# CHAPTER 5 GYNAECOLOGY

# **5.1 DYSMENORRHOEA**

N94.4-6

## DESCRIPTION

Lower abdominal pain that starts with the onset of menstruation and subsides after menses have ended. This may be associated with headaches, nausea, and vomiting. It may be primary or secondary. Primary dysmenorrhoea is menstrual pain without organic disease. Secondary dysmenorrhoea is associated with identifiable disease, e.g. chronic pelvic infection, fibroids, endometriosis, adenomyosis; or the use of an intrauterine contraceptive device.

#### **GENERAL MEASURES**

For secondary dysmenorrhoea, investigate and treat the underlying condition.

## MEDICINE TREATMENT

Symptomatic relief:

- NSAID, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly, with or after a meal.

#### OR

- Paracetamol, oral, 500mg-1 g, 4–6 hourly as required (to a maximum of 4g in 24 hours).
  - Maximum dose: 15 mg/kg/dose.

For dysmenorrhoea caused by endometriosis:	LoE:IVb
<ul> <li>Combined oral contraceptive and review after 3 months.</li> <li>OR</li> </ul>	LoE:IIIb <sup>iii</sup>
<ul> <li>Medroxyprogesterone acetate (long-acting), IM, 150 mg 12 weekly.</li> <li>Review after 3 months.</li> </ul>	LoE:IIb <sup>iv</sup>
REFERRAL	

- » If there is uncertainty about the diagnosis.
- » Young women with pain not responding to conventional treatment.
- » Older (>40 years of age) women with persistent pain.

LoE:IIIb

LoE:IVb<sup>ii</sup>

# 5.2 UTERINE BLEEDING, ABNORMAL (AUB)

N92.0-6

# DEFINITION

Abnormal uterine bleeding (AUB) is defined as any symptomatic variation from normal menstruation in terms of regularity, frequency, volume, or duration. AUB can either be acute, i.e. an episode of heavy bleeding of a sufficient volume to require immediate intervention to prevent further blood loss, or chronic, i.e. present for more than 6 months.

## **GENERAL MEASURES**

- » All women >45 years of age with AUB should have a transvaginal ultrasound and endometrial sampling to exclude pathology.
- » Actively exclude organic causes, e.g. fibroids, for abnormal uterine bleeding.
- » All women should receive a speculum examination to rule out cervical pathology. A cervical cytology smear should be performed if the cervix appears abnormal or if indicated according to the national screening program.

# MEDICINE TREATMENT

The management of AUB due to a pathological condition is aimed at that particular pathology. If no organic cause is found, manage medically as follows:.

#### Arrest of acute haemorrhage

- Progestin, e.g.:
- Norethisterone, oral, 5 mg 4 hourly until bleeding stops.
   Maximum duration of use: 48 hours.

OR

- Tranexamic acid, oral, 1 g 6 hourly on days 1-4 of the cycle.
- After bleeding has stopped, continue with:
- Combined oral contraceptive, oral, 1 tablet 8 hourly for 7 days.
   o Follow with 1 tablet once daily for 3 months.

#### For restoring cyclicity (N92.6)

For women in the reproductive years:

Combined oral contraceptive, oral, 1 tablet daily for 6 months.
 OR

<u>Alternative to combined oral contraceptives:</u> Progestin only:

- Medroxyprogesterone acetate, oral, 30 mg daily from day 5 to day 26 of the cycle.
  - Use for 3–6 cycles.

OR

LoE:IVb<sup>vi</sup>

LoE:IIa<sup>vii</sup>

LoE:IIb<sup>v</sup>

Norethisterone, oral, 15 mg 8 hourly from day 5 to day 26 of the cycle. 0 Use for 3–6 cycles.

#### OR

- NSAID, oral: e.g. .
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 2 to 3 weeks.
  - Begin trial of NSAID starting on 1<sup>st</sup> day of menses until menses cease.
- OR
- Tranexamic acid, oral, 1 g 6 hourly on days 1-4 of the cycle.

#### For perimenopausal women, hormone therapy (HT): N92.4

Conjugated estrogens, oral, 0.625 mg daily for 21 days.

#### AND

- Medroxyprogesterone acetate, oral 10 mg daily from day 11 to day 21.
  - Omit treatment from day 22-28 no treatment. 0
  - Continue both treatment for 3-6 cycles. 0

For dysmenorrhoea and abnormal bleeding:

- NSAID, oral, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly for 2–3 days with or after a meal, depending on severity of pain.

## REFERRAL

Treatment failure - refer for consideration of levonorgestrel intrauterine system or surgical procedures as dictated by the diagnosis.

# 5.3 PELVIC INFLAMMATORY DISEASE (PID)

N70.0-1/N70.9/N71.0-1/N71.9/N72/N73.0-6/N73.8-9

## DESCRIPTION

Pelvic inflammatory disease (PID) includes salpingitis with or without opphoritis. As precise clinical localisation is often difficult, PID denotes a spectrum of conditions resulting from infection of the upper genital tract.

Sequelae include:

- » recurrent infections if inadequately treated.
- » infertility.
- » increased probability of ectopic pregnancy, and
- » chronic pelvic pain.

LoE:IIIbix

LoE:IIIb<sup>x</sup>

LoE:IIa<sup>xi</sup>

Stage	Manifestations	
Stage I	<ul> <li>cervical motion tenderness and/or uterine tenderness and/or adnexal tenderness</li> </ul>	
Stage II	<ul> <li>as stage I, plus pelvic peritonitis</li> </ul>	
Stage III	<ul> <li>as stage II, plus</li> </ul>	
	» tubo-ovarian complex or abscess	
Stage IV	<ul> <li>generalised peritonitis</li> </ul>	
	» ruptured tubo-ovarian complex	
	» septicaemia	

#### GENERAL MEASURES

- » Hospitalise all patients with stage II–IV PID for parenteral antibiotic therapy.
- » Frequent monitoring of general abdominal and pelvic signs is essential.
- » Admission for parenteral therapy, observation, further investigation and/or possible surgical intervention should also be considered in the following situations:
  - a surgical emergency cannot be excluded
  - lack of response to oral therapy
  - clinically severe disease
  - presence of a tubo-ovarian abscess
  - intolerance to oral therapy
  - pregnancy
- » In stage III, surgery is indicated if:
  - the diagnosis is uncertain,
  - there is no adequate response after 48 hours of appropriate therapy,
  - the patient deteriorates on treatment, or
  - there is a large or symptomatic pelvic mass after 6 weeks.

#### **Further Investigation**

All sexually active patients should be offered:

- » a pregnancy test: an ectopic pregnancy forms part of the differential diagnosis.
- » screening for sexually transmitted infections including HIV.

Note: Remove IUCD if present, and provide alternative contraception.

# MEDICINE TREATMENT

#### Stage I

• Azithromycin, oral, 1 g as a single dose.

AND

- Ceftriaxone, IM, 250 mg as a single dose.
  - Dissolve ceftriaxone, IM, 250 mg in 0.9 mL lidocaine 1% without adrenaline (epinephrine).

# AND

LoE:IVb<sup>xiii</sup>

LoE:IIb<sup>xii</sup>

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#### CHAPTER 5

• Metronidazole, oral, 400 mg 12 hourly for 7 days.

#### Severe penicillin allergy: (Z88.0)

• Azithromycin, oral, 2 g as a single dose.

