



and
Primary Care Partners

**Management of Pathway of Care
for
MENORRHAGIA
(Heavy Menstrual Bleeding)**

Excludes Post-Menopausal Bleeding

PILOT PROGRAMME

Information Package

May 2015

INTRODUCTION

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)

Counties Manukau Health and Primary Care representatives have collaborated to design a new pathway of care for the **non surgical treatment** of menorrhagia which will see a seamless end-to-end service provided for women, largely through primary care. 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.

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

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

To Arrange Training in Your Practice,

Please Contact: Dr Sue Tutty who will come to your Practice. Please contact Sue directly as per details below

To Arrange Mirena Insertion Training

Please Contact: Dr Sue Tutty directly as per details below

GP Liaison

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

Fax Number for East Health Limited

To order Ultrasound, please Fax EHL on: **09 535 7154**

For Administrative Queries

Adrienne Laing, Service Manager Gynaecology, 021 573 587 or email adrienne.laing@middlemore.co.nz

Pauline Hanna, Executive Project Director, 021 365 355 or email pauline.hanna@middlemore.co.nz.

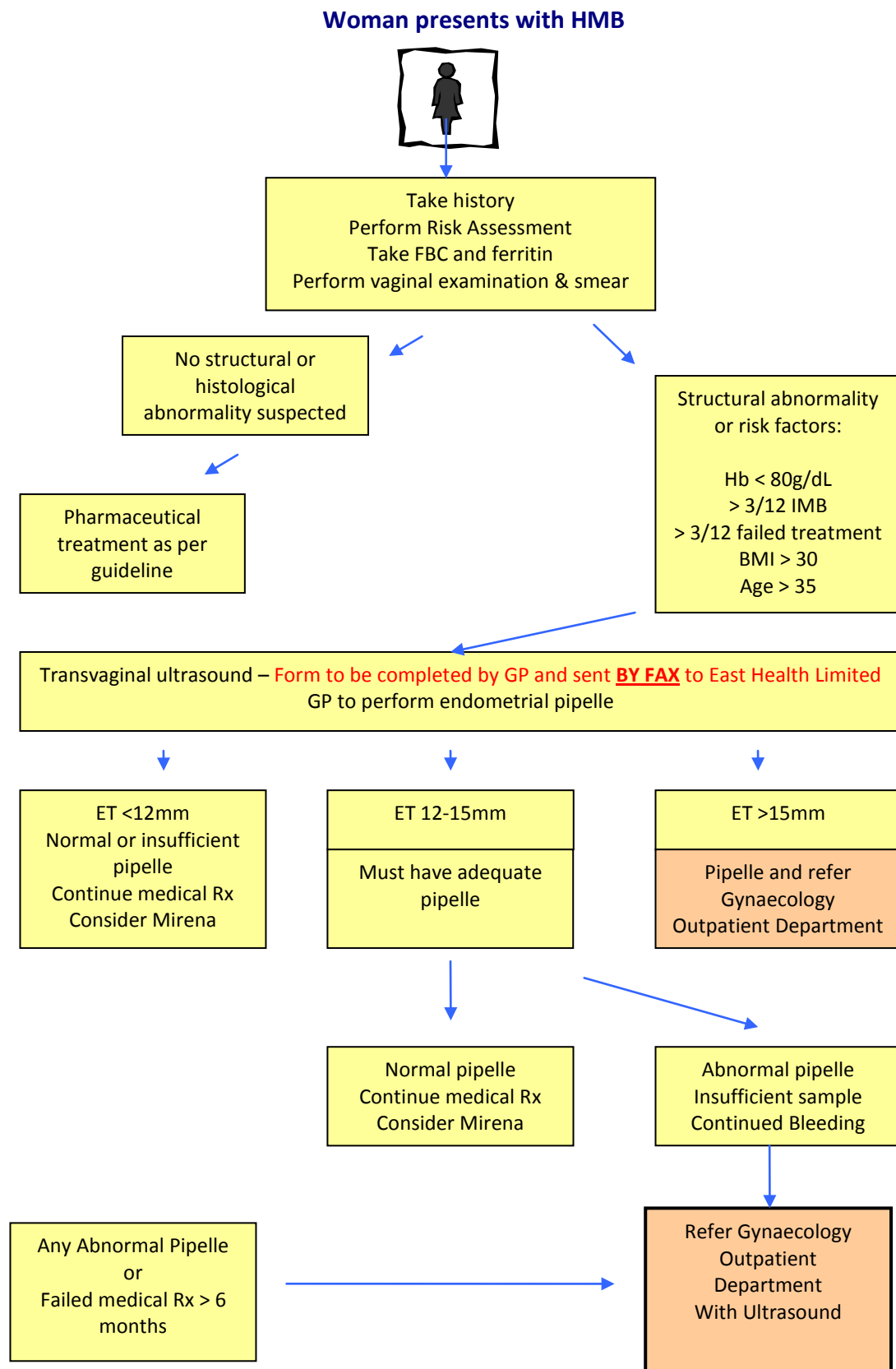
PART A

Clinical Information

- **Diagrammatic view and Description: Care Pathway for Menorrhagia: Heavy Menstrual Bleeding (HMB)**
- **Endometrial Sampling:**
 - **Credentialing for Trainers**
 - **Credentialing for General Practitioners**
 - **Background Information**
 - **Taking an Endometrial Pipelle**
 - **Guidelines/Protocols**

Figure 1:

CARE PATHWAY FOR HEAVY MENSTRUAL BLEEDING



The Pathway of Care

The model of care incorporates a credentialing module for General Practitioners (GPs) to **diagnose and provide non surgical treatment and management** for patients presenting in primary care with symptoms of menorrhagia.

This is an extension to the scope of practice for primary care.

Training, credentialing and over-sight 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 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.

The preferred option for non surgical treatment of menorrhagia under this pathway is Mirena® levonorgestrel-releasing intrauterine system. The Mirena® is a subsidised item through the *Pharmac* Pharmaceutical Schedule.

Endometrial Sampling

