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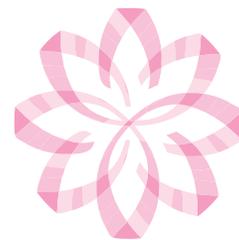
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www.medabon.info





Medabon

Medabon[®]
medical abortion

A Framework for
Introduction



Medabon®: A Framework for Introduction

Experience in the fields of family planning and abortion has shown that achieving broad population access within a program or country requires a systematic approach and a process of strategic decision-making. In other words, successfully expanding use of products rarely just happens spontaneously. Providing the broadest possible access with the necessary quality of care is most likely to be successful when attention is paid to these outcomes from the beginning.

Product introduction refers to the integrated set of activities that prepares health systems to accept and manage the provision of new, improved, or underutilized health technologies. Effective introduction is essential to sustaining a product's public health impact and includes:

- Developing a country-specific introductory strategy for service delivery in the context of a supportive health system.
- Providing information to diverse audiences in order to increase awareness of this new product.
- Scaling up service provision at all appropriate levels of the healthcare system throughout a country (which is most likely to be successful if addressed from the earliest stages of the process).

Medabon® is a safe and effective method for early medical abortion. Strategic introduction of Medabon® is even more critical than with other medicines. In many countries, abortion services remain a sensitive issue, and there is a continuing need for advocacy with providers as well as with society more broadly. A carefully developed introductory strategy must be considered when making drugs for medical abortion available and ensuring their appropriate use by all who require them.

In some countries, Medabon® may be introduced as part of a comprehensive abortion care (CAC) program along with other methods that are new for the country. It may be introduced as the first approved method for medical abortion (MA) in a country with other existing safe methods (such as vacuum aspiration), or it may be a new MA product joining others already on the market. In each case, ensuring broad availability of Medabon® will depend on successfully engaging stakeholders—in both the public and private health sectors—and implementing a process of strategic decision-making. Such a process can also help to improve the quality of sexual and reproductive health services, and especially CAC, in each setting.

This document is intended primarily for program managers, policymakers, and civil-society groups who hope to coordinate the introduction of Medabon® in their context, and briefly outlines some key steps in this process. For more information on strategic introduction and strengthening of sexual and reproductive health services, visit www.who.int/entity/reproductivehealth/publications/general/HRP_RHR_07_7/en/.

Steps to consider in strategic introduction of Medabon®

Note that the steps outlined here do not necessarily have to be started or completed in sequence; for example, it may be important in some settings to complete the strategic assessment (Step 3) before succeeding in making the product available (Step 2).

Step 1: Build support for safe abortion care and Medabon® introduction at all appropriate levels.

Step 2: Ensure that the product can be made available.

Step 3: Assess user needs, legal and policy requirements, and service- and health-system capabilities.

Step 4: Design a pilot study.

Step 5: Develop a distribution plan.

Step 6: Train providers.

Step 7: Meet information needs of women.

Step 8: Monitor and evaluate Medabon® services.

Step 9: Disseminate results of introduction strategy.

Step 10: Scale-up.

1 Build support for safe abortion care and Medabon® introduction at all appropriate levels

Given the often-sensitive nature of the topic of abortion, having key stakeholder support is critical. Gaining the support of key government officials and community leaders early on—and continuing to do so as part of the steps that follow—can help to ensure initial acceptance of the method and facilitate introduction and scaling-up. It is important to listen to the concerns of a broad range of individuals and groups and take them into consideration when making decisions about how to introduce Medabon®. In addition, providing clear, scientifically based information to government and community groups can help to address any concerns they may have.

It is helpful always to emphasize that medical abortion—like vacuum aspiration—is safe for women and makes it possible for them to have abortions very early in pregnancy. The “Key Talking Points” in this resource packet provide useful language for framing the issue and responding to challenging questions about Medabon®, medical abortion, and abortion in general. There will likely be an ongoing need for advocacy activities, which should be planned for beyond the introductory period. Local advocacy groups are important partners in these activities—and consulting with groups like these may, in fact, be a helpful first step in building an effective advocacy plan.

2 Ensure that the product can be made available

Ensuring the availability of Medabon® will include identifying and addressing national regulatory requirements, identifying an importer or distributor, and submitting an application for the trademark. Different countries have different requirements that need to be met before drug registration and marketing approval are issued, and a regulatory dossier meeting the country’s requirements must be developed. Regulatory agencies may require technical inspections of the manufacturer’s facilities; development and execution of an agency agreement between the manufacturer and the principal importer or distributor of the drug may be required before submission of the regulatory dossier; and recommended pricing for the product may be necessary. The Concept Foundation has been working to support this process in a number of countries. For more information on this step, contact medabon@conceptfoundation.org.