#### AND

• Metronidazole, oral, 400 mg 12 hourly for 7 days.

## Stage II-IV

• Ceftriaxone, IV, 1 g daily.

#### AND

• Metronidazole, IV, 500 mg 8 hourly.

#### AND

• Azithromycin, oral, 1 g, as a single dose.

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change IV therapy to:

 Amoxicillin/clavulanic acid, oral, 875/125 mg 12 hourly to complete 10 days of antibiotic therapy.

**Note**: The addition of metronidazole to amoxicillin/clavulanic acid is unnecessary as amoxicillin/clavulanic acid has adequate anaerobic cover.

#### Severe penicillin allergy: (Z88.0)

• Clindamycin, IV, 600 mg 8 hourly.

#### AND

• Gentamicin, IV, 6 mg/kg daily (see Appendix II for guidance on prescribing).

# AND

• Azithromycin, oral, 1 g, as a single dose.

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change to:

• Clindamycin, oral, 450 mg 8 hourly.

## AND

• Ciprofloxacin, oral, 500 mg 12 hourly to complete 10 days of antibiotic therapy.

**Note**: The addition of metronidazole to clindamycin is unnecessary as clindamycin has adequate anaerobic cover.

## REFERRAL

- » Stages III and IV should be managed in consultation with a gynaecologist.
- » For surgical intervention See indications above.

#### GYNAECOLOGY

LoE:IIIb<sup>xiv</sup>

LoE:Ib<sup>xv</sup>

LoE:IIIb<sup>xvii</sup>

LoE:IIIbxvi

# **5.4 ENDOMETRIOSIS**

N80.0-6/N80.8-9

## DESCRIPTION

The presence and proliferation of endometrial tissue outside the uterine cavity, usually within the pelvis. It may manifest as dysmenorrhoea, dyspareunia, and chronic pelvic pain. Diagnosis is made by laparoscopy.

## MEDICINE TREATMENT

For pain:

- NSAID, oral: e.g.
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal.

LoE:IVb

# AND

- Combined oral contraceptives for 6 months.
   OR
- Medroxyprogesterone acetate, oral, 30 mg daily for at least 3 months.

Note: The recurrence of symptoms is common following cessation of treatment.

#### REFERRAL

- » Women with infertility.
- » No response to treatment after 3 months.

# 5.5 AMENORRHOEA

N91.0-2

## DESCRIPTION

- » Primary amenorrhoea: no menstruation by 16 years of age in the presence of secondary sexual characteristics.
- » Secondary amenorrhoea: amenorrhoea for at least 3 months in women with previous regular menses, or for at least 6 months in women with irregular cycles.

#### Investigations

- » Body mass index.
- » Urine pregnancy test.
- » Pelvic ultrasound.
- » Serum for TSH, FSH, LH, prolactin.
  - FSH>15 units/L in a woman <40 years of age suggests premature ovarian failure.</li>
  - LH/FSH ratio of >2:1 suggests polycystic ovarian syndrome.

#### MEDICINE TREATMENT

For treatment of hyperprolactinaemia, hypo- or hyperthyroidism, see Chapter 8: Endocrine System.

#### Progestin challenge test:

If no cause for secondary amenorrhoea is found:

- Medroxyprogesterone acetate, oral, 10 mg daily for 10 days.
  - Anticipate a withdrawal bleed 5-7 days following conclusion of treatment.

### REFERRAL

- » All cases of primary amenorrhoea.
- » Secondary amenorrhoea not responding to medroxyprogesterone acetate.
- » Polycystic ovarian syndrome and premature ovarian failure, for further evaluation.

# **5.6 HIRSUTISM AND VIRILISATION**

L68.0/E25.0/E25.9

#### DESCRIPTION

Hirsutism refers to terminal hair growth in amounts that are socially undesirable, typically following a male pattern of distribution. Virilisation refers to the development of male secondary sexual characteristics in a woman.

#### REFERRAL

Refer all cases to a tertiary hospital for investigation and management.

# **5.7 INFERTILITY**

N97.0-4/N97.8-9

#### DESCRIPTION

Inability to conceive after a year of regular sexual intercourse without contraception.

## **GENERAL MEASURES**

- » Counselling.
- » Lifestyle modification, e.g. weight optimisation, smoking cessation, and regular sexual intercourse.

#### Investigations

- » Partner semen analysis.
- » Anti-mullerian hormone (AMH) levels to evaluate ovarian reserve (>1.1 ng/ml suggests good ovarian reserve).
- » If AMH is unavailable Mid-luteal (day 21) progesterone assay: >30 nmol/L suggests adequate ovulation (Specialist indication).
- » Laparoscopy and/or hysterosalpingography (Specialist supervision).

Treat the underlying disease.

For induction of ovulation in women with confirmed anovulation:

- » There are two options available: letrozole or clomifene.
- » Letrozole is likely to result in more pregnancies and sooner pregnancies but both agents are effective.
- » Administer letrozole following a spontaneous menses or a medroxyprogesterone acetate withdrawal bleed.
- Letrozole 2.5 mg daily on days 3-7 of the cycle (Specialist only).

#### Note:

- » Letrozole for ovulation induction is an off-label indication. Counsel patient and obtain patient consent.
- » Consider the use of an alternative agent in patients with moderate or severe hepatic disease, porphyria, or osteoporosis.

If letrozole cannot be used:

- Clomifene, oral, 50 mg daily on days 5–9 of the cycle (Specialist only).
  - Monitor the progress of ovulation.

LoE:IIb<sup>xix</sup>

l oF:IIb<sup>xviii</sup>

For hyperprolactinaemia after further investigation:

See section 8.15.1: Prolactinoma.

**Note:** Women should be counselled on the risk of multiple births with ovulation inducing medicines.

# 5.8 MISCARRIAGE

Both manual vacuum aspiration (MVA) and medical evacuation are equally effective for miscarriage. However, MVA is preferred in the follow settings:

- » anaemia
- » haemodynamic instability
- » second trimester miscarriage

#### **5.8.1 SILENT MISCARRIAGE OR EARLY FETAL DEATH** 002.1

## GENERAL MEASURES

- » Counselling.
- » Evacuation of the uterus.

# MEDICINE TREATMENT

Before MVA, to ripen the cervix:

Misoprostol, PV, 400 mcg as a single dose.

# Medical evacuation: (004.9)

Misoprostol, oral/PV, 600 mcg as a single dose. Repeat after 24 hours if necessary.

## 5.8.2 INCOMPLETE MISCARRIAGE IN THE FIRST TRIMESTER 003.3-4

# GENERAL MEASURES

- » Counselling.
- » Evacuation of the uterus.

# MEDICINE TREATMENT

Before MVA, to ripen the cervix (if needed):

Misoprostol, oral/PV, 400 mcg as a single dose.

# Medical evacuation: (004.9)

- Misoprostol, SL/PV/buccal, 800 mcg immediately as a single dose.
  - Repeat after 24 hours if necessary.

Routine analgesia for vacuum aspiration:

Morphine, IM, 0.1 mg/kg 30 minutes before aspiration procedure, to a maximum of 10 mg (Doctor prescribed).

Alternatively, consider paracervical block - see section 5.9.1: TOP: Management of pregnancies up to the twelfth week of gestation (12 weeks and 0 days).

