





FOGSI - ICOG Good Clinical Practice Recommendations GCPR

MTP Upto and Beyond 24 Weeks' Gestation

Convenor – Richa Sharma Co-Convenor – Asish Mukhopadhyay Mentors – Hrishikesh D Pai, Madhuri Patel, Laxmi Shrikhande Advisors – Sanjay Gupte, Hema Divakar National Co-ordinators – CN Purandare, Rishma Dhillon Pai, Nandita Palshetkar, Jaydeep Tank Co-ordinator – Surekha Tayade

Medical Termination of Pregnancy Committee

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Fogsi Good Clinical Practice Recommendations

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ICOG Co-Convenor	: Asish Mukhopadhyay
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Disclaimer: These recommendations for FOGSI GCPR on MTP up to and beyond 24 weeks' gestation has been developed for assistance of obstetricians, gynecologists, consulting physicians, and general practitioners providing guidance and recommendation for managing medical termination of pregnancy (MTP). The recommendations included here should not be viewed as being exclusive or other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. Since MTP is governed by an act and rules which are open for judicial interpretation as well as amendments, each clinician is expected to practice MTP as per the law and also provide the best care possible with necessary safety precautions and own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.

AIM OF THE DOCUMENT

The medical termination of pregnancy (MTP) is governed by the MTP Act, so the main purpose of this document is to provide good clinical practice points for safe MTP within the purview of MTP Act.

The MTP Act amendment 2021 has further empowered women and expands the access to safe and legal abortion services to ensure universal access to comprehensive abortion care. It includes improved access to unmarried women, increased gestational upper limit to 24 weeks and beyond 24 weeks ((with the permission of the medical board) with no gestational upper limit in the cases of fetal congenital malformations only.

SCOPE OF THE DOCUMENT

This guidance aims to provide recommendations to registered medical practitioners, organizations and professional societies, health workers, and other stakeholders in the field of sexual and reproductive health and rights (SRHR). This document also provides recommendations for national and subnational policymakers and implementers.

METHODOLOGY

The recommendations were developed after extensive literature search, identified using the search engines such as PubMed, Medline, Embase, Science Direct, and Google Scholar. According to the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach, this update does not generate a universal level of evidence. However, each section and the generated recommendations use the degrees of evidence that were identified in the bibliographic review.

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from the multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
В	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation, but should remain alert to new information and sensitive to patients' preferences
С	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patients' preference should have a substantial influencing role
D	Option	Level V evidence: little or no systematic empirical evidence	Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patients' preference should have a substantial influencing role

Grade of Practice Recommendations

Levels of Evidence

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Level	Type of evidence
Level 1: (higher quality of evidence)	High-quality randomized controlled trial (RCT) or prospective study, values obtained from many studies with multiway sensitivity analyses; systematic review of Level I RCTs and Level I studies
Level 2	Lesser quality RCT; prospective comparative study; retrospective study; untreated controls from an RCT, systematic review of Level II studies or Level I studies with inconsistent results.
Level 3	Case-control study (therapeutic and prognostic studies), retrospective comparative study, systematic review of Level III studies.
Level 4	Case series; case-control study (diagnostic studies)
Level 5 (lower quality of evidence)	Expert opinion.

INTRODUCTION

Abortion is a common health intervention. Six out of 10 (61%) of all unintended pregnancies, and 3 out of 10 (29%) of all pregnancies, end in induced abortion. Globally, around 73 million induced abortions take place each year and nearly 1 out of 2 (45%) abortions are unsafe.

Abortions account for 8% of maternal mortality ratio (MMR) in India and nearly 10 women reportedly die due to unsafe abortions every day in India.¹⁻³ Access to safe and legal abortion is an essential part of sexual and reproductive health services.

The cost of the abortion service in India is covered fully by the government's public national health insurance funds, Ayushman Bharat, and Employees' State Insurance (ESI).

MTP ACT WITH AMMENDMENTS⁴

1. WHO SHOULD DO MTP: PERSON ELIGIBILITY

Registered Medical Practitioner (RMP) meaning Practitioner with recognized MBBS/PG degree or diploma (as defined in the Indian Medical Council Act, 1956) and name has been entered in a state medical register.

1.1 RMP with PG Degree or Diploma in Obstetrics & Gynecology

[Can do MTP at any gestational age]

1.2 RMP – MBBS

[Can do MTP after specific training]

1.2.1 MTP up to 9 weeks by medical method only -

If having an experience of at least 3 months at any hospital in Obstetrics and Gynecology or has independently performed 10 cases of MTP by the medical method of abortion (MMA) under the supervision of RMP, in a hospital established or maintained by the government or government-approved training center.

1.2.2 MTP up to 12 weeks by medical and surgical method

If they have assisted 25 cases of MTP out of which at least 5 has been done independently in a hospital established or maintained by the government or government-approved training center.

1.2.3 MTP up to and beyond 24 weeks

One year experience in Obstetrics and Gynecology or 6 months house job in Obstetrics and Gynecology.

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1.3 Who and how many RMPs should give the opinion for MTP -

[Note: RMP must fulfill the criteria as above]: See points 1.1 to 1.2.3.

- 1. MTP <20 weeks: 1 RMP opinion.
- 2. MTP between 20 weeks and 24 weeks: Not less than 2 RMP opinion.
- 3. Beyond 24 weeks: Medical board decision [Note: After 24 weeks, two RMPs should perform the MTP].
- 4. In order to save the life of mother, MTP can be done at any place (registered or unregistered) and the opinion of two RMPs is not applicable. RMP must inform the authority within 24 hours of such termination under section 5 of the MTP Act.

1.4 Medical Board

1.4.1 Members

Gynecologists, pediatricians, radiologists, and any other members as notified by the government.

1.4.2 Functions

- 1. To examine the woman and her reports.
- 2. Provide the opinion of Medical Board in Form D (rejection or approval) within 3 days of receiving the request for MTP.
- 3. To ensure that MTP, when advised by the Medical Board, is carried out with all safety precautions along with appropriate counseling within 5 days of the receipt of the request.

1.4.3 Powers of Medical Board

- 1. To allow or deny MTP beyond 24 weeks of gestation.
- Only after due consideration and ensuring that the procedure would be safe for woman at that period of gestation (POG) and whether fetal malformation has a substantial risk of it being incompatible with life; or, if the child is born, it may suffer from such physical or mental abnormalities to be seriously handicapped.
- 2. Co-opt other specialists in the Board and ask for any additional investigations if required, for deciding on the termination of pregnancy.

2. WHEN MTP SHOULD BE DONE: INDICATIONS

2.1 Up to 20 Weeks

- 1. In order to save the life of the pregnant woman.
- 2. In order to prevent grave injury to the physical and mental health of the pregnant woman.
- 3. In view of the substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.
- 4. As the pregnancy is alleged by the pregnant woman to have been caused by rape.
- 5. As the pregnancy has occurred as a result of the failure of any contraceptive device or methods used by a woman or her partner for the purpose of limiting the number of children or preventing pregnancy.

2.2 Between 20 Weeks and 24 Weeks

- 1. Survivors of sexual assault or rape or incest
- 2. Minors
- 3. Change of marital status during the ongoing pregnancy (widowhood and divorce)
- 4. Women with physical disabilities
- [Major disability as per the criteria laid down under the Rights of Persons with Disabilities Act, 2016 (49 of 2016)]
- 5. Mentally ill women including mental retardation
- 6. Fetal malformation that has a substantial risk of being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped
- 7. Women with pregnancy in humanitarian settings or disaster or emergency situations as declared by the government.

2.3 Beyond 24 Weeks

2.3.1 For fetal malformations only FETAL

- 1. Malformations that are incompatible with life or the risk of physical/mental abnormalities that can lead to serious handicapped after birth.
- 2. Only after due consideration and ensuring that the procedure would be safe for the particular woman at that particular gestational age.
- 3. *Medical Board's discretion:* There is no gestational upper limit, provided the Medical Board gives the permission.
- 4. This implies that any other case requiring MTP, e.g. rape, that exceeds 24 weeks, the only recourse remains through a **Writ Petition.**

3. WHERE MTP SHOULD BE DONE: PLACE

- 3.1 Hospital established or maintained by the government (no separate registration needed):
 - Primary Health Center (PHC): Up to 8 weeks
 - Community Health Center (CHC): Up to 12 weeks
 - District Hospital: Up to 20 weeks
 - Medical College: Any POG (up to 24 weeks & beyond).
- 3.2 Private health facility which are approved by the government, i.e. District Level Committee (DLC).
- 3.3 For MTP up to 9 weeks, the MMA drugs can be prescribed by an RMP at his/her clinic, provided such an RMP has access to a place which is approved for MTP (under Section 4 of the MTP Act, 1971 read with MTP Amendment Act, 2002 and Rules 5 of the MTP Rules) and should display a certificate to this effect from the owner of the approved place.