In some countries, regulatory approval may be required before any of the activities included in Steps 4 through 10 can be undertaken. If not, permission should be obtained from the relevant national authorities so that these steps can take place during the process of regulatory review, allowing scaling-up of provision of the product to occur as soon as regulatory approval is obtained.

3 Assess user needs, legal and policy requirements, and service and health system capabilities

An initial review and assessment will help to map a strategic introduction strategy, as well as identify actions required for eventual scale-up. While a preliminary desk review of existing data, policies, and relevant literature can be a helpful starting point, a participatory assessment of needs and priorities for introducing Medabon® will provide multiple perspectives, new insights, and ultimately, better recommendations. This step will also help to further the process of consensus-building, as more stakeholders are engaged in the introduction of Medabon®.

The participatory assessment can include individual and group interviews with policymakers, health and regulatory authorities, clinic managers, providers (in the public, private, and nongovernmental/social-marketing sectors), community leaders, and women (both in and outside health facilities); surveys of potential users and providers; and reviews of policies and service-delivery statistics for both the public and private sectors. Areas to consider in the discussions and analysis include women's needs, regulatory requirements, service-delivery capabilities, health-systems capacity, and the needs of specific populations such as youth, refugees, or minority women. See Appendix 1 for suggested questions in each area.

4 Design a pilot study

Following the assessment, it is likely that program managers will require local evidence of feasibility of the recommended abortion care program. Local data and experience on the effectiveness, efficiency, acceptability (to providers and women), and cost implications can help decision-makers determine whether they can commit resources for wide-scale implementation—both beyond the original pilot area and throughout the levels of the health system. Steps 5–9 are best undertaken in the context of a pilot study in a limited number of geographical areas to develop and test the required training program and informational materials, assess the logistic and health system constraints to provide the product, and ensure that medical abortion can be provided with appropriate quality of care and that any necessary referral services can be accessed. These steps can be revisited once scale-up is initiated.

The process of developing or revising national norms and standards for high-quality medical abortion care can also be initiated during the pilot study. Standards and guidelines should include, among other issues:

- Where medical abortion can be provided and who can provide it.
- Essential equipment, supplies, medications, and facility capabilities required for providing this service.
- Referral mechanisms.
- Information on the importance of respect for women's informed decision-making, autonomy, confidentiality, and privacy.

Health service budgets should also be updated to include the costs of staff, training, supplies, and medications, as well as any capital costs. Other specific service-delivery or community-related issues may become evident from the results of the assessment or during the pilot phase. Operations research should be undertaken to address these issues during implementation of the introduction strategy.

5 Develop a distribution plan

In the public sector, the national logistics and distribution system will be the principal means of supply to governmental health care facilities (in decentralized settings, regional or district systems may be the primary suppliers). However, the selection of which health care facilities will be supplied must be addressed. The distribution of Medabon® should be ensured to all facilities in which a provider has been or will be trained (see below). In addition, other channels should also be considered, including private health practitioners and social-marketing programs. Any distribution channel must involve trained providers and the capacity for referral in cases of emergency and for post-abortion family planning.

Once distribution channels have been selected, systems must be put in place to ensure that these channels have a consistent supply of the product (typically this can be done through the existing reproductive health commodities-logistics system). In addition, record-keeping systems must be updated to include Medabon®.

6 Train providers

The timing for training providers should be carefully planned so that they are trained before Medabon® is introduced to women seeking abortion services, but not so early in the introduction process that they will need to be retrained by the time the product is widely available. Of particular importance is ensuring that providers treat women respectfully and maintain a nonjudgmental attitude when providing services. See Appendix 2 for recommended training content for Medabon® providers. Information on medical abortion and emergency back-up care must be incorporated as part of overall training on reproductive health, including all basic and refresher training for service providers.

Participatory adult-education tools, such as case studies and role-playing, can be helpful training methods. Conducting values-clarification workshops may also be helpful in addressing negative provider attitudes toward safe abortion services and preventing potential bias against particular methods or particular groups of women. A variety of training curricula for medical abortion are available. Please note that these materials may refer to alternate regimens for medical abortion that deviate from the Medabon® labeling and how Medabon® should be administered (see the “Medical and Service Delivery Guidelines” in this packet for more information). Such curricula will need to be adapted prior to use. For a model training curriculum, please refer to Ipas’s Medical Abortion Training Package (see Related Resources).