# Oral analgesia as required for 48 hours:

- Paracetamol, oral, 500mg-1 g, 4–6 hourly as required (to a maximum of 4g in 24) hours).
  - Maximum dose: 15 mg/kg/dose.

# AND

Ibuprofen, oral, 400 mg 8 hourly with or after a meal, if needed. .

# Note:

- » Follow up after one week to ensure that bleeding has stopped, or sooner with worsening symptoms.
- » Perform a pregnancy test three weeks after medical management.

LoE:IIIbxxii

LoE:IIIbxx

LoE:IVb<sup>xxi</sup>

LoE:IIIb<sup>xxiii</sup>

LoE:IIIb<sup>xxiv</sup>

# 5.8.3 MIDTRIMESTER MISCARRIAGE (FROM 13-22 WEEKS GESTATION)

003.3-4/003.9

# GENERAL MEASURES

- » Counselling.
- » Evacuation of the uterus after the fetus has been expelled.

#### MEDICINE TREATMENT

If cervical dilatation needed:

- Misoprostol, PV/SL/buccal, 200 mcg every 4–6 hours until products of conception have been expelled.
  - o Duration of treatment must not exceed 5 doses within 24 hours.

#### Previous Caesarean delivery:

- Misoprostol, PV/SL/buccal 100 mcg every 4–6 hours products of conception have been expelled.
  - o Duration of treatment must not exceed 5 doses within 24 hours.

#### If cervical dilatation already present:

- Oxytocin, IV.
  - Dilute 20 units in 1 L sodium chloride 0.9%, i.e. 20 milliunits/mL solution, and infuse at 125 mL/hour.
  - o Reduce rate if strong contractions are experienced.

**Note:** Check serum sodium if used for more than 24 hours because of the danger of dilutional hyponatraemia.

For analgesia:

• Morphine, IV, to a maximum dose of 10 mg (See Appendix II, for individual dosing and monitoring for response and toxicity).

If Rh-negative: (O36.0)

• Anti-D immunoglobulin, IM, 100 mcg as a single dose.

#### REFERRAL

- » Uterine abnormalities.
- » Recurrent miscarriages (3 consecutive spontaneous miscarriages).
- » Suspected cervical weakness: mid-trimester miscarriage(s) with minimal pain and bleeding.
- » Diabetes mellitus.
- » Parental genetic defects and SLE or other causes of autoimmune disease.

# 5.8.4 SEPTIC MISCARRIAGE

O03.0/O03.5 + (A41.9/N71.0/R57.2)

#### **GENERAL MEASURES**

» Counselling.

LoE:IVb

» Urgent evacuation of uterus (under general anaesthesia and not an MVA) and surgical management of complications.

# MEDICINE TREATMENT

- Oxvtocin. IV.
  - Dilute 20 units in 1 L sodium chloride 0.9%, i.e. 20 milliunits/mL solution administered at a rate of 125 mL/hour.
  - Reduce infusion rate if strong contractions are experienced.

#### Antibiotic therapy

Amoxicillin/clavulanic acid, IV, 1.2 g, 8 hourly.

Change to oral treatment after clinical improvement:

Amoxicillin/clavulanic acid, oral, 875/125 mg 12 hourly for 7-10 days.

Note: The addition of metronidazole to amoxicillin/clavulanic acid is unnecessary as amoxicillin/clavulanic acid has adequate anaerobic cover.

Severe penicillin allergy: (Z88.0)

Clindamycin, IV, 600 mg 8 hourly. •

AND

Gentamicin, IV, 6 mg/kg daily (see Appendix II for guidance on prescribing). •

Change to oral treatment after improvement:

Clindamycin, oral, 450 mg 8 hourly for 5 days. ٠

AND

Ciprofloxacin, oral, 500 mg 12 hourly for 5 days. •

Note: The addition of metronidazole to clindamycin is unnecessary as clindamycin has adequate anaerobic cover.

If patient has severe sepsis, consider urgent hysterectomy.

#### REFERRAL

- » Evidence of trauma.
- » No response to treatment within 48 hours.

#### 5.8.5 TROPHOBLASTIC NEOPLASIA ('HYDATIDIFORM MOLE') 001.0-1/001.9

# GENERAL MEASURES

- Misoprostol is not indicated in this condition because of risk of dissemination. »
- Send products of conception for histology. »

## REFERRAL

All patients.

# **5.9 TERMINATION OF PREGNANCY (TOP)**

Early ultrasound examination is more accurate than last normal menstrual period at determining gestational age and is also useful in identifying ectopic-, molar-, or twin pregnancies.

The clinical management for all pregnancies up to 14 weeks can be done as outpatient procedures. From 14 weeks onwards, TOP should be done in a medical facility. Note that the gestational ages used for clinical management differ from the legal cut-offs, e.g. a patient at 12 weeks and 1 day will meet the legal requirements as described in the act for TOP after 12 weeks, but the clinical management is the same as for a pregnancy from day one up to 14 weeks (see below). The legal criteria for TOP follow below.

#### Summary of Choice of Termination of Pregnancy Act of 1996

Women eligibility

Up to 12 completed weeks and 0 days: On request.

From the thirteenth week (12 weeks and 1 day) up to the twentieth week (20 weeks and 0 days): "If the doctor is of the opinion that i) the pregnancy resulted from rape or incest, ii) there is substantial risk of severe fetal physical or mental abnormality, iii) the continued pregnancy poses a risk to mother's physical or mental health, or social/economic circumstances".

<u>More than 20 weeks (≥ 20 weeks 1 day):</u> "If the doctor, after consulting with a second doctor or registered midwife, is of the opinion that continued pregnancy i) would endanger the mother's life, or ii) would result in risk of injury or severe malformation to the fetus"

Venue

An accredited facility with staff trained in performing TOP, designated by the Member of Executive Council at provincial level. A facility with a 24-hour maternity service does not require specific designation - *The Choice on Termination of Pregnancy Act, 1996 (as amended by Act 38 of 2004), expands access to TOP services, allowing registered nurses, as well as registered midwives, to perform TOPs up to the twelfth week of pregnancy.* 

#### Practitioner

<u>Up to 12 weeks and 0 days:</u> Doctor, midwife, or registered nurse with appropriate training.

From the thirteenth week (12 weeks and 1 day) up to the twentieth week (20 weeks and 0 days): Doctor responsible for decision and prescription of medication; registered nurse/midwife may administer medication according to prescription.

#### Note:

- » Pre-and post-termination counselling and contraceptive counselling is essential.
- » Consent of spouse/partner is not necessary.

» Consent for TOP and related procedures e.g. laparotomy may be given by minors. Minors are encouraged to consult parents or others, but consent is not mandatory.

# 5.9.1 TOP: MANAGEMENT OF PREGNANCIES UP TO THE TWELFTH WEEK OF GESTATION (12 WEEKS AND 0 DAYS)

O04.9/O06.9

# GENERAL MEASURES

- » Counselling.
- » Outpatient procedure by nursing staff with specific training.
- » Discuss TOP options with patient: Medical TOP or manual vacuum aspiration of the uterus.

\_.\_.

## MEDICINE TREATMENT

#### Medical TOP:

(Up to 12 weeks and 0 days)

• Mifepristone, oral, 200 mg, immediately as a single dose.