4. CENTER APPROVAL BY DISTRICT LEVEL COMMITTEE

The government health facilities are approved for MTP, no separate approval is needed by DLC, but all private health facilities need to get their centers approved for MTP. Approval depends upon the infrastructures. Form A has to be filled and necessary documents must be attached – hospital registration certificate, owner's photo, RMP degree/diploma/ MBBS degree with specified training certificate and Medical Council of India (MCI) or state medical registration certificate, anesthetist's degree and registration certificates, and affidavit undertaking specifying RMP and anesthetists are consultants in the particular health facility. Approval is given in Form B. This form should be displayed in the area where MTP services are scheduled (*See* Form A and B – **Annexures 1 and 2**)

4.1 Infrastructure Requirement up to 12 Weeks (Category A)

- 1. Gynecology examination/labor table
- 2. Resuscitation and sterilization equipment
- 3. Drugs and parenteral fluids for emergency use, notified by the Government of India from time to time
- 4. Back-up facilities for the treatment of shock
- 5. Facilities for transportation.

4.2 Infrastructure Requirement up to 24 Weeks (Category B)

- 1. Operation table
- 2. Instruments for performing abdominal or gynecological surgery
- 3. Anesthetic equipment
- 4. Resuscitation and sterilization equipment
- 5. Drugs and parenteral fluids for emergency use
- 6. Facilities for transportation.

4.3 Infrastructure Requirement Beyond 24 Weeks

- 1. Operation table and instruments for performing abdominal or gynecological surgery.
- 2. Anesthesia equipment, resuscitation, and sterilization equipment.

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- 3. Availability of drugs, parenteral fluids, and blood for emergency use, as may be notified by the Central Government from time to time.
- 4. Facilities for the procedure under ultrasound guidance.

Once approval is given, it is permanent and renewal is not required, but periodic inspections will be there. The Chief Medical Officer (CMO) can recommend to cancel/suspend the approval, based upon the inspections.

Report to the DLC and they may suspend or cancel the approval after hearing from the owner.

4.4 Reasons for Cancellation of Registration

- 1. If the place is not maintained properly and MTPs are not done under safe and hygienic condition.
- 2. If there was death or injury to a pregnant woman due to unsafe and unhygienic conditions, can seek any information or seize any article, medicine, admission register, or other documents,

5. DOCUMENTATIONS (ANNEXURES 3 TO 8)

It is mandatory to fill all 4 forms, whenever MTP of a normally localized and live pregnancy is done. Forms need not be filled in the cases of ectopic pregnancy, missed or incomplete abortion, etc. Record all the information in the following forms, irrespective of the technique of abortion, i.e. MMA or surgical and also irrespective of any trimester.

5.1 Consent Form

5.1.1 Form C

The consent of a woman is sufficient provided she is more than 18 years and mentally sound, the consent of husband or male partner is desirable, but not mandatory. If she is <18 years or mentally ill, then the guardian must give the consent. The guardian need not be blood related but can be anyone taking care of that patient.

5.2 Opinion Form

- 1. For MTP <20 weeks of gestation: FORM I
- 2. For MTP between 20 weeks and 24 weeks of gestation: FORM E
- For MTP >24 weeks of gestation: FORM D by the Medical Board.
 Form I or Form E should be filled within 3 hours of MTP (both by surgical and MMA).

5.3 Form II

Monthly Reporting Form (previous month data must be sent to the district CMO, within the first week of every month).

5.4 Form III

Admission Register for case records (all the cases of surgical as well as medical method of termination of pregnancy must be entered).

It is a secret document, do not open to all, but open under the authority of law, confidentiality has to be maintained, keep under the custody of owner/head of hospital and preserve for a period of 5 years, from the last entered case.

5.5 Custody of Forms

Duly filled Form C and Form I/E must be placed in an envelope and sealed by an RMP, to be kept in safe custody until it is sent to the head of the hospital or the owner of the approved place.

5.6 Confidentiality

A *"Serial number*" should be assigned to all the MTP seekers, according to the current year Form III or "*Admission register*". All subsequent records including discharge card should mention the same serial number and not the name.

5.6.1 In case a woman needs named documents or medical certificate with her name for abortion leaves or reimbursements, then a letter of request must be taken from the woman and the document must be handed over to her only [not applicable for the Protection of Children from Sexual Offences (POCSO) cases, see below].

5.6.2 If the patient is a minor or mentally ill, then a letter of request must be taken from the guardian and the document must be handed over to the guardian only.

5.7 MTP – POCSO Mandate⁵

5.7.1 Under the POCSO Act, any minor girl (<18 years) is not eligible to consent to sexual intercourse, so a pregnant minor girl married or unmarried is considered a victim of sexual assault. It is mandatory to Report to the Police (failure to report shall be liable for 6 months imprisonment). Reporting to the police can be done by dialing 1098 or 100, on the letter head, or a case sheet of the patient. Take the receiving signature from the authority, keep this document for your medicolegal safety.

According to the National Commission for the Protection of Child Rights (NCPCR), providing Medicolegal Certificate (MLC) to authorities is sufficient on our part, to comply with the reporting requirements of the POCSO Act. Need not wait for the police procedure to complete before MTP, but legal proceeding can continue simultaneously. The products of conception (POC) preservation is to be done by the service provider and to be kept in refrigerator, till it is handed over to the police.

There is a Supreme Court order 2022, bench of Justices DY Chandrachud, AS Bopanna, and JB Pardiwala: the benefit of Rule 3B (b) is extended to all women aged below 18, indicates that: "*Registered Medical Practitioners (RMPs) need not disclose the identity of the minor to the police [as is mandated under Section 19(1) POCSO Act] if requested in writing by the minor and her guardian"*.

Irrespective of whether the minor is married or otherwise, states her consent or otherwise, the RMP must report such an incidence to the police and take the acknowledgement of the same.

5.7.2 Pregnancy due to nonconsensual sexual activity⁶

The police should be informed, remember three points:

- 1. Ask the police to collect DNA Kit from the forensic laboratory (FSL) and bring it to the hospital at the time of MTP. DNA Kit is used to collect the blood sample of the victim, fill the form, and paste her photograph.
- 2. POC should be rinsed with normal saline and collected in a container brought from the forensic laboratory and must be sealed and labeled.
- 3. POC) should be handed over to the police, to be transported in ice-box, at 4°C to the FSL for identifying the accused.

6. CLINICAL ASSESSMENT

Detailed history, general physical examination, pelvic examination, and investigations.

6.1 Mandatory Investigations before MMA (Up to 9 Weeks)

Hemogram, urine examination for albumin and sugar, blood grouping and Rh typing. Ultrasonography is not mandatory but can be considered in early gestation if clinical findings are inconclusive and to rule out cesarean scar pregnancy and ectopic gestation.

6.2 Investigations before surgical or second trimester terminations

Apart from mandatory investigations, other investigations should be considered, based on case selection. Ultrasonography should be considered for the diagnosis of fetal congenital or uterine anomalies and placental conditions.

7. ANTIBIOTIC PROPHYLAXIS

7.1 Medical Method of Abortion

Antibiotic prophylaxis is not needed for the women undergoing medical abortion, unless otherwise indicated or in the cases of nulliparous women or having any focus of infection, must receive antibiotics which are effective against *Chlamydia trachomatis*, anaerobes, and *Neisseria gonorrhoeae*.⁷⁻⁹

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7.2 Surgical Termination of Pregnancy

Antibiotic prophylaxis at the time of first trimester surgical abortion is effective in preventing postabortal upper genital tract infection (GTI). Antibiotic choice should take into consideration the local epidemiology of GITs including sexually transmitted infections (STIs). The use of nitromidazoles (e.g., metronidazole), tetracyclines, and beta lactams causes reduction in post-abortion infection. However, local policies should be used to determine which of these is most appropriate.¹⁰

7.3 Regimens

[World Health Organization (WHO) 2022, Royal College of Obstetricians and Gynaecologists (RCOG) 2022] **7.3.1** Tab. Azithromycin 1 g + Tab. Metronidazole 800 mg (at the time of abortion) or

7.3.2 Tab. Doxycycline 100 mg BD × 3 days or 7 days (starting on the day of abortion) + Tab. Metronidazole 800 mg at the time of abortion or within 2 hours of the procedure, evidence suggest that a 3-day course is as effective as a 7-day course).

