openly about SRH issues. Tarun Jha, medical abortion project coordinator at Ipas India, says that the communal aspect of street drama creates a “public and non-intrusive form of communication”, where “you can talk about sensitive social issues without being put on the spot”.

Ipas India has held over 350 interactive street dramas. By combining street dramas with other innovative communication methods, such as local health intermediaries and colourful billboards, Ipas expects to have reached over 25,000 women in Jharkhand State by the end of 2009.

Source: http://www.ipas.org/Library/News/News_Items/Shakespeare_in_Hindi_Acting_out_to_save_lives_in_India.aspx?ht
Chapter Four: Meeting the global demand: promising innovations

This chapter explores promising new approaches and models for meeting the global demand for medical abortion. It examines the case for demedicalisation of medical abortion provision and identifies specific ways in which demedicalisation could increase access through task-shifting and self-administration of the drugs.

It is clear that a range of innovative strategies are already being implemented in different countries to meet the high demand for medical abortion. Promising models include: mobilising the private sector through social franchising; using social marketing to increase access for healthcare providers; and harnessing the power of the internet to provide services.

4.1 Demedicalisation as an approach for increasing access

Within the public health community there is increasing acknowledgement of the potential afforded by demedicalising the provision of some healthcare services. The increasing shift from surgical to medical abortion is an example of demedicalisation in practice: medical abortion requires less technology, can be carried out in non-clinical settings, does not necessarily need to be delivered by high-level providers such as physicians, and users can play a more active role in the process through self-administration of medication. Furthermore, women and men prefer less clinical environments.

4.1.1 Home-administration of medical abortion drugs

Medical abortion has the potential to transform traditional relationships between reproductive healthcare providers and their clients. In contrast to surgical abortion, medical abortion is not done to women but by them, with appropriate support provided by health professionals. For example, in some countries, such as the USA, the second set of pills can
be administered by women in the privacy of their own homes with no increase in complications or failure rates.\[^{36}\] Allowing women to take the second pills at home has multiple benefits, as it also reduces strain on the healthcare system and many women prefer this option.\[^{36}\]

In the UK, the British Pregnancy Advisory Service (BPAS) has identified that women do not want to make three separate clinic visits because of the considerable demands this makes upon their time, together with the cost burden. The organisation has therefore eliminated the third check-up clinic visit in favour of home urine testing and telephone follow-up (a 24-hour support line is available). However, a recent audit revealed very low compliance with both the use of pregnancy tests and the telephone follow-up call. Also, because of the use of high-sensitivity pregnancy tests, continuing pregnancy rates requiring a follow-up appointment were very high. This indicates the need for a low-sensitivity pregnancy test that could reassure women that their medical abortions were complete before the three weeks it takes for the pregnancy hormone to become undetectable in urine.

Nonetheless, some women prefer to attend a clinic for medical abortion. In Ethiopia, for example, women attend a clinic, receive the first dose and return 36 hours later for the second dose. Women are offered the options of going home or staying at the clinic until abortion occurs. Many choose to stay at the clinic because the majority have no toilet facilities at home (G Petersen, Personal Communication, 2009).

### 4.1.2 Task-shifting

The process of demedicalisation encourages the use of simple and less painful procedures that do not rely on expensive and complicated technology. As a result, tasks are being shifted to less highly trained staff members, thereby reducing the burden on the health system and improving access to services and products. Given chronic health worker shortages in the countries with the highest unmet need for health services, task-shifting is a promising solution for increasing access. Task-shifting has recently gained prominence in discussions about universal access to HIV treatment. However, the strategy has actually been used within the reproductive health community for many decades.

Task-shifting is defined by WHO as:

“The process of delegation whereby tasks are moved, where appropriate, to less specialised health workers. By reorganising the workplace in this way, task-shifting can make more efficient use of the human resources currently available.” \[^{36}\]

MSI has used new simpler technologies (such as the Manual Vacuum Aspirator or MVA pioneered by Ipas in 1973) so that lower-level providers can provide safe abortion with the same level of quality and success as higher level providers.\[^{38}\]

In terms of medical abortion, there is the potential to task-shift provision to trained outreach providers, pharmacists and community

---

**Box 8: Self-administration of medical abortion drugs in Uruguay: overcoming legal restrictions**

*The following is adapted from an article by Will Alexander, Mife Matters, 2008*

In Uruguay, abortion remains illegal and many women resort to unsafe abortions. Between 1996 and 2001, complications resulting from unsafe abortion were the cause of nearly half of all pregnancy-related deaths recorded at one large public hospital.\[^{37}\] This situation has been exacerbated by paternalistic and judgmental attitudes on the part of many healthcare providers.

