To: The Chief Directors: Metro and Rural District Health Services/Health Programmes/General Specialist & Emergency Services
The Directors: Health Programmes/Districts and Sub-structures/Pharmacy Services
The Executive Director: City of Cape Town
Heads of Institutions

CIRCULAR: H35/2016

PROVINCIAL STANDARDISED GUIDELINES AND PROTOCOLS ON THE CHOICE OF TERMINATION OF PREGNANCY (CTOP)

1. **This circular replaces circular H157/2010.**

2. Attached are the revised Provincial policy, standardized guidelines and protocols to guide the Choice of Termination of Pregnancy services in the Western Cape.

3. It replaces all existing CTOP guidelines.

4. The contents of this circular must be brought to the attention of all relevant staff.

5. Your cooperation in this regard is appreciated.

[Signature]

DR B ENGELBRECHT

WCG: HEAD OF HEALTH

DATE: 2016-03-15
Policy Guidelines & Protocols for Choice on Termination of Pregnancy Service

Western Cape Department of Health
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| Annexure D: | Royal College of Obstetricians &amp; Gynaecologists: Best practice in abortion care (Best Practice Paper No 2 June 2015) |
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<table>
<thead>
<tr>
<th>ACRONYMS &amp; ABBREVIATIONS</th>
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<tr>
<td>ACOG</td>
<td>American Congress of Obstetricians and Gynaecologists</td>
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<td>BANC</td>
<td>Basic Antenatal Care</td>
</tr>
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<td>CTOP</td>
<td>Choice of Termination of Pregnancy</td>
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<tr>
<td>D&amp;E</td>
<td>Dilatation and Evacuation</td>
</tr>
<tr>
<td>EML</td>
<td>Essential Medical List</td>
</tr>
<tr>
<td>IUD</td>
<td>Inter Uterine Device</td>
</tr>
<tr>
<td>MTOP</td>
<td>Medical Termination of Pregnancy</td>
</tr>
<tr>
<td>MVA</td>
<td>Manual Vacuum Aspiration</td>
</tr>
<tr>
<td>PACK</td>
<td>Practical Approach to Care Kit</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>STG</td>
<td>Standard Treatment Guidelines</td>
</tr>
<tr>
<td>TOP</td>
<td>Termination of Pregnancy</td>
</tr>
<tr>
<td>WCG</td>
<td>Western Cape Government</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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</table>
1. PURPOSE

The purpose of this document is to provide a policy framework to guide the provision of equitable, accessible, cost-efficient and user-friendly services for women with unwanted pregnancies as part of the Sexual and Reproductive Health and Rights Programme, integrated into the comprehensive health care services.

This document does not include criteria & protocols for Termination of Pregnancy (TOP) after 20 weeks in terms of the Choice on Termination of Pregnancy (CTOP) Act of 1996.

Included in this policy are guidelines for the provision of Medical and Surgical TOPs:

- Referral guidelines for clients requesting Termination of Pregnancy
- Outline of Management protocols
- Client assessment and preparation
- Referral routes for non-designated sites
- Standard procedure for performing TOPs and referrals
- Combined mifepristone and misoprostol protocol
- Keeping of records and Submission of data (H55/2013)
- Confidentiality
- Ethical and legal obligations
- Staff support

Also consult the Annexure D: Royal College of Obstetricians and Gynaecologists: Best practice in abortion care (Best Practice Paper No 2 June 2015)
According to the WCG "Levels of Care" policy document, a first trimester TOP should take place in the district health service and second trimester TOP at specialist level (secondary hospital or appropriate service with specialist backup). Clients requesting the service should enter the Provincial Health System at the primary care level.

The CTOP Act is quite specific in its definition of first and second trimester termination:

First trimester: "during the first 12 weeks of the gestation period of a woman who so requests". The first 12 completed weeks of pregnancy is up to 12 weeks and 0 days.
Second trimester: "from the 13th up to and including the 20th week of the gestation period..." The thirteenth week of pregnancy starts after the 12th week (from 12 weeks and 1 day) and the 20th week ends at 20 weeks and 0 days.

3. OUTLINE OF MANAGEMENT PROTOCOL:

- A client presenting at a primary care provider setting (clinic, community day centre, community health centre, general practitioner) requesting termination of pregnancy, should have full assessment and preparation before referral.

- If the service is not available at primary care facilities, clients wishing to proceed with the termination of pregnancy must then be referred to the appropriate designated district or regional facility.

- The procedure will depend on the eligibility criteria. For the first trimester it will either be a medical TOP (if gestation 63 days or less), or a combination of medical priming followed by surgical evacuation of products using Manual Vacuum Aspiration (MVA) under local anesthesia/sedation/analgesia. For second trimester the procedure will either be medical termination in a facility providing 2nd Trimester abortion; followed by evacuation of products if the abortion was not complete; or a Dilatation and Evacuation (D&E) procedure done by specially trained staff as an outpatient procedure in specially designated sites.

The preferred evidence based management of TOP according to gestation is:

- Up to 63 days (9 weeks) - Medical TOP with Mifepristone and Misoprostol as outpatient.

- 9 weeks +1 day to 12 weeks 0 days – Surgical TOP with Manual Vacuum Aspiration (MVA). As an alternative to MVA from 9 weeks +1 day to 12 weeks 0 days MTOP may be administered with the following provisions:
  ➢ That the procedure be conducted by a medical practitioner.
  ➢ That the facility has beds for observation and administration of drugs.
- 12 weeks + 1 day to 17 weeks 0 days – Surgical TOP by D&E.

- 17 weeks 1 day to 20 weeks 0 days – Medical TOP with Mifepristone and Misoprostol in hospital.

- The client should be counselled and commenced on a contraceptive method of choice before leaving the facility. The only exception is the client who chooses an IUD following medical TOP. This client must preferably use an interim method.

- The client must also have a follow-up appointment at her local clinic to ensure appropriate future contraceptive use.

- The normal referral routes between levels of care in the Western Cape Province apply to termination of pregnancy referrals.

4. **CLIENT ASSESSMENT AND PREPARATION:**

- **History:** Complete medical history.

- **Examination:** General health assessment; physical examination, including abdominal palpation, bimanual examination, and speculum examination where indicated.