8. PAIN MANAGEMENT

8.1 Medical Abortion

8.1.1 Nonsteroidal anti-inflammatory drugs (NSAIDs) or Acetaminophen: Use if and when wanted.

8.1.2 Tab. Tramadol 50 mg or Ibuprofen 400 mg with Tab. Metoclopramide 10 mg coadministered with misoprostol and repeated 4 hours later resulted in lower mean maximum pain scores in MMA \leq 63 days of gestation[**Level of evidence 1**].¹¹ 8.1.3 Tab. Ibuprofen 1,600 mg, as a single dose given with Misoprostol prophylactically, or in response to pain as needed was shown to be effective in medical abortion <14 weeks of gestation [Cochrane 2022 low- to very low-certainty evidence].¹²

Epidural anesthesia can be considered for medical abortion (if available) for more than 12 weeks of gestation.⁷

8.2 Surgical Abortion at any Gestational Age

8.2.1 NSAIDs Ibuprofen 600–800 mg orally, 30–60 minutes before the procedure. Paracervical block or the combination of conscious sedation plus paracervical block.

8.2.2 General anesthesia usually is not recommended but can be considered in cervical stenosis, nulliparous women or adolescent girls, anxiety, etc.

8.2.3 The combination of intravenous (IV) fentanyl 100 μg and midazolam 2 mg is effective in reducing pain associated with the first-trimester surgical abortion (GRADE 1B) (Table 1).¹³

Drugs	Initial dose		Incremental dose	
	Usual	Maximum	Usual	Maximum
Fentanyl (opioid analgesic)	50–100 µg	200 µg	50–100 μg	100 µg
Midazolam (benzodiazepine sedative)	1–3 mg	4 mg	1–2 mg	2 mg

 Table 1
 Recommended dosing for commonly used medications for mild-moderate sedation^{13,14}

8.2.4 Conscious sedation (2 mg midazolam and 25 µg fentanyl) IV 5 minutes before cervical dilatation and paracervical block 2 minutes later, significantly improved patient satisfaction during the termination of first trimester by suction evacuation under local anesthesia, despite a lack of improvement in pain relief and the presence of increased severe dizziness/drowsiness in the postoperative period [Level of evidence 1].¹⁵

8.2.5 Low-risk patients undergoing surgical abortion in the first and second trimesters may safely receive moderate or deep sedation without routine endotracheal intubation (Level of evidence 1, Grade C).¹³

8.2.6 Patients receiving sedation and analgesia should be monitored by pulse oximetry both during and after surgery to detect oxygen desaturation and hypoxemia (Level of evidence 1, Grade C).¹³

8.2.7 Premedication with 4 mg betamethasone IV followed by sedation and peripheral block, results in significantly less intraoperative and postoperative pain and the greater degree of satisfaction [Level of evidence 1].¹⁶

8.2.8 Deep sedation without intubation during the first trimester of pregnancy suction evacuation, require the use of sedatives. Sedation with intranasal dexmedetomidine (1 μ g/kg), an α 2-adrenorecepter agonist provided effective analgesia and anxiolysis, reduced consumption of propofol and lower blood loss in the termination of first trimester pregnancy by suction evacuation, higher satisfaction scores with no unforeseen perioperative respiratory and cardiovascular adverse events.¹⁷

9. ADDITIONAL DRUGS

9.1 Iron, Folic acid

9.2 Anti-D 50–300 µg to unsensitized Rh negative women

9.3 In the cases of MMA injection (inj) Anti-D, should be given with Tab. Mifipristone [GOI]^{18,19}

9.4 In medical or surgical MTP, Inj. Anti-D should be given [American College of Obstetricians and Gynecologists (ACOG) Level C recommendations]

9.5 There is unclear benefit from the recommendation for Rh testing and immunoglobulin administration among women seeking abortion at less than 12 weeks of gestation [Level I, Grade C]

9.6 For both medical and surgical abortion at <12 weeks: anti-D immunoglobulin administration should not be considered [WHO 2022]

9.7 Inj. TT (tetanus toxoid) must be considered in unimmunized woman.

10. METHODOLOGY

10.1 Medical Method of Abortion (MMA)

10.1.1 MMA typically means the medical method of abortion up to 9 weeks on an outpatient department (OPD) basis. Mifepristone + Misoprostol (1 tab mifepristone 200 mg + 4 tablets misoprostol 200 µg each) combipack has been approved by the Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, for the medical termination of intrauterine pregnancy (MTP) for up to 63 days of gestation. The combination of mifepristone and misoprostol has a success rate of 95–99% for early abortions.

10.1.2 Patients with twin gestations can be treated with the same regimens as those with singleton gestations.

10.1.3 Between 9 weeks and 12 weeks of gestation, the surgical method of abortion is to be considered and in the second trimester MMA (mifipristone & misoprostol) is not approved in India [GOI].

10.1.4 Women should be offered the choice of medical or surgical methods of abortion between 13⁺⁰ and 23⁺⁶ weeks of gestation, unless not clinically appropriate [National Institute for Health and Care Excellence (NICE) 2020].

10.2 Indications for Admission in MMA

- 1. Pregnancy with uterine scar: Lower segment cesarean section (LSCS), hysterotomy, or myomectomy.
- 2. Controlled diabetes, hypertension (HTN), asthma, and epilepsy.
- 3. Large fibroid encroaching on endometrial cavity as may cause heavy bleeding and can interfere with uterine contractility.

10.3 Indications for Surgical Abortion

10.3.1 Conditions where medical methods are contraindicated and surgical evacuation must be done, after stabilizing the patient

- 1. Pre-existing heart disease, coagulopathy, or on anticoagulant therapy.
- 2. Anemia (hemoglobin <8 gm%).
- 3. Severe renal diseases including (BP >160/100.mmHg).
- 4. Severe liver diseases.
- 5. Severe respiratory diseases, bronchial asthma with a long-term use of systemic. corticosteroids (including those with severe uncontrolled asthma).
- 6. Chronic adrenal failure, uncontrolled seizure disorder, inherited porphyria, glaucoma, allergy, or intolerance to mifepristone/misoprostol or other prostaglandins.

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10.4 Precautions

- 1. Intrauterine contraceptive device (IUCD) has to be removed before MMA.
- 2. If a woman is breastfeeding, then she has to withhold feeding for 4 hours after misoprostol administration.
- 3. Women on antitubercular drugs: Rifampicin is a liver enzyme-inducing drug, which can lead to increased metabolism and, hence, decreased efficacy of MMA drugs.

10.5 MMA-specific Counseling

- 1. She needs to make 3 visits to the facility (Days 1, 3, and 15); or 2 visits in the case of home administration of misoprostol (provider's discretion).
- 2. Bleeding and the expulsion of POC will occur in 24 hours of misoprostol, but bleeding may continue for 1–2 weeks.
- 3. If there is method failure (no bleeding in 24 hours of misoprostol), then repeat dose or vacuum aspiration can be considered.
- 4. If the patient vomits within 30 minutes of misoprostol intake, then the dose has to be repeated.
- 5. Transient adverse effects are commonly associated with misoprostol use, include nausea (43–66%), vomiting (23–40%), diarrhea (23–35%), headache (13–40%), dizziness (28–39%), and thermoregulatory effects such as fever, warmth, hot flushes, or chills (32–69%).
- 6. **Danger signs and symptoms** should be explained, the woman should report to health facility if there is increased bleeding or continued heavy bleeding (soaking ≥ 2 pads/hour for 2 consecutive hours), persistent fever, dizziness or fainting, abdominal pain, or foul-smelling vaginal discharge.
- 7. Once MMA drugs are taken, pregnancy termination should be considered, as there is a risk of fetal malformation, e.g. Möbius syndrome, though the risk is only slightly higher (2–3%) than the general population. Women with ongoing pregnancy after failed abortion with misoprostol administration should be informed of this risk. Möbius syndrome is characterized by unilateral or bilateral palsy of the abducens (VI) and facial (VII) cranial nerves. Other cranial nerves [e.g., the hypoglossal (XII)], craniofacial or orofacial anomalies and limb malformations. The critical period for the development of Möbius syndrome following teratogen exposure appears to be 5–8 weeks of gestation.
- 8. Total drug schedule with misoprostol must be completed; however, 3% women may expel products with mifepristone alone also.
- 9. Intercourse should be avoided to prevent infection or use barrier methods.
- 10. Contraception counseling.

