COUNTIES MANUKAU HEALTH

and

Primary Care Partners

Management of Pathway of Care for

Abnormal Uterine Bleeding (AUB) in Pre-Menopausal Women and Post-Menopausal Bleeding (PMB)

Information Package

November 2020

INTRODUCTION

Counties Manukau Health and Primary Care representatives have collaborated to design a new pathway of care for **treatment** of Menorrhagia, Inter-menstrual Bleeding (IMB) and Post-Menopausal (PMB) which will see a more seamless end-to-end service provided for women. This will mean a transition of some services from secondary to primary care and marks the beginning of a new model of care for many women within Counties Manukau who require assessment and management of a range of gynaecological problems.

Menorrhagia is defined as: *An abnormally heavy and prolonged menstrual period at regular intervals. It can be caused by abnormal blood clotting, disruption of normal hormonal regulation of periods or disorders of the endometrial lining of the uterus. Depending upon the cause, it may be associated with abnormally painful periods (dysmenorrhea).*

Inter-menstrual Bleeding is defined as: *Any vaginal blood loss outside of the normal menstrual period.*

Post-menopausal Bleeding is defined as*: any vaginal bleeding after at least 12 months amenorrhoea in a woman over 40 years or with a previously diagnosed premature menopause*.

This information pack is presented as Part A - Clinical detail and Part B - Administrative detail - for implementation of the new model of care.

CONTACT DETAILS

For Credentialed GPs : 0800-1700 Monday to Friday
Direct contact with secondary care consultants for credentialed GPs will be available through the On-Call Gynaecology Senior Medical Officer (SMO) via switchboard on **09 276 0000.** Written advice is also available via the "Specialist Advice" option on e-referrals.

Training Video
Endometrial Biopsy Full Details Procedures Consults is available on You Tube:
http://youtu.be/at-CfWUiClg

To Arrange Pipelle Training in Outpatient Clinic, Manukau Health Park
Please Contact: Donna Hill, Senior Gynaecology Nurse – email donna.hill@middlemore.co.nz

GP Liaison
Dr Sue Tutty, General Practitioner Liaison (GPL) Women's Health, 021 875 002 or email sue.tutty@middlemore.co.nz.

To Arrange Training in Your Practice
Please Contact the GPL

To Arrange Mirena Insertion Training
Please Contact the GPL

To Order a Transvaginal Ultrasound
Make two copies of the Ultrasound request form.

- Fax one copy to East Health Limited. **FAX: 09 535 7154**
- Give one copy to the Patient.

East Health Limited will phone you with an appointment within two weeks.

For Administrative Queries
Sharon Ranson, Service Manager Gynaecology, 021 518 238 or email
sharon.ranson@middlemore.co.nz

Priya Srivastava, Programme Manager – Primary Care, 021 512 486 or email
priya.srivastava@middlemore.co.nz

