Handbook on Medical Methods of Abortion

by Government of Madhya Pradesh and Ipas to expand access to new technologies for safe abortion

2013
About Ipas

Ipas works globally to increase women’s ability to exercise their sexual and reproductive rights and to reduce abortion-related deaths and injuries. We seek to expand the availability, quality and sustainability of abortion and related reproductive health services, as well as to improve the enabling environment. Ipas believes that no woman should have to risk her life or health because she lacks safe reproductive health choices.

Ipas India program, established in 2001, is partnering with 11 state Governments in advancing women's access to safe abortion services through strengthening of training systems; establishing service delivery in primary health-care settings; promoting early abortion technologies such as MVA (Manual Vacuum Aspiration) and MMA (Medical Methods of Abortion); conducting research on abortion issues; and advocating for policies that support women’s health and rights.

Acknowledgment

This manual has been largely adapted from Woman centered abortion care: Reference Manual by Alyson G. Hyman and Laura Castleman, 2005. Chapel Hill, NC, Ipas

And


And

National CAC Training and Service Delivery Guidelines by MOHFW, 2010
Handbook on Medical Methods of Abortion

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Unsafe abortion is a significant yet preventable cause of maternal mortality across the country and in Madhya Pradesh. While we have been successful in reducing the maternal mortality rate of our state, concerted efforts and innovative approaches are needed for us to meaningfully contribute to reaching the Millennium Development Goals. While under the National Rural Health Mission, we are constantly making endeavours to address the lack of availability of providers; one key area that also needs to be given attention is expanding availability of new and safe technologies for abortion.

In this regard, medical methods of abortion have proved to be a technology that is safe and affordable and if made adequately available in the public sector, will go a long way in meeting the needs of women, augmenting services especially in low resource settings.

To further advance one of the key focus areas under NRHM- increasing access to safe abortion services- the Directorate of Health Services, Government of Madhya Pradesh has developed this handbook with the objective of improving medical methods of abortion in the ongoing CAC trainings, thereby expanding their correct use and availability in the public sector through the state.

I hope this handbook will be extensively used by trainers as a resource and further by the providers as a reference, and will play a significant role in integrating medical methods of abortion into the public health system. I believe this will not only expand the choices for women in our state but also move forward the agenda of increasing access to high quality safe abortion services.

In our mission of improving women’s health, we look forward to working closely with Ipas that has been our long-term partner in increasing access to and quality of comprehensive abortion care services in the state.

Bhopal
01-07-2013

(Dr. M. Geetha)
Foreword

The maternal mortality ratio (MMR) in Madhya Pradesh has declined from 379 per 100,000 live births in 2001-2003 (RGI 2006) to 269 in 2007-2009 (RGI 2011). However, this is still higher than the national average and the Government of Madhya Pradesh is committed to reducing it further to achieve the Millennium Development Goals.

One of the most easily preventable reasons for maternal deaths is unsafe abortions - although abortion has been legal in India for more than four decades, eight percent of all reported maternal deaths in the country (10% in EAG states including Madhya Pradesh) are due to unsafe abortions.

The government of Madhya Pradesh has taken many steps to address this, including training of doctors from the public health system, establishing comprehensive abortion care services at the primary health facilities and increasing awareness in the community about the legality and availability of these services. According to the state MTP data, we are serving 10% women with safe abortion services. Given this, we recognize that we can do more to keep pace with the fast-evolving technologies for abortion to further expand access to safe services and provide these as a right for women in all parts of the state.

One such potential lies in medical methods of abortion (MMA). It is a simple technology that is highly recommended for termination of early pregnancies. Evidence from across the globe shows that it has significantly expanded women's options and improved clinicians' practices. It gains even more relevance in our context since it can be easily incorporated in primary care settings.

It is with this vision of harnessing the new and safe abortion technologies that I am introducing this reference manual – Handbook on Medical Methods of Abortion – that contains all required information for providing high-quality abortion services through medical methods. This is a resource for certified abortion providers to guide them to administer and manage early first trimester abortion through approved medication (Mifepristone & Misoprostol).

I hope that providers of abortion services will extensively use this manual to further update their knowledge and continuously improve the quality of their services thus expanding the availability of medical methods of abortion, and giving much-needed choices to women seeking to exercise their right to safe abortions.

Bhopal
26-06-2013

Sanjay Goel (I.A.S.)
Medical Methods of Abortion (MMA)

Introduction

This module gives information and describes the skills required by providers to administer and manage first-trimester abortion procedures by medical methods. Medical Methods of Abortion is also referred to as Medical Abortion.

Course Objectives

- List eligibility criteria and contraindications for women seeking Medical Methods of Abortion
- Compare relative benefits and risks of medical methods of abortion (MMA) and vacuum aspiration (VA) procedures
- Explain MMA protocol and describe/recognize side effects and complications
- Share experience of providing abortion services by medical methods post-CAC training
- Recall essential information to be given to women availing MMA

Climate Setting

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Content</th>
<th>Methodology</th>
<th>Materials &amp; Aids</th>
</tr>
</thead>
</table>
| Climate setting     | • Registration  
                     | • Pre training assessment  
                     | • Individual exercise  
                     | • Registration sheet  
                     | • Pre training assessment forms (one for each trainee)  
                     | • Course objectives  
                     | • Presentation  
                     | • Objectives written on flip chart |

This refresher course has been organized for gynecologists & medical officers who have successfully completed the Comprehensive Abortion Care (CAC) training earlier. The course seeks to update you for providing MMA services to women at your health centre in the future.