10.6 Route of Administration of MMA Drugs

10.6.1 Tab. Mifepristone - oral

10.6.2 Tab. Misoprostol (Table 2).

Table 2 Route of administration of MiNA drugs			
Route of administration	Onset of action	Peak Levels attained	Bioavailability
Sublingual: Pills are placed under the tongue and swallowed after 30 minutes	Rapidly	30 minutes	Long duration (6 hours)
Vaginal	Gradually	70–80 minutes	Longest duration (>6 hours)
Buccal: Pills are placed between the cheeks & gums and swallowed after 20–30 minutes			Moderate duration (3 hours)
Oral: Pills are swallowed immediately	Rapidly	30 minutes	Short duration (2 hours)

Table 2Route of administration of MMA drugs

MTP DRUG PROTOCOLS

11. FIRST TRIMESTER MTP PROTOCOLS

11.1 MMA <9 Weeks of Gestation (GOI)

- 1. *Day 1:* Mifipristone 200 mg PO once.
- 2. *Day 2:* Misoprostol 800 μg B (buccally), PV (per vaginally), or SL (sublingually) (minimum recommended interval between the use of mifepristone and misoprostol is 24 hours).
- 11.2 Vacuum Aspiration (Manual or Electric) before 12 weeks of gestation.

11.3 Between 9 weeks and 12 weeks of gestation, the surgical method of abortion is to be considered. In the second trimester, MMA (mifipristone & misoprostol) is not approved in India.^{18,19}

12. MTP DRUG PROTOCOLS BY WHO 2022,^{7,20} FIGO 2017²³

12.1 Medical Termination of Pregnancy at <12 Weeks

- a. Tab. Mifepristone 200 mg orally, followed 1–2 days later by 800 µg misoprostol (per vaginally, sublingually, or buccally)
- b. Tab. Misoprostol alone 800 µg misoprostol (buccally, sublingually, or per vaginally).

12.2 Medical Termination of Pregnancy at ≥12 Weeks

- a. Tab. Mifepristone 200 mg orally, followed 1–2 days later by the repeat doses of 400 µg misoprostol (buccally, sublingually or per vaginally every 3 hours, minimum recommended interval between the use of mifepristone and misoprostol is 24 hours and there is no maximum dose).
- b. Tab. Misoprostol alone 400 μg misoprostol (buccally, sublingually, or per vaginally) and the repeat doses of 400 μg misoprostol every 3 hours.

12.3 Medical Termination of Pregnancy for up to 14 Weeks^{7,20}

12.3.1 Combination regimen

Letrozole 10 mg PO \times 3 days, followed by Misoprostol 800 µg SL on Day 4 (Safe & effective option).

12.4 Medical Termination of Pregnancy 12–24 Weeks^{7,23}

12.4.1 Combination regimen

- a. Mifipristone 200 mg PO at Day 1 followed by Tab. Misoprostol 400 µg on Day 2, or Day 3 B, PV, SL, and repeat 3 hourly.
- b. Misoprostol only regimen Tab. Misoprostol 400 µg B, PV, SL, and repeat 3 hourly.

12.5 Medical Termination of Pregnancy Between 25 Weeks and 28 Weeks²³

Tab. Mifipristone 200 mg orally at Day 1 followed by Tab. Misoprostol 200 µg on Day 2, or Day 3 B, PV, SL, and repeat 3 hourly.

12.6 Medical Termination of Pregnancy Beyond 28 Weeks²³

Tab. Mifipristone 200 mg orally at Day 1 followed by Tab. Misoprostol 100 µg on Day 2, or Day 3 B, PV, SL, and repeat 3 hourly.

12.6 Prior Scarred Uterus

The risk of uterine rupture among women with a prior cesarean delivery at 13–26 weeks using misoprostol is less than 0.3%. Misoprostol can be used in previous cesarean or other transmural uterine scar throughout 13–26 weeks. Insufficient evidence exist regarding misoprostol use beyond 26 weeks of gestation in women who had a previous cesarean or transmural uterine scar (FIGO 2017).²³

The use of prostaglandin 1 (PGE1) in the second trimester was not associated with significantly increased risk for uterine rupture among women with only 1 cesarean; however, this risk was substantially increased among women with ≥ 2 cesareans although the absolute risk appeared to be relatively small [Level 1].²²

The combined use of intracervical Foley's catheter and oxytocin is an effective and safe alternative to vaginal misoprostol for the termination of the second trimester pregnancy in women having a previous cesarean delivery [Level 1].²³

The combination of low-dose vaginal misoprostol (100 μ g every 6 hours per vaginally) and Foley's catheter (18F Foley catheter, bulb filled with 30 mL saline) introduced beyond the internal os, slight traction on the catheter was exerted through tapping it to the inner thigh. An effective and safe method for the termination of 20–27 weeks of gestation, in women with previous multiple cesarean sections.²⁴

The combined use of intracervical Foley's catheter with IV oxytocin infusion is a safer option than vaginal misoprostol with less serious maternal complications.²⁵

Both, double balloon catheter (with 80 mL in each balloon) intracervical placement beyond internal os and in situ for 12 hours or until spontaneous expulsion and PGE2 gel into the posterior fornix, initially 1 mg followed by a further 1 mg 6 hours later if required, are equally efficacious in induction and no significant morbidity occurred.²⁶

Tab. Mifepristone²⁷⁻³¹ 200 mg TDS × 48 hours (success rate 63–75 %)

- 13–20 weeks: 400 μg misoprostol PV/SL 6 hourly for 24 hours maximum.
- 21–26 weeks: 200 µg misoprostol PV/SL 6 hourly for 24 hours maximum. (The success rate of termination was 70–80% and there was no scar rupture reported)

13. TELEMEDICINE IN ABORTION CARE: (FOGSI RECOMMENDATIONS)

According to the WHO, there is an estimated shortage of 18 million health workers by 2030, mainly in low- and middleincome countries (LMICs). Access to safe, legal, and person-centered abortion is an essential part of sexual and reproductive health services and also vital to prevent unsafe abortions. Telemedicine can be defined as the use of information and communication technologies to improve patient outcomes by increasing access to care and medical information. Using a telephone, video call, or the Internet can allow those who need an abortion to have a part, of their care at home, with remote support during and after treatment from the abortion provider, while an in-person consultation is essential to the provisions of MTP.

13.1. Telemedicine Model for MMA up to 9 Weeks (For Low-risk Women)

(Mifipristone & misoprostol drugs are Schedule H drugs; hence, they have to be prescribed by a qualified RMP. Proper regulatory provision should be enforced to prevent over-the-counter sale. Pharmacists should not dispense the MMA drugs without the RMP prescription)

- 1. Model A: First physical visit followed by virtual visits.
- 2. Model B: Virtual visits followed by 1 mandatory physical visit.

One physical visit is mandatory, because the patient has to sign the MTP forms and for clinical examination. Warning signs, address of hospital, and contact number should be clearly explained and mentioned in the card.

The self-confirmation of the success of abortion can be done by urine pregnancy test (if low-sensitivity test with a detection limit of 1,000 IU human chorionic gonadotropin (hCG) on Day 15, or if high-sensitivity test with a detection limit of 50 IU hCG or less than on Day 30)

Serum hCG level decrease of at least 80% over 6–7 days after initiating treatment with mifepristone and misoprostol indicates a successful abortion.

14. FETAL ABNORMALITIES

The following is the list of <u>fetal abnormalities that are considered substantial</u>⁴¹ and can be the candidates for MTP. This list should not be considered to be complete. Consider the opinion of fetal medicine specialist and neonatologist.

14.1 Classification of Major Abnormalities

14.1.1 Central Nervous System Abnormalities

- 1. Anencephaly
- 2. Arnold-Chiari Malformation
- 3. Cerebellar hypoplasia
- 4. Corpus callosum agenesis with additional major abnormalities
- 5. Craniosynostosis syndromic
- 6. Dandy–Walker syndrome (to be decided by an expert)
- 7. Encephalocele (In consultation with neurosurgeon)
- 8. Holoprosencephaly alobar and semilobar
- 9. Hydrocephalus over 20 mm with the dilatation of all ventricles
- 10. Hydranencephaly
- 11. Inencephaly
- 12. Intracranial tumors
- 13. Megalencephaly
- 14. Meningomyelocele with severe hydrocephalus
- 15. Microcephaly
- 16. Porencephaly with ventriculomegaly over 12 mm
- 17. Schizencephaly
- 18. Others (in consultation with experts).