Followed 1-2 days later by:

- Misoprostol, PV/SL/buccal, 800 mcg by self-administration
  - If expulsion has not occurred 4 hours after misoprostol administration, a second dose of misoprostol 400 mcg may be given.

**Note**: Bleeding may persist for up to 1 week. If there is no bleeding after the second dose of misoprostol, the woman must return to the facility as soon as possible as there is a possibility of an incomplete procedure or ectopic pregnancy.

For pain:

Paracetamol, oral, 500mg-1 g, 4–6 hourly as required (to a maximum of 4g in 24 hours).

o Maximum dose: 15 mg/kg/dose.

## ADD

After expulsion is complete:

- NSAID, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal.

#### Manual vacuum aspiration:

• Misoprostol, PV, 400 mcg 3 hours before routine vacuum aspiration of the uterus.

Routine analgesia for vacuum aspiration:

 Morphine, IM, 0.1 mg/kg 30 minutes before aspiration procedure, to a maximum of 10 mg.

5.13

GYNAECOLOGY

LoE:IIb<sup>xxvi</sup>

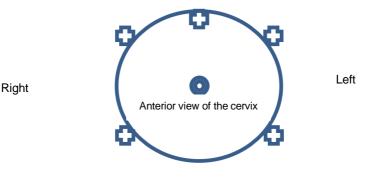
LoE:IIIbxxv

LoE:IIIb<sup>xxvii</sup>

Do not give intravenous benzodiazepines and parenteral opioid analgesics concurrently.

Alternatively, consider a paracervical block:

- Use Lidocaine 1%. (Without adrenaline)
- Draw up lidocaine 1% in a 20 mL syringe.
- Attach a 20-gauge spinal needle. Inject 2 mL superficially in the cervix at 12h00 and immediately grab the cervix with a tenaculum at 12h00 to stabilise cervix.
- Inject remaining 18 mL slowly over 60 seconds into the cervicovaginal junction in four equal doses of 4–5mL at 2, 4, 8, and 10 o'clock (see Figure 5.1: Anterior view of the cervix).
- This injection is continuous from superficial to deep (a depth of 3 cm) and again to superficial (injecting with insertion and withdrawal).
- Manual vacuum aspiration can start after 3 minutes.



#### Figure 5.1: Anterior view of the cervix

Oral analgesia as required for 48 hours:

• Paracetamol, oral, 500mg-1 g, 4–6 hourly as required (to a maximum of 4g in 24 hours).

o Maximum dose: 15 mg/kg/dose.

## AND

- NSAID, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal.

I oF:IIIb<sup>xxix</sup>

# 5.9.2 TOP: FROM THE THIRTEENTH WEEK (12 WEEKS AND 1 DAY) UP TO THE TWENTIETH WEEK (20 WEEKS AND 0 DAYS)

004.9/006.9

# GENERAL MEASURES

- » Medical TOP: From 12 weeks onwards, this should be performed as an inpatient with 24-hour services and facilities for general anaesthesia, as there is a greater risk for bleeding or a need for surgical completion of the procedure.
- » Manual vacuum aspiration can be performed up to 14 weeks. Dilation and sharp curettage (D&C) are not recommended and should preferably be replaced by vacuum aspiration.
- » Surgical TOP (Dilatation and Evacuation procedure after cervical preparation) can be done by specially trained providers as a day theatre procedure after 14 weeks.

#### MEDICINE TREATMENT Medical TOP:

• Mifepristone, oral, 200 mg, oral, immediately as a single dose.

#### Follow 1-2 days later with:

Misoprostol, PV/SL/buccal, 400 mcg, every 3 hours until TOP occurs.

#### Analgesia:

• Morphine, IM, 0.1 mg/kg 4 hourly or as needed, to a maximum of 10 mg.

#### If Rh-negative: 036.0

• Anti-D immunoglobulin, IM, 100 mcg as a single dose.

#### Contraception:

Counsel all women on effective contraception, especially long-acting reversible methods. All methods can be given at the time of the procedure, except for an IUCD after a medical TOP. IUCD may be inserted after medical TOP if reasonably certain that individual is no longer pregnant.

#### Note:

Medical TOP should be followed by manual vacuum aspiration of the uterus if expulsion of products of conception is not complete.

#### Cervical preparation for manual vacuum aspiration or surgical TOP:

• Misoprostol PV/SL, 400 mcg, 2 to 3 hours prior to the procedure.

5.15



LoE:IIIb<sup>xxx</sup>

LoE:IIb <sup>xxx</sup>	

LOEIIIb	
LoE:IIIb <sup>xxxiv</sup>	

#### **CHAPTER 5**

#### REFERRAL

- » Complicating medical conditions, e.g. cardiac failure, etc.
- » Failed procedure.
- » Ectopic pregnancy.

# 5.10 SEXUAL ASSAULT

T74.2 + (Y05.0-99)

#### INVESTIGATIONS

- » Urine pregnancy test.
- » Blood for:
  - Syphilis serology
  - HIV
  - Hepatitis B if no history of previous Hep B immunisation

#### **GENERAL MEASURES**

- » Trauma counselling and completion of J88 forms.
- » Examination under anaesthesia may be required for adequate forensic sample collection, or repair of genital tract trauma.

#### **MEDICINE TREATMENT**

#### **Emergency contraception** (Z29.8)

- » Do a pregnancy test in all women and female adolescents.
- » Children must be tested and provided with emergency contraception from Breast Tanner Stage III.
- » If unsure of staging, give Emergency contraception in the presence of any breast development (DO NOT REGARD MENARCHE AS AN INDICATION).
- Copper IUCD, e.g.:
- Cu T380A, inserted as soon as possible after unprotected intercourse and not later than 5 days.

#### OR

- Levonorgestrel 1.5 mg, oral, as a single dose as soon as possible after unprotected intercourse, and not later than 5 days.
  - o If the person vomits within 2 hours, repeat the dose.

#### Note:

» Advise women that the emergency contraception should not affect their usual menstrual cycle: very rarely it is delayed but it should not be more than 7 days late. If this occurs, they should come back for a pregnancy test.

LoE:IIIb<sup>xxxv</sup>

LoE:laxxxvi

# CAUTION

- » Emergency contraceptive tablets must be taken as soon as possible, preferably within 72 hours of unprotected intercourse, and not later than 5 days.
- » Enzyme inducers (including efavirenz, carbamazepine, and rifampicin) cause a significant reduction in levonorgestrel concentrations. Women on these medicines should preferably have copper IUCD inserted or alternatively double the dose of levonorgestrel.
- » Women weighing > 80 kg or with a BMI ≥ 30 should also preferably have copper IUCD inserted, or alternatively, double the dose of levonorgestrel.
  LoE:IIIb<sup>∞xvii</sup>

#### If there is vomiting (Z29.8):

• Metoclopramide oral, 10 mg 8 hourly or as needed.

## STI prophylaxis (Z29.8):

- Ceftriaxone, IM, 250 mg as a single dose.
  - For ceftriaxone IM injection: Dissolve ceftriaxone 250 mg in 0.9 mL lidocaine 1% without adrenaline (epinephrine).

#### AND

- Azithromycin, oral, 1 g, as a single dose.
- AND
- Metronidazole, oral, 2 g immediately as a single dose.

#### HIV post-exposure prophylaxis (PEP) (Z20.6+Z29.8):

See section 10.5.3: Non-occupational post exposure prophylaxis, inadvertent non-occupational.