In addition to service providers, staff who interact with women requesting or inquiring about services (including receptionists and other nonclinical staff) should receive basic information about Medabon® so that they can answer inquiries about the availability of the method and help women obtain services in a timely and caring way. The assessment in Step 3 may also help to identify opportunities for the public and private sectors to work together in training the full range of Medabon® providers.

7 Meet information needs of women

Women who seek safe, legal abortion services need specific information about available methods, including safety and effectiveness, possible risks, common side effects, use instructions, follow-up requirements, and information on accessible referral services. This information should be provided during counseling to all women who use Medabon[®] as well as in simple written/visual materials that women can take home. In many settings, materials should be developed for low-literacy women. A prototype information brochure and a compilation of sample illustrations that can be adapted for use in various settings are included in this packet.

Lack of public information about abortion laws and women's rights under such laws, lack of awareness about facilities providing abortion, family attitudes, and concerns about privacy and confidentiality can all present obstacles to accessing safe abortion services. Where possible, these should be addressed with advocacy and education. Women should be encouraged to seek care as early as possible in their pregnancy in order to have access to the full range of abortion options available.

Where possible, it may be helpful to organize means of reassurance and support for women who need it during the medical abortion process. Some options could include telephone hotlines or community outreach workers affiliated with women's groups or health centers.

8 Monitor and evaluate Medabon[®] services

Ongoing monitoring and supervision of Medabon[®] provision and use, including adverse-events monitoring, can help to identify necessary adaptations to service management and informational and educational materials. This is important both in the pilot stage—before the method is more widely introduced—and as an ongoing performance-improvement strategy designed to adapt services to the (likely evolving) needs of a particular setting. Evaluation activities should include assessments of user and provider perceptions and experiences with Medabon[®], the service-delivery channels through which it is being provided, and effective links with a supportive health system and back-up care. Evaluation activities can assist in ensuring that Medabon[®] is used appropriately, that no undue obstacles exist to its use in the public or private sectors, and that safe medical abortion services serve as a bridge to family planning and other sexual and reproductive health services for women who need them.

Where regulations and guidelines are more conservative, especially in a context where abortion services are newly introduced, evaluation data can provide evidence supporting guidelines for expanding use.

9 Disseminate results of introduction strategy

The results of the monitoring and evaluation activities included in Step 8 can be most useful if they are disseminated among and discussed by a broad group of constituencies—both globally and nationally—and are subsequently used in the development of strategies for the broader provision of Medabon®.

10 Scale-up

The findings from the introductory pilot study and the outcomes of the dissemination process will provide necessary information for expanding the provision of services as well as the basis for the design of a comprehensive strategy for scaling-up. Plans for scaling-up and their implications should be considered as early in the process as possible. Scaling-up should be considered as early as the time of the assessment and should be considered in designing the initial pilot study. As with the previous elements of the introduction process, this activity should be participatory in nature and should be aimed at ensuring that expansion of services is done in a way that ensures high-quality and acceptability of services. There should be no discontinuation of initial introduction activities while plans are made for expanding the availability of Medabon® through public and private health facilities; in fact, these vanguard sites can be very useful as demonstration and/or training sites for managers/trainers from other regions in the country. Scale-up should ultimately lead to complete geographic coverage, enabling all women in the country to have access to medical abortion. A comprehensive series of documents on the process of scaling-up are available from ExpandNet and the World Health Organization at www.expandnet.net/.

Appendix 1. Questions to guide a review and assessment (Step 3)

The following questions should be considered for a review and assessment that will help guide product introduction. Refer to Step 3 for more information on target audiences and appropriate methodologies for answering these questions.

Women's needs and perspectives:

- Are women aware of safe abortion options in general and medical abortion in particular?
- When told about medical abortion with Medabon®, do women demonstrate or perceive an interest in it?
- What questions and concerns do they have?
- Are there rumors or misinformation about abortion or medical abortion and, if so, are they widespread and what are they?
- Which population groups report the greatest need for medical abortion services?
- What service-delivery sites would be most convenient or acceptable to women?
- What are women's preferences regarding home- or clinic-based administration of misoprostol?
- What are user perceptions of existing services (public, private, and nongovernmental/social-marketing) through which Medabon® might be provided?
- What information channels (formal or informal) are preferred by women?