At the initiative of Iniciativas Sanitarias (an organisation of healthcare professionals), supported by Ipas and the International Federation of Gynaecology and Obstetrics (FIGO), a ‘harm-reduction’ strategy was introduced in Uruguay. This assumed that women would access over-the-counter drugs and that the best way to reduce the harm associated with pharmacy sales was to include complementary information and support.

The harm reduction model involves a minimum of two clinic visits for women. During the first visit, women receive a physical examination and those who do not wish to continue with their pregnancy are provided with information concerning their options. This includes information about medical abortion with Misoprostol, which is available on prescription for other purposes in Uruguay.

This information is intended to prevent women from misusing the widely known drug or from resorting to more dangerous means of ending their pregnancy. The importance of returning for follow-up and adopting contraception are emphasised. Women can then access Misoprostol independently, knowing how to take the medication and when and where to seek support if needed.

Since the healthcare team is neither providing Misoprostol nor inducing abortion, the initiative is within the limits of Uruguayan law (which criminalises the deliberate interruption of a pregnancy) and is endorsed by the Ministry of Public Health. Approximately 100 women make use of the initiative each week at one large public hospital. Recent evidence suggests that nearly 90% of women attending for a first visit subsequently induced abortion by using Misoprostol, while four percent carried their pregnancy to term.

---

\[^{36}\] Source: [http://www.who.int/healthsystems/task_shifting_booklet.pdf](http://www.who.int/healthsystems/task_shifting_booklet.pdf)
health workers. However, there will always be a need for back-up referral to support women who do not know the date of their last menstrual period, have a positive pregnancy test after medical abortion, or have other complications, such as suspected ectopic pregnancy.

MSI Viet Nam is currently working with the government to clarify which groups of professionals can provide medical abortion. So far, this is limited to obstetricians/gynaecologists, and only then when they are certified by the handful of authorised government-recognised training facilities. However, Hang Nguyen Thi Bich, Country Director of MSI Viet Nam thinks this could change in the future:

“We are confident that nurses and midwives are well-trained and could provide medical abortion up to 7 weeks, even up to 10 weeks.”

Although attempts are underway to encourage task-shifting in government policies on medical abortion, the reality in many countries is that task-shifting has already happened informally as healthcare providers respond to the high demand and what is consequently a lucrative market.

Some healthcare providers, such as pharmacists and community health workers, are providing medical abortion illegally. Some of these task-shifting programmes have been assessed and are discussed below.

a) Task-shifting to community health workers

In Ethiopia, the government recently liberalised the law on abortion and placed task-shifting at the centre of the access challenge:

“In order to make safe abortion services as permitted by law accessible to all eligible women, the role of midlevel providers such as nurses and midwives should be expanded to include providing comprehensive abortion services, including uterine evacuation using MVA and medical abortion. Pre-service and in-service training for midlevel providers should reflect this expanded role.” Government of Ethiopia Article 545, Section IX, 2006

The government is now partnering with VSI to assess whether or not medical abortion can be provided by community health workers. VSI is training community healthcare workers to provide Misoprostol alone for medical abortion or post-abortion care and mid-level healthcare workers (clinical officers/nurses/midwives) to deliver the Mifepristone and Misoprostol regime.

b) Task-shifting to pharmacists

Pharmacists and other providers are known to be providing Mifepristone, Misoprostol and other abortifacients, both on and off prescription, in various countries, including: India, USA (for example, to Latin American immigrants), Mexico, Brazil, Bolivia, Nicaragua, Colombia, Peru, Venezuela and Uruguay. Studies suggest that this level of task-shifting can be successful, but that there are concerns about lack of sufficient knowledge amongst pharmacists.