PART A
Clinical Information

CONTENTS

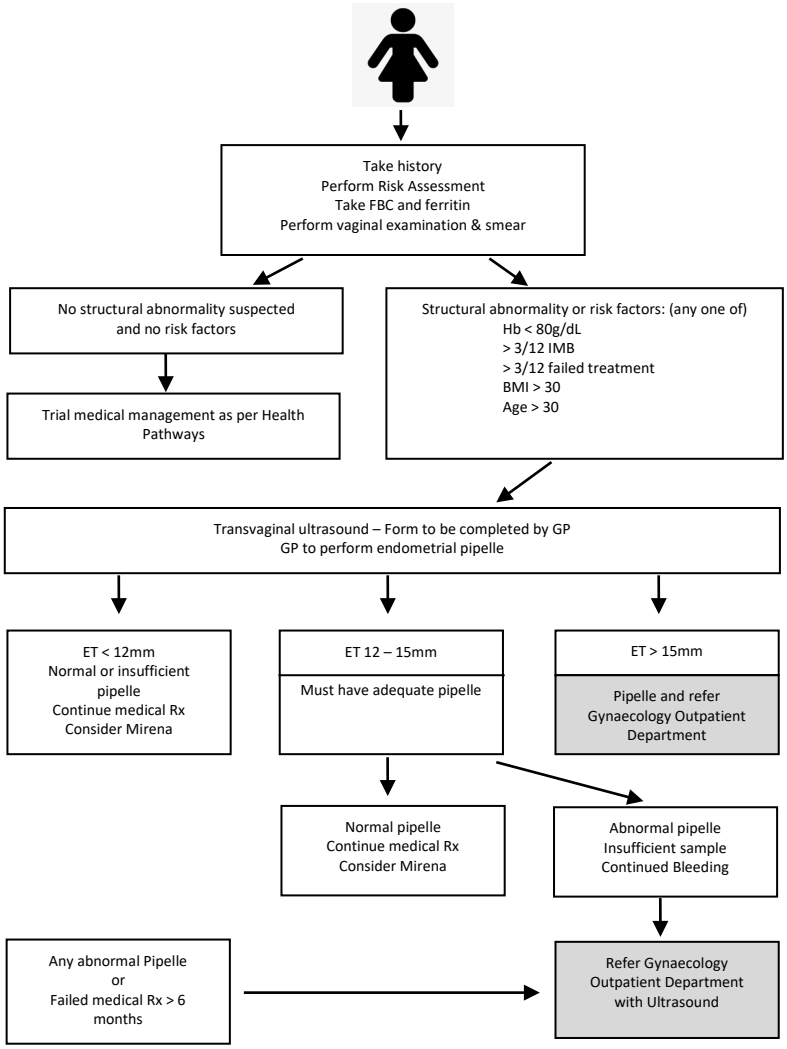
- **Diagrammatic view and Description: Care Pathway for Abnormal Uterine Bleeding (AUB) in Pre-Menopausal Women and Post-Menopausal Bleeding (PMB)**

- **Endometrial Sampling:**
  - **Credentialing for General Practitioners**
  - **Background Information**
  - **Taking an Endometrial Pipelle**
  - **Guidelines/Protocols**