14.1.2 Cardiovascular Abnormalities

- 1. Absent pulmonary valve syndrome
- 2. Aortic arch coarctation or interruption aortic stenosis or atresia
- 3. Atrial or ventricular tumors:
 - Coronary anomalies
 - Complex ventricular septal defects.
- 4. Double outlet fight or left ventricle Ebstein's anomaly of the tricuspid valve or Uhl's anomaly
- 5. Ectopia cordis
- 6. Hypoplastic right or left heart syndromes mitral stenosis, mitral atresia, mitral regurgitation
- 7. Pulmonary stenosis or atresia resistant arrhythmias with fetal hydrops
- 8. Single ventricle tetralogy of Fallot
- 9. Transposition or corrected transposition of the great arteries
- 10. Tricuspid stenosis, tricuspid atresia, tricuspid regurgitation
- 11. Ventricular dysfunction right or left
- 12. Congenital heart block
- 13. Others (in consultation with experts).

14.1.3 Musculoskeletal Abnormalities

- 1. Achondroplasia
- 2. Achondrogenesis
- 3. Arthrogryposis congenita multiplex with thin ribs with polyhydramnios
- 4. Asphyxlating thoracic dysplasia (Jeune's syndrome)
- 5. Campomelic dysplasia
- 6. Chondrodysplasia punctata
- 7. Congenital hypophosphatasia
- 8. Jarcho-Levin syndrome
- 9. Lethal skeletal dysplasia
- 10. Limb-body wall complex

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- 11. Myotonic dystrophy
- 12. Osteogenesis imperfecta type II and III
- 13. Phocomelia
- 14. Short rib polydactyly syndromes
- 15. Sirenomelia
- 16. Thanatophoric dysplasia
- 17. Others (in consultation with experts).

14.1.4 Gastrointestinal Abnormalities

- 1. Large ventral wall defects gastroschisis or omphalocele
- 2. Megacystis-microcoloh-intestinal hypoperistalsis syndrome
- 3. Others (in consultation with experts).

14.1.5 Urinary Tract Abnormalities

- 1. Bilateral renal agenesis
- 2. Bladder exstrophy
- 3. Cloacal exstrophy
- 4. Posterior urethral valve with bilateral hydronephrosis with severe oligohydramnios
- 5. Potter type I autosomal recessive polycystic kidney disease
- 6. Potter type II bilateral multicystic dysplastic kidney with severe oligohydramnios
- 7. Unilateral multicystic dysplastic kidney with contralateral renal agenesis
- 8. Others (in consultation with experts).

14.1.6 Thoracopulmonary Abnormalities

- 1. Bilateral cystic adenomatoid malformation of lungs
- 2. Congenital diaphragmatic hernia with mediastinal compression and associated polyhydramnios
- 3. Congenital high airway obstruction (CHAOS) with hydrops
- 4. Pulmonary hypoplasia
- 5. Others (in consultation with experts).

14.1.7 Facial Abnormalities

- 1. Bilateral anophthalmia or severe microphthalmia
- 2. Severe micrognathia associated with other non-correctable abnormalities
- 3. Others (in consultation with experts).

14.1.8 Chromosomal Abnormalities

- 1. Tetrasomy 12p (Pallister-Killian syndrome)
- 2. Trisomy 13, 18, or 21
- 3. Triploidy
- 4. Unbalanced chromosomal rearrangements
- 5. Others (in consultation with experts).

14.1.9 Single Gene Disorder

- 1. Beta thalassemia (major)
- 2. Congenital muscular dystrophy: Duchenne muscular dystrophy
- 3. Cystic fibrosis
- 4. Fragile X syndrome
- 5. Myotonic dystrophy
- 6. Spinal muscular dystrophy
- 7. Others: intermittent explosive disorder (IED) in consultation with experts.

14.1.10 Fetal Syndromes

- 1. Referenced from the Online Mendelian Inheritance in Man (OMIM) morbid list
- 2. www.ncbi.nlm.nih.gov

14.1.11 Dermatological Abnormalities

- 1. Epidermolysis bullosa letalis
- 2. Harlequin ichthyosis or congenital ichthyosis
- 3. Restrictive dermopathy
- 4. Others (in consultation with experts).

14.1.12 Other Abnormalities

- 1. Anhydramnios associated with more than 2 major non-correctable structural fetal abnormalities
- 2. Conjoint twins
- 3. Fetal akinesia deformation sequence
- 4. Rapidly growing fetal tumors and hydrops
- 5. Others (in consultation with experts).

15. MANAGEMENT OF LIVEBORN FETUS

Advanced pregnancy termination with uterotonic agents have their inherent risk for the occurrence of a live birth, which can be the source of emotional anguish for women and the wastage of healthcare resources.

Feticide before MTP must be considered for MTP beyond 24 weeks of gestation. The Ministry of Health and Family Welfare in its guidance note for medical boards has recommended procedure to stop heart beats as per the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines (M12015/58/2017-MCH, dated 14/08/2017 by Ministry of Health and Family Welfare, GOI).^{32,33,42}

Couple should be informed about the options and the risks, a written and informed consent should be obtained before admitting the patient for MTP. Their sociocultural, ethical, and legal perspectives must always be taken into consideration. Feticide can be done by the Gynecologist, capable of performing feticide.

15.1 Methods (Table 3)

- Intracardiac potassium chloride (KCl) 2–3 mL strong (15%) injection into a cardiac ventricle. A repeat injection may be required if asystole has not occurred after 30–60 seconds. Asystole should be observed for at least 2 minutes and fetal demise should be confirmed by ultrasound scan after 30–60 minutes^{32,33}
- 2. Intra-amniotic or intrathoracic injection of digoxin (up to 1 mg) and by umbilical venous or intracardiac injection of 1% lidocaine (up to 30 mL).

Intracardiac injection of either KCI or intrathoracic injection of digoxin requires considerably more skill than intraamniotic injection of digoxin. While the latter may be slightly less effective in inducing fetal demise, its use may be an option for services that lack personnel with sufficient skill in administering intracardiac injections.³⁴⁻³⁸

16. DISPOSAL OF PRODUCT OF CONCEPTION/FETUS

Dead fetus, below the viability (weight <500 gm), can be considered as human anatomical waste. Such waste should be handed over to the operator of common biomedical waste treatment and disposal facility in yellow bag with 2 copies of letter (one copy to be handed to biomedical waste person and the other copy to be kept in the hospital records). In the cases of late abortion, fetus must be handed over to the patient/relatives for cremation or deep burial after making stillbirth certificate at that time.

17. POSTABORTION CONTRACEPTION

Nearly 75% women ovulate and 6% conceive within 2–6 weeks after abortion, if they are not using contraception. MTP should not be denied just because the woman does not opt for contraception, but contraception counseling should be continued in her subsequent visits till she chooses one (Table 4).

Table 3 Comparision of drugs used for feticide ²⁰			
Injection of potassium chloride (KCl) (intrafunic or intracardiac)	Injection of digoxin (intra-amniotic or intrafetal)	Injection of lidocaine (intra-cardiac or intra-thoracic)	
Highly effective	Digoxin has a higher failure rate than KCI when used to induce intrauterine fetal asytole	Lidocaine is rapidly effective	
Administered on the day of the abortion or one day prior	Digoxine requires time for fetal absorption one day before misoprostol regardless of whether or not mifepristone is also used	Administered on the day of abortion or one day prior	
Asytole is immediately observed at the time of the injection	Asytole is usually confirmed before initiation of abortion	Cardiac cessation is observable within approximately 5 mitues	
Requires expertise	Technically easier to use and does not require USG if administered intra-amniotically Digoxin has demonstrated safe maternal serum levels at or below therapeutic digoxin levles	Precise intracardiac injection requires more expertise than intrathoracic placement both methods are highly effective Lidocaine presents minimal maternal risks. It may be a safe alternative in settings where digoxin or KCl are not available	
4 to 5 mEq	1 to 2 mg	200 to 240 mg	

Table 4Types of contraception

Type of contraception	1 st trimester	2 nd trimester	3 rd trimester
Hormonal (oral/injectables/implants) Nonhormonal Centchroman	Surgical abortion – within 7 days MMA can be started at Day 2 or 3 with misoprostol or within Day 15 after confirmation of complete abortion	Within 7 days	Centchroman – soon after delivery
IUCD	Within 12 days of MTP MMA – at D15 after confirmation of a complete abortion		Postabortion IUCD (PAIUCD) Within 48 hours of placenta delivery Or after 1 month of delivery
Female sterilization	Lap ligation/Minilap	Minilap	Minilap
Vasectomy	Any time		

Abbreviations: IUCD, intrauterine contraceptive device; MMA, medical method of abortion; MTP, medical termination of pregnancy

18. MANAGEMENT OF MISSED ABORTION AT <14 WEEKS UTERINE SIZE

18.1 Tab. Mifepristone 200 mg orally followed after 24–48 hours by 800 µg misoprostol by any route (buccal, sublingual, or vaginal).