This course has the following sections:

1. Overview of Medical Methods of Abortion
2. Protocols for administration of drugs for Medical Methods of Abortion, identifying side effects and complications.
3. Sharing of experience especially for MMA during service delivery at work site post-CAC training

4. Key information for women seeking Medical Methods of Abortion

**Overview for Administration, Comparison of MMA vs VA**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Content</th>
<th>Methodology</th>
<th>Materials &amp; Aids</th>
</tr>
</thead>
</table>
| Describe the drugs listed for Medical Methods of Abortion in India; Eligibility criterion and contraindication for a woman seeking Medical Methods of Abortion; Compare MMA vs VA procedures | • Overview  
• Steps prior to procedure  
• Comparison of MMA vs VA | • Presentation  
• Brainstorming  
• Discussion  
• Recall, Questions and Answers | • Key points written on flipcharts  
• Heading for comparison table written on flipchart |

- Medical Methods of Abortion is a method for termination of pregnancy in a non-surgical, non-invasive way by using a drug or a combination of drugs.

- Medical Methods of Abortion provides women with a new option for termination of pregnancy and should be offered in addition to other (or) aspiration abortion methods whenever possible.

- Medical Methods of Abortion has the potential to increase access to safe abortion services because it can be offered by providers in settings where Vacuum Aspiration (VA) or other methods of abortion may not be possible.

**Drugs Used**

Commonly used drugs for Medical Methods of Abortion are a combination of Mifepristone and Misoprostol. Drug Controller General of India approved the use of Mifepristone (in April 2002) and Misoprostol (in December 2006) for termination of pregnancy up to 49 days gestation period.

In December 2008, Mifepristone + Misoprostol (1 tab of mifepristone 200mg and 4 tab of misoprostol 200mcg each) CombiPack was approved by the Central Drugs Standard Control Organization, Directorate General of Health Services for the medical termination of intrauterine pregnancy (MTP) for up to 63 days gestation.
Mifepristone

- It was commonly called RU-486, however, the term Mifepristone is more common now. It was invented in 1980. RU is the initials of pharmaceutical company Roussel-Uclaf which manufactured it and 486 is a random laboratory serial number.

- **Mechanism of action:** It is an antiprogestin, which blocks the progesterone receptors in the endometrium and decidua causing the necrosis of uterine lining and detachment of implanted embryo. It also causes cervical softening and increased production of prostaglandins, causing uterine contractions. It sensitizes the uterus to the effect of prostaglandins.

- It is more effective in early pregnancy when progesterone is present in lower concentrations due to limited production by the corpus luteum. As the placenta takes over the production of progesterone, the progesterone is produced in large quantities.

- **Dosage:** 200 mg orally on day 1 (first visit)
  When used with prostaglandin, complete abortion rate is 95-99%.

Side-effects: Serious side effects are rare. However, women may experience:
- Nausea
- Vomiting
- Fatigue
- Diarrhoea

Misoprostol

- It is a synthetic prostaglandin E1 analogue

- In December 2006, Drug Controller General of India approved its use in gynaecological indications for cervical ripening, prevention of post partum hemorrhage and with Mifepristone, for early abortions up to 7 weeks.

- **Mechanism of action:** It binds to myometrial cells causing strong uterine contractions, cervical softening and dilatation. This leads to expulsion of conceptus from the uterus.
• **Dosage:**
  Dose is variable, depending on gestation age and route of administration. Approved protocol in India is 400 mcg given orally or vaginally on day 3 (second visit) for gestation period upto 49 days and 800 mcg sublingually or vaginally for gestation period upto 63 days. Depending on the woman and the clinician’s decision, even home use of Misoprostol on day 2 or 3 may be tried to reduce one follow-up visit.

• It is economical and stable at room temperature.

• It gets absorbed fairly well in gastrointestinal tract and vaginal mucosa. Through vaginal route, it has lesser side effects, is absorbed slowly and is effective for a longer time whereas by oral route it leads to more gastrointestinal side effects, is absorbed quickly and is effective for a shorter time. Sublingual and buccal routes also show very promising results. There is no problem if the tablets do not completely dissolve on vaginal administration.

• It has fewer side effects as compared to other prostaglandins. Being selective for PGE1 receptors, it has no significant effect on bronchi and blood vessels.

• Originally it was developed for prevention and treatment of gastric ulcer.

• **Side-effects:**
  - Nausea
  - Vomiting
  - Diarrhoea
  - Fever (sometimes with shivering)
Effectiveness

A combination of Mifepristone and Misoprostol has the following efficacy for termination of early pregnancy:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Effectiveness*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete abortion</td>
<td>95 - 99%</td>
</tr>
<tr>
<td>Heavy bleeding requiring vacuum aspiration</td>
<td>1 - 2%</td>
</tr>
<tr>
<td>Incomplete abortion requiring other methods of evacuation</td>
<td>1 - 2%</td>
</tr>
<tr>
<td>Heavy bleeding requiring blood transfusion</td>
<td>0.1 - 0.2%</td>
</tr>
</tbody>
</table>


Failure

Medical Methods of Abortion is said to be a failure when the clinician has to resort to other methods of abortion. It could be from:

- Heavy bleeding/Hemorrhage
- True drug failure/continuing pregnancy

Sometimes, it may be due to Clinician's / woman's decision:

- For **heavy bleeding**, blood loss is estimated taking into account the number of normally used average sized pads soaked at a given time (described later). If indicated, VA is done as soon as possible.

- **True drug failure** is presence of gestational cardiac activity 2 weeks after Mifepristone and Misoprostol administration leading to continuing pregnancy. This has to be terminated by VA.