Figure 1 CARE PATHWAY FOR ABNORMAL UTERINE BLEEDING (AUB) IN PREMENOPAUSAL

These guidelines are available via Auckland Regional HealthPathways

Link: **https://aucklandregion.communityhealthpathways.org/15976.htm**

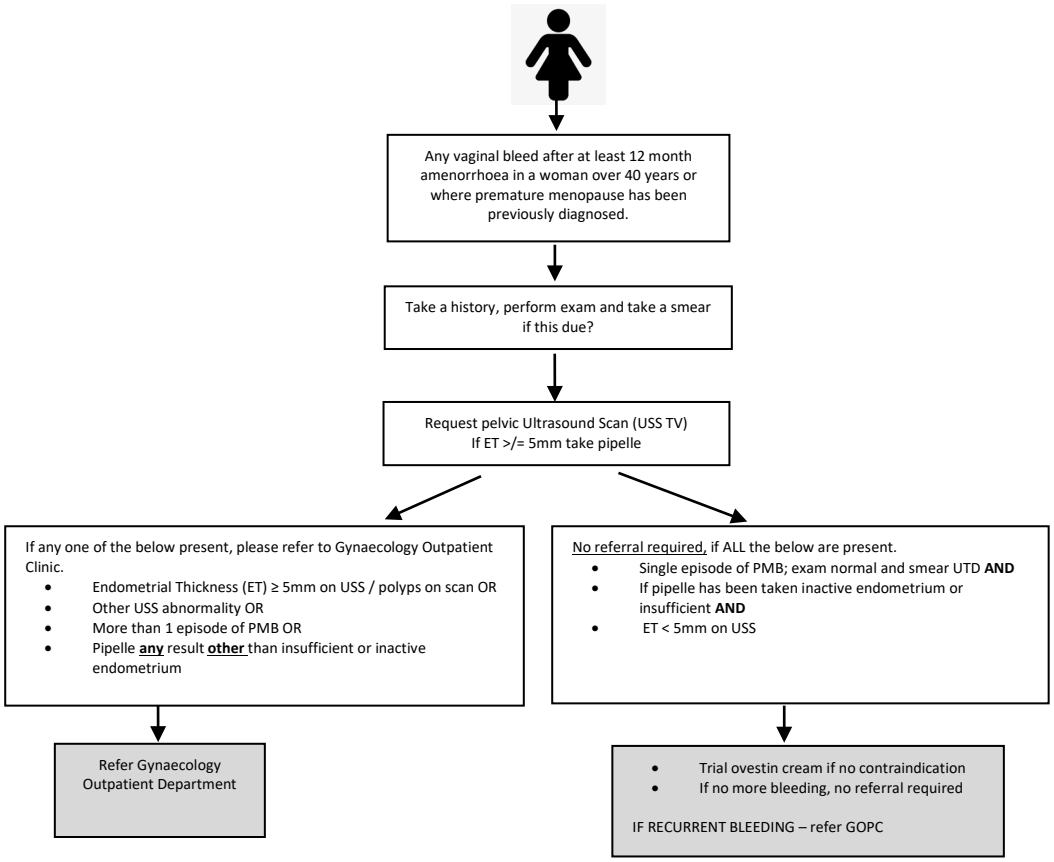


**If high index of suspicion based on risk factors or symptoms alone, perform ultrasound and pipelle and consider referral to GOPD for advice. December 2013.*

Figure 2 CARE PATHWAY FOR POST-MENOPAUSAL BLEEDING (PMB) IN WOMEN

These guidelines are available via Auckland Regional HealthPathways

Link: https://aucklandregion.communityhealthpathways.org/16007.htm



The Pathway of Care for AUB and PMB

The model of care incorporates a credentialing module for General Practitioners (GPs) to assist in **diagnosis and management** of patients with AUB and PMB.

Training, credentialing and oversight to maintain **quality** of service delivery and care will be provided by secondary care Gynaecologists in partnership with primary care.

The intent of the new model is that as many GPs as possible will be credentialed so a patient can be treated and managed by her "regular" GP.

The credentialed GP will potentially perform an **endometrial pipelle biopsy** and refer the patient for a **trans-vaginal ultrasound** through a local radiology provider for the convenience of the patient.

On receipt of the results the credentialed GP will be able to explain the diagnosis to the patient and where appropriate provide non-surgical treatment under protocol or refer to secondary care.

Endometrial Sampling

The GPL for Women's Health will be responsible for keeping a register of GPs trained in the technique. The GPL will arrange clinical audit for these GPs with the Gynaecology Clinical Lead at Counties Manukau Health on a quarterly basis.

❖ Credentialing for General Practitioners

1.1. Aims

1.1.1. For GPs to safely and effectively perform endometrial sampling using a pipelle device in appropriately counselled women.

1.1.2. This will allow more detailed investigation of abnormal vaginal bleeding in the community, providing a more timely diagnosis of any abnormality, and allowing some treatment plans to be instigated without referral to secondary care.

1.2. Knowledge requirements

- ❖ Aetiology of abnormal vaginal bleeding
- ❖ Use of Guidelines for AUB and postmenopausal bleeding (PMB) in primary care
- ❖ Indications and contra-indications for pipelle sampling
- ❖ Perform an appropriate history and vaginal examination
- ❖ Use of the sampling device and potential risks/inadequacies of sampling
- ❖ Management of normal and abnormal histological findings

2.3. Aetiology of abnormal vaginal bleeding

- The majority of cases are hormonal in origin

- Any structural abnormality in the genital tract
  - Endometrial polyps
  - Fibroids
  - Endo-cervical polyps
  - Cervical eversion/erosion
  - Atrophic vaginitis
  - Infection with STI
  - Endometrial hyperplasia
  - Any malignancy of the genital tract - endometrial/cervical/vaginal/vulval

- Bleeding disorders, anticoagulants and other rarer causes

The assessment form will be completed at the end of the clinic, with feedback to the GP. *The form is attached as Appendix 1*

It is anticipated that a 'sign off' will be possible when the trainer is confident that the GP is not only able to safely perform the pipelle biopsy, **but also that they understand the importance of selection of the most appropriate patients and how to deal with the results of the sampling,** as above.

This credentialing process is a Royal New Zealand College of General Practitioners (RNZGP) endorsed activity and attracts Continuing Medical Education (CME) points**.**

Endometrial Sampling: Information

3.1. Indications for pipelle biopsy

Refer: AUB Guideline, Page 4

- Haemoglobin (Hb) < 80g/L
- Failed medical treatment of menorrhagia after 3 months
- If there are significant risk factors such as BMI > 30, age > 30
- Inter-menstrual Bleeding > 3/12
- Endometrial cells on cervical smears, with abnormal symptoms