18.2 Alternative regimen: 800 µg misoprostol by any route (buccal, sublingual, vaginal).

18.3 Vacuum aspiration.

19. COMPLICATIONS AND MANAGEMENT

19.1 Incomplete Abortion at <14 Weeks Uterine Size

- 1. Vacuum aspiration or medical method
- Misoprostol 600 μg orally or 400 μg sublingually.
 Prophylactic antibiotics after incomplete abortion are effective in reducing GITs [Level 1, Grade A].

19.2 Incomplete Abortion at >14 Weeks Uterine Height

Misoprostol 400 µg sublingually, per vaginally, or buccally every 3 hours.

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20. MEDICAL METHOD FAILURE

20.1 Criteria

- 1. If no bleeding in 24 hours of intake of misoprostol.
- 2. If there is a need for uterine aspiration because of ongoing pregnancy or retained tissue.

20.2 Management

Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference. If gestational cardiac activity persists at follow-up after a second dose of misoprostol, then uterine aspiration should be performed.

SURGICAL ABORTION

21. SURGICAL ABORTION

The preferred methods of surgical abortion is vacuum aspiration (manual or electric) before 12–14 weeks and dilatation and evacuation after 14 weeks of gestation. Surgical procedures require a high level of skill, sound preoperative diagnosis, careful attention to sterile technique and the prevention of infection, gentle handling of tissue, and conscientious follow-up care with the efficacious management of complications.

21.1 Vacuum for uterine aspiration can be produced with either an electric pump or a handheld syringe (manual vacuum). Manual vacuum aspiration (MVA) cannula which accommodates cannulas with a 12-mm base which will attach 14 and 16 mm cannulas, adequate uterine evacuation throughout the first trimester and even the early second trimester. They are autoclavable.

MMA may be preferable to surgical methods after 14 weeks of gestation. Dilatation and evacuation requires skill and expertise, should not be routinely practised.

21.2 Preoperative Evaluation

- Confirm gestational age.
- Careful examination to exclude uterine abnormalities, multiple pregnancy, hydatidiform mole (H-mole), or other conditions.
- Comorbidities and complications such as diabetes, pre-eclampsia, neurologic disorders, previous cesarean delivery, obesity, placenta previa, or cardiovascular disease, etc.
- Investigations: Baseline investigations and others if indicated, ultrasonograohy (USG) must be done to rule out uterine
 anomalies and if clinically indicated, e.g. fibroids, multiple gestation, etc.

21.3 Consent for Surgical Abortion

Informed consent is essential before performing surgical abortion. Apart from the MTP forms, a brief description of the procedure, its benefits, relevant risks, alternatives, and consequences of the refusal of the procedure (high-risk consent can be referred from https://fogsi.org/wp-content/uploads/brochure/fogsi-uniform-consents.pdf).

21.4 Preferred Methods for Surgical Abortion (Table 5)^{7,8,39,40}

21.5 With the advent of medical methods, D&E is rarely used method in 2nd trimester MTP and it should be restricted to MTP below 15 weeks gestation [MOHFW, WHO]

Table 5	Methods of surgical abortion

<7 weeks	7–14 weeks	14–16 weeks	16–24 weeks
Vacuum aspiration	Manual or electronic vacuum aspiration may be used. Both have their advantages and disadvantages.	Electronic vacuum aspiration or dilatation and evacuation are the preferred methods for surgical	Dilatation and evacuation is the preferred method for surgical abortion. Atraumatic ovum forceps
	Sharp curettage is not recommended	abortion	may be used to assist the evacuation. Sharp curettage is not recommended

22. PREPROCEDURE CERVICAL PREPARATION

Preprocedure cervical preparation must be done in all women undergoing surgical abortion, to reduce the chances of difficult dilatation, pain and discomfort, cervical injury, and uterine perforation. Cervical preparation before 12 weeks gestation is not required but consider using 400 µg misoprostol 1-2 hours before procedure in patients \leq 17 years of age. Consider using Osmotic Dilators in patients \leq 17 years old or in patients with a stenotic cervix.²³

22.1 Mechanical Dilatation

- 1. Serial dilatation by dilators
- 2. In cervical stenosis lacrymal probe, dilators (sizes 0.5–1.2 mm) or Foley's catheter with guide wire can help.

22.2 Osmotic Dilators: Dilapan-S™

22.3 Pharmacological Dilators

22.3.1 For gestational age < 12 weeks of pregnancy^{7,8}

- 1. Mifepristone 200 mg orally, 24–48 hours before the procedure.
- 2. Misoprostol 400 µg sublingually, 1–2 hours before the procedure.
- 3. Misoprostol 400 µg per vaginally or buccally, 2–3 hours before the procedure.
- 4. Inj. 15 Methyl F2 Alpha PG (carboprost) 250 µg IM (intramuscular), 45 minutes before.

Sublingual misoprostol has high effectiveness but more gastrointestinal (GI) side effects than vaginal misoprostol. Mifepristone 24 hours prior to the abortion is superior to misoprostol, but takes more time and is expensive. Misoprostol and osmotic dilators have similar effectiveness, but dilator placement is associated with increased pain, increased time to procedure, and reduced satisfaction for women

22.3.2 For gestational age 12–19 weeks of pregnancy

- 1. Combination of mifepristone + misoprostol.
- 2. Osmotic dilator + medication (mifepristone, misoprostol, or a combination of both) period between osmotic dilator placement and procedure should not extend beyond 2 days.

22.3.3 For gestational age \geq 19 weeks of pregnancy

Osmotic dilator + medication (mifepristone, misoprostol, or a combination of both) limited evidence for cervical priming for gestational ages between 12 weeks and 14 weeks, use your clinical judgement to decide on the most convenient method.

23. TECHNIQUES

23.1 Vacuum Aspiration (<12–14 Weeks)

Dilatation should be just sufficient to allow a gentle insertion of a suitable sized vacuum cannula. The diameter of the cannula should generally be 1–2 mm smaller than the gestational age, e.g. for a 9-week pregnancy, 8 mm cannula; and for a 12-week gestation, a 10 mm cannula. Uterine evacuation is done with 60–80 mmHg of negative pressure for an electric pump, or full vacuum for a 60 cc manual syringe.

- Attach the prepared aspirator/vacuum connection to the cannula.
- Initiate suction when cannula is mid-uterus.
- Evacuate the contents by rotating the cannula gently and slowly by 180° in each direction to evacuate the uterus.

23.1.1 Products of conception

Products of conception (POC) should be examined:

- Up to 9 weeks: Presence and quantity of villi, decidua, sac, and membranes.
- Beyond 9 weeks: Presence of fetal parts additionally.
- If any abnormality is suspected, then the tissue is sent for histopathological examination.

23.1.2 Inadequate products of conception

If inadequate POC^{39,40} are obtained at the time of the procedure, then the following options can be considered (always rule out ectopic gestation and uterine anomalies):

- a. To repeat aspiration immediately.
- b. If available, intraoperative ultrasound guidance to guide re-aspiration, to assure the cannula is reaching the uterine fundus and pregnancy tissue.
- c. Serum beta hCG level can be drawn on the day of the aspiration as a baseline, and a repeat hCG is measured in 24–48 hours, more than 50% decline indicates a successful abortion.

23.2 Dilatation and Evacuation (14–16 Weeks)

USG-guided procedures are preferred beyond 14 weeks of gestation.

- Insert MTP cannula through the cervix and aspirate the amniotic fluid.
- Attach the aspirator/vacuum connection up to the mid-uterus.
- Avoid reaching into the upper uterine cavity to avoid perforation.
- Suction in a gentle rotational movement.
- Clean and reinsert cannula if necessary.
- Suction the POCs up to the lower uterine cavity and then use atraumatic ovum forceps to complete the evacuation.
 POC must be examined: Four extremities, thorax/spine, calvarium, and placenta.