- **Incomplete Abortion:**
  - Some women have a persistent gestation sac without cardiac activity 2 weeks after the Misoprostol administration. This is called incomplete abortion.
  - Sometimes gestation sac is expelled but women keep bleeding due to blood clots/ decidual bits in the uterine cavity. This can be managed conservatively as mostly it is expelled spontaneously. But if bleeding is profuse, VA may have to be done.
Safety

- Using Mifepristone and Misoprostol is a safe method to terminate pregnancy as long as the woman does not have any contraindications for its use.

Advantages and Limitations of Medical Methods of Abortion

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abortion can be offered at an early stage</td>
<td>At least three clinic visits required</td>
</tr>
<tr>
<td>Potentially more private, similar to a natural miscarriage</td>
<td>Takes longer than VA, mean duration of bleeding being 9.5 days</td>
</tr>
<tr>
<td>Less invasive than VA. No instruments are used</td>
<td>Unpredictable outcome: may end in a complete/ incomplete abortion/continued pregnancy</td>
</tr>
<tr>
<td>No anesthesia</td>
<td>Possibility of side effects of drugs</td>
</tr>
<tr>
<td></td>
<td>Risk of fetal malformation if pregnancy continues</td>
</tr>
</tbody>
</table>
Eligibility Criteria

Eligibility of the Provider

- Medical Methods of Abortion is not a surgical intervention. However, it is a termination of pregnancy and, therefore, falls under the purview of the MTP Act 1971. In case of termination of pregnancy using Mifepristone and Misoprostol, the registered medical practitioner, as defined by the MTP Act, can only prescribe the drugs.

Eligibility of the Place

- Medical Methods of Abortion, as per the amended MTP Rules 2003, can be provided from approved sites as well as non-approved clinics with referral linkage to approved MTP site. The law requires that a certificate of access to a registered place (i.e. showing that a referral link has been established) from the owner of the approved site must be displayed in the clinic where MMA is being provided.

Medical Methods of Abortion and the Law

The key conditions/requirements of MTP using the medical methods are:

- Can be provided only by certified abortion providers
- Can be provided from approved sites as well as non-approved clinics with referral linkages provided a certificate of access to a registered place is displayed
Women seeking Medical Methods of Abortion

Option for Medical Methods of Abortion should be given to all women coming to a health facility seeking termination of pregnancy up to 7 weeks of gestation (49 days from the first day of the last menstrual period in women with regular cycles of approximately 28 days) provided that the following aspects have been assessed and found appropriate:

- Frame of mind of the woman
  - Acceptability of minimum three follow-up visits
  - Ability to understand the instructions and give informed consent
- Agrees for vacuum aspiration procedure, if failure or excessive bleeding occurs
- Support from family or others
- Consent of guardian in case of minor as per MTP Act 1971
- Easy access to appropriate health care facility in an emergency
### Contraindications to Medical Methods of Abortion

<table>
<thead>
<tr>
<th>Contraindications</th>
<th>Special precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ectopic pregnancy either confirmed or suspected. Or undiagnosed adnexal mass</td>
<td>Hemorrhagic disorder</td>
</tr>
<tr>
<td>Allergy to Misoprostone, Mifepristone or other Prostaglandins</td>
<td>Current anticoagulant therapy</td>
</tr>
<tr>
<td>Current use of long term corticosteroid</td>
<td>Uncontrolled hypertension, BP&gt;160/100</td>
</tr>
<tr>
<td>Uncontrolled seizure disorder</td>
<td>Inherited porphyria</td>
</tr>
<tr>
<td>Anemia (Hemoglobin &lt;8 gm%)</td>
<td></td>
</tr>
</tbody>
</table>

### Special precautions (where drug need to be used cautiously)

<table>
<thead>
<tr>
<th>Psycho - Social Situations (unsuitable for MMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woman unable to take responsibility for her condition</td>
</tr>
<tr>
<td>Language or comprehension barrier, inability to give informed consent</td>
</tr>
</tbody>
</table>
**Comparison: VA and MMA procedure**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Vacuum Aspiration</th>
<th>Medical Methods of Abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technique used</td>
<td>Uterine contents evacuated through a cannula attached to vacuum source (manual or electric)</td>
<td>Uterine evacuation with drugs (Mifepristone &amp; Misoprostol), a non-surgical method</td>
</tr>
<tr>
<td>Gestation limit of the technique</td>
<td>Can be used upto 12 weeks of pregnancy</td>
<td>Can be used upto 7 weeks of pregnancy</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>More than 98% effective</td>
<td>93-98% effective</td>
</tr>
<tr>
<td>Time taken for the procedure completion</td>
<td>5-15 minutes</td>
<td>May take 9-16 days</td>
</tr>
<tr>
<td>POC Check</td>
<td>POC are examined and confirmed immediately</td>
<td>POC may be expelled at home</td>
</tr>
<tr>
<td>Number of visits for the procedure</td>
<td>One visit</td>
<td>Require minimum 3 visits</td>
</tr>
<tr>
<td>Follow up visit</td>
<td>Not mandatory</td>
<td>Must to ensure completion</td>
</tr>
<tr>
<td>Anaesthesia used</td>
<td>Local Anaesthesia &amp; oral analgesics</td>
<td>Oral pain control medication</td>
</tr>
<tr>
<td>Procedure done by</td>
<td>Health care provider</td>
<td>Process similar to a miscarriage</td>
</tr>
<tr>
<td>Risk of cervical and uterine injury</td>
<td>Possible but rare</td>
<td>No risk of injury to cervix and uterus since no instrumentation is done</td>
</tr>
<tr>
<td>Post - procedure bleeding</td>
<td>Minimal</td>
<td>Post - medication bleeding usually heavy</td>
</tr>
<tr>
<td>Post - procedure pain</td>
<td>For a very short period</td>
<td>Pain could be intense and prolonged</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>Few hours</td>
<td>Few hours on each visit</td>
</tr>
<tr>
<td>Risk of fetal malformation</td>
<td>None</td>
<td>Potential risk exists</td>
</tr>
<tr>
<td>Cost involved</td>
<td>Cost effective as lesser resources required and lesser hospital stay</td>
<td>Cost of the drug used is still high to be affordable by all women</td>
</tr>
</tbody>
</table>