# 5.11 URINARY INCONTINENCE

## DESCRIPTION

- » The involuntary leak of urine. Occurs in 10-17% of all women.
- » Risk factors include: Age (prevalence and severity increase with age), increased parity, obesity, smoking, caffeine intake, diabetes and menopausal vaginal atrophy.
- » Most common types are stress incontinence, urgency incontinence (overactive bladder) or a mixed incontinence (features of both stress and urgency).

# 5.11.1 STRESS INCONTINENCE

N39.3

## DESCRIPTION

» Incontinence that occurs with increased abdominal pressure (e.g. cough, sneeze or laugh) in the absence of a bladder contraction.

LoE:IVb

LoE:IIIb<sup>xxxviii</sup>

#### **GENERAL MEASURES**

- » Exclude urinary tract infection or diabetes.
- » Pelvic examination to exclude pelvic masses, pelvic organ prolapse, or menopausal vaginal atrophy.
- » Stop smoking.
- » Manage obesity.
- » Reduce or avoid caffeine.
- » Reduce alcohol intake.
- » Manage constipation and avoid excessive fluid intake.
- » Keep a bladder diary.
- » Pelvic floor exercises (see section 7.3.6: Overactive bladder).

# **MEDICINE TREATMENT**

There is insufficient evidence for the use of pharmacological interventions to treat stress incontinence.

# REFERRAL

- » If any pelvic pathology, immediate referral to specialist
- » If no underlying pathology, refer for bladder stress testing if no improvement with conservative measures after 3-6 months.

# 5.11.2 URGENCY INCONTINENCE (OVERACTIVE BLADDER)

See section: 7.3.6: Overactive bladder.

# 5.12 MENOPAUSE AND PERIMENOPAUSAL SYNDROME

N95.0-3/N95.8-9

For primary management with hormone therapy (HT), refer to the PHC STGs and EML, section 6.13: Hormone therapy (HT).

#### If HT is contra-indicated, poorly tolerated or ineffective:

- Fluoxetine, oral
  - o Initiate at 20 mg on alternate days.
  - $\circ~$  If there is no response after 12 weeks, increase the dose to 20 mg daily.

#### If on tamoxifen:

- Citalopram, oral, 10 mg daily.
  - o If there is no response after 12 weeks, increase the dose to 20 mg daily.

#### Note:

Start at the lowest possible dose to alleviate symptoms. The need to continue therapy should be reviewed annually.

#### REFERRAL

» Premature menopause, i.e. <40 years of age.

LoE:IIIb<sup>xxxix</sup>

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LoE:IIIb<sup>x/</sup>

- » Severe osteoporosis.
- » Post-menopausal bleeding.
- » Hormone-dependent cancers, thrombo-embolism, liver disease; and unacceptable side-effects to hormone replacement therapy e.g. exacerbation of depression, enlargement of uterine fibroids, exacerbation of endometrioses (see section 5.4: Endometriosis).

# 5.13 MEDICAL MANAGEMENT OF ECTOPIC PREGNANCY

000.0-2/000.8-9

# **GENERAL MEASURES**

- » Ruptured or suspected rupture of an ectopic pregnancy should be managed with urgent resuscitation and surgery.
- » There must be certainty that there is no viable intra-uterine pregnancy.
- » The discriminatory zone is the β-hCG level above which an ultrasound is likely to visualise a gestational sac within the uterus in a normal intra-uterine pregnancy (>1500 IU/L for a transvaginal ultrasound).
- » If the initial  $\beta$ -hCG level is below the discriminatory threshold (or level) to diagnose a pregnancy on transvaginal ultrasound, or the ultrasound cannot definitively identify an intrauterine or extra-uterine gestation, then serial  $\beta$ -hCG measurements are necessary to differentiate between a growing, potentially viable pregnancy, and a non-viable pregnancy.
- » A minimum rise in β-hCG of 53% every two days is expected for a potentially viable pregnancy in women who present with symptoms of pain and/or vaginal bleeding.
- » Repeat the  $\beta$ -hCG in 48 hours:
  - If the level has dropped, conservative management may be appropriate.
  - If the level has increased by >50% or is now above the discriminatory zone, repeat the ultrasound scan to exclude an intra-uterine pregnancy before methotrexate is administered.

LoE:IIIb<sup>×li</sup>

## MEDICINE TREATMENT

Methotrexate should be the first-line management for women who are able to return for follow-up and who have the following characteristics:

- » haemodynamic stability and no significant pain.
- » an unruptured ectopic pregnancy with a mass <35 mm and no visible heartbeat.
- » low serum  $\beta$ -hCG, ideally less than 1500 IU/L but can be up to 5000 IU/L.
- » certainty that there is no intrauterine pregnancy.
- » willingness to attend for follow-up.

There are single and multiple dose methotrexate protocols available. The single dose protocol is less expensive, requires less intensive monitoring and does not require folinic acid rescue. The single dose protocol is recommended for the medical management of ectopic pregnancy.

#### Methotrexate single-dose protocol:

Day 1: Check urea, creatinine, ALT and FBC to exclude abnormalities.

- Methotrexate, IM, 50 mg/m<sup>2</sup> of body surface area (BSA).
  - BSA may be calculated based upon height (cm) and weight (kg) on the day
    of treatment using the following formula:

$$BSA(m^2) = \sqrt{\frac{(Height \ x \ Weight)}{3600}}$$

Day 4: Repeat β-hCG.

**Day 7**: Repeat β-hCG.

If the decrease from day 4 to day 7 is ≥15%:

» Continue with weekly β-hCG until undetectable.

If decrease <15% and patient still fulfils the criteria for medical management:

• Methotrexate, IM, 50 mg/m<sup>2</sup> BSA.

**Day 14**: Repeat β-hCG.

CAUTION

- » Methotrexate is associated with blood disorders and is hepatotoxic.
- » Caution patients and their carers to immediately report the onset of any feature of blood disorders (e.g. sore throat, bruising, and mouth ulcers), liver toxicity (e.g. nausea, vomiting, abdominal discomfort and dark urine), and respiratory effects (e.g. shortness of breath).

LoE:Ivb<sup>xliv</sup>

#### REFERRAL

If the decline in  $\beta$ -hCG is still <15% on day 14 after two doses of methotrexate, refer for specialist care.

LoE:Iib<sup>xliii</sup>

# 5.14 FAMILY PLANNING REFERRALS FROM PRIMARY CARE

# 5.14.1 INTRA-UTERINE CONTRACEPTIVE COPPER OR LEVONORGESTREL DEVICE

# **GENERAL MEASURES**

Where there is excessive bleeding after insertion of IUCD or levonorgestrel device: N92.0-1 + (Z30.5)

» Exclude perforation of the uterus.

Irregular bleeding and/or cramping for >3 months:

N92.1/N92.5-6/N94.5-6/R25.2 + (Z30.5)

» Exclude cervical or pelvic infection, partial expulsion, intrauterine or ectopic pregnancy (rare) or other pathology.

If no pathology is detected:

» Counsel women that irregular bleeding can take up to 6 months to resolve.

# MEDICINE TREATMENT

If no pathology is detected:

- NSAID, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 5 days. Use for every cycle for 1–3 months.

LoE:IIb<sup>x/v</sup>

 Follow up after three months and if bleeding/cramping is unacceptable, offer alternative contraception and remove intra-uterine device.

