

National Clinical Audit and Patient Outcomes Programme Project Summary

National Audit of Heavy Menstrual Bleeding

Purpose

The primary objective of this audit is to assess patient outcomes and experience of care for women with heavy menstrual bleeding (HMB). Specifically, it aims to investigate:

- The organisation of care for women with HMB within NHS acute trusts in England and Wales.
- Variation in referral rates to hospital gynaecology outpatient clinics, as well as variation in patient-reported symptom severity and quality of life of referred women.
- Variation in treatment patterns among women with HMB, with adjustment for symptom severity. The audit will capture all treatments in the year after a woman's first outpatient visit, and examine patterns by NHS acute trusts and geographical region.
- Variation in patient-reported outcomes one year after a woman's first outpatient visit by NHS acute trust.
- Experience of women in the first year after the first outpatient visit. This will include the availability of treatment options and the provision of information about possible treatments.
- Determinants of regional and provider-level variations in referral rates, treatment patterns and outcomes that may guide the quality of care improvement initiatives.

Methodology

Organisational audit: In the first year of the study, an organisational audit will be carried out through a postal survey of all NHS acute trusts in England and Wales providing gynaecological care for women with HMB. It will collect information on the local organisation of services, the health professionals involved, and access to diagnostic and therapeutic facilities. Trusts will also be asked to send their local protocol which will be compared against NICE guidance and the RCOG service standards.

Data collection and analysis: There will be two phases of data collection. The first questionnaires will be given to consenting patients at the time of the first outpatient visit. The 1-year follow-up questionnaire will be mailed to the patients' home address. Both questionnaires will have a condition-specific quality of life (QoL) instrument and the EQ-5D generic QoL instrument to measure general health-related quality of life. The outpatient questionnaire will have additional questions on age of the patient, ethnicity, duration of the condition, obstetric history, previous treatments and co-morbid conditions. The 1-year questionnaires will capture data from patients on co-morbidity, treatment received and complications.

An appropriate risk-adjustment strategy will be adopted to ensure that the outcomes and performance indicators of NHS acute trusts can be compared reliably. Patient-reported information as well as characteristics of NHS acute trusts that may influence choice of treatment and outcomes will be used to risk-adjust outcomes and define homogenous patient groups to compare process measures. The potential for patients to be more alike within hospitals than between hospitals will be taken into account using approach regression techniques, such as multi-level modelling.

Linkage with existing databases: Patient's questionnaire responses will be linked to the HES database for women treated in England, and to the PEDW database for those treated in Wales.

Key Quality Indicators

Standards of care for HMB has been outlined in the *NICE Clinical Guideline on Heavy Menstrual Bleeding* (published in January 2007, available at <http://www.nice.org.uk/CG44>) and the *RCOG Standards for Gynaecology: Report of a Working Party* (published in June 2008, available at <http://www.rcog.org.uk>).

A paper has recently been published in *BJOG*¹ demonstrating variation in practice in the management of heavy menstrual bleeding in England and Wales. These data will inform the basis for defining National Quality Indicators.

1. Cromwell D, Mahmood T, Templeton A, van der Meulen J. Surgery for menorrhagia within English regions: variation in rates of endometrial ablation and hysterectomy. *BJOG* 2009;116:1373–1379.

Data Collection Schedule

The HMB audit has a duration of four years:

In the first year, the project team will:

- carry out an organisational audit within NHS acute trusts, and an assessment of trust treatment protocols for compliance with NICE guidance.
- carry out a pilot study to evaluate enrolment, recruitment rates and collection of patient-reported outcomes in outpatient clinics as well as to validate the prospective data collection instruments.
- prepare the NHS acute trusts for the audit.

In the second year, the project team will:

- recruit women who are referred for an outpatient visit for the first time with a complaint of HMB in England and Wales.
- collect patient-reported information about their symptoms and quality of life when seen at the outpatient clinic.
- analyse and report on the organisational survey, including protocol compliance, and longitudinal patterns of care using routine hospital databases.

In the third year, the project team will:

- collect patient-reported outcomes and patient experience information 1-year after the initial outpatient visit via a questionnaire posted to the patient's home address.
- analyse and report the patterns of care and patient characteristics at the time of first outpatient visits.
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In the fourth year, the project team will:

- complete the linkage of the patient-reported outcomes data with routine hospital databases.
- analyse and report 1-year outcomes, experiences and patterns of treatment.
- develop recommendations on a sustainable infrastructure to monitor treatment patterns and patient outcomes among women with HMB.

Is the Audit Process or Outcome focused?

This audit will investigate variation in both process and outcomes of care for women with HMB. With respect to the process of care, the audit will study:

- Patterns of referral among PCTs by looking at the referral rate per 1000 women as well as comparing the differences in symptom severity and quality of life of women referred for the first time.
- Hospital-based treatment patterns, adjusted for the symptom severity and quality of life at the first outpatient visit. We will focus on the use of endometrial ablation and hysterectomy, combining the patient-reported data with HES and PEDW databases. We will also collect information on other medical therapies such as MIRENA IUS offered at the first outpatient visit as it is an important determinant of hysterectomy rates.
- The women's care experience including the information they received about the treatment options and the extent to which they were involved in the choices made about their treatment.

With respect to the outcomes of care, the audit will study:

- Complications of treatments given during the first year after the first outpatient visit reported by patients. For surgical complications, these will be compared with complications reported in HES and PEDW databases.
- Symptom severity and quality of life, one year after the first outpatient visit, adjusting for symptom severity and quality of life at the first outpatient visit and comparing the results for women who had medical treatment, endometrial ablation and/or hysterectomy.

Who is involved in the audit?

The audit will be carried out by the Royal College of Obstetricians and Gynaecologists (RCOG) in partnership with Ipsos-MORI and the London School of Hygiene and Tropical Medicine (LSHTM):

- The RCOG endeavours to improve standards in the practice of obstetrics and gynaecology for the benefit of the public and has been involved in a number of national audit projects.
- Ipsos MORI is one of the leading market and opinion research organisations in the United Kingdom and has vast experience of collecting information from the public and patients about their health and the health service.
- The LSHTM hosts a unit that is a centre of expertise in methods, organisation and logistics of national audits and large-scale studies of the quality of care.

Who are the main stakeholders?

- Women with heavy menstrual bleeding (patients)
- Clinicians (Clinical Directors, Gynaecologists, GPs, Specialist nurses)
- Commissioners and regulators

Date of the next Annual Report and outline content

The first Annual Report will contain information about the organisation of care for women with HMB within NHS acute trusts in England and Wales. It will describe the results of the organisational audit, the compliance of hospital protocols with the NICE HMB guideline, and longitudinal patterns of care in England and Wales using HES/PEDW datasets. It will also contain the results of the pilot study, including the validation of the quality of life instrument.

The first Annual Report will be published 15 months after the start date of the audit. [Currently start date is November 2009, with the first Annual Report to be published by February 2011]

More information: <http://www.rcog.org.uk>

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