POC: Product of Conception
Acceptability to women
- lower levels of pain medication
- done in OPD setting (more acceptable than a hospital stay)
- woman awake during procedure
- noiseless procedure with MVA

Involvement of male partner
- Not allowed in the procedure room.
- Male partner could be fully involved in the whole process

Tissue samples for E.B
- 82% effective
- Not relevant

Summary
- Two drugs, namely, Mifepristone and Misoprostol is approved for use as per protocol for providing abortion services to women with pregnancy up to 7 weeks LMP.
- Medical Methods of Abortion is a simple, effective and safe non-surgical option for induced abortions and should be offered as an option to all women seeking abortion services within 7 weeks of pregnancy.

Drug Protocol, Follow-up and Contraceptive Services

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Content</th>
<th>Methodology</th>
<th>Materials &amp; Aids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explain the protocol MMA recognize and manage the side effects and complications</td>
<td>Protocols for administration and new concepts</td>
<td>Presentation</td>
<td>Flip chart</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion</td>
<td>Correct sequence of administration protocol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Role plays</td>
<td>Role plays</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Side effect exercise</td>
<td>'MMA Side Effect' cards</td>
</tr>
</tbody>
</table>
Steps Taken during the Preparation of a Woman for Medical Methods of Abortion:

- Provide counseling to the woman and obtain informed consent
- Perform clinical assessment including medical history and physical examination
- Discuss her contraceptive needs and services required
- Confirm her access to emergency health care services if required

General Counseling

While counseling, attention must be paid to the following points:

- Tell her about all the methods available for abortion and how each method differs from the other.
- Ask about her existing knowledge and beliefs about abortion options.
- Discuss her contraceptive needs and counsel her accordingly for a regular contraceptive after abortion.
- If she chooses Medical Methods of Abortion then inform her that she will have to sign a written consent for termination of pregnancy using medical methods.

Method-Specific Counseling / Basic Information on Medical Methods of Abortion If the method chosen by the woman is MMA, then she should be given following information related to MMA:

- It is non-invasive and non surgical
- The process is similar to a miscarriage
- She needs to make a minimum of three visits to the facility
- She has to follow a definite drug protocol
- She may have vaginal bleeding for 9-16 days
- She has to be ready for VA procedure in case of failure or excessive bleeding
- She has to stay within the accessible limits of the appropriate health care facility
- She has to be told about the side effects of the drugs, i.e, she may experience nausea, vomiting, diarrhea, etc.
- Potential teratogenic (harmful) effect on the fetus, if pregnancy continues
- Contact phone number and address to be given to her for emergency
- Signs and symptoms of when to seek care for emergencies
- During treatment, it is ideal to avoid intercourse to prevent infection or use barrier methods
Medical History & Physical Examination
Record the complete history of the woman including her menstrual, obstetric and contraceptive history and rule out all contraindications.

Physical Examinations:
- To check for pallor. If pallor exists, heavy bleeding during the procedure may worsen the condition and increase the risk of shock and ill health.
- Blood pressure
- Cardiovascular and respiratory system for any abnormality
  Pelvic examination (P/S & P/V) to:
  - Confirm the period of gestation
  - Rule out ectopic pregnancy, if possible
  - Identify any fibroids to take precautionary measures. (There is a possibility of increased bleeding, so counseling/warning about this would be prudent,
  - Look for any infection

Investigations:
- Recommended:
  - Haemoglobin
  - Complete Urine Examination
  - ABO Rh
- Optional:
  - Ultrasound is done only if :
    - Woman is unsure of LMP/ she has irregular periods and/or the uterine size and menstrual dates do not match
    - There is suspicion of ectopic pregnancy or fibroid during P/V examination

PROTOCOL FOR Medical Methods of Abortion

<table>
<thead>
<tr>
<th>VISIT</th>
<th>DAY</th>
<th>DRUGS USED</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>One (1)</td>
<td>• 200 mg Mifepristone orally</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Anti D, if Rh negative</td>
</tr>
<tr>
<td>Second</td>
<td>Two (2) or Three (3) For gestation upto 49 days:</td>
<td>• 400 mcg Misoprostol orally or vaginally</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For gestation upto 63 days:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 800 mcg Misoprostol sublingually or vaginally</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Analgesics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Home administration by the woman may be tried in some cases</td>
</tr>
<tr>
<td>Third</td>
<td>Fifteen (15)</td>
<td>• Confirm and ensure completion of procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Contraceptives</td>
</tr>
</tbody>
</table>
• Record her complete history, ruling out contraindications (as discussed in previous section) and noting any precautions
• Conduct a complete physical and pelvic examination
• Counsel her and obtain informed consent in Form-C
• Discuss contraceptive options with her
• Prescribe tablet Mifepristone 200 mg orally
• Give injection Anti-D 50 mcg to Rh negative women (with pregnancy of more than 6 weeks)
• Complete the follow up card and give it to her. Explain different sections of the card and what she needs to record on it