If all parts are not identified, then consider:

- Ultrasonography to confirm complete evacuation
- Tab. Misoprostol 400–600 μg sublingually, orally, reassess 3–4 hours later and repeat the evacuation.

The completion of procedure is confirmed by:

- Appearance of red/pink foam.
- No more tissue is passing in the cannula.
- Uterus grips the cannula.
- Cramping or pain indicating uterine contractions.

Negative urine pregnancy test 2 weeks postabortion rules out the possibility of gestational trophoblastic neoplasia (GTN).

24. COMPLICATIONS AND MANAGEMENT

24.1 Hemorrhage During and After Abortion

- Incomplete evacuation (0.5–2% of surgical abortions) evacuating the uterus rapidly but gently, then massage between two hands.
- Uterine atony: Bleeding in excess of 100 mL is uncommon with abortion under paracervical block. Massage the uterus, oxytocin (10–20 units) or oral, buccal, or rectal misoprostol (400–1000 µg) should be used to contract the uterus. Prostaglandin F2α (carboprost) can be given intramuscularly.
- Cervical or vaginal injury repair with 1-0 round body sutures.

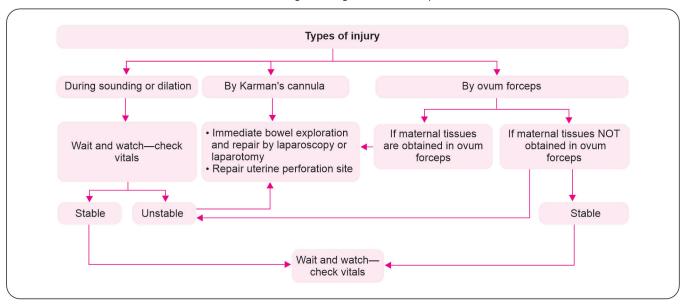
24.2 Uterine Perforation

Uterine perforation during the performance of abortion is a potentially serious complication that can result in hemorrhage or visceral injury (Flowchart 1). The reported rates of perforation range from less than 1 to 3 per thousand abortions and become more frequent with increasing gestational age.

Most perforations occur during sounding or dilation and the most common site of perforations is the junction of the cervix and the lower uterine segment.

Suspect uterine perforation if:

- Cannula passes for a long distance than anticipated in the uterine cavity.
- There is no resistance when cannula is passed.



Flowchart 1: Management algorithm—uterine perforation

- Difficulty in withdrawing the cannula.
- Bits of omentum or intestine is seen in the aspirate (should not happen).

24.3 Sepsis

High fever [102°F (39°C) or more] within 72 hours of abortion should be considered an evidence of retained tissue with sepsis until proved otherwise.

Septic shock: Persistent hypotension requiring vasopressors to maintain mean arterial pressure (MAP) \geq 65 mmHg + serum lactate level >2 mmol/L despite adequate volume resuscitation. Assess the patient with bed side obstetrically modified quick sequential organ failure assessment (qSOFA) score (Table 6 and Flowcharts 2 and 3).

 Table 6
 Obstetrically modified qSOFA score

Parameters	Score		
Furumeters	0	1	
SBP (mm Hg)	≥90	<90	
RR	< 25 breaths/min	≥25 breaths/min	
Altered mentation	Alert	Not alert	

Abbreviations: qSOFA, quick sequential organ failure assessment; RR, respiratory rate; SBP, systolic blood pressure

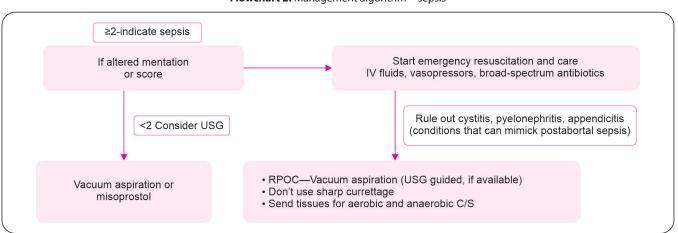
Antibiotics must be started to cover the following common organisms:

- Gram-positive: Streptococci (A, B, D), Staphylococcus aureus
- Gram-negative: Escherichia coli, Enterobacteriaceae including Klebsiella, Enterobacter, Citrobacter, Pseudomonas aeruginosa, Proteus mirabilis, Gardnerella vaginalis, Bacteroides, Clostridium perfringens.

25. OFFENCES AND PUNISHMENTS FOR CONTRAVENING MTP ACT

All offences under the MTP Act have three common features (Table 7):

- 1. Cognizable: Arrest without warrant.
- 2. Nonbailable: Serious offence and bail is a matter of discretion (Bailable means bail is claimed as a matter of right).
- 3. *Compoundable:* Parties cannot compromise after the complaint (noncompoundable means complainant can agree to take back the charges levied against the accused).



Flowchart 2: Management algorithm—sepsis

Flowchart 3: Monitoring and ongoing management of patients

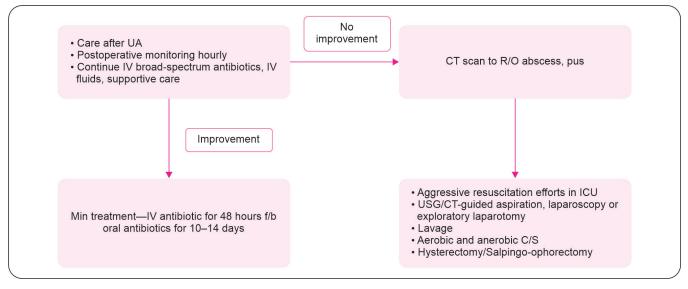


Table 7 Offences and punishment			
Offences	Punishment	Person Punished	
MTP by unauthorized person	Rigorous imprisonment 2–7 years	Person performing the MTP	
MTP in an unapproved place		Person performing the MTP and Owner of hospital	
Failure: Documentation, record keeping, consent, admission register, etc.	Fine up to Rs 1000 with or without 1 year imprisonment	Concerned person	

KEY RECOMMENDATIONS

Strong Recommendations

(Level I evidence or consistent findings from the multiple studies of Level II, III, IV)

1. Antibiotics is not recommended in MMA, unless the women is nulliparous or has infection.

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- 2. Antibiotics after surgical abortion is recommended for the prevention of postabortal genital infection.
- 3. Analgesics and antiemetics coadministration with mifepristone is recommended to reduce pain scores maximum.
- 4. Conscious sedation followed by paracervical block improves satisfaction during the first trimester surgical abortion.
- 5. Preprocedure cervical preparation with pharmacological or mechanical methods is recommended in all women undergoing surgical abortion.

Recommendations

(Level II, III, IV evidence and findings are generally consistent)

1. Unclear benefit for Rh testing and immunoglobulin administration before 12 weeks of gestation in both medical and surgical abortion.

2. Combined use of intracervical Foley's catheter and oxytocin is an effective and safe alternative to vaginal misoprostol

for the termination of the second trimester pregnancy in women having a previous cesarean delivery.

- 3. Teleabortion model can be used for MMA up to 9 weeks.
- 4. Prophylactic antibiotics after incomplete abortion are recommended for reducing GTIs.

Options

(Level II, III, or IV evidence, but findings are inconsistent)

1. Ibuprofen 1,600 mg single dose given along with misoprostol is effective in the first trimester (<14 weeks) medical abortion.

2. Epidural anesthesia may be considered for the medical abortion of >12 weeks of gestation.

3. Feticide prior to MTP or the end-of-life care of liveborn neonate must be considered, if MTP is undertaken after the period of viability. Before admission options must be explained to the couple and written informed consent should be taken prior to admission for MTP.

4. The feticide methods include intracardiac KCl, intrathoracic/intra-amniotic digoxin and intracardiac lignocaine.

5. Intra-amniotic procedures require less skill than intrathoracic/cardiac; hence, an option for center that lacks personnel with sufficient skill in administering intracardiac injections.

6. Ultrasound prior to MMA must be considered if clinical findings are inconclusive or in cases with prior scarred uterus to rule out scar pregnancy.