3.2. Absolute Contra-indications for pipelle biopsy

- Pregnancy
- Endometritis or acute PID

3.3. Relative contra-indications for pipelle biopsy

- Coagulation disorders or anti-coagulant therapy
- Synthetic Heart valves or heart murmurs/valve disease– cover procedure with a dose of antibiotics 2 hours beforehand
- Previous LLETZ or Cone Biopsy – these can stenose the cervical canal and make insertion difficult

Taking a Pipelle

Available on You Tube is a video entitled, Endometrial Biopsy Full Details Procedures Consults http://youtu.be/at-CfWUiClg

4.1. Pre Procedure

- Check indications and refer to guidelines
- Obtain informed consent – may be uncomfortable or cause infection
- Consider oral NSAIDs 1-2 hours beforehand

4.2. Procedure

- Perform vaginal examination to assess cervix position, whether uterus anteverted or retroverted and whether enlarged. Compare with ultrasound report if available
- Insert a Cuscoes speculum to visualise the cervix
- Apply a single tooth tenaculum (less pain than the crushing type) to the anterior lip of the cervix
- You do not need to clean the cervix or give prophylactic antibiotics (unless synthetic heart valve – see above)
- Gently insert pipelle into external cervical os and push slowly. Some resistance may occur but do not force the device. If acutely positioned uterus, consciously aim the pipelle anteriorly or posteriorly
- Once fundus reached, note length, then withdraw whole device ½ (0.5) cm. The average length of the cervix and uterus is approximately 7-8 cm
- Try to avoid touching the fundus again as this causes discomfort.
- Withdraw central piston completely to achieve a vacuum then rotate the device whilst moving back and forth / up and down the cavity, approximately 3 to 5 times. Sample should be seen in the chamber of the device.
- If the suction is lost, by pulling too far out of the cervix, deposit the sample obtained into a formalin pot and re-insert. Take care not to dip the pipelle into the formalin. If this occurs, wash the device in normal saline or use a new device
- Send the labelled pot and form to histology

4.3. Post procedure

- Cervical Shock – About cervical shock/vasovagal reaction, **Appendix 2**
- Expect some cramps and discomfort
- May cause spotting/bleeding, so suggest a panty liner for 24 hours
- If persistent pain/offensive discharge after 24-48 hours, consider HVS and antibiotics such as oral augmentin.

4.4. Management of Results

- Depends on indications for pipelle
- Be aware of limitations of sampling
- Advice can be obtained from a Gynaecology Senior Medical Officer by writing to the virtual clinic via an **electronic** referral.

For Credentialing Assessment Form (For Endometrial Pipelle) – please see Appendix 1.

PART B
Administrative Information

- **Funding Primary Care**
- **Mirena®levonorgestrel-releasing intrauterine system**
- **Financial Transactions: Process**
- **Governance**

Funding Primary Care

Funding will be provided through the Counties Manukau Health to cover the full costs of primary care as per Table 1. The package of funding is based on the average cost per patient for the volume of patients per annum to be managed in primary care for abnormal uterine bleeding pre & post-menopausal by credentialed providers in the catchment.

This volume of patients to be managed in primary care is based on the **current volumes of patients seen for AUB & PMB in secondary care.**

5.1. Funding Assumptions

- As many general practitioners as possible will be trained and credentialed for endometrial sampling.
- Therefore, each general practitioner will see his/her own enrolled patients and receive the capitation payment.
- Credentialed GPs are encouraged to accept referrals from non-credentialed GPs.

5.2. Funding

The objective of the new model of care is to manage patients **who would have previously have been referred to secondary care for the treatment and management of AUB and PMB.**

Therefore, following the initial consultation which the patient has now (and which attracts a normal consultation fee) patients are not required to contribute further to the cost of their care in the primary sector.

The Subsidised patient (Table 1)

For the patient who is diagnosed with AUB or PMB and requires a Mirena® levonorgestrel-releasing intrauterine system as their treatment option **and they are eligible for the Pharmac subsidy:**

The patient pays for the first assessment visit. The DHB pays for ultrasound and pipelle biopsy. If a Mirena® is required, this will be inserted in the second *funded* visit which includes follow up if needed. The dispensing fee of $5.00 will also be reimbursed. This is shown in Table 1.