# 5.14.2 IMPLANTS

Failure to locate an implant (in the arm) by palpation:

T85.9 + (Z30.4)

» Ultrasound guided removal of deep implants must be done by specially trained providers at regional hospitals.

# 5.14.3 INJECTABLE CONTRACEPTION

# **GENERAL MEASURES**

<u>Heavy or prolonged bleeding despite adequate treatment with combined oral contraceptives:</u>

N92.0-1 + (Z30.4/Z30.8-9)

- » Do thorough gynaecological examination to exclude other pathology.
- » Check haemoglobin and prescribe iron if needed. See section 2.1.1 Anaemia, iron deficiency.

# MEDICINE TREATMENT

Ethinylestradiol, oral, 50 mcg daily for 3 months.

#### OR

Combined oral contraceptive, containing 50 mcg ethinylestradiol, oral, for 3 months.

#### If no response to high dose ethinylestradiol, replace with:

- NSAID, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 5 days.

LoE:IVb<sup>xlvi</sup>

#### If no response to NSAID, replace with:

Tranexamic acid, oral, 500 mg 8 hourly for 4 days.

LoE:IIb<sup>xIvii</sup>

#### If there is no response to above-mentioned treatment:

» Change to another method of contraception. See Standard Treatment Guidelines and Essential Medicines List, Chapter 7: Family planning.

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Citalopram, oral (concomitant tamoxifen): Grant MD, Marbella A, Wang AT, Pines E, Hoag J, Bonnell C, et al. Menopausal Symptoms: Comparative Effectiveness of Therapies [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 [cited 2018 Aug 30]. (AHRQ Comparative Effectiveness Reviews). Available from: http://www.ncbi.nlm.nih.gov/books/NBK285463/

Citalopram, oral (concomitant tamoxifen): Davari-Tanha F, Soleymani-Farsani M, Asadi M, Shariat M, Shirazi M, Hadizadeh H. Comparison of citalopram and venlafaxine's role in treating sleep disturbances in menopausal women, a randomized, double-blind, placebo-controlled trial. Arch Gynecol Obstet. 2016 May;293(5):1007–13. <u>https://www.ncbi.nlm.nih.gov/pubmed/26437957</u> <sup>xil</sup> Management of ectopic pregnancy and miscarriage: Practice Committee of American Society for Reproductive Medicine. Medical treatment of ectopic pregnancy: a committee opinion. Fertil Steril. 2013 Sep;100(3):638-44. <u>https://www.ncbi.nlm.nih.gov/pubmed/23849842</u>

<sup>xill</sup> Methotrexate, IM (Single dose protocol for ectopic pregnancy): Hajenius PJ, Mol F, Mol BW, Bossuyt PM, Ankum WM, van der Veen F. Interventions for tubal ectopic pregnancy. Cochrane Database Syst Rev. 2007 Jan 24;(1):CD000324. https://www.ncbi.nlm.nih.gov/pubmed/17253448

xiii Methotrexate, IM: Ectopic pregnancy and miscarriage: diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. National Guideline Clearinghouse [Internet]. [cited 2017 Jun 8]. Available from: https://guideline.gov/summaries/summary/39274/ectopic-pregnancy-and-miscarriage-diagnosis-and-initial-management-in-earlypregnancy-of-ectopic-pregnancy-and-miscarriage?g=ectopic-pregnancy.

Methotrexate, IM: Diagnosis and Management of Ectopic Pregnancy [Internet]. Royal College of Obstetricians & amp; Gynaecologists. [cited 2017 Jun 8]. Available from: <a href="https://www.rcog.org.uk/en/quidelines-research-services/quidelines/qtg21/">https://www.rcog.org.uk/en/quidelines-research-services/quidelines/qtg21/</a> <sup>th/\*</sup> Methotrexate, IM (caution): Joint Formulary Committee. British National Formulary. 80. London: BMJ Group and Pharmaceutical Press: 2020.

<sup>xtv</sup> NSAIDs (bleeding associated with IUCDs): Grimes DA, Hubacher D, Lopez LM, Schulz KF. Non-steroidal anti-inflammatory drugs for heavy bleeding or pain associated with intrauterine-device use. Cochrane Database Syst Rev. 2006 Oct 18;(4):CD06034. <u>https://www.ncbi.nlm.nih.gov/pubmed/17054221</u>

<sup>xtvi</sup> NSAIDs (bleeding associated with injectable progestins): National Department of Health. National Contraception and Fertility Planning and Service Delivery Guidelines, 2019. <u>https://www.knowledgehub.org.za/content/standard-treatment-guidelines-andessential-medicines-list</u> <sup>xtvii</sup> Tranexamic acid. oral (bleeding associated with injectable progestins): Brvant-Smith AC. Lethaby A. Farguhar C. Hickey M.

<sup>xhvii</sup> Tranexamic acid, oral (bleeding associated with injectable progestins): Bryant-Smith AC, Lethaby A, Farquhar C, Hickey M. Antifibrinolytics for heavy menstrual bleeding. Cochrane Database Syst Rev. 2018 Apr 15;4(4):CD000249 https://pubmed.ncbi.nlm.nih.gov/29656433/





# SOUTH AFRICAN ADULT HOSPITAL LEVEL ESSENTIAL MEDICINES LIST CHAPTER 5: GYNAECOLOGY

# NEMLC RECOMMENDATIONS FOR MEDICINE AMENDMENTS (2020 - 2024 REVIEW CYCLE)

The Adult Hospital Level (AHL) Gynaecology chapter underwent detailed clinical editing resulting in both clinical changes and editorial changes for clarity.

Medicine amendment recommendations, with supporting evidence and rationale are listed below. Kindly review the medicine amendments in the context of the respective standard treatment guideline (STG).

#### **MEDICINE AMENDMENTS:**

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
5.8.2 Incomplete miscarriage in the first	Misoprostol, SL/PV	Directions for use amended
trimester - medical evacuation	Morphine, parenteral	Added
	Paracetamol, oral	Added
	Ibuprofen, oral	Added
	Pregnancy test	Added as follow-up after medical management
5.9 Termination of pregnancy (TOP)	TOP criteria	Aligned with the Choice of TOP Act
5.12 Menopause and perimenopausal syndro	me	
- Continuous combined therapy	Estradiol/Norethisterone acetate, oral	Deleted with cross reference to PHC STGs and
	Conjugated estrogens, oral	EML
	Medroxyprogesterone acetate, oral	
- Sequentially opposed therapy	Estradiol valerate/ cyproterone acetate, oral	Deleted with cross reference to PHC STGs and
	Estradiol valerate/ medroxyprogesterone acetate, oral	EML
	Conjugated estrogens/medroxyprogesterone acetate, oral	
- Women with no uterus (post-hysterectomy)	Estradiol valerate, oral	Deleted with cross reference to PHC STGs and
	Conjugated estrogens, oral	EML
5.13 Medical management of ectopic pregnancy	Methotrexate, parenteral	Retained
5.14 Family planning referrals from primary care	NSAID, e.g., ibuprofen	Directions for use clarified
- 5.14.1 Intra-uterine contraceptive copper or levonorgestrel device		

Paracetamol<sup>1</sup> dosing has been amended in the chapter with dosage range amended and maximum dose reiterated and aligned to AHL Chapter 25: Pain.