Legal and policy requirements:

- What is the legal and policy framework of the country and/or locality with regards to abortion?
- Are there any limitations or requirements related to medical abortion in particular?
- Does the law require that abortions take place in a clinic registered for that purpose and/or by licensed providers? Who can provide care in what types of settings?
- If so, does this requirement apply when the drugs are prescribed, when the drugs are administered, or where the products of conception are expelled?
- What are the practical implications of this requirement, including for home-based administration of misoprostol?
- What safeguards can ensure that Medabon® is not provided by untrained and unlicensed providers?
- What are the public/private regulatory issues? Are there any policy obstacles to private-sector provision of Medabon®?

Service-delivery capabilities:

- What do health providers (physicians, nurses, midwives, community health workers, pharmacists) know about medical abortion, particularly mifepristone-misoprostol regimens? Are medical and service delivery guidelines for medical abortion available?
- Do providers perceive a need for Medabon®?
- What settings exist for the safe provision of Medabon®, within national legal and policy requirements (reproductive health clinics, primary health centers, hospitals, community-based outlets, private physician offices)?
- What types of health facilities and providers are currently offering safe abortion services (surgical, medical, or both)? What is the quality of existing services at different types of facilities?
- What levels of facilities and types of providers are most accessible to women geographically and socially?

- How do women typically reach facilities, and what are the types, costs, and availability of transportation methods, average travel times, and distances travelled?
- What is the capacity of non-specialist health care providers (e.g., emergency rooms, maternal and child health clinics, sexual assault crisis centers, pharmacies) to provide referral for medical abortion services?
- What kind of provider training will be required to ensure high-quality services?
- What training and information mechanisms are preferred by providers?
- What do providers consider as barriers to providing high-quality medical abortion services?
- What resistance exists among clinicians to providing medical abortion services?
- What are the costs of existing abortion services to women and to the health system?
- What will be the costs of medical abortion? How will the costs of other abortion methods affect choice for women?

Supportive health system capacity:

- Can potential service settings for Medabon® provision also provide vacuum aspiration, blood transfusions, fluid replacement, and/or antibiotics in the rare cases of incomplete abortion, excessive bleeding, or infection?
- If not, can they be effectively linked to referral services with emergency back-up care?
- Where do women currently access health care in emergencies?
- What might the training needs be in these settings to prepare health care professionals to provide emergency back-up care?
- Can potential service settings also provide post-abortion contraception?
- Is there health-system capacity to provide ongoing monitoring and oversight of medical abortion services?
- How are sexual and reproductive health and, specifically, abortion services financed?
- What are the structures within the ministry of health responsible for reproductive health services? Is there a national reproductive health program or a division of family health responsible for comprehensive abortion care?

Collaboration and coordination:

- What national institutions/programs exist for provider training; development of information, education, and communications materials; logistics management; and monitoring and evaluation?
- What national and international nongovernmental organizations (NGOs) are involved in reproductive health and abortion-related activities?
- Are there coordinating mechanisms between the ministry of health, donors, private-sector providers, and national and international NGOs?
- What local advocacy organizations are addressing abortion-related issues, and are they doing any work specifically to address medical abortion?

Appendix 2. Training requirements for Medabon® providers

Providers at facilities offering Medabon® should be trained in each of the following:

- Protocols for medical abortion, including eligibility and contraindications.
- Counseling of women on available abortion methods, including clear information about the procedures, benefits, possible side effects, and risks.
- Confirmation of pregnancy and assessment of gestational age by physical examination and medical history.
- Identifying or screening for rare pregnancy abnormalities, including ectopic pregnancies.
- Instructing women on how to use misoprostol at home when feasible and chosen by the woman.
- Assessing and addressing a woman's needs for pain management.
- Verifying that the abortion is complete and the woman is no longer pregnant.
- Appropriate follow-up care, including provision of or referral for vacuum aspiration services when indicated.
- Identifying and managing risks and complications, as well as side effects.
- Identifying access to referral services where any complications can be managed.
- National/local laws and policies on abortion (including legal age of consent and requirements for women below that age).
- Providing family-planning counseling and contraceptive methods.
- Screening and referring women with other sexual and reproductive health needs.

Related resources

Abuabara K, Blum J, eds. *Providing Medical Abortion in Developing Countries: An Introductory Guidebook. Results of a Team Residency at the Bellagio Study and Conference Center*. New York: Gynuity Health Projects; 2004. Available at: www.gynuity.org/documents/guidebook_eng.pdf.

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Hyman AG, Castleman LD. *Woman-centered abortion care: Reference manual*. Chapel Hill, NC: Ipas; 2005. Available at: www.ipas.org/Publications/Woman-centered_abortion_care_Reference_manual.aspx. **Also available in French, Portuguese, and Spanish.**

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