Table 1: Funding Primary Care: For the Patient Who receives Pharmac subsidy for Mirena®

	Funding breakdown $$
GP Consultation – 1st visit: Patient to Pay	Normal Fee
Diagnosis:	**Reimbursed by DHB**
Gp Consultation: 2nd visit	$0.00
Pipelle device cost	$30.00
Pipelle procedure cost	$150.00
Transvaginal Ultrasound cost	Free to practice
Treatment:	**Reimbursed by DHB**
Insertion of Mirena® (*and follow up if required, excludes Mirena® that can be funded under the LARC programme*)	$150.00
Mirena® dispensing fee	$5.00

The non-Subsidised patient (Table 2)
It is anticipated the majority of patients will be subsidised, however there may be some who are not. For these patients:

The patient pays for the first assessment visit.

The DHB pays for the ultrasound and pipelle biopsy and the patient will be referred to the Gynaecology Service at the Manukau Superclinic through the normal referral method, ***for treatment***. Diagnostic information will be sent with this referral to the Superclinic so repeat tests will not be necessary

The patient will be discharged from the Gynaecology Service at the Manukau Superclinic to be followed up by her GP. The GP will be paid for the follow up visit.

Table 2: Funding Primary Care:

	Funding breakdown $$
GP Consultation 1st visit: Patient to Pay	Normal Fee
Diagnosis:	**Reimbursed by DHB**
2nd visit - Consultation for diagnostics	$0.00
Pipelle device cost	$30.00
Pipelle procedure	$150.00
Transvaginal Ultrasound cost	Free to practice
Treatment:	**Cost incurred by DHB**
Insertion of Mirena®	
Follow up by GP	$55.00

Access to Mirena® levonorgestrel-releasing intrauterine system through *Pharmac*

6.0 Overview

The preferred option for non-surgical treatment of menorrhagia under this pathway, is Mirena® levonorgestrel-releasing intrauterine system 20 mcg per day. Women with fibroids with a uterine size less than 16 weeks, an endometrial thickness <15mm and a normal pipelle should be trailed with a Mirena prior to referral to secondary care. Fibroids >4cm should be rescanned in 1year to detect the risk of cancerous change. The Mirena® system is now available through *Pharmac* with a dispensing fee of $5.00 per item. The dispensing fee will be covered through the AUB pathway programme.

Co-ordination and Support for New Model of Care

7.1 Financial Transactions

Counties Manukau Health will be supported by East Health Services Limited (EHSL) to coordinate and manage all financial transactions. This will be seamless to the GP and the patient. It is EHL who currently manages the *Primary Options for Acute Care* (POAC) programme.

Please note however, this programme is a separate initiative to POAC.

7.2. Ultrasound Provider

Each Locality Clinical Partnership has an existing contract with a Radiology service provider under their POAC programme. This same provider will provide trans-vaginal ultrasound for each patient on referral from credentialed GPs and be reimbursed through the new AUB or PMB model of care programme.

7.3. Pipelle biopsy kits

Practices in Counties Manukau Health can source pipelle kits direct and claim it via POAC.

7.4 Orientation of Practices to the new model of care

East Health Services Limited will visit every Practice Manager prior to 'go live' to ensure all mechanism are in place to implement the model.

Specifically, EHSL is responsible for:

- Co-ordinating all ultrasound appointments for patients who meet the clinical criteria and are referred by a credentialed GP
- Managing all claiming components for service providers, as per the schedule outlined in the Pathway Information Package
- Tracking pipelle kit claims
- Ensuring all referral and claiming criteria are met
- Maintaining an accurate database on patient information, referrals and financial transactions in order to meet reporting requirements outlined in this agreement

7.3.1. Claiming Process

- Claiming process will be through the EHSL claims management system as per process outlined in the Information Package
- Supporting clinical notes are to be included with the GP claim in order to be accepted
- Claims must meet the specific criteria as outlined in the Information Package

7.3.2. Reporting and Monitoring of Transactions and Process

- EHSL will provide three monthly reporting to Counties Manukau Health and participating clinicians as well as other key stakeholders as agreed
- Reports will include:

  - Referral volumes by locality

- Referral volumes by GP and Practice
- Patient demographics (NHI, age, ethnicity)
- Range of services provided and funded

EHSL will monitor demand and inform Counties Manukau Health immediately should there be indication that demand will exceed the estimated volumes.