First Visit (Day1)

What to do

• Explain what she should expect after taking Mifepristone
• She must return for Misoprostol administration after two days
• She may have pain and bleeding during these two days
• She can take Ibuprofen to relieve the pain
• She should avoid intercourse or use barrier method, such as condoms
• Give her the contact address and phone number of the facility center where she can go in case of any emergency
• Explain to the woman that she should record her experience of any side effect on the follow up card given to her. Show her the back-up facility address and phone number on the card where she can go in emergency and explain signs and symptoms which could indicate seeking care
• She must return to the clinic after 48 hours on day 3
• Explain that a small percentage of women (3%) may expel products with Mifepristone alone, but total drug dosage schedule with Misoprostol must be completed

Instructions to woman

Mifepristone Misoprostol Protocol

200 mg mifepristone
Visit 1

400/800 µg misoprostol
Visit 2

Follow-up
Visit 3

Protocol Day
1 2 3 15

Mifepristone Misoprostol Protocol

Follow-up
Visit 3

Protocol Day
1 2 3 15

First Visit (Day1)
### Second Visit - Day 3

<table>
<thead>
<tr>
<th>What to do</th>
<th>Instructions to woman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note any history of bleeding/pain or any other side effects after Mifepristone</td>
<td>What she should expect to feel after Misoprostol administration</td>
</tr>
<tr>
<td>Take 2/4 tablets of Misoprostol (400/800 mcg) orally/sublingually/vaginally</td>
<td>She should avoid intercourse till the bleeding stops or use condoms</td>
</tr>
<tr>
<td>Keep her under observation for 4 hours in the clinic/hospital or if she wants to go home explain what to expect in the next few hours and what to do; keep her under observation if clinically necessary</td>
<td>She should use clean sanitary napkins</td>
</tr>
<tr>
<td>Monitor her pulse, blood pressure and any side effects during her stay</td>
<td>She should avoid tampons and douche</td>
</tr>
<tr>
<td>Prescribe drug for pain relief. Usually the pain starts within 1-3 hours of taking Misoprostol, so analgesic can be taken well in time before pain becomes intolerable. The commonly used drug is Ibuprofen</td>
<td>She should preferably avoid going out of station till the third visit</td>
</tr>
<tr>
<td>Receiving complete information during counseling and reassurance during the process helps the woman to tolerate pain. If pain does not subside on taking drugs, report to the doctor. In such cases, possibility of ectopic pregnancy/infection/incomplete abortion should be ruled out</td>
<td>She should report if there is no bleeding 24 hrs after Misoprostol intake. The doctor should consider several possibilities:</td>
</tr>
<tr>
<td></td>
<td>Rule out ectopic pregnancy and confirm intrauterine pregnancy</td>
</tr>
<tr>
<td></td>
<td>The drug may not have worked and/or more time is needed; repeating the dose may be an option</td>
</tr>
<tr>
<td></td>
<td>She can have side effects like:</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
</tr>
<tr>
<td></td>
<td>Vomiting (antiemetics usually not required)</td>
</tr>
<tr>
<td></td>
<td>Diarrhea (usually mild)</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Fever (if &gt; 100 degree F, medication advised)</td>
</tr>
<tr>
<td></td>
<td>Dizziness (if accompanied with heavy bleeding, should be evaluated for hypovolemia</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
</tr>
<tr>
<td></td>
<td>Report in case of excessive bleeding which means soaking 2 or more pads (average pads used normally during periods) per hour for 2 hours continuously. Mean period for bleeding is 9-16 days. Heaviest bleeding lasts 1-4 hours that coincides with the expulsion of POC</td>
</tr>
<tr>
<td></td>
<td>How to handle the expelled pregnancy tissue if it is passed when the woman is not at the clinic</td>
</tr>
<tr>
<td></td>
<td>She may see blood clots but it is unlikely that she will see anything resembling a foetus</td>
</tr>
<tr>
<td></td>
<td>She should return for follow up on the 15th day</td>
</tr>
</tbody>
</table>

- 75% women abort within 4-6 hours after Misoprostol administration
- 30% of the remaining abort later at home on the same day
- Rest mostly abort within the next 5 days
#### Third Visit - Day 15

<table>
<thead>
<tr>
<th>What to do</th>
<th>Instructions to woman</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Take clinical history and note related signs and symptoms</td>
<td>• Contraception after abortion</td>
</tr>
<tr>
<td>• Pelvic examination should be carried out to ensure the completion of abortion</td>
<td></td>
</tr>
<tr>
<td>• Ultrasonography should be advised if examination does not confirm the expulsion of POC or completion of procedure</td>
<td>• Hormonal methods, whether combined (estrogen and progestogen) or progestin-only, can be started as soon as the day of the Misoprostol administration (commonly day three of the combined Mifepristone-Misoprostol MMA regimen). These methods include oral contraceptives, injectable methods like depot medroxyprogesterone acetate, or DMPA</td>
</tr>
<tr>
<td>• The woman should not leave the facility without the contraceptive counseling and services</td>
<td>• IUCD can be inserted after confirmed complete abortion provided the presence of infection can be ruled out</td>
</tr>
<tr>
<td>• <strong>Follow up instructions:</strong> The woman should be counseled regarding prevention of sexually transmitted infections and HIV/AIDS.</td>
<td>• Condoms can be used as soon as she resumes sexual activity after abortion</td>
</tr>
<tr>
<td>• She should report back if there are no periods within 6 weeks of completion of the abortion process</td>
<td>• Female sterilization can be done after the first menstrual cycle</td>
</tr>
<tr>
<td>• <strong>Antibiotics:</strong> These are generally not prescribed routinely but should be given to a woman showing signs of infection</td>
<td>• Vasectomy, if chosen, can be done independent of the procedure</td>
</tr>
</tbody>
</table>