xv In addition, some healthcare providers will also be providing medical abortion for public health reasons rather than just monetary reasons. See, for example, Kruse B. Advanced practice clinicians and medical abortion: Increasing access to care. Journal of the American Medical Women’s Association 2000; 55(3 supplement):167–8.


xvi Known as Health Extension Workers in Ethiopia.
Several studies have investigated over-the-counter availability of medical abortion drugs. For example, a study in Bolivia, Brazil, Nicaragua and Mexico found a general lack of information about Misoprostol and its safe use, despite widespread use of the drug.xvi A study of pharmacy worker practices related to use of Misoprostol for abortion in a Mexican state⁶² concluded that pharmacy workers (in urban and rural areas) were increasingly becoming aware of Misoprostol as an effective medication for abortion and were willing to provide information to consumers. However, their information was limited and often inaccurate. The legal context of abortion in Mexico (with restrictions in every state, except Mexico City); the restricted registration of Misoprostol as a therapeutic agent only for gastric ulcers; and the fact that the majority of pharmacy workers are not considered to be health workers were identified as among the most important barriers to advances in training pharmacy workers in the correct application of Misoprostol. Ipas has been training pharmacists in Mexico to improve knowledge about dosage, timing and routes of administration.

A study in India of service providers, pharmacists, women and men assessed awareness of Mifepristone and Misoprostol for abortion. Pharmacists knew that Mifepristone and Misoprostol were prescription drugs but had less knowledge about dosage and side effects. Most sales appeared to be prescription driven, but some over-the-counter sales did occur, especially when ability to pay seemed high or the pharmacist knew the customer. Another study from India, in the states of Gujarat and Jharkhand, reported that medical abortion was popular among clients and providers, as well as easy to access.⁶³ Pharmacist provision was far cheaper than doctor provision (at US$12 versus $60), but pharmacists had less knowledge about regimens, contraindications and side-effects.

4.2 Innovative models to increase access

In addition to demedicalisation as a strategy for increasing access to medical abortion for women who want it, other innovative models of service delivery are being developed. This section highlights three models:

1) Networks and accreditation.
2) Social marketing techniques to ensure access for providers.
3) Internet and telemedicine to provide direct access to women.

4.2.1 Network and accreditation

In countries where medical abortion is legal but not easily accessible, one strategy to increase access is to mobilise the private sector by developing networks of trained and accredited providers. Network and accreditation models can serve to increase the quality of services, as well as giving providers incentives to focus on neglected public health issues such as abortion. Private providers benefit from joining an accredited quality-monitored network for many reasons, including: opportunities for knowledge-sharing; cross-referrals; simpler and less expensive procurement of commodities; as well the benefits of training and education.⁶⁴

Ipas has been developing networks of trained private providers in order to increase access to medical abortion. In Maharashtra, India, Ipas worked closely with the Federation of Obstetrics and Gynaecology Societies of India (FOGSI) to develop a network of private providers known as MAPnet. The network included 87 doctors who were enrolled and trained in 2005. The network also provided peer-to-peer support and ongoing educational opportunities. At the end of the project, an increased number of doctors provided medical abortion (from 60 to 77) but more importantly, the number of private providers who were correctly prescribing the drugs nearly doubled. Although the quality of the service provision improved, the network struggled to develop peer-to-peer support mechanisms, possibly because of the taboo that continues to be associated with medical abortion in India.⁶⁵

These types of accredited networks can be created by healthcare providers themselves.

---

xvi Please see Gynuity work on: Choices for Medical Abortion Introduction in Brazil, Colombia, Mexico and Peru, Gynuity, December 2007.
Box 11: Social franchising in Viet Nam to provide high-quality medical abortion services

MSI Viet Nam has been successful in rolling out medical abortion through the MSI social franchising network BlueStar.

In 2007, the Vietnamese Ministry of Health liberalised the provision of medical abortion to allow private providers to provide services in private facilities. Non-government organisations (NGOs) such as Ipas and Pathfinder have been working with the Ministry of Health to revise technical standards and provide training for government service providers. Over 140 national master trainers for reproductive health services have been recruited and now provide training for all public service providers.

However, there was a significant gap in terms of the involvement of private providers, so MSI Viet Nam started training and working with the private sector through social franchising. In 2007, MSI Viet Nam launched 32 BlueStar social franchising clinics. The objective is to set up a network of at least 300 nationwide clinics for the social franchising of high-quality family planning and medical abortion services.