❖ Credentialing for General Practitioners

2.1. Aims

2.1.1. For General Practitioners to safely and effectively perform endometrial sampling using a pipelle device in appropriately counselled women.

2.1.2. 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.

2.2. Knowledge requirements

- ❖ Aetiology of abnormal vaginal bleeding
- ❖ Use of Guidelines for the management of heavy menstrual bleeding (HMB) and inter-menstrual bleeding (IMB) 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 due to dysfunctional uterine bleeding and are hormonal in origin
- ❖ Any structural abnormality in the genital tract
 - o Endometrial polyps
 - o Fibroids
 - o Endo-cervical polyps
 - o Cervical eversion/erosion
 - o Atrophic vaginitis
 - o Infection with STI
 - o Endometrial hyperplasia
 - o 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 SMO 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 is a Royal New Zealand College of General Practitioners (RNZGP) endorsed activity and attendance at the Clinic will attract Continuing Medical Education (CME) points.

Endometrial Sampling: Information

3.1. Indications for pipelle biopsy

Heavy Menstrual Bleeding - cf guideline A below (Section 5.0 Guidelines/Protocols)

- ❖ Failed medical treatment of menorrhagia after 3 months
- ❖ If the ET > 12mm on TV U/S
- ❖ If there are significant risk factors such as BMI > 30, Age > 35 years, HB<80.
- ❖ Inter-menstrual Bleeding - cf guideline A below
- ❖ Endometrial cells on cervical smears, with abnormal symptoms

3.2. Absolute Contra-indications for pipelle biopsy

Pregnancy
Endometriosis 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 can stenose the cervical canal and make insertion difficult

Taking a Pipelle

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 (U/S is not always required if vaginal examination confirms a uterus < 12 weeks size)
- ❖ 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 etc)
- ❖ 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 1/2cm. The average length of the cervix + uterus is approx 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

- ❖ 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 SMO by writing to the virtual clinic on [e-referral](#) or the usual fax number at RAC for referrals 09 277 1627

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

Guidelines/Protocols

These guidelines are also available via Healthpoint, under Womens Health.

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

Guideline A: Heavy Menstrual Bleeding (HMB) [includes inter-menstrual bleeding (IMB)]

a) Primary Care Management of HMB (Including Acute Management)

- ❖ Take a menstrual history including the presence of inter-menstrual bleeding (IMB) or post-coital (PCB). (For PCB see guideline M).
- ❖ Perform a speculum and pelvic examination and record findings. Take a cervical smear [as per cervical screening guidelines (CSG)] and consider swabs for sexually transmitted infections (STI swabs).
- ❖ Request a full blood count (FBC) and serum ferritin and if anaemic:
 - Prescribe oral iron (325mg elemental iron per day)
 - See acute management for HMB below
 - See referral criteria to GOP (guideline Ac)
- ❖ Consider thyroid function tests (TFT) if also symptoms of hypothyroidism.
- ❖ Screen for Von Willebrand's disease if suspicious features in the history.
- ❖ Trial 3 months of medical management (unless contraindicated); options listed below. (Options i and ii are the drugs of choice if trying to conceive.)
 - i. Tranexamic acid (Cyclokapron®) 1 - 1.5g 3-4 times daily for 3-4 days (during heavy bleeding).
 - ii. Non-steroidal anti-inflammatory drugs (NSAIDs). Particularly useful if there is associated dysmenorrhoea and should be taken just prior to and during menstruation e.g. mefenamic acid (Ponstan®) 500mg 3 times daily.
 - iii. Combined oral contraceptive pill (COCP) e.g. Levlen ED®.
 - iv. Cyclical oral progesterone (days 5-25 of the menstrual cycle) e.g. norethisterone (Primolut®) 5mg 3 times daily.
 - v. Depo-provera 150mg IM, repeat every 12 weeks.
 - vi. Levonorgestrel intra-uterine system [LNG-IUS (Mirena® IUS)].
 - Recommend continuing for up to 6 months if some improvement at 3 months.
 - Apply for Pharmac subsidy if criteria met.
 - Refer to Family Planning for insertion if not available at local primary care facility.
- ❖ Acute management of HMB:
 - i. Suppression of a heavy prolonged menstrual bleed:
 - Norethisterone 15mg/day or medroxyprogesterone acetate (Provera®) 30mg/day for 3 weeks. (Advise to expect a withdrawal bleed.)

- Either of the above can be combined with tranexamic acid and/or NSAID.

ii. Treat anaemia:

- Consider blood transfusion with red blood cells if:

Hb <70g/l with ongoing bleeding

Hb 70 – 100g/l with symptoms and signs of impaired oxygen transport.

- Otherwise iron supplementation:

Use oral iron as first line (65mg elemental iron per day)

Consider intramuscular (IM) iron if the oral route has failed or is not tolerated or an iron infusion if IM is declined or a more rapid response is required.

iii. For further advice, discuss with the 'acute gynaecologist' at Middlemore Hospital (09 276 0000)

- A higher dose of progesterone may be appropriate.

- Acute admission may be required for bleeding management or a blood transfusion or an iron infusion as above.

b) Indications for a Pelvic Ultrasound Scan (USS) and Endometrial pipelle biopsy, for Women with HMB

❖ Please see flow chart and either perform pipelle if appropriately credentialed, or refer to a GP Colleague who is credentialed, or order an ultrasound using *Access to Diagnostics* funding.

b) Referral Indications to Gynaecology Outpatients (GOP) for Women with HMB – once initial investigations are completed

HMB which is impacting on the woman's life, plus one or more of the following:

❖ Hb < 80g/L.

❖ Inter-menstrual bleeding (IMB), unless a pipelle sample and ultrasound have been performed.

❖ A failed 6 month trial of medical treatment or where all options are contraindicated.

❖ Abnormal cervical/vaginal appearance. Abnormal smear. Clinical suspicion of pathology.

❖ If the pelvic USS is abnormal including:

○ Fibroids ≥ 3cm

○ Endometrial thickness ≥ 12mm where an endometrial pipelle sample is not available or has been performed and pathology confirmed

○ Endometrial polyp or features of endometrial hyperplasia or malignancy

○ Other concerning USS findings.

PART B

Administrative Information

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

Funding Primary Care

In the pilot phase, 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 menorrhagia for each Locality.

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

When the initial pilot phase is completed a set volumes per Locality will be negotiated between Counties Manukau Health with the General Manager for each Locality Partnership.

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 patient and receive the capitation payment.
- ❖ This proposal applies to patients who fit the *Pharmac* subsidy criteria for Mirena®. Please see Section 6.0.

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 menorrhagia.**

Therefore patients are not required to contribute to the cost of their care in the primary sector as a result of this new model.

The analysis for the business case showed current costs for the non surgical management of patients presenting with menorrhagia in the outpatient setting by Counties Manukau Health clinicians. This was broken out by *variable* cost and *total* cost (variable, fixed inclusive of overhead).

Within this current funding envelope, Counties Manukau Health will fund care for the new model in recognition of the additional skills, pipelle biopsy and trans-vaginal ultrasound required. The GP will also attract the capitation payment for their enrolled patient.

○ The Subsidised patient (Table 1)

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

The GP is paid for first assessment, ultrasound and pipelle biopsy, treatment at the second visit which includes insertion of the Mirena® and a follow-up visit. The dispensing fee of \$5.00 will also be reimbursed. This is shown in Table 1.

○ 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 GP is paid for first assessment, ultrasound and pipelle biopsy.

The patient will be referred to the Gynaecology Service at the Manukau Superclinic through the normal referral method, **for insertion of Mirena**. Diagnostic information will be sent with this referral to the Superclinic so repeat tests will not be made.

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

	\$
Initial GP Consultation	55.00
Pipelle Biopsy	25.00
Pelvic Ultrasound	123.00
Treatment (insertion of Mirena® and follow up if required)	100.00
Mirena® dispensing fee	5.00
New Primary Care costs to be funded by Counties Manukau Health	\$307.00

Table 2: Funding Primary Care: For the Patient Who does not receive the Pharmac subsidy for Mirena®

	\$
Initial GP Consultation	55.00
Pipelle Biopsy	25.00
Pelvic Ultrasound	122.00
Patient referred to Manukau Superclinic	(Cost to be borne by Secondary Care)
Follow Up Visit with GP	55.00
New Primary Care costs to be funded by Counties Manukau Health	\$252.00

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

The preferred option for non surgical treatment of menorrhagia under this pathway, is Mirena® levonorgestrel-releasing intrauterine system 20 mcg per day. The Mirena® system is available through *Pharmac* as a subsidised item under certain conditions in their Pharmaceutical Schedule.

The full cost of a Mirena® device is \$270.00 per item but for women who meet the criteria for subsidised Mirena® this drops to a dispensing fee of \$5.00 per item. The dispensing fee will be covered through the new pathway programme.

This new pathway and associated funding does not include application of Mirena® for contraception.

Co-ordination and Support for New Model of Care

7.1. Ultrasound Provider

Each Locality Clinical Partnership has an existing contract with a Radiology service provider under their *Primary Options for Acute Care* (POAC) programme. This same provider will provide trans-vaginal ultrasound for each patient on referral from credentialed GPs and be reimbursed through the new Menorrhagia model of care programme.

7.2. Pipelle biopsy kits

Pipelle biopsy devices are currently procured for Counties Manukau Health through a regional contract negotiated by healthAlliance. The benefits of this contract have been extended to primary care and reimbursed by Counties Manukau Health.

Until further notice is given, Counties Manukau Health will provide pipelle kits direct to Practices.

7.3 Financial Transactions

Counties Manukau Health will be supported by East Health Services Limited (EHS�) to coordinate and manage all financial transactions. This will be seamless to the GP and the patient.

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, EHS� will provide the payment mechanism and co-ordination support to the Pathway and be responsible for:

- ❖ Co-ordinating all ultrasound appointments for patients who meet the clinical criteria and are referred by an accredited GP
- ❖ Managing all claiming components for service providers, as per the schedule outlined in the Pathway Information Package
- ❖ Tracking orders for pipelle through healthAlliance
- ❖ 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 POAC 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 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 pilot 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 menorrhagia pathway 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 GP Liaison 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 GP Liaison (with participating GPs) every three months.

Information for audit will be provided through EHL.

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

<u>Name of GP</u>	
<u>Date of Clinic attendance</u>	
<u>Name of SMO Assessor</u>	
<u>Number of Pipelle samples Observed</u>	

<u>Knowledge requirements</u>	<u>Tick when competent</u>
<ul style="list-style-type: none">• 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	

<u>Post Training</u>	<u>Tick when complete</u>
<u>Feedback and Discussion</u>	
<u>GP Signature</u>	
<u>SMO Signature</u>	

If competency is not achieved after one session, then a further session will be arranged for the GP trainee. We will retain this form and complete a second form.