# 5.2 UTERINE BLEEDING, ABNORMAL (AUB)

A definition<sup>2</sup> was added to the STG.

<sup>2</sup> Abnormal uterine bleeding: Symptoms, diagnosis and treatment | BMJ Best Practice [Internet]. Bmj.com. 2023 [cited 2024 Jan 3]. Available from: https://bestpractice.bmj.com/topics/engb/658#:~:text=Definition,%2Dmenstrual%20bleeding%20(IMB).

<sup>&</sup>lt;sup>1</sup> South African Medicines Formulary, 14th Edition. Division of Clinical Pharmacology. University of Cape Town, 2022.

# The STG was updated as follows:

5.2 UTERINE BLEEDING, ABNORMAL (AUB) N92.0–6

# DEFINITION

Abnormal uterine bleeding (AUB) is defined as any symptomatic variation from normal menstruation in terms of regularity, frequency, volume, or duration. AUB can either be acute, i.e. an episode of heavy bleeding of a sufficient volume to require immediate intervention to prevent further blood loss, or chronic, i.e. present for more than 6 months.

Because the term dysfunctional uterine bleeding is poorly defined<sup>3</sup> and no longer considered to be a useful diagnostic term for use in practice, the statement that "Dysfunctional uterine bleeding implies that no organic cause is present" was deleted from the STG.

The STG was updated as follows:

MEDICINE TREATMENT Dysfunctional uterine bleeding implies that no organic cause is present. The management of AUB due to a pathological condition is aimed at that particular pathology. If no organic cause is found, manage medically as follows:

For restoring cyclicity (N92.6), as an alternative to oral contraceptives, it was noted that there is variation in the recommended dose of norethisterone, with some texts recommending 5 mg three times daily. In line with RCT<sup>4,5</sup> evidence the dose was aligned to three times daily.

For restoring cyclicity (N92.6), as an alternative to oral contraceptives a maximum duration of use of 2 to 3 weeks was set for NSAIDs before other treatment is considered to reduce the risk of NSAID associated adverse effects, e.g. peptic ulcers.

The STG was updated as follows:

For restoring cyclicity (N92.6)
For women in the reproductive years:
<ul> <li>Combined oral contraceptive, oral, 1 tablet daily for 6 months.</li> </ul>
OR
Alternative to combined oral contraceptives:
Progestin only:
<ul> <li>Medroxyprogesterone acetate, oral, 30 mg daily from day 5 to day 26 of the cycle.</li> </ul>
<ul> <li>Use for 3–6 cycles.</li> </ul>
OR
<ul> <li>Norethisterone, oral, 15 mg daily 8 hourly from day 5 to day 26 of the cycle.</li> </ul>
<ul> <li>Use for 3–6 cycles.</li> </ul>
OR
<ul> <li>NSAID, oral: e.g.</li> </ul>
<ul> <li>Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 2 to 3 weeks.</li> </ul>
<ul> <li>Begin trial of NSAID starting on 1<sup>st</sup> day of menses until menses cease.</li> </ul>

<sup>3</sup> Fraser, I.S., Critchley, H.O.D., Munro, M.G., Broder, M., 2007. A process designed to lead to international agreement on terminologies and definitions used to describe abnormalities of menstrual bleeding\*. Fertility and Sterility 87, 466–476. <u>https://doi.org/10.1016/j.fertnstert.2007.01.023</u>

<sup>&</sup>lt;sup>4</sup> Irvine GA, Campbell-Brown MB, Lumsden MA, Heikkila A, Walker JJ, Cameron IT. Randomised comparative trial of the levonorgestrel intrauterine system and norethisterone for treatment of idiopathic menorrhagia. Br. J. Obstet. Gynaecol. 1998;105(6):592–598

<sup>5</sup> Hatem Abu Hashim; Waleed Alsherbini; Mohamed Bazeed (2012). Contraceptive vaginal ring treatment of heavy menstrual bleeding: a randomized controlled trial with norethisterone. , 85(3), 0–252. doi:10.1016/j.contraception.2011.07.012

# OR

• Tranexamic acid, oral, 1 g 6 hourly on days 1–4 of the cycle.

For perimenopausal women, hormone therapy (HT): N92.4

• Conjugated estrogens, oral, 0.625 mg daily for 21 days.

# <u>AND</u>

- with the addition of mMedroxyprogesterone acetate, oral 10 mg daily from day 11 to day 21.
  - o <u>Omit treatment from</u> <del>d</del>Day 22– 28 <del>no treatment</del>.
  - Use <u>Continue both treatments</u> for 3–6 cycles.

# ADD

For dysmenorrhoea and abnormal bleeding:

- NSAID, oral, e.g.:
- Ibuprofen, oral, 400 mg 8 hourly for 2–3 days with or after a meal, depending on severity of pain.

# 5.8.2 PELVIC INFLAMMATORY DISEASE (PID)

For Stage II–IV medicine treatment, chlamydia which was historically mentioned for the indication of azithromycin was deleted as other likely sexually transmitted organisms are not listed in this section, e.g. ceftriaxone use for *N Gonorrhoea*, and metronidazole for trichomoniasis/bacterial vaginosis. Additionally, the ordering of prescribed medicines was revised to ensure clarity.

The STG was updated as follows:

FROM:

Stage II–IV

• Ceftriaxone, IV, 1 g daily

AND

• Metronidazole, IV, 500 mg 8 hourly.

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change to:

• Amoxicillin/clavulanic acid, oral, 875/125 mg 12 hourly to complete 10 days therapy.

AND

To treat chlamydia: A56.1+(N74.4\*)

• Azithromycin, oral, 1 g, as a single dose.

Note: The addition of metronidazole to amoxicillin/clavulanic acid is unnecessary as amoxicillin/clavulanic acid has adequate anaerobic cover.

Severe penicillin allergy: (Z88.0)

• Clindamycin, IV, 600 mg 8 hourly.

AND

• Gentamicin, IV, 6 mg/kg daily (see Appendix II for guidance on prescribing).

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change to:

• Clindamycin, oral, 450 mg 8 hourly.

AND

• Ciprofloxacin, oral, 500 mg 12 hourly to complete 10 days therapy.

To treat chlamydia: A56.1+(N74.4\*)

• Azithromycin, oral, 1 g, as a single dose.

Note: The addition of metronidazole to clindamycin is unnecessary as clindamycin has adequate anaerobic cover.

# TO:

# Stage II-IV

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• Ceftriaxone, IV, 1 g daily.

AND

• Metronidazole, IV, 500 mg 8 hourly.

AND

• Azithromycin, oral, 1 g, as a single dose.

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change <u>IV therapy</u> to:
Amoxicillin/clavulanic acid, oral, 875/125 mg 12 hourly to complete 10 days <u>of antibiotic</u> therapy.

Note: The addition of metronidazole to amoxicillin/clavulanic acid is unnecessary as amoxicillin/clavulanic acid has adequate anaerobic cover.

Severe penicillin allergy: (Z88.0)

Clindamycin, IV, 600 mg 8 hourly.

AND

• Gentamicin, IV, 6 mg/kg daily (see Appendix II for guidance on prescribing).

AND

• Azithromycin, oral, 1 g, as a single dose.

Continue intravenous therapy until there is definite clinical improvement (within 24-48 hours). Thereafter, change to: • Clindamycin, oral, 450 mg 8 hourly.