As Hang Nguyen Thi Bich, Country Director of MSI Viet Nam, says:

“We can expand coverage very quickly and increase access to services and hope to improve quality. The Ministry of Health is very interested in our work and wants us to pilot working with the private sector in order to strengthen the accreditation and monitor and improve the quality of the private sector.”

Box 12: India – achieving scale through social marketing

In India, there are an estimated 11 million abortions every year, four million of which are considered unsafe. Population Health Services (PHS) India uses commercial distribution strategies to provide Mifepristone and Misoprostol outside PHS centres at scale. Khushi-branded Mifepristone and Misoprostol are promoted and sold together to existing qualified abortion providers by experienced medical sales agents. The low cost of Khushi medical abortion products ensures that they remain affordable to clients, as well as being profitable for providers. In 2009, PHS India sold over 227,000 tablets of Mifepristone and 1 million tablets of Misoprostol.

4.2.3 Telemedicine

Telemedicine is a new and growing application of clinical medicine in which medical information and...
services are transferred in real time through the internet, telephone or other interactive technologies. More complex telemedicine can include online consultations, diagnosis and prescription for treatments. The rationale behind the approach is to increase access to healthcare at low cost and in time-efficient ways.

In an ambitious and pioneering endeavour to take advantage of the opportunities presented by the internet, telemedicine is being used by Women on Web (WoW) to help women in countries without safe abortion care to access Mifepristone and Misoprostol. The model is not currently legal. Nonetheless it offers promise for increasing future access to medical abortion.

WoW provides telemedicine to help women access Mifepristone and Misoprostol in countries without safe abortion care. Following an online consultation, women with an unplanned pregnancy of up to nine weeks are referred to an online doctor who checks for contraindications. The medication is sent by mail to the client for self-administration.

A recent audit (sample size unknown) with a follow-up rate of 77.6% found that 12.6% of women who received the medication decided not to go ahead with an abortion. Of those who took the medications, only 6.8% of the women subsequently needed a vacuum aspiration procedure. These are similar to rates at regular healthcare facilities, indicating the potential for further ‘remote access’ service provision in the future.

A review of this service argues that the main difference between the WoW service and face-to-face encounters lies in providers being unable to confirm gestational age by physical examination. There is also a risk that women will underreport gestational age in order to access help. For this reason, the WoW website warns about increased risk of complications associated with longer gestation. During the online consultation, women are also advised to have an ultrasound examination in order to establish the duration of the pregnancy and to exclude the possibility of an ectopic pregnancy. In order to minimise the risk of underestimating gestational age, women are advised to estimate the duration of their pregnancy based on the first day of their last menstruation.

This study of medical abortion via telemedicine shows that outcomes of the procedure are comparable with the results reported in studies of medical abortion in outpatient settings. It shows that women can self-administer Mifepristone and Misoprostol at home without visiting a doctor, as long as proper information and instructions are provided, understood and followed. This can be performed remotely with standard information, and with additional interactive online consultation and email correspondence. In the US, a pilot project is using ‘telepharmacy’ and ‘lock-box’ rural delivery of medical abortion drugs in order to increase access to medical abortion by women in rural areas (M Fjerstad, Personal Communication 2009).

While telemedicine appears to have potential in terms of increasing access to medical abortion drugs, it also has potential for abuse. In common with many other services provided over the internet, there are serious concerns about how such services can be regulated and their quality controlled. Moreover, there are many counterfeit websites that claim to sell medical abortion drugs but actually provide poor quality or completely fake pills.

The current unmet need for 19 million safe abortions a year is of grave concern. Access to safe abortion services needs to be expanded. Safe abortion saves lives. Medical abortion provides safe abortions at minimal cost. Expanding access to medical abortion is relatively simple and cheap. Most important, given the choice, many women prefer medical abortion to the surgical alternative.

Global demand for abortion is stabilising and even decreasing in many parts of the world. This is good news and is evidence of the positive impact of expanded family planning programmes. The aim of SRH programmes is to reduce the number of unintended pregnancies through increased education and access to affordable modern contraception. However, even with universal access to modern contraception, there will always be significant numbers of unintended pregnancies, and therefore a demand for abortion. Access to safe abortion is both a public health challenge and a reproductive rights issue.