N.B. Skills Checklist for Provision of MMA is given in Annexure 1.
New Recommendations in CAC Training and Service Delivery Guidelines, MOHFW, 2010

<table>
<thead>
<tr>
<th>Previous recommendations</th>
<th>New recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol on day 3 after 48 hrs of mifepristone</td>
<td>Misoprostol on day 2-3 (24 to 48 hrs) after mifepristone</td>
</tr>
<tr>
<td>Misoprostol dose to be taken under supervision of the doctor and to stay at the clinic for four hours</td>
<td>Home use of Misoprostal vaginally or orally by women herself. This helps to prevent an additional visit of the woman to the hospital. It enables the woman to complete the drug protocol for better effectiveness and reduce chances of drug failure</td>
</tr>
<tr>
<td>Contraception on day 15-visit 3</td>
<td>Contraception with Misoprostol on visit 2</td>
</tr>
</tbody>
</table>

Side Effects and Complications and their Management

**Side Effects**
- Bleeding and cramping
- Severe vaginal bleeding
- Fever, warmth and chill
- Headache & dizziness

**Bleeding and cramping:**
- These are expected normal symptoms of the MMA process, and usually heavier than what is experienced during a menstrual period; the woman will experience symptoms resembling an early miscarriage. Bleeding often lasts for 9-16 days
- When discussing cramping, providers should refrain from describing cramping pains as similar to labor pains. Instead, pain can be compared to heavy or severe menstrual cramps. Sometimes it begins following ingestion of Mifepristone, but most often starts one to three hours after Misoprostol administration and is heaviest during the actual abortion process, often lasting up to four hours
Persistent cramping may be evaluated with other symptoms to exclude possible ectopic pregnancy.

Counseling and assurance helps the woman. Pain medication like NSAIDs or Opioids may be provided.

Woman may be advised to come to the clinic if she experiences pain associated with bleeding heavier than expected or with fever.

**Severe vaginal bleeding:**
- May be accompanied by clots
- Treated by vacuum aspiration
- Heavy bleeding requiring transfusion is rare. A US based study found out that of 80,000 women who received Mifepristone and Misoprostol for MMA, only 13 received blood transfusion (Hausknecht, 2003).
- Soaking of two thick average sized pads per hour after taking Misoprostol, with decreasing flow over time is normal. Soaking two or more than two pads per hour for two consecutive hours need close monitoring of the woman.
- Severe bleeding and prolonged heavy bleeding requires immediate attention.

**Gastrointestinal side effects:**
- Diarrhoea, nausea and vomiting are commonly reported by women following the use of Misoprostol.
- These side effects are mild and self limiting and pass off without any treatment.
- Antiemetic and anti-diarrhoeal medicines may be prescribed when needed.
• **Fever, warmth and chill:**
  - Fever, feeling of warmth and chill are short-lived side effects. Treatment for this is generally not required but the woman should know that she may experience these symptoms.
  - Post-abortion infection is rare after MMA. Persistent fever may indicate infection and must be evaluated and treated accordingly with broad-spectrum antibiotics.

• **Headache and dizziness:**
  - Mild side effect of MMA. Approximately one-fifth of women studied reported headache and dizziness associated with MMA. (Honkanen, 2004)
  - Headache is treated with non-narcotic analgesics and mild dizziness of short duration is managed by hydration-advising the woman to take plenty of fluids, rest and by exercising caution while changing position.
  - Women with dizziness and heavy bleeding should be treated for hypovolemia

• **Complications and Management**
  Complications of Medical Methods of Abortion are:
  - Failed abortion
  - Haemorrhage
  - Infection

• **Failed Abortion**
  - If the woman has not expelled the pregnancy by the time of her follow-up visit and the uterus remains soft and bulky
  - Confirm the status of pregnancy by ultrasound. Pregnancy is said to be viable if the gestation sac is complete with active cardiac activity.
  - If the gestation sac is seen but it is non-viable, then expectant management may be offered to the woman:
    - Wait for the pregnancy to be expelled naturally with time without any further intervention
    - Alternatively, an additional dose of Misoprostol may be provided to her
    - Proper counseling of the woman is required to comply with return visits if she does not want any intervention
– The woman should be willing to return to the clinic after one week to ensure that the abortion is complete
- If the woman does not wish to return for follow up visits or has continued viable gestation sac or heavy bleeding, vacuum aspiration may be performed to remove products of conception (POC)

• **Hemorrhage**
  - Acute hemorrhage associated with Medical Methods of Abortion in the absence of any physical trauma to the pelvic organs should be managed with vacuum aspiration
  - Fluid replacement with Ringers lactate solution IV infusion at 30 drops per minute depending on the general condition of the woman to be started
  - In some cases blood transfusion may be required. Refer the woman to a higher facility for management

• **Infection**
  - Infection of uterus is rare in Medical Methods of Abortion
  - If POC are retained and the woman has symptoms like fever, chill, foul smelling discharge or bleeding and pain in lower abdomen, uterine infection may be suspected
  - Start broad spectrum antibiotics as soon as possible and remove the POC using vacuum aspiration
Sharing Experience of MMA Service Provision