Clinical Governance

A Clinical Governance process for Gynaecology within each Locality will be required for two reasons:

- ❖ to observe and monitor the performance of the integrated AUB and PMB pathways as components of non-surgical care transition from secondary to primary care
- ❖ to provide a vehicle through which continuing education and development can occur.

The GPL will coordinate all activities related to training, audit and education.

Clinical audit will be provided by the senior medical officer Clinical Lead for Gynaecology and the GPL (with participating GPs) every three months.

Information for audit will be provided through EHSL.

Should any issues arise or changes to the programme recommended as the result of audit, these will be jointly presented to the Locality Clinical Partnership and the Women's Health Service, Counties Manukau Health

APPENDIX 1

Credentialing Assessment Form for Endometrial Pipelle Sampling in Primary Care

Name of GP	
Date of Clinic attendance	
Name of SMO Assessor	
Number of Pipelle samples Observed	

Knowledge requirements	Tick when competent
• Aetiology of abnormal vaginal bleeding • Use of Guidelines for the management of heavy menstrual bleeding (HMB) and inter-menstrual bleeding (IMB) and PMB in primary care • Indications and contra-indications for pipelle sampling • Perform an appropriate history and vaginal examination • Use of the sampling device and potential risks/inadequacies of sampling • Management of normal and abnormal histological findings	

Post Training	Tick when complete
Feedback and Discussion	
GP Signature	
SMO Signature	

Please hand the completed form to the GP
If competency is not achieved after one clinic visit, then please arrange a further clinic, retain this form and complete a second form.

APPENDIX 2

Cervical Shock

About cervical shock/vasovagal reaction

About cervical shock/vasovagal reaction

Vasovagal reaction is usually the result of a strong sensory or emotional stimulus which causes widespread vasodilation and bradycardia.

Prolonged vasovagal reactions due to dilatation or instrumentation of the cervix are termed cervical shock. This can occur during or within a few minutes of taking pipelle biopsies or inserting an intrauterine device.

Vasodilatation causes pooling of blood in the peripheries and vagal stimulation causes slowing of the heart. This combination causes a dramatic fall in blood pressure and can result in transient loss of consciousness due to a reduction in blood supply to the brain.

A brief convulsion can occur as a result of a vasovagal reaction.

Practice Point!

When performing procedures on the cervix (e.g., IUD insertion) record a pre-procedure pulse rate. Consider having an assistant to monitor for signs of vasovagal reaction, sweating, pallor, bradycardia.

Assessment

1. Symptoms can include:
   - Light headed or dizzy sensation
   - Nausea
   - Feeling unwell or agitated
2. Signs – the patient may become pale and sweaty with a thready slow pulse and hypotension. This may progress to loss of consciousness and tonic clonic movements.
3. Consider other diagnoses e.g., anaphylaxis, panic attack, or hyperventilation.

Management

Most vasovagal responses only last a few minutes. Cervical shock is more prolonged with recovery usually within 20 to 30 minutes.

1. If signs of vasovagal attack occur during a procedure, remove stimulus and record time, pulse rate and blood pressure.

Stimulus

- Instruments and IUCD if not fully inserted
- The products of conception from the cervical os during a miscarriage

2. Elevate legs and give high flow oxygen.
3. If the **patient fails to improve or the reaction is prolonged**:

- Start appropriate emergency treatment i.e., call for help, and initiate ABC (Airway, Breathing, Circulation).
- Remove the IUCD if not already done. Judgement is required depending on symptoms and clinical findings.
- If severe persistent bradycardia (< 60 beats/minute) or hypotension (systolic < 90 mmHg), call for an ambulance.
- If pulse < 40 beats/minute, or systolic BP < 90 mmHg – insert IV line and give 0.6 mg atropine by slow intravenous injection, followed by a 10 ml saline flush.

  For full prescribing details, see the NZ Formulary – atropine sulfate
- If response is not satisfactory, this can be repeated every three to five minutes up to a dose of 3 mg.
- Consider IV fluid bolus – 500 to 1000 ml of normal saline.
- When more support is available, monitor signs e.g., pulse, blood pressure, pulse oximetry, ECG. Record dose and time of all medications.

4. Once pulse and blood pressure recover, slowly raise patient to seated position.

Request

If cervical shock is severe or prolonged, or unresponsive to treatment as per pathway above, refer to the Emergency Department.

Information

References

Resuscitation in the family planning and reproductive health care setting