This publication has highlighted effective and innovative practice in medical abortion. For example, task-shifting makes it possible for medical abortion to be provided to women in rural and remote areas by trained low-level providers, such as pharmacists and community health workers. Medical abortion can also be partly or fully administered by women themselves, thereby transforming traditional relationships between healthcare provider and patient. Implemented with appropriate attention to informed choice and safety, these strategies have considerable potential to reduce the burden on over-stretched health systems.

Key components of effective medical abortion programmes include training for healthcare providers to ensure that they are able to prescribe the drugs correctly, to provide adequate information and counselling about the procedure, and to offer post-abortion family planning and referral systems. Developing referral systems is another critical and challenging element in an effective medical abortion programme. Although complications are rare, they do occur and a small percentage of women will need follow-up surgical procedures or else will need to receive treatment for complications. With increasing demedicalisation of medical abortion provision, a particular challenge lies in responding to the needs of women who experience complications in remote rural communities without health facilities.
Safe abortion remains a politically explosive issue, provoking considerable opposition throughout the world. Education and advocacy are therefore crucially important in increasing knowledge, changing attitudes and facilitating the introduction of medical abortion in many countries.

A small but increasing number of countries are also changing legislation to increase access to safe abortion and are registering drugs for medical abortion. This process is complex and time-consuming. However, there are success stories in countries such as Ghana and Ethiopia. Unfortunately, it is clear that legal reform and the legal registration of medical abortion drugs is not happening at a sufficiently rapid pace to keep up with demand. It is therefore hardly surprising that a profitable black market has sprung up in many parts of the world. Although there is some evidence from countries like India that the illegal supply of medical abortion drugs can be delivered successfully, there are also stories of vulnerable women being sold fake drugs.

Underpinning the failure to meet women’s demand for medical abortion is a more profound failure to prioritise reproductive health and rights. Without a significant and immediate shift in priorities, achieving MDG 5 by reducing maternal deaths remains unattainable. Expanding access to modern contraception and medical abortion represents one of the most cost-effective and easiest ways to accelerate efforts and is – after all – what women want.

**Recommendations**

*In order to accelerate progress on MDG 5, it is recommended that governments and development partners:*

- ensure that the law supports women’s access to safe abortion services
- increase funding and prioritisation of family planning and safe abortion programmes
- register Misoprostol for the management of PPH, medical abortion and post-abortion care
- increase access to and awareness of medical abortion programmes.

*For governments or organisations that wish to register and procure medical abortion drugs, it is important to:*

- ensure that existing manufacturers reach cGMP standards of good practice
- undertake complementary stakeholder analysis, education and advocacy campaigns to promote stakeholder buy-in and inclusion of these drugs on the EDL
- ensure a consistent supply of high-quality drugs
- encourage market competition to reduce prices and create incentives for improved quality
- develop harmonised procurement and prequalification lists.

*Organisations setting up high-quality medical abortion programmes should consider the need to:*

- train healthcare providers to provide safe and effective medical abortion
- provide counselling to women about the procedure, post-abortion family planning and follow-up
- develop monitoring and evaluation systems to ensure that the programme is achieving its intended impact and to track adverse outcomes
- provide referral mechanisms to women with complications or incomplete abortions. These could include a 24-hour helpline or dedicated internet site together with access to a hospital or surgical abortion provider
- undertake stakeholder, educational and advocacy activities in order to increase knowledge and acceptance of medical abortion.

*Successful strategies to expand access in low-resource countries include:*

- task-shifting the provision of medical abortion from high-level providers to lower level providers, such as nurses, midwives, community health workers or pharmacists
- encouraging the demedicalisation of the medical abortion process, for example, by empowering women to administer the pills themselves
- mobilising all sectors of the health system (including private providers through social franchising and social marketing) and emphasise training and high-quality products and service.
References


47. Gomperts RJ, Jelinska K, Davies S, Gemzell-Danielsson K, Kleiverda G. Using telemedicine for termination of pregnancy with mifepristone and misoprostol in settings where there is no access to safe services. BJOG 2008;115(9):1171-5; discussion 75-8.