<table>
<thead>
<tr>
<th>Share experience of providing medical methods of abortion services</th>
<th>Experience of service providers</th>
<th>Questions and Answers</th>
<th>Blank flipcharts, markers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Management of problems</td>
<td>- Discussion</td>
<td></td>
</tr>
</tbody>
</table>

Practical problems encountered during initiation or provision of MMA services in the Public Sector in India are related to:

A. **Non-availability of drugs**
Non-availability of MMA drugs - Mifepristone and Misoprostol at the Health Centre

B. **Use of wrong protocol of drugs**
- Provision of MMA drugs without prescription by chemists and illegal providers like nurses, ANMs, ISMPs in inadequate doses or inappropriate drugs
- Self medication by women through their husbands in inadequate dose or inappropriate drugs
- Prescription of drugs using varied protocols by doctors (trained)
- Inappropriate period of gestation for the use of MMA drugs

C. **Consequences of irrational use of MMA drugs**
Complications of MMA:
- Failed abortion (continuing pregnancy or incomplete abortion)
- Heavy bleeding with or without shock
- Infection

**Common problems and their possible solutions are listed below:**

**Problem: Non-availability of MMA drugs - Mifepristone and Misoprostol at the Health Centre**
**Possible Solution:**
Drugs should be procured from the government procurement system.
Problem: Provision of MMA drugs without prescription by chemists and illegal providers like nurses, ANMs, ISMPs in inadequate doses or inappropriate drugs
Possible Solution:

It is also envisioned that once the unauthorized providers become aware of the legal issues related to abortion service provision and the liable punishment, they may also act as link persons to refer the women to the appropriate place for such services.

Problem: Self medication by women through their husbands in inadequate dose and inappropriate drugs
Possible Solution:

- IEC effort and community workers counseling may help empower the women and communities to understand the dangers of receiving abortion services from unsafe providers and take recommended actions of seeking services at your centres which they will know are safe and close to their home. This will prevent unnecessary deaths and ill health of women from use of inappropriate drugs.
- Availability of drugs at your clinic will also assure that women get proper and adequate dose and protocol.

Problem: Prescription of MMA drugs using varied protocols by doctors (trained)
Possible Solution:

The purpose of this refresher course on MMA is to strengthen your knowledge and skills once again. This will help you provide the drugs in adequate dose and protocol as per GoI recommendations.
Problem: Inappropriate period of gestation for the use of MMA drugs

Possible Solution:

- Once knowledgeable and trained providers start providing MMA services after appropriately screening the women for eligibility (up to 7 weeks of pregnancy from the LMP) chances of failure of MMA will be less.
- Women will also become aware of the duration of pregnancy for the effectiveness of MMA drugs. They may come for services early to avoid a surgical procedure later.

Important Points to be Emphasized During Provision of Medical Methods of Abortion

- Minimum three visits to the facility will be required
- Definite drug protocol to be followed
- Bleeding may be present for 9-16 days
- The woman should be ready for evacuation by VA if failure or excessive bleeding occurs
- The woman should be able to reach an appropriate health care facility within a short time
- Contact the doctor immediately in case of emergency
- Understand the side effects of drugs, recognition of warning signs and to contact the doctor immediately
- Once initiated, the process of abortion has to be completed to avoid even a slight risk of congenital defects in a continuing pregnancy
Bibliography

Annexures
Annexure - 1

**Medical Methods of Abortion Skills Checklist**

**Note:** The provider may use this checklist to observe their own skills while performing MMA services with women in the clinic. Write 'yes' or 'no' if the task was done or not respectively in the appropriate column. If the task was performed but was not as per standards, mark 'yes' and write about the quality of the task performed in the column for comments. To mark a task with subtasks, all the subtasks need to be performed correctly to mark 'Yes'. Write the comment if improvement is required or a subtask was not performed as per standards.

<table>
<thead>
<tr>
<th>Day 1 - Skills required during first visit to clinic (Mifepristone Administration)</th>
<th>Yes / no</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre -procedure tasks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greet the woman in a friendly, respectful manner; ensure privacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm with her that she wants to terminate her pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain what to expect during the clinic visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask if she has come with someone and if she would like that person to join her in the counseling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask about her general health, reproductive and medical history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain which abortion methods are available, including characteristics, effectiveness and the timing/visits required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm that she is eligible for Medical Methods of Abortion (Pregnancy upto seven weeks)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the woman chooses Medical Methods of Abortion, provide more information on the method in simple way</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clarify the woman's feelings on the possibility of having the abortion at home and ask what support she has at home</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ensure that she understands:
- Common side effects
- Importance of attending required clinic visits
- Warning signs indicating the need to return to the clinic

Explain how the Mifepristone and Misoprostol will be administered and what to expect after taking it

Explain that if the Medical Methods on Abortion fails, vacuum aspiration will be necessary to terminate the pregnancy

Ask the woman whether she has additional questions

Obtain written informed consent

**First dose for MMA**

Provide Mifepristone one tablet 200 mg orally

**Post-procedure tasks**

Explain how to take pain-management medications (analgesics), if needed

Explain what to do in case of problems

Explain how to record the side effects experienced, if any on the follow up card, and the details of the clinic where she may go in case of an emergency

Return to the clinic for the second dose after one-two days
### Day 3 - Skills required during second visit to clinic (Misoprostol Administration)

<table>
<thead>
<tr>
<th>Pre-procedure tasks</th>
<th>Yes / no</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greet the woman in a friendly, respectful manner; ensure privacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain what to expect during the clinic visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inquire about the woman’s experience since taking Mifepristone (bleeding, passage of POC, discomfort, side effects). Check the follow up card</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Second dose for MMA