- **Pregnancy Test:** Confirm pregnancy by urine pregnancy test.

- **Indications to refer for ultrasonography:**
  - Ultrasound is the preferred method of determining gestational age.
  - Where ultrasound is not available clinical assessment of gestational age that agrees with the menstrual dates is acceptable.
  - Signs and symptoms of ectopic pregnancy or other early pregnancy complications.
• Treat symptomatic vaginal discharge or any sexually transmitted infections using Essential Medicines List (EML); Standard Treatment Guidelines (STG's) and in accordance with the Practical Approach to Care Kit (PACK) guidelines but do not delay the TOP procedure.
Do a cervical cytology if necessary and available.
Do laboratory and other investigations if necessary and available.

• Special investigations should be done by the referring facility and should not delay the procedure.

• Counselling should cover all aspects.

• Complete the standard referral letter and hand it to the patient.

• A booking must be made in all cases.

• As a minimum standard, women should be assessed and referred within 2 weeks of requesting a TOP procedure.

• Arrange a follow-up appointment at the local clinic to ensure continuity of contraceptive use and further post TOP counseling.

It must be stated that referral of a client is an important consideration and applies throughout the management of a client undergoing TOP. Facilities not designated to provide TOP services must refer clients to designated facilities. All facilities must provide counselling before referral.

5. REFERRAL ROUTES (FOR NON-DESIGNATED SITES)

• If gestation is <9 weeks (63 days), make an urgent appointment at the nearest site dedicated to MTOP. If gestation is 9 weeks -12 weeks 0 days, refer to the nearest site offering first trimester TOP.

• For sites where MTOP is not available, if pregnancy gestation is <12 weeks 0 days and uncomplicated, give a date for the procedure at the nearest site offering first trimester TOP.

• If the pregnancy gestation is assessed to be in the 13th week or more (12 weeks 1 day up to 20 weeks 0 days), refer to the appropriate facility for a second trimester TOP service.
• If the pregnancy gestation assessed to be more than 20 weeks, book the patient for pregnancy (using the BANC approach or refer to the closest BANC site) and refer to a social worker to discuss options on adoption.

Refer any client, regardless of gestation, to a district or secondary hospital service in any of the following cases:

➢ Early pregnancy complications suspected (e.g. vaginal bleeding & abdominal pain);

➢ Suspected ectopic pregnancy;

➢ Acute or chronic medical conditions such as:
  ▪ Heart disease
  ▪ Asthma
  ▪ Diabetes
  ▪ Anaemia
  ▪ Blood clotting disorders
  ▪ Seizure disorder
  ▪ Alcohol or Drug abuse
  ▪ Hypertension.
  ▪ Large fibroids (hampering determination of gestation age and/or MVA)
6. STANDARD PROCEDURE FOR PERFORMING TOPS AND REFERRALS

Counseling done
Determine gestational age
Write referral letter

<12 weeks 0 days

≤63 days (9 weeks)
Refer for MTOP

≥ 12 weeks 1 day (up to 20 weeks 0 days)

>63 days or no MTOP site or not eligible for MTOP
Refer for MVA

Refer to appropriate second trimester TOP site by completing Annexure E

Clients that are close to a cut-off gestational age e.g. 11 weeks and 2 days or 19 weeks and 2 days should be referred urgently on the same day.
7. **Combined Mifepristone and Misoprostol Protocol**

<table>
<thead>
<tr>
<th>Gestational age</th>
<th>Mifepristone Day 1</th>
<th>Misoprostol</th>
<th>Route</th>
<th>Dose</th>
<th>Timing</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Up to 9 weeks (63 days)</strong></td>
<td>• 200 mg</td>
<td>• sublingual</td>
<td>• Oral</td>
<td>800 ug</td>
<td>24 hrs-48 hrs after taking mifepristone</td>
<td>Every 3 hours up to 5 doses</td>
</tr>
<tr>
<td></td>
<td>• Single dose</td>
<td>• Single dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>9-12 weeks (63-84 days)</strong></td>
<td>• 200 mg</td>
<td>• 1st dose vaginal or sublingual;</td>
<td>• Oral</td>
<td>800 ug, then 400ug</td>
<td>36-48 hrs after taking mifepristone</td>
<td>Every 3 hours up to 5 doses</td>
</tr>
<tr>
<td></td>
<td>• Single dose</td>
<td>• Additional doses sublingual</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Above 12 weeks (84 days)</strong></td>
<td>• 200 mg</td>
<td>• 1st dose vaginal or sublingual;</td>
<td>• Oral</td>
<td>800 ug, then 400ug</td>
<td>36-48 hours after taking mifepristone</td>
<td>Every 3 hours up to 5 doses</td>
</tr>
<tr>
<td></td>
<td>• Single dose</td>
<td>• Additional doses sublingual</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**References**

8. **NOTIFICATION KEEPING OF RECORDS AND SUBMISSION OF DATA IN THE PUBLIC AND PRIVATE SECTOR**

- The requirements for the notification of termination of pregnancy in terms of Regulation R168 must be noted.
- All healthcare facilities, public and private, must keep record of all TOP’s performed.
- Complications referred to another facility must be managed and documented as a NEW case of TOP.
• **Annexure A** must be completed for every procedure performed. The original copy (one with client’s name) should be filed in the client’s folder. Forward the anonymous copy via the Facility Manager to the District / Sub-structure Offices for filing.

• Detailed client notes must be kept in the client folder.

• **Annexure C** must be completed on a monthly basis to provide statistics and should be forwarded via the Facility Manager to the District / Sub-structure Office where the data will be entered onto Sinjani.

9. **CONFIDENTIALITY**

All clients seeking abortion have the right to confidentiality from all the staff involved in the care of the client. Women should be informed that all procedures are notified at the district office, but that an anonymous copy of the form (Annexure A) is used. Clients have a right to auditory and visual privacy.

10. **ETHICAL and LEGAL OBLIGATION**

**CONSCIENTIOUS OBJECTIONS**

The Department respects the right of health care workers to conscientious objections in participating in the termination of pregnancy. According to section 15 (1) of The Constitution of the Republic of South Africa, 1996 (Act 108 of 1996), “everyone has the right to freedom of conscience, religion, thought, belief and opinion”.

However, the clients’ right to information and access to health care services, including termination of pregnancy, must also be respected. Should a health care provider wish to exercise his/her right to conscientious objection, he/she may do so providing the client is offered all the necessary information that will allow her access to services. The client must be respectfully referred to a colleague who is willing to assist the client in obtaining the service. Protection of the health care worker’s spiritual interest should not be at the cost of the patient’s health or other interests, nor should a health care worker subordinate a patient’s religious convictions to his/her own.
It must be emphasized that public health facilities are public domain. The management therefore must ensure that women have access to the services, which they are legally entitled to.

There are some important circumstances when conscientious objections are no longer applicable:

- When continuation of a pregnancy poses a serious danger to the life or health of women, regardless of gestational age.

- A health care worker may not legally or ethically object to the rendering of care in cases of life-or health-endangering emergencies associated with TOP procedures, in the same way that they have to deal with the emergency consequences arising from unlawful procedures.

- Objection is limited to the staff directly involved in the TOP procedure. Ancillary staff (e.g. ward clerks, catering etc) and staff involved in the general care of a patient may not refuse to provide general or standard care to a TOP client.

Health professionals who have conscientious objection must inform their Facility Manager in writing. The manager needs to place this in the staff members’ personnel file. The Facility Manager must also inform the staff member of the client’s right to access to CTOP and information.

To ensure the availability of sufficient personnel for rendering termination of pregnancy services, it may be necessary when posts are advertised to indicate that the duties of the incumbent will include termination of pregnancy services and it should then be reflected in the appointment letter. Conscientious objection should only be dealt with when expressed by individual staff members, not as a group action.

Employees could be encouraged to discuss possible conscientious objections electively. Refusal to discharge obligations as it appears in the employee’s job description when faced with a particular task could lead to breach of contract.

11. STAFF SUPPORT

The Management of the services concerned must ensure that adequate support is provided for staff involved in termination of pregnancy. Confidential access to professional counselling should be made available to personnel in need of it.
ANNEXURES:

Annexure A: Notification of Termination of Pregnancy in terms of Section 7 of the CTOP Act (Act No 92 of 1996)

Annexure C: Monthly data collection form

Annexure D: Royal College of Obstetricians and Gynecologists Best practice in abortion care (Best Practice Paper No 2 June 2015)

Annexure E: Referral form for Second trimester TOP

Supporting literature to Termination of Pregnancy (TOP) Service


4. WHO Clinical practice handbook for safe abortion. 2014

5. RCOG Leading Safe Choices: Best practice in comprehensive abortion care. Best Practice Paper No. 2 June 2015
# Annexure A

**Notification of Termination of Pregnancy in Terms of Section 7 of the Act**

**Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996)**

To be completed by a medical practitioner or a registered midwife

(To be completed in duplicate)

This copy remains in the client folder.

## 1. Patient Details

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<thead>
<tr>
<th>Surname</th>
<th>Race</th>
<th>Present Marital Status</th>
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## 2. Institution

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## 3. Abortion Details

**Indications for termination of pregnancy (tick the appropriate block):**

- <13 weeks: On demand
- 13-20 weeks: Maternal physical/mental health
- 13-20 weeks: Fetal physical/mental health
- 13-20 weeks: Rape or incest
- 13-20 weeks: Social/economic

Gestation (weeks):

<10  10 - 15  >15

## 4. Counselling

- Pre-abortion counselling
- Contraception counselling
- Booking for post abortion counselling
- Counselling refused

## 5. Consent

I have been informed about termination of pregnancy (including the possible adverse effects of drugs used) and give consent for terminating this pregnancy and/or removal of pregnancy products.

(Date where appropriate)

I also understand that this consent includes management of any complication that may arise from the termination. (This may include anaesthesia or hysterectomy)

**Signature**

**Witness**

**Date**

## 6. Management and Complications

<table>
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<th>Drugs Used</th>
<th>Method(s)</th>
<th>Complications</th>
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<tbody>
<tr>
<td>Analgesia pre-TOP</td>
<td>Manual vacuum aspiration Date / /</td>
<td>No complications</td>
</tr>
<tr>
<td>Analgesia intra-operatively</td>
<td>MTOP Date / /</td>
<td>Perforation of uterus</td>
</tr>
<tr>
<td>Analgesia post-TOP</td>
<td>D&amp;E Date / /</td>
<td>Laparotomy for complications</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>Sharp curettage (D&amp;C) Date / /</td>
<td>Method failure</td>
</tr>
<tr>
<td>Mifepristone</td>
<td>Hysterectomy Date / /</td>
<td>Excessive bleeding</td>
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<td>Prostaglandin E2</td>
<td>Hysterotomy Date / /</td>
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<tr>
<td>Prostaglandin F2alpha</td>
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<td>Prophylactic Antibiotics</td>
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<td>Rhesus anti-D</td>
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## 7. Detail of Practitioner(s) for Counselling and Consent

I declare the above information as correct.

<table>
<thead>
<tr>
<th>Name</th>
<th>Qualification</th>
<th>Signature</th>
<th>Reg. No</th>
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(*) Nurse practitioner  Medical practitioner

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<th>Signature</th>
<th>Reg. No</th>
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## 8. Detail of Practitioner Performing the Procedure

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</table>

(Date: Admitted  Date of Procedure  Date of Discharge)
ANNEXURE A
NOTIFICATION OF TERMINATION OF PREGNANCY IN TERMS OF SECTION 7 OF THE ACT
CHOICE ON TERMINATION OF PREGNANCY ACT, 1996 (Act No. 92 of 1996)
TO BE COMPLETED BY A MEDICAL PRACTITIONER OR A REGISTERED MIDWIFE
(To be completed in duplicate).

Anonymous copy

1. PATIENT DETAILS
Surname
First Names
Hospital No.
Age
Gravida
Parity
Miscarriages

4. INSTITUTION
Name
[Public] [Private]
[Hospital] [Clinic]

5. ABORTION DETAILS
Indication for termination of pregnancy (tick the appropriate block)
< 13 weeks: On demand
13-20 weeks: Maternal physical/mental health
13-20 weeks: Fetal physical/mental
13-20 weeks: Rape or incest
13-20 weeks: Social/economic

4. COUNSELLING
Pre-abortion counselling
Contraception counselling
Booking for post abortion counselling
Counselling refused

CONTRACTION AFTER TOP
Sterilisation
Oral contraception
Long acting progesterone
IUCD
Condoms

5. CONSENT
I have been informed about termination of pregnancy (including the possible adverse effects of drugs used) and give consent for terminating this pregnancy and/or removal of pregnancy products.
(Delete where appropriate)
I also understand that this consent includes management of any complication that may arise from the termination. (This may include anaesthesia or hysterectomy)

9. MANAGEMENT AND COMPLICATIONS

<table>
<thead>
<tr>
<th>Drugs used</th>
<th>Method(s)</th>
<th>Complications</th>
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<tr>
<td>Analgesia pre-TOP</td>
<td>Manual vacuum aspiration</td>
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<td>D&amp;E</td>
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<td>Sharp curettage (D&amp;C)</td>
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<td>Hysterectomy</td>
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<td>Prostaglandin F2alpha</td>
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10. DETAIL OF PRACTITIONER(S) for COUNSELLING AND CONSENT
I declare the above information as correct.
Name
Qualification
Reg. No

*Name
Qualification
Reg. No

11. DETAIL OF PRACTITIONER PERFORMING THE PROCEDURE
Name
Qualification
Reg. No

Date Admitted
Date of Procedure
Date of Discharge
1. FACILITY DETAILS

SUB-DISTRICT: 
FACILITY: 
PERIOD (Month / Year): 
COMPLETED BY: 
NAME OF PERSON IN CHARGE OF FACILITY: 

2. DETAILS OF TERMINATIONS PERFORMED

<table>
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<tr>
<th>Total number of terminations performed</th>
<th>&lt; 10</th>
<th>10 - 15</th>
<th>&gt;15</th>
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Waiting time ime from first consultation to TOP procedure (total in working days) – put total number of patients per month in applicable block

3. AGE & ETHNIC GROUP OF WOMEN

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<tr>
<th>Age</th>
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4. GESTATION PERIOD

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<td>13 - 20 weeks</td>
<td></td>
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<tr>
<td>21 - 24 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. MANAGEMENT

5.1 Drugs

Number of TOP’s done aided by Misoprostol

Number of TOP’s done aided by Mifepristone & Misoprostol

5.2 Surgical (Number of procedures done using the following methods)

- Manual Vacuum Aspiration
- Suction Curettage
- Sharp Curettage

Signature (Head of Institution): ........................................... Date: ....................

Form to be completed by the person in charge of the designated facility in terms of Section 7(2) at the end of each month.

Send to your District Office by the 8th of the following month.
Best practice in comprehensive abortion care

Best Practice Paper No. 2
June 2015
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Introduction to the Best Practice Papers

Professionals providing reproductive health care have a responsibility to ensure that the women and men they treat benefit from the latest evidence-based clinical practices. In support of these, and in line with the Royal College of Obstetricians and Gynaecologists’ mandate of improving health care for women everywhere, by setting standards for clinical practice, this Best Practice Paper sets out the essential elements of a high-quality abortion care service including comprehensive post-abortion care and contraception.

The best practices described are drawn from current evidence-based guidance produced by organisations such as the World Health Organization (WHO), the Royal College of Obstetricians and Gynaecologists, and Ipas. So as to be readable and useful to people providing healthcare on a daily basis, the paper has been deliberately kept short and succinct. Therefore the primary evidence for the recommendations and the strength of that evidence have been omitted but can be found in the original source documents. Very recently published evidence has been assessed to determine whether any of the recommendations from current guidelines should be amended.

Recognising that different healthcare providers may be involved at different stages of the management of induced abortion, the paper has been divided into sections specific to these stages where appropriate.

The use of the clinical recommendations should be individualised to each woman, with emphasis on her clinical needs.

The recommendations may also be used as a tool to assist policy makers in moving their services forward.

While the paper may be used for reference in any country, varying legal, regulatory, policy and service-delivery contexts may require some recommendations to be adapted to the local context; however, it is important to ensure that best practice is maintained.

For support on adapting the document while still maintaining good practice, please write to leading-safe-choices@rcog.org.uk.

Acknowledgements

This document was developed by Anna Glasier in close consultation with David Baird, Paul Blumenthal, Sharon Cameron, Alison Fiander, Ailsa Gebbie, Stefan Gebhardt, Natalie Kapp, Hawa Kawawa, Judy Kluge, Patricia Lohr, Grace Magembe, Gileard Masenga, Projestine Muganyizi, Malika Patel, Gregory Petro, Lesley Regan, Sam Rowlands, Petrus Steyn and Zephine van der Spuy. It was peer reviewed by Kelly Culwell, Kristina Gemzell-Danielsson and Angela Hyde.

The Leading Safe Choices Initiative

Globally, 222 million women would like to prevent or delay pregnancy but have no access to contraception. Meeting this need would allow women to control their own fertility and reduce maternal deaths by one-third, with lasting benefits for their families and communities.

Thanks to a three-year, multi-million pound grant, an important new initiative called Leading Safe Choices offers the RCOG a unique opportunity to address this unmet need. Leading Safe Choices will initially pilot in Tanzania and South Africa and focus on postpartum family planning (PPFP) in both countries, and on comprehensive abortion care in South Africa and comprehensive post-abortion care in Tanzania.

The initiative will take an integrated systems approach, working within existing health structures and with professionals currently working in women’s health in these two countries. The pilot phase will focus on selected high-volume maternity hospitals and midwifery units, increasing skills and improving quality in PPFP and comprehensive abortion care.

The programme has three broad objectives:
1. developing RCOG Best Practice Papers on PPFP and comprehensive abortion care in South Africa and on comprehensive post-abortion care in Tanzania
2. training healthcare providers and supporting the delivery of high-quality PPFP and comprehensive abortion care in South Africa and comprehensive post-abortion care in Tanzania
3. establishing a formal accreditation and certification process to:
   • recognise competence
   • raise standing within professions
   • increase the uptake and quality of service provision.

The long-term vision is to expand the Initiative across South Africa and Tanzania and to other countries, following on from this pilot phase.
Introduction

Each year, 22 million unsafe abortions are estimated to take place, resulting in the death of approximately 47,000 women. Some 5 million women suffer injury as a result of complications due to unsafe abortion, often leading to chronic disability. Abortion need not be unsafe. Safe abortion should be and can be available and accessible for all women, to the full extent that the law allows. Even in countries where legal abortion is severely restricted, in circumstances where it is permitted, such as to save the life of the woman, it should always be done safely.

Abortion is not a complex procedure. A range of providers, including nurses and midwives, have been shown to be competent to deliver abortion services safely in a number of settings. As with many other medical procedures, adherence to best practice standards will ensure that the most effective and the safest services are delivered. This Best Practice Paper is designed to be used on a daily basis by healthcare workers who are responsible for delivering pre-abortion counselling and assessment, and abortion and post-abortion care services including post-abortion contraception.

All aspects of abortion care should be delivered in a respectful and sensitive manner that recognises women as decision makers.

Information for women requesting abortion

Women should be informed about their pregnancy options so that they can make an informed choice about their preferred course of action.

All women who require more support in deciding whether to continue the pregnancy or have an abortion should be identified and offered further opportunities to discuss their decision.

If performed in line with best practice, abortion is safer than childbirth.

The following information should be provided to women requesting abortion, with an emphasis on the overall safety of the procedure and in a way that women can understand:

- the choice of abortion method available (if appropriate) and the characteristics of each (see Table 1)
- the side effects, risks and complications associated with each available abortion method
- what will be done during and after the abortion
- symptoms likely to be experienced both during and after the abortion (e.g. menstrual-like cramps, pain and bleeding)
- how long it will take for the abortion to be completed
- what pain management will be made available
- follow-up care, including contraceptive advice and provision
- the range of emotions commonly experienced after having an abortion
- other services that are available, such as sexually transmitted infection (STI) testing and support for women experiencing sexual coercion or domestic violence.
Table 1 Characteristics of abortion procedures; adapted from WHO (2014) Clinical Practice Handbook for Safe Abortion

<table>
<thead>
<tr>
<th>Medical abortion</th>
<th>Surgical abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>avoids surgery</td>
<td>quick procedure</td>
</tr>
<tr>
<td>mimics miscarriage</td>
<td>complete abortion is easily verified by evaluation of aspirated products of conception</td>
</tr>
<tr>
<td>controlled by the woman and may take place at home (at less than 9 weeks of pregnancy)</td>
<td>takes place in a healthcare facility</td>
</tr>
<tr>
<td>takes time (hours to days) to complete abortion, and the timing may not be predictable</td>
<td>sterilisation of the woman or placement of an intrauterine device (IUD) may be performed at the same time as the procedure</td>
</tr>
<tr>
<td>women experience bleeding and cramping, and potentially some other side effects (nausea, vomiting)</td>
<td>requires instrumentation of the uterus</td>
</tr>
<tr>
<td>may require more clinic visits than surgical abortion</td>
<td>small risk of uterine or cervical injury</td>
</tr>
<tr>
<td><strong>May be necessary in the following situations:</strong></td>
<td>timing of abortion is controlled by the facility and provider</td>
</tr>
<tr>
<td>for severely obese women</td>
<td></td>
</tr>
<tr>
<td>if the woman has uterine malformations or fibroids, or has had previous cervical surgery</td>
<td></td>
</tr>
<tr>
<td>if the woman wants to avoid surgical intervention</td>
<td></td>
</tr>
<tr>
<td>if a pelvic examination is not feasible or is unwanted</td>
<td></td>
</tr>
</tbody>
</table>

The information should be given in a non-judgemental and supportive way.

This is particularly important for adolescent girls who may be visiting a reproductive health facility for the first time. If the law requires an adult to consent to her procedure, this should be clearly explained at the start of the consultation. While all young people should be encouraged to involve a trusted adult in their decision if possible, do not insist on parents’ authorisation unless it is a legal requirement.

The **pre-abortion consultation** should confirm the woman’s decision and should include the following information:

1. Abortion is a safe procedure for which major complications and mortality are rare at all gestations. If performed in line with best practice, abortion is safer than childbirth.
2. The earlier in pregnancy an abortion is undertaken, the safer it is likely to be.
3. Surgical and medical methods of abortion carry a small risk of failure to end the pregnancy (1 or 2 per 100 procedures).
4. There is a small risk (less than 2 in 100 for surgical and 5 in 100 for medical) of the need for further intervention to complete the procedure, i.e. surgical intervention following medical abortion or re-evacuation following surgical abortion.

5. The following complications may occur:
   - severe bleeding requiring transfusion – the risk is lower for first-trimester abortions (less than 1 in 1000), rising to around 4 in 1000 at gestations beyond 20 weeks
   - uterine rupture in association with second-trimester medical abortion – the risk is less than 1 in 1000.
For surgical abortions only:
- cervical trauma – the risk of damage is no more than 1 in 100 and is lower for first-trimester abortions; trauma is less likely if cervical preparation is undertaken in line with best practice
- uterine perforation – the risk is in the order of 1–4 in 1000 and is lower for first-trimester abortions.

6 Further treatment (e.g. blood transfusion, laparoscopy, laparotomy or hysterectomy) may be required, should one of these complications occur.

7 Upper genital tract infection of varying degrees of severity is unlikely, but may occur after medical or surgical abortion and is usually associated with pre-existing infection.

There are a number of myths about the consequences of abortion. If the woman expresses concern, she can be reassured that there are no proven associations between induced abortion and subsequent ectopic pregnancy, placenta praevia, infertility, breast cancer or psychological problems.

It is best practice to discuss contraception at the initial consultation.

The benefits of the most effective methods (IUDs and implants) should be explained.

If a contraceptive method is chosen, that choice should be documented so that it can be provided when the abortion is undertaken.

Information for staff assessing women prior to induced abortion

It should be confirmed that the woman is seeking abortion voluntarily. Those responsible for assessing women in respect of medical eligibility for abortion should be able to ensure that women who need specialist care (e.g. women with serious chronic medical conditions such as heart disease) are referred as soon as possible to an appropriate service.

It is important at this stage to make sure that abortion eligibility by gestation is correctly assessed and that any ongoing genital tract infection is excluded or properly managed.

Taking the medical history

It should be determined whether the woman is eligible to undergo abortion safely in the service concerned by taking a general medical history to exclude serious or relevant acute or chronic medical conditions.

Blood tests

Pre-abortion assessment should include determination of Rhesus blood status if testing is available. Where clinically indicated, pre-abortion assessment may also include measurement of haemoglobin concentration.
Determining gestational age

It is not necessary to determine the exact gestational age but rather to make sure that the gestation falls within the range of eligibility for a particular method of inducing abortion. The date of onset of the last menstrual period, bimanual pelvic examination, abdominal examination and recognition of symptoms of pregnancy are usually adequate after a positive pregnancy test. Table 2 shows gestation in both weeks and days of amenorrhoea.

<table>
<thead>
<tr>
<th>Completed weeks</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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<tr>
<th>Completed weeks</th>
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<th>15</th>
<th>16</th>
<th>17</th>
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<th>19</th>
<th>20</th>
<th>21</th>
<th>22</th>
<th>23</th>
<th>24</th>
</tr>
</thead>
</table>

Routine pre-abortion ultrasound scanning is unnecessary but, if available, may be useful if there are concerns about complications such as ectopic pregnancy.

STI screening

It is best practice to undertake a risk assessment for STIs for all women (e.g. HIV, chlamydia, gonorrhoea, syphilis), and then to screen for them if appropriate and available. This should be done without delaying the abortion. The partners of women who test positive for STIs should be informed and advised about treatment, provided that the woman gives her consent to this.

Ideally, a system for partner notification and follow-up or referral should be in place.

Services should make available information about the prevention of STIs, and offer condoms for STI prevention to all women undergoing abortion.

Prevention of infective complications

Routine use of antibiotics at the time of surgical abortion is best practice as it reduces the risk of infection after the abortion. However, abortion should not be delayed if antibiotics are not available.

The following regimens are recommended for perisurgical abortion antibiotic prophylaxis:

- 200 mg doxycycline within 2 hours before the procedure

OR

- 500 mg azithromycin within 2 hours before the procedure.

Contraception

Effective methods of contraception should be discussed with women at the initial assessment and a plan agreed, and documented, for contraception after the abortion. Women should be advised of the greater effectiveness of long-acting reversible methods of contraception (LARC: implants and
IUDs) and encouraged (but not coerced) to choose them. Immediately after surgical abortion is an optimal time for insertion of an IUD (and is safe after both first- and second-trimester surgical abortions). Contraceptive implants can be provided at any time once the abortion procedure has started.

**Information for staff providing the abortion**

The most appropriate abortion methods/regimens (surgical or medical) should be determined and discussed with the woman (see Table 1).

Dilatation and sharp curettage (D&C) is an obsolete method of surgical abortion, for which the current recommended method is vacuum aspiration.

**For pregnancies of less than 14 weeks of gestation**

**Surgical abortion**

Either manual or electric vacuum aspiration:

- There is no lower limit of gestation for surgical abortion.
- It is best practice to inspect aspirated tissue at all gestations to confirm complete evacuation; this is essential following vacuum aspiration at under 7 weeks of gestation.
- During vacuum aspiration, the uterus should be emptied using the suction cannula and forceps (if required) only. The procedure should not be routinely completed by sharp curettage.
- Use of medications containing either oxytocin or ergometrine are not recommended for prophylaxis to prevent excessive bleeding either at the time of vacuum aspiration or afterwards.
- Sharp curettage should not be performed.

**OR**

**Medical abortion**

If mifepristone is available, it is best practice to use it in combination with misoprostol as it shortens the induction-abortion interval, reduces side effects and decreases the rate of ongoing pregnancy.

Effective regimens for medical abortion include:

- at up to 63 days of gestation, mifepristone 200 mg orally, followed 24–48 hours later by misoprostol 800 micrograms given by the vaginal, buccal or sublingual route; if misoprostol is provided for a woman to use at home, a single dose of 800 micrograms should be provided
- from 64 days to 13 weeks and 6 days, mifepristone 200 mg orally, followed 24–48 hours later by misoprostol 800 micrograms given by the vaginal, buccal or sublingual route, followed by misoprostol 400 micrograms every 3 hours until abortion occurs

**OR**

- If mifepristone is not available, and for all gestations up to 13 weeks and 6 days, misoprostol 800 micrograms given by the vaginal, buccal or sublingual route, followed by misoprostol 400 micrograms every 3 hours until abortion occurs.
For pregnancies of 14 weeks of gestation or more

Surgical abortion

Surgical abortion can be performed by trained providers using:
- vacuum aspiration using large bore cannulae
- dilatation and evacuation (D&E).

OR

Medical abortion

At 14 weeks of gestation or more, medical abortion should be undertaken in a medical facility. If mifepristone is available, it should be used in combination with misoprostol as it shortens the induction-abortion interval, reduces side effects and decreases the rate of ongoing pregnancy. The regimens are as follows:
- mifepristone 200 mg orally, followed 12–48 hours later by misoprostol 800 micrograms vaginally, followed by misoprostol 400 micrograms orally or vaginally every 3 hours until abortion occurs; if after 24 hours abortion does not occur, mifepristone can be repeated 3 hours after the last dose of misoprostol, and 12 hours later misoprostol may be recommenced

OR

- where mifepristone is not available, misoprostol 800 micrograms followed by misoprostol 400 micrograms every 3 hours until abortion occurs.

Cervical preparation before surgical abortion

Cervical preparation should be used for all women with a pregnancy of gestational age over 14 weeks. Suitable preparations include:
- osmotic dilators 12–24 hours before the procedure; if the pregnancy is at less than 18 weeks of gestation, osmotic dilators will be effective at just 3–4 hours before the procedure

OR

- mifepristone 200 mg 12–24 hours before the procedure

OR

- misoprostol 400 micrograms vaginally 3 hours or sublingually 2 hours before the procedure.

Cervical preparation may be considered for women before 14 weeks if there is a high risk for cervical injury or uterine perforation. The following regimen is recommended:
- Misoprostol 400 micrograms administered vaginally 3 hours before the procedure or sublingually 2 hours before the procedure.

Medication for pain management

For both medical and surgical abortions, analgesia (pain relief) should always be offered and provided without delay, if requested.
- In most cases, analgesics (e.g. nonsteroidal anti-inflammatory drugs (NSAIDs)), local anaesthesia and/or conscious sedation supplemented by verbal reassurance are sufficient.
- The need for pain management increases with gestational age and narcotic analgesia may be required.
- Prophylactic NSAIDs at the time of initiation of misoprostol for second-trimester medical abortion may reduce the need for narcotic analgesia.
- Prophylactic paracetamol (oral or rectal) is ineffective in reducing pain after surgical abortion.

**Local anaesthesia**, such as lidocaine, can be used to alleviate discomfort from mechanical cervical dilatation and uterine evacuation during surgical abortion.

General anaesthesia is not recommended for routine abortion procedures, as it has been associated with higher rates of complications than analgesia and local anaesthesia.

**Contraceptive provision**

If a woman has chosen a contraceptive method that can be provided as part of or during the abortion procedure (e.g. IUD insertion once manual vacuum aspiration is completed), it should be ensured that this is done. IUDs can be inserted at the time of the abortion in both the first and second trimesters. Contraceptive implants can be inserted at any time during the abortion procedure.

**Information for staff concerned with care after induced abortion**

Healthcare staff involved in post-abortion care should ensure that the woman leaves the abortion service knowing what to expect following the procedure and where to get help if necessary. They should also ensure that every woman is able to leave with a method of contraception that she can start immediately. Women should be informed of the superior effectiveness of IUDs and implants in preventing unintended pregnancy.

**Information to provide**

Before leaving the facility, women should receive instructions about how to care for themselves after they go home, including:
- how much bleeding to expect in the next few days and weeks
- how to recognise potential complications, including signs of ongoing pregnancy
- when they can resume normal activities (including sexual intercourse)
- how and where to seek help if required.

**Contraception**

Before they leave the healthcare facility, all women should receive contraceptive information and, if desired, the contraceptive method of their choice. If the chosen method is not available, they should be referred to a service where the method can be provided.

Women should be advised of the greater effectiveness and duration of LARC methods (implants and IUDs) and of their safety, and healthcare staff should dispel any myths there may be about these methods.

Sterilisation can be safely performed at the time of induced abortion although it can be more likely than interval sterilisation to be associated with regret.
**Anti-D IgG**
If available, anti-D IgG should be given intramuscularly to all non-sensitised RhD-negative women within 72 hours following abortion.

**Management of incomplete abortion**
Post-abortion care can reduce the morbidity and mortality associated with complications of either miscarriage or incomplete abortion (including abortion that was performed unsafely). Options for management for incomplete abortion include surgical and medical methods of uterine evacuation.

For women who wish to avoid another pregnancy, contraception should be discussed and a method provided. Women experiencing a miscarriage who wish to get pregnant again should be advised to wait until after having at least one normal menstrual period, longer if chronic health problems (e.g. anaemia) require treatment.

**Assessment**
Incomplete abortion should be suspected when any woman of reproductive age presents with vaginal bleeding and/or abdominal pain after one or more missed menstrual periods. Ectopic pregnancy should be suspected if the uterus is small, the cervix closed and/or there is an adnexal mass.

**Unsafe abortion**
In many settings it is important to distinguish between safe and unsafe abortion since the latter is much more likely to be associated with infection. Indications that an abortion has been attempted by unsafe methods include the presence of:
- vaginal laceration
- cervical injury
- uterine enlargement equivalent to a pregnancy of more than 12 weeks of gestation
- products of conception visible at the cervix.

**Infection**
It is vital to identify women who may have an infection and to manage this urgently. Infection is much more likely, and much more likely to be severe, if the abortion has been performed unsafely. Clinical features suggestive of infection include:
- temperature above 37.5°C
- localised or general abdominal tenderness, guarding and rebound
- foul odour or pus visible in the cervical os
- uterine tenderness.

Features suggestive of sepsis and indicating the need for urgent intervention include:
- hypotension
- tachycardia
- increased respiratory rate.
Management

If there is no suspicion of infection and uterine size is less than 14 weeks

- uterine evacuation with vacuum aspiration:
  - antibiotic prophylaxis should be given before surgical evacuation – 200 mg doxycycline within 2 hours before the procedure or a single dose of 500 mg azithromycin within 2 hours before the procedure (NB. If antibiotics are not available, the procedure should not be delayed.)
  
OR

- misoprostol 600 micrograms orally or 400 micrograms sublingually.

If there is no suspicion of infection and uterine size is 14 weeks or larger

- evacuation using vacuum aspiration and blunt forceps if necessary:
  - antibiotic prophylaxis should be given before surgical evacuation – 200 mg doxycycline within 2 hours before the procedure (with or without 200 mg doxycycline after the abortion) or a single dose of 500 mg azithromycin within 2 hours before the procedure (NB. If antibiotics are not available, the procedure should not be delayed.)
  
OR

- misoprostol:
  - 14–28 weeks: at least 200 micrograms administered vaginally, sublingually or buccally at least 6-hourly:
    - If available and time permitting, mifepristone 200 mg orally should be administered 12–48 hours before misoprostol
    - In order to align protocols, services may use the same dosing and intervals as recommended in regimens for induced abortion
  - 28+ weeks: 25 micrograms vaginally 6-hourly or 25 micrograms orally 2-hourly.

If infection is present the uterus should be evacuated urgently

- start broad-spectrum antibiotics immediately – intravenously if infection is severe
- transfer to a unit with the facilities for undertaking surgical evacuation if it cannot be done in the facility to which the woman presents
- if the woman is in septic shock, she should be transferred immediately to a specialist unit for surgical uterine evacuation – broad-spectrum antibiotics (such as a combination of ampicillin 0.5–1 g 6-hourly, metronidazole 500 mg 8-hourly and gentamicin 120 mg daily) should be administered intravenously prior to transfer if available
- if the skills necessary for urgent surgical uterine evacuation are not available, misoprostol can be used:
  - 14–28 weeks: At least 200 micrograms administered vaginally, sublingually or buccally at least 6-hourly
  - 28+ weeks: 25 micrograms vaginally 6-hourly or 25 micrograms orally 2-hourly.
**Information to provide after the abortion**

Before leaving the facility, women should receive instructions about how to care for themselves after they go home, including:

- how much bleeding to expect in the next few days and weeks
- how to recognise potential complications, including signs of ongoing pregnancy
- when they can resume normal activities (including sexual intercourse)
- how and where to seek help if required
- women who want to try again to conceive should be advised to wait until after having at least one normal menstrual period, longer if chronic health problems (e.g. anaemia) require treatment.