Clindamycin
 AND

• Ciprofloxacin, oral, 500 mg 12 hourly to complete 10 days of antibiotic therapy.

Note: The addition of metronidazole to clindamycin is unnecessary as clindamycin has adequate anaerobic cover.

Surgical intervention was added as a referral criterion for the pelvic inflammatory disease STG.

# The STG was updated as follows:

# REFERRAL

- » Stages III and IV should be managed in consultation with a gynaecologist.
- » For surgical intervention See indications above

# 5.8.2 INCOMPLETE MISCARRIAGE IN THE FIRST TRIMESTER

# **Medical evacuation**

<u>Misoprostol, SL/PV/buccal</u>: *directions for use amended* The STG text was amended to align with NICE<sup>6</sup> and WHO<sup>7</sup> guidelines as follows:

- Misoprostol, PV, 800 mcg every 3 hours for 2 doses.
- Repeat after 24 hours if necessary.

OR

- Misoprostol, SL, 600 mcg every 3 hours for 2 doses
   Repeat after 24 hours if necessary
- Misoprostol, SL/PV/buccal, 800 mcg immediately as a single dose.
- <u>Repeat after 24 hours if necessary.</u>

# Level of Evidence: III Guidelines

# Analgesia

<u>Morphine, parenteral</u>: added <u>Paracetamol, oral</u>: added <u>Ibuprofen, oral</u>: added Aligned with the PHC STGs and EML, Section 6.2.1: Management of incomplete miscarriage in the 1st trimester, at primary health care level.

Pregnancy test: added as follow-up after medical management

<sup>6</sup> NICE. Guideline: Abortion Care, 25 September 2019. <u>https://www.nice.org.uk/guidance/ng140</u>

<sup>7</sup> WHO. Guideline: Medical management of abortion, 2018. <u>https://www.who.int/reproductivehealth/publications/medical-management-abortion/en/</u>

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The following STG text was added, aligned with NICE guidance, providing a 3-week period before testing to minimise false-positives (bHCG 25miu/ml is the cut-off for positive pregnancy test).<sup>8</sup> Women with a positive pregnancy test to be referred, accordingly.

# Perform a pregnancy test three weeks after medical management

# 5.9 TERMINATION OF PREGNANCY (TOP)

<u>Top criteria:</u> *aligned with the Choice of TOP Act* 

- Designated periods: The STG text is currently aligned with the The Choice on Termination of Pregnancy Act, 1996 (as amended by Act 38 of 2004).
- *Venues:* The Choice on Termination of Pregnancy Act, 1996 (as amended by Act 38 of 2004), provides expanded access to abortions; allows registered nurses, as well as registered midwives, to perform abortions up to the twelfth week of pregnancy. The following text was added to the STG:

A facility with a 24-hour maternity service does not require specific designation - *The Choice on Termination of Pregnancy Act, 1996 (as amended by Act 38 of 2004), expands access to TOP services, allowing registered nurses, as well as registered midwives, to perform TOPs up to the twelfth week of pregnancy.* 

# 5.12 MENOPAUSE AND PERIMENOPAUSAL SYNDROME

# **Continuous combined therapy**

<u>Estradiol/Norethisterone acetate, oral:</u> *deleted with cross reference to PHC STGs and EML* <u>Conjugated estrogens, oral:</u> *deleted with cross reference to PHC STGs and EML* <u>Medroxyprogesterone acetate, oral:</u> *deleted with cross reference to PHC STGs and EML* 

# Sequentially opposed therapy

<u>Estradiol valerate/ cyproterone acetate, oral:</u> *deleted with cross reference to PHC STGs and EML* <u>Estradiol valerate/ medroxyprogesterone acetate, oral:</u> *deleted with cross reference to PHC STGs and EML* <u>Conjugated estrogens/medroxyprogesterone acetate, oral:</u> *deleted with cross reference to PHC STGs and EML* 

# Women with no uterus (post-hysterectomy)

<u>Estradiol valerate, oral:</u> *deleted with cross reference to PHC STGs and EML* <u>Conjugated estrogens, oral</u>: *deleted with cross reference to PHC STGs and EML* 

For primary management with hormone therapy (HT), a cross-reference was included to the PHC STGs and EML, section 6.13: Hormone therapy (HT).

# 5.13 MEDICAL MANAGEMENT OF ECTOPIC PREGNANCY

<u>Methotrexate, parenteral:</u> *retained and caution box added* Despite dosing of methotrexate as a single IM dose, a caution box was added, aligned with BNF guidelines<sup>9</sup>:

CAUTION

Methotrexate is associated with blood disorders and is hepatotoxic.

<u>Caution patients and their carers to immediately report the onset of any feature of blood disorders (e.g. sore throat, bruising, and mouth ulcers), liver toxicity (e.g. nausea, vomiting, abdominal discomfort and dark urine), and respiratory</u>

effects (e.g. shortness of breath).

<sup>8</sup> Barnhart K, Sammel MD, Chung K, Zhou L, Hummel AC, Guo W. Decline of serum human chorionic gonadotropin and spontaneous complete abortion: defining the normal curve. Obstet Gynecol. 2004 Nov;104(5 Pt 1):975–81. <u>https://pubmed.ncbi.nlm.nih.gov/15516387/</u> <sup>9</sup> Joint Formulary Committee. British National Formulary. 80. London: BMJ Group and Pharmaceutical Press; 2020.

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Under the Methotrexate single-dose protocol, AST was changed to ALT testing as ALT may be more beneficial and specific than AST in excluding liver pathology.

The STG was updated as follows:

# Methotrexate single dose protocol:

Day 1: Check urea, creatinine, AST, ALT and FBC to exclude abnormalities

# 5.14 INTRA-UTERINE CONTRACEPTIVE COPPER OR LEVONORGESTREL DEVICE

The STG narrative and heading were updated to include guidance on the NEMLC-approved levonorgestrel Intra-uterine copper device (LNG IUCD) as a contraceptive device.

# **General measures**

The STG text was editorially amended *from*:

Where there is excessive bleeding after insertion:

» Exclude perforation of the uterus.

Abnormal bleeding for >3 months:

» Exclude cervical or pelvic infection, partial expulsion, intrauterine or ectopic pregnancy (rare) or other pathology.

If no pathology is detected:

» Counsel.

То:

Where there is excessive bleeding after insertion:

» Exclude perforation of the uterus.

Irregular bleeding and/or cramping for >3 months:

» Exclude cervical or pelvic infection, partial expulsion, intrauterine or ectopic pregnancy (rare) or other pathology.

If no pathology is detected:

» Counsel women that irregular bleeding can take up to 6 months to resolve.

# **Medicine treatment**

NSAID, e.g. ibuprofen: directions for use clarified

The STG text was editorially amended for clarity purposes, from:

If no pathology is detected:

- NSAID, e.g.:

- Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 5 days.
- Follow up and if bleeding is unacceptable, offer alternative contraception and remove IUCD.

То:

If no pathology is detected:

NSAID, e.g.:

Ibuprofen, oral, 400 mg 8 hourly with or after a meal for 5 days. Use for every cycle for 1-3 months.

• Follow up after three months and if bleeding/cramping is unacceptable, offer alternative contraception and remove intra-uterine device.

Level of Evidence: High certainty evidence<sup>10</sup>