Administer Misoprostol in clinic (per protocol) 2/4 tablets one after the other sublingually/vaginally/orally

<table>
<thead>
<tr>
<th>Post-procedure tasks</th>
<th>Yes / no</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask the woman to rest in the clinic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observe the woman in the clinic for bleeding, cramping, expulsion of POC for at least four hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the woman leaves the clinic before she aborts, provide her (pain medication, written instructions) for aborting at home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain how to record her experience of any side effect on the follow up card and remind her of the address and contact number of the clinic to visit in case of emergency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record the date of Misoprostol administration in her records and on card and counsel the woman to come for a follow-up visit on day 15. Reinforce how to fill the card</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask the woman if she has any additional questions and clarify</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Day 15 - Skills required during third visit at clinic (Follow-Up)

<table>
<thead>
<tr>
<th>Pre-procedure tasks</th>
<th>Yes / No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greet the woman in a friendly, respectful manner; ensure privacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain what to expect during the clinic visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inquire about the woman’s experience with the abortion process, asking her if she saw the expulsion of any POC and feel that the abortion is complete. Ask whether the woman is still having symptoms of pregnancy. Check the follow up card for any symptoms marked</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Assessment to ensure abortion is complete**

Assess the completeness of the abortion by:

- Taking a history of the abortion process (amount and duration of bleeding, side effects, cramping, any visible parts of POC expelled)
- Conducting a physical examination (pelvic examination to assess the size and consistency of the uterus and opening of the cervical os)
- If it is still unclear whether the abortion is complete, advise/perform an ultrasound, to assess the presence of gestation sac

If the abortion is not complete, discuss treatment options: expectant management or vacuum aspiration

If the pregnancy is continuing:

- Discuss need for vacuum aspiration to terminate it
- Arrange to complete the procedure by MVA

**Post-procedure tasks**

If the abortion is complete, provide:

- Information on how to contact the clinic if she has questions or problems]
- Information about return to fertility
- Explain risks of repeated induced abortions
- Counsel regarding contraception and provide method desired by the woman

Ask the woman if she has any additional questions and clarify them

Explain to the woman that she can come back to the clinic whenever she has any problem
Annexure - 2

Medical Methods of Abortion Refresher Course
Pre-training Assessment

A. Please mark a tick ‘✓’ in the column of the correct response for the following statements:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Statement</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Medical Methods of Abortion is a safe way to end an early pregnancy by taking some specific medications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Medical Methods of Abortion is another method to vacuum aspiration and dilatation and curettage to terminate early pregnancy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Medical Methods of Abortion is not safe as it may lead to many dangerous side effects and complications.</td>
<td></td>
<td></td>
</tr>
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<td>4.</td>
<td>Medical Methods of Abortion may affect the woman’s future fertility, menstrual cycle and sexual activity adversely.</td>
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<td></td>
</tr>
<tr>
<td>5.</td>
<td>A physical examination of the woman is not required to provide MMA services.</td>
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</tr>
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<td>6.</td>
<td>A written consent of the woman seeking Medical Methods of Abortion is mandatory on the prescribed format.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>The tablet Mifepristone can cause congenital anomalies.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>A minimum of four visits are recommended to complete the Government of India’s standard drug protocol.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>After Medical Methods of Abortion, contraception can be started immediately after confirming that the abortion is complete.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Fertility can return within 10 days of an abortion.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. Match the statement/word in Column I with the correct corresponding statement / word in Column II.

<table>
<thead>
<tr>
<th>S.No</th>
<th>I</th>
<th>II</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>Only a Registered Medical Practitioner can prescribe</td>
<td>63 days (9 weeks)</td>
</tr>
<tr>
<td>2.</td>
<td>WHO recommends use of MMA upto</td>
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<td>4.</td>
<td>Misoprostol</td>
<td>MMA drugs</td>
</tr>
</tbody>
</table>
C. Complete the following statements by circling one correct option provided in the bracket:

1. During MMA, pain management to the woman is usually provided by giving her (Tablet Ibuprofen / Injection Diazepam / local anesthesia).

2. Effectiveness of Medical Methods of Abortion is (95-99% / 80% / 82-83%).

3. In India, it is (legal / Illegal) to buy tablets of Mifepristone and Misoprostol over-the-counter from a chemist shop.

4. Cramping and bleeding are (acceptable / unacceptable) with MMA drugs.

5. Most women abort within (4 hours / ½ hour / 1 hour) of taking Misoprostol.

6. The heaviest bleeding occurs during the (actual abortion / immediately after Mifepristone / after the abortion).

7. Decrease in bleeding, cramping and nausea are signs of (completion / failure) of abortion.

8. After giving MMA tablets, the woman should be called for follow-up on Day (7/ 15/ 20).

9. Confirmation of completion of abortion, excluding infection is done during the (second / third / fifth) follow up visit.

10. The instructions given to the woman after providing the tablets for Medical Methods of Abortion are (what side effects to expect/ that she may find it difficult to get pregnant again/ that she should not take bath for 2 weeks).
Medical Methods of Abortion Refresher Course
Post-training Assessment

A. Please mark a tick ‘✓’ in the column of the correct response for the following statements:

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10. The instructions given to the woman after providing the tablets for Medical Methods of Abortion are (what side effects to expect/ that she may find it difficult to get pregnant again/ that she should not take bath for 2 weeks).
Please Answer in Brief

1. What did you like MOST in the workshop?
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

2. What did you like LEAST in the workshop?
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........................................................................................................................................
........................................................................................................................................

3. Suggestion for future workshops
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................