7. USG-guided surgical dilatation and evacuation is preferred beyond 14 weeks of gestation.

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FORM A [See sub-rule (2) of rule 5] FORM OF APPLICATION FOR THE APPROVAL OF A PLACE UNDER CLAUSE (b) OF SECTION 4 OF THE ACT							
Category of approved place:							
(A) Pregnancy can be terminated up to twelve weeks							
(B) Pregnancy can be terminated up to twenty-four weeks							
(i) Name of the place (in capital letters):							
(ii) Address in full:							
(iii) Non-government or Private or Nursing Home or Other Institution							
(iv) State, if the following facilities are available at the place:							
Category A							
(i) Gynecological examination or labor table.							
(ii) Resuscitation equipment.							
(iii) Sterilization equipment.							
(iv) Facilities for treatment of shock, including emergency drugs.							
(v) Facilities for transportations, if required.							
Category B							
(i) An operation table and instruments for performing abdominal or gynecological surgery.							
(ii) Drugs and parental fluids in sufficient supply for emergency cases.							
(iii) Anesthetic equipment, resuscitation equipment and sterilization equipment.							
Place:							
Date:							
Signature of the owner of the place							

FORM B [See sub-rule (6) of rule 5] CERTIFICATE OF APPROVAL

The place described below is hereby approved for the purpose of the Medical Termination of Pregnancy Act, 1971 (34 of 1971).

As read within up to	
Name of the Place	
Address and other descriptions	
Name of the owner	
Place:	
Date:	
-	To the Government of the

CONSENT FORM FORM C (See rule 9)							
I daughter/wife of aged about							
terminated).	sieghtiney is to be						
Place: Date:	Signature						
(To be filled in by guardian where the woman is a mentally ill person or mino	or)						
I daughter/ wife of							
aged about years of							
(p at present residing at	do						
hereby give my consent to the termination of the pregnancy of my ward who is a minor/ mentally ill person at							
	tion of pregnancy)						
Place:							
Date:	Signature						

FORM I RMP Opinion Form (For gestation age up to 20 weeks) [See Regulation 3]
(Name and qualifications of the Registered Medical Practitioner in block letters)
(Full address of the Registered Medical Practitioner)
hereby certify that I am of opinion, formed in good faith, that it is necessary to terminate the pregnancy of
(Full name of pregnant woman in block letters)
resident of (Full address of pregnant woman in block letters)
for the reasons given below*.
I hereby give intimation that I terminated the pregnancy of the woman referred to above who bears the Serial No
Place:
Date:
Signature of the Registered Medical Practitioner
*of the reasons specified items (a) to (e) write the one which is appropriate:
a. in order to save the life of the pregnant women,
b. in order to prevent grave injury to the physical and mental health of the pregnant woman,
c. in view of the substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped,
d. as the pregnancy is alleged by pregnant woman to have been caused by rape,
e. as the pregnancy has occurred as a result of failure of any contraceptive device or methods used by a woman or her partner for the purpose of limiting the number of children or preventing pregnancy.
Note: Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.
Place:
Date: Signature of the Registered Medical Practitioner

FORM E Opinion Form of Registered Medical Practitioners (For gestation age beyond twenty weeks till twenty-four weeks) [See sub-rule (2) of rule 4A]
Name and qualifications of the Registered Medical Practitioner in block letters)
(Full address of the Registered Medical Practitioner)
I
(Full address of the Registered Medical Practitioner)
hereby certify that I am of opinion, formed in good faith, that it is necessary to terminate the pregnancy of
(Full name of pregnant woman in block letters)
resident of
(Full address of pregnant woman in block letters)
which is beyond twenty weeks but till twenty-four weeks under special circumstances as given below*.
*Specify the circumstance(s) from (a) to (g) appropriate for termination of pregnancy beyond twenty weeks till twenty- four weeks:
(a) Survivors of sexual assault or rape or incest
(b) Minors
 (c) Change of marital status during the ongoing pregnancy (widowhood and divorce) (d) Woment with physical disabilities [major disability as per criteria laid down under the Rights of Persons with Disabilities Act, 2016 (49 of 2016)]
(e) Mentally ill women including mental retardation
(f) The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped
(g) Women with pregnancy in humanitarian settings or disaster or emergency situations as declared by Government
We hearby give intimation that we terminated the pregnancy of the woman referred to above who bears the Serial No. in the Admission Register of the hospital/approved place.
Place:
Date: Signature of the Registered Medical Practitioner
Note: Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.

FORM D (See sub-clause (ii) of clause (b) of rule 3A) Report of the Medical Board for Pregnancy Termination Beyond 24 weeks

Details of the woman seeking termination of pregnancy:

- 1. Name of the woman:
- 2. Age:
- 3. Registration/Case Number:
- 4. Available reports and investigations:

S. No.	Reports	Opinion of the findings		

5. Additional Investigations (if done):

S. No.	Investigations done	Key findings		

6. Opinion by Medical Board for termination of pregnancy:

a. Allowed

b. Denied

Justification of the decision:

7. Physical fitness of the woman for the termination of pregnancy:

- a. Yes
- b. No

Members of the Medical Board who reviewed the case:

	S. No.	Name	Signature			
Date and Time:						

FORM II [Refer Regulation 4(5)]								
1.	Name o	f the State: Month & Year:						
		f Hospital/approved place:						
		n of pregnancy: (Give total number only under each sub-head)						
	(a) Up to 9 weeks (Medical Methods of Abortion Only):							
		to 12 weeks (Surgical Methods of Abortion Only):						
	(c) Betv	ween 12-20 weeks:						
	(d) Betv	ween 20 -24 weeks:						
	(e) Beyo	ond 24 weeks:						
4.	Religior	n of woman: (Give total number under each sub-head)						
	(a) Hind	du:						
	(b) Mus	lim:						
	(c) Chri	istian:						
	(d) Oth	ers:						
5.	Termina	ation with acceptance of contraception: (Give total number under each sub-head)						
	(a) Ster	ilization:						
	(b) IUCI	D:						
	(c) OCP	P/Injectable Contraceptive:						
	(d) Oth	ers:						
6.	Reasons	s for termination: (Give total number under each sub-head)						
	A. Up	to 20 weeks of gestation						
	(a)	Danger to the life of the pregnant woman:						
	(b)	Grave injury to the physical and mental health of the pregnant woman:						
	(c)	Pregnancy caused by rape:						
	(d)	Substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to						
		be seriously handicapped:						
	(e)	Failure of any contraceptive device or method:						
	B. Bet	ween 20-24 weeks of gestation						
	(a)	Survivors of Sexual Assault/Rape/Incest:						
	. ,	Minors:						
	(c)	Change of marital status during the ongoing pregnancy (widowhood and divorce):						
	(d)	Women with physical disabilities [major disability as per criteria laid down under the Rights of Persons with Disabilities Act, 2016 (49 of 2016)]:						
	(e)	Mentally ill women including mental retardation:						
	(f)	The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped:						
	(g)	Women with pregnancy in humanitarian settings or disasters or emergency situations as declared by Government:						
	C. Bev	rond 24 weeks of gestation						
		The foetal malformation that has substantial risk of being incompatible with life or if the child is born it may suffer from such physical or mental abnormalities to be seriously handicapped:						
		Signature of the Officer In-charge with Date						

			Year	Post Abortion Contraception (Tubal Ligation (TL)/IUCD/ OCP/ Injectables/ Others/ None)	16		
			•	D&C/ Others)	15		
		-		Method of MTP (MVA/ EVA/ MMA/	14		
		n the Register		Name of Registered Medical Practitioner(s) by whom Pregnancy is terminated	13		
		if the last entry i	Month	Result & Name of Registered Remarks Medical Practitioner(s) by whom the opinion is formed (<i>For</i> <i>pregnancy beyond</i> 24 weeks mention the names of Medical Board members)	12		
	<i>,5]</i> 5ТЕR	date o			11		
	ulation N REGIS	(To be destroyed on the expiry of five years from the date of the last entry in the Register)		Date of discharge of patient	10		
	[Refer Regulation 5] ADMISSION REGISTER		•••••••••••••••••••••••••••••••••••••••	Date of termination of pregnancy	6		
	A	the expiry of	Name of Facility:	Reasons on which pregnancy is terminated	8		
		royed on	•	Duration of Pregnancy	7		
		oe dest		Address	9		
		(To b	•	Religion	5		
				Age	4		
			lity:	Wife / Daughter of	m		
			ne of Faci	Date of Admission Name of the Patient	2		
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Good Clinical Practice Recommendations

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Disclaimer - These recommendations for FOGSI GCPR on MTP upto and beyond 24 weeks gestation has been developed for assistance of obstetrician gynecologist, consulting physician and general practitioner providing guidance and recommendation for managing medical termination of pregnancy. The recommendation included here should not be viewed as being exclusive or other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. Since MTP is governed by an act and rules which are open for judicial interpretation as well as amendements, each clinician is expected to practice medical termination of pregnancy as per the law and also provide the best care possible with necessary safety precautions and own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.