



Royal College of  
Obstetricians and Gynaecologists

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**HQIP**

Healthcare Quality  
Improvement Partnership

First Annual Report

May 2011

# National Heavy Menstrual Bleeding Audit

A national audit to assess patient outcomes and experiences of care for women with heavy menstrual bleeding in England and Wales





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- Dr Boon Lim FRCOG and Ms Lynn George, Hinchingsbrooke Hospital, Hinchingsbrooke Health Care NHS Trust
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- members of the Clinical Reference Group (Chair, Angela Hyde) for overseeing the delivery of the audit and providing clinical guidance
- members of the Project Board (Chair, Robert Shaw) for providing project governance

- the clinical advisors to the project.

A list of members of the Clinical Reference Group and the Project Board and the clinical advisors is provided in Appendix 2.

The project team consists of:

#### Royal College of Obstetricians and Gynaecologists

- Suzanne Cox, Heavy Menstrual Bleeding Audit Lead
- Tahir Mahmood, Chair of National Heavy Menstrual Bleeding Audit Project Team
- Allan Templeton, Honorary Clinical Director of the Office for Research and Clinical Audit
- Benedetta La Corte, Office for Research and Clinical Audit Coordinator
- Charnjit Dhillon, Director of Standards

#### London School of Hygiene & Tropical Medicine

- David Cromwell, Senior Lecturer
- Sarah Smith, Lecturer
- Ipek Gurol-Urganci, Lecturer
- Donna Lamping, Professor of Psychology
- Jan van der Meulen, Professor and Honorary Director of the Office for Research and Clinical Audit

#### Ipsos MORI

- Michele Corrado, Director of Health and Social Research
- Stefan Durkacz, Senior Research Executive
- Tomasz Mludzinski, Research Executive
- Jonathan Nicholls, Director of Health Research
- Kate Smith, Research Director

# Abbreviations

CI	confidence interval
EA	endometrial ablation
EQ-5D	European Quality of Life-5 Dimensions
GP	general practitioner
HES	Hospital Episode Statistics
HMB	heavy menstrual bleeding
HRQoL	health-related quality of life
HYS	hysterectomy
ICD-10	International Classification of Diseases and Related Health Problems, 10th edition
LNG-IUS	levonorgestrel-releasing intrauterine system
MAS	Multi-Attribute Quality Assessment
MDQ	Menstrual Distress Questionnaire
MOQ	Menorrhagia Outcomes Questionnaire
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OPCS	Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision
PCT	primary care trust
RCOG	Royal College of Obstetricians and Gynaecologists
SHA	strategic health authority
UFS-QOL	Uterine Fibroid Symptom and Quality of Life questionnaire

## