

**Protocol for the Post Menopausal Bleeding Rapid Access Service
 (2 week rule)**

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Author		Approved by	Date
Marion Webb / Adrian Barnett/Janette Percy/Linda Tunstall/Paul Smith		Gynaecology Consultants/ Gynaecology Services Group.	Nov 2010

CONTENTS

1.	INTRODUCTION	1
1.1.	Rationale.....	1
1.2.	Scope.....	1
2.	PROTOCOL	2
2.1.	ENDOMETRIAL CANCER.....	2
2.2.	The Post Menopausal Bleeding Clinic	3
3.	TEAM MEMBERS	5
3.1.	Consultant Gynaecologist.....	5
3.2.	Nurse Led Service.....	5
3.3.	Support Systems	5
4.	REFERENCE DOCUMENTS	8
5.	EQUALITY AND DIVERSITY	8
6.	RATIFICATION PROCESS	8
7.	IMPLEMENTATION PROCESS	8
7.1.	Training.....	8
7.2.	Publication and Distribution	8
7.3.	Communication.....	8
7.4.	Access	8
7.5.	Storage Media	9
8.	MONITORING, AUDIT AND FEEDBACK PROCESS	9
9.	REVIEW PROCESS	9
10.	GLOSSARY OF TERMS	10
11.	APPENDICES	10
11.1.	Consultation Summary.....	10
11.2.	Monitoring, Audit and Feedback Summary.....	11

1. INTRODUCTION

The aim of this service is to work as a team of Health professionals in creating a Rapid Access Service for Urgent Post Menopausal Bleeding (PMB) referrals received into the Trust. An In house audit had identified a number of areas to which improvement of services could be addressed.

The Lead Consultant, The Lead Nurse in the Womens Unit and the Macmillan Nurse Specialist, along with the Cancer Site Specific Team and the Gynaecology Team have worked together to discuss and to create an Access Clinic which will be Consultant and Nurse Led in the first instance.

1.1. Rationale

Aims

- The aim of the Rapid Access Service is to provide the highest quality: evidence based service for all women presenting with post menopausal bleeding.
- The PMB staff, including Consultant, Specialist Nurse Hysteroscopist, staff grade and nurses will perform history taking, preliminary diagnostic investigations, counselling and continuing management (including when appropriate Hysteroscopy).

Objectives

- The provision of a Rapid access clinic will assist the Gynaecology Department in achieving the cancer two week targets and urgent referrals for PMB.
- Patients will benefit in terms of early diagnosis, continuity and reduction in the number of appointments and clinic visits.

1.2. Scope

This policy applies to all patients and staff involved in the delivery of a rapid access service for investigation of urgent post menopausal bleeding.

2. PROTOCOL

2.1. ENDOMETRIAL CANCER

The incidence of endometrial cancer is low in women under 40 years old (under 2 per 100,000), but rises rapidly between the ages of 40 and 55, levelling off after the menopause at around 44 per 100,000. 93% of uterine cancers are diagnosed in women aged 50 years and over.

Risk factors mainly relate to high oestrogen levels, and include:-

- Obesity
- Prolonged unopposed oestrogen therapy
- Late menopause
- Tamoxifen
- Polycystic ovary syndrome
- Nulliparity

An opportunity for the early diagnosis of endometrial cancer, because the most common symptom, namely post menopausal bleeding (PMB), may occur early in the disease process. Surgery by way of total hysterectomy with bilateral salpingo oophorectomy is often sufficient to treat the disease, but radiotherapy and/or chemoradiotherapy is used when the cancer is more advanced. Recent figures for England show that the age standardised five years survival rate is just over 70%.

Rapid access outpatient assessment allows early identification of the 5-10% of women with PMB who will be found to have malignancy. Transvaginal ultrasound is a safe, low cost, effective investigation, which is used to identify high risk patients by virtue of increased endometrial thickness. The majority of patients will have a normal endometrial thickness, and can be immediately reassured. The use of invasive procedures such as hysteroscopy can then be minimised, allowing efficient use of hospital resources.

Transvaginal ultrasound is highly reliable for the detection of endometrial cancer. The negative predictive value in patients with PMB approaches 100%. Where endometrial sampling is required because of increased endometrial thickening, this may be undertaken after hysteroscopy, using a Pipelle biopsy device.

Further imaging i.e. MRI after discussion at Gynaecology MDT is used to stage endometrial cancer and define ongoing management.

It is anticipated that 80% of women with PMB can be safely and effectively assessed as outpatients.

2.2. The Post Menopausal Bleeding Clinic

There is one PMB session each week, containing seven appointment slots. These appointments should be preferentially reserved for patients whose symptoms fit the criteria of the two week rule with regard to post menopausal bleeding, as stated below:-

1. **When a woman who is not on hormone replacement therapy presents with postmenopausal bleeding, an urgent referral should be made.**
2. **When a woman on hormone replacement therapy presents with persistent or unexplained postmenopausal bleeding after cessation of hormone replacement therapy for 6 weeks, an urgent referral should be made.**
3. **If a women decides to continue with HRT then an urgent referral should be made. (NICE Guidance 27 2005)**

N.B. PELVIC EXAMINATION IS ESSENTIAL PRIOR TO REFERAL TO EXCLUDE ANY SIGNIFICANT LOWER GENITAL TRACT PATHOLOGY

Patients fulfilling the above criteria should be seen within two weeks.

GP referrals to the PMB Clinic under the two week rule should be by fax (01423 554455).

Definitions of abnormal bleeding

1. An episode of PMB usually occurs after 12 months of amenorrhea, however significant bleeds before this time should be referred.
2. For women on sequential regimens abnormal bleeding may be heavy or prolonged loss at the end of or after their progesterone phase or occur at any other time (break through bleeding).
3. For women on continuous combined regimens including Livial (Tibolone), abnormal bleeding may occur after the first six months of commencing treatment or it occurs after amenorrhoea has been established.

If you have any concerns or would like advice on individual cases please contact the Womens Unit 01423 554479

PMB CLINIC PROTOCOL

Transvaginal ultrasound is used to assess endometrial thickness, and the presence of any other pelvic masses.

All patients are to have a consultation where a full history is taken and patient consent if applicable (meets criteria for Hysteroscopy).

Abdominal and pelvic examination will be performed including a vaginal speculum examination.

Hysteroscopy and pipelle sampling to be undertaken if the endometrial thickness at scan is greater than 4.9 mm and in circumstances where there are any clinically suspicious features (see flow chart). Although most women will successfully have an out patient hysteroscopy there will be a small number that require a General Anaesthetic (Day Surgery) procedure. This will be arranged via the Gynaecology secretaries and the patients placed on the next available theatre list (All consultants), this consultant will then continue with their care.

All hysteroscopies are to be performed by appropriately trained staff (Consultant, Staff Grade, specialist registrar or Specialist Nurse Hysteroscopist (Clinical Operating Practitioner)).

Before the woman leaves the clinic, she should be given information with regard to the findings of the PMB assessment. Where material has been sent for histological examination, the woman should be informed that the results will be communicated to both her and her GP within two weeks. If a malignancy is diagnosed, arrangements will be made for an urgent MRI scan and review of results with the patient.

All cases of endometrial cancer and suspected pelvic mass will require discussion at the weekly gynaecological MDT meeting. Following the MDT, arrangements made to attend a gynaecology Out Patient clinic as appropriate, alternatively patients may be reviewed in the Women's Unit.

In some circumstances early endometrial cancer will be treated in Harrogate otherwise treatment is at the Leeds Oncology Centre.

3. TEAM MEMBERS

3.1. Consultant Gynaecologist.

A designated Gynaecological Consultant leads and participates in the delivery of this rapid access service.

3.2. Specialist Nurse Hysteroscopist.

The Specialist Nurse Hysteroscopist is part of the PMB services and works within the Nursing and Midwifery Councils scope of Professional Practice (2008) and HDFT Policies and Protocols.

3.3. Medical Staff

Other "Team" members include senior staff practitioner, Registrars (ST), and SHO (ST1, 2 & FY2) depending on experience they will be supervised by the Consultant or Specialist Nurse Practitioner.

3.4. Nursing Staff

Responsible for the smooth running of the clinic and supporting the patients.

3.5. Macmillan Gynaecology Nurse Specialist

The Nurse Specialist will be working with the team and will be informed of any diagnosis or suspected gynaecological cancer.

3.6. Support Systems

- A designated Gynaecological consultant (lead for PMB) will be available and participate in this service and will be available on request in the event of assistance being required or a problem being encountered during a Nurse led clinic.
- The Specialist Nurse Hysteroscopist, and the Nursing Team involved in this service, will be able to discuss any of the Rapid Access Clinic with the designated gynaecological consultant if required.
- The designated consultant will review all the documentation with the Nursing Team following each clinic.
- The Nurse Hysteroscopist will participate in six monthly reviews with the Consultant.

- The Specialist Nurse Hysteroscopist will continue to receive management support from the Elective Directorate and guidance by clinical supervision.
- The Nursing Team involved in this service will continue to receive management support from the Surgical Directorate and guidance by clinical supervision.
- Issues raised through clinical audit of practice will be addressed through support and guidance by clinical supervisor.
- The Specialist Nurse Hysteroscopist and nurses involved in this service will receive practice development advice/ support/ education from the Assistant Director of Training and Development and the Risk Management team. External and internal training will be examined in support of this role.

Referrals

- Any women referred by her General Practitioner under the two week cancer wait scheme, in which postmenopausal bleeding is identified as the reason for referral (as per guidance).
- The referrals should be received on the designated two week fax referral form, when received in the centre bureau these will be identified and appointments will be made in the available slots.
- Once all PMB slots have been filled, any further referrals will be dealt with through the two week slots available in all the general Gynaecology clinics.

Rapid Access Clinic Format

- All patients will have an appointment and information leaflet sent to them. Informing them of the reason for referral and information about hysteroscopy, a scan 30 minutes prior to clinic, history, examination and possible hysteroscopy/ pipelle.
- Each clinic held in the Womens Unit will have up to 7 slots of 30 minutes each.
- A consultation including counselling and written consent will occur prior to further investigation in the Unit.
- The proposed diagnostic investigation will be explained in detail to the patient and written consent will be obtained.
- The Clinical Operating Practitioner will perform a hysteroscopy / pipelle biopsy as per protocol.
- The Clinical Operating Practitioner will dictate letters to the GP at the end of each clinic.
- The patient and the GP will be informed of the results within two weeks.

Patient assessment / Procedure

- The Clinical Operating Practitioner prior to performing any examination will assess the general health status of all patients.
- If there is concern regarding a patient's suitability for hysteroscopy, that patient will be discussed on an individual basis with the medical staff.
- During hysteroscopic examination digital images of the uterine cavity and any abnormalities seen will be documented (if available).
- Endometrial biopsy will be performed as per protocol
- All biopsies will be sent for histological analysis (If necessary marked with green spot as urgent).
- The Clinical Operating Practitioner will debrief the patient following investigation and discuss any further management required.
- If no further management is required the patient will be discharged to her General Practitioner. Relevant information and guidance will be given to the patient.
- The Clinical Operating Practitioner will check the patient has recovered from examination prior to leaving the patient in the examination room to dress. An appropriate area for recovery is available if required by the patient.
- If at any time for any reason the Specialist Nurse Hysteroscopist is unsure or concerned about the patient then advice from designated consultant will be obtained.
- During ultrasound if an ovarian cyst is detected, management as per protocols.

4. REFERENCE DOCUMENTS

SIGN: Scottish Intercollegiate Guidelines Network (2002) Edinburgh

DOH Getting it right for people with Cancer: Clinical case for change, (2007). National Cancer Director

NICE Guideline – Referral for suspected cancer (2005)

Cancer Research Uk.

5. EQUALITY AND DIVERSITY

The policy fully respects equality and diversity and aims to ensure that all requirements are met and are accessible, appropriate and sensitive to the needs of the whole community.

6. RATIFICATION PROCESS

The policy will be ratified by the Obstetric and Gynaecology Department.

7. IMPLEMENTATION PROCESS

7.1. Training

This policy will be highlighted in the training package on Hysteroscopy Examinations, which is given to all staff directly involved in the PMB rapid access service.

7.2. Publication and Distribution

This policy once approved will be stored on the electronic document library under the Women's Services.

7.3. Communication

The policy will be communicated by the Trusts intranet. The ratification of the policy will be communicated to all staff involved in the delivery of the PMB Rapid Access Service.

7.4. Access

Copies of this document should not be printed unless it is absolutely necessary as there is risk that out of date copies may be in circulation. Requests for this policy in an alternative language or format (such as Braille, audiotape, large print etc) will be considered and obtained whenever possible.

7.5. Storage Media

This policy will be posted on the Trusts Intranet for read access only in PDF format.

8. MONITORING, AUDIT AND FEEDBACK PROCESS

Monitoring the effectiveness of the policy will provide assurance that patients receive a high quality service.

Audit and Evaluation

Data will be collected detailing clinic appointments, and appointments and outcomes.

- A continual review of the referral patterns will be undertaken.
- Bi Monthly evaluation meetings with all Rapid Access Clinic Users.
- Multidisciplinary clinical review meetings.
- Patient satisfaction questionnaires will be distributed after the Rapid Access Clinics, to assist in the auditing of the quality of service. This questionnaire will be based on The Women's health Questionnaire (WHQ): Frequently asked questions: **Health and Quality of Life Outcomes**.
- The staff will seek advice re audit and evaluation strategies from the Clinical Audit & Effectiveness Department. Discussion of a data base system will also be discussed.

Feedback of the results

The results of any monitoring and audit will be presented to the Obstetric and Gynaecology Department Clinical Audit.

Action Plans will be produced and it will identify any new standards or changes to the diagnostic service that will need to be implemented, the action plan will include identified staff leads and timescales,

9. REVIEW PROCESS

This policy will be reviewed two yearly from the date of issue, earlier if significant changes in national guidelines/standards or audit advises change.. However, it will be reviewed earlier if there are monitoring or audit reports that suggest that protocol review is required. Similarly if there are relevant new external standards or evidence, review will be undertaken earlier.

10. GLOSSARY OF TERMS

- PMB: Post Menopausal Bleeding
- Hysteroscopy: Procedure that allows direct visualization of the uterine
- MDT: Multi Disciplinary Team
- MRI: Magnetic resonance Imaging
- HRT: Hormone Replacement Therapy

11. APPENDICES

11.1. Consultation Summary

<p>Those listed opposite have been consulted and comments/actions incorporated as required.</p> <p>The author must ensure that relevant individuals/groups have been involved in consultation as required prior to this document being submitted for approval.</p>	List Groups and or Individuals Consulted
	Consultant Gynaecologists including clinical lead.
	Elective Directorate.
	Manager Cancer Services
	Macmillan Clinical Nurse Specialist
	Womens Unit Staff
	Patient/ User involvement
	Senior Staff Practitioner

11.2. Monitoring, Audit and Feedback Summary

Audit/ Monitoring Criteria e.g.	Audit / Monitoring questions	Audit / Monitoring performed by	Audit / Monitoring frequency	Audit / Monitoring reports distributed to	Action plans approved and monitored by
Patient quality Service questionnaire	<p>Did the patient receive relevant information about the service?</p> <p>Did the patient get seen in a timely manner?</p> <p>Did the patients receive adequate information about the findings?</p> <p>Did the patient receive enough time to discuss any concerns or issues?</p>	Nurse Practitioner and Clinical Nurse Specialist	6 months	<p>Consultant Gynaecologists.</p> <p>Womens and Children CBU</p> <p>Cancer Services Manager</p>	
Was the appropriate assessment tool/ flow chart used effectively?	<p>Was the appropriate tool used and documented in the care pathway?</p> <p>Is there compliance in accordance with the Guidelines?</p>	Nurse Practitioner and Clinical Nurse Specialist	6 months		
Has the relevant staff undertaken training and education as required by the Trust, regulatory Authorities and national legislation?	Have all the staff completed and documented their competency framework and assessment relevant to their role?	Nurse Practitioner and Clinical Nurse Specialist	At least one a year		