**Contraception**

Before they leave the healthcare facility, all women should receive contraceptive information and, if desired, the contraceptive method of their choice. If the chosen method is not available, they should be referred to a service where the method can be provided.

Women should be advised of the greater effectiveness and duration of LARC methods (implants and IUDs) and of their safety, and healthcare staff should dispel any myths that exist about these methods.

IUD insertion or female sterilisation should be delayed until the woman’s health is restored and any infection is resolved. Interim contraception should be provided using the most effective acceptable method until an IUD can be inserted or sterilisation performed.

**Anti-D IgG**

If available, anti-D IgG should be given intramuscularly to all non-sensitised RhD-negative women within 72 hours following abortion.

**Service delivery**

The provision of a safe and effective comprehensive abortion care service depends on everyone involved in the service ensuring that everything can be done to meet the essential standards for safe abortion care. It is not enough for doctors, nurses and midwives to perform effectively if the facilities and tools that they need are not reliably available and if the service is not organised in a way that ensures safe and effective comprehensive abortion care. Best practices for service delivery are listed below.

**Access to services**

1. Abortion services must be available to the fullest extent that the law allows. Healthcare providers should know what the law does allow in their country and be clear about the circumstances for which abortion is legal.

2. If a woman requesting abortion fulfils the legal criteria, there should be no further restriction of access on grounds such as age, marital status or the number of previous abortions.

3. Abortion is safer the sooner it is done. Services should be able to meet the local demand for abortion so that women can have their abortion at the earliest possible gestation and as close to home as possible.
4 As the equipment needed for routine early medical abortion is not sophisticated, this service can be provided in basic facilities, thereby increasing access to safe abortion care and enhancing convenience to women.

5 As the equipment and space required for a safe abortion service are similar to those needed for routine women's healthcare and family planning services, efforts should be made to provide safe abortion services in a wide range of health facilities and in an integrated manner.

6 All healthcare providers should be trained to provide comprehensive abortion care in line with their skills and licences. This can help spread the workload and improve the skills of all providers of women’s health care, thereby enhancing access to and increasing the safety of abortion care.

7 Integrating abortion services within overall maternal/women’s health care minimises the stigma associated with abortion care for both women and providers.

8 Where abortion services are provided but there is no provision for emergency or specialist care, there must be robust and timely pathways for referral.

Information provision

1 There should be local arrangements in place for providing information to women and healthcare professionals on routes of access to safe abortion care.

2 Services should ensure that written, objective, evidence-guided information is available in a way that is understandable to women considering abortion. Information should be available in a variety of languages and formats.

3 Women should have access to objective information and, if required, counselling and decision-making support about their pregnancy options.

4 Information for women and providers should emphasise the need for confidentiality.

Initial assessment

1 There should be a pathway to appropriate medical care for women with known significant medical conditions requiring specialist abortion care (e.g. heart disease).

2 Women presenting for induced abortion who are found to have a non-viable pregnancy also require contraception and sexual health care.

3 Women requesting abortion but who subsequently decide to continue the pregnancy should be referred for antenatal care (together with all their relevant information, such as ultrasound scan reports)

4 Services should identify issues/characteristics that make women particularly vulnerable (e.g. adolescents, victims of domestic abuse or gender-based violence) and refer/signpost them on to appropriate support services.

Arrangements for the procedure

1 To minimise delay, service arrangements should be such that the abortion can be provided as soon as possible, ideally on the same day as the assessment.

2 A system should be in place to ensure that the required legal documentation is completed accurately and in a timely manner.

3 The setting for the abortion service (the consultation room, the procedure room and the recovery room) should respect the need for women's privacy and dignity.
Evidence sources


Additional literature reviewed


Appendix: Post-abortion contraception
(Adapted from World Health Organization (2014) Clinical Practice Handbook for Safe Abortion)

Generally, almost all methods of contraception can be initiated immediately following a surgical or medical abortion. Immediate start of contraception after surgical abortion refers to the same day as the procedure, and for medical abortion refers to the day the first pill of a medical abortion regimen is taken. As with the initiation of any method of contraception, the woman’s medical eligibility for a method should be verified.

Post-abortion medical eligibility recommendations for hormonal contraceptives, intrauterine devices and barrier contraceptive methods

<table>
<thead>
<tr>
<th>POST-ABORTION CONDITION</th>
<th>FIRST TRIMESTER</th>
<th>SECOND TRIMESTER</th>
<th>IMMEDIATE POST-SEPTIC ABORTION</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>CIC</td>
<td>1</td>
<td>1</td>
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</tr>
<tr>
<td>Patch &amp; vaginal ring</td>
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</tr>
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<td>1</td>
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<td>1</td>
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<tr>
<td>LNG/ENG implants</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Copper-bearing IUD</td>
<td>1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>LNG-releasing IUD</td>
<td>1</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Condom</td>
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<td>Spermicide</td>
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<tr>
<td>Diaphragm</td>
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</table>

CIC, combined injectable contraceptive; COC, combined oral contraceptive; DMPA/NET-EN, progestogen-only injectables: depot medroxyprogesterone acetate/norethisterone enantate; IUD, intrauterine device; LNG/ENG, progestogen-only implants: levonorgestrel/etonorgestrel; POP, progestogen-only pill.

Definition of categories
- 1: a condition for which there is no restriction for the use of the contraceptive method.
- 2: a condition where the advantages of using the method generally outweigh the theoretical or proven risks.
- 3: a condition where the theoretical or proven risks usually outweigh the advantages of using the method.
- 4: a condition that represents an unacceptable health risk if the contraceptive method is used.

Contraception for women on antiretroviral therapy for HIV
There are potential drug interactions between some antiretroviral drugs and hormonal contraception. However, WHO has reviewed the data and concluded that the benefits of using hormonal contraception outweigh the risks (2015 MEC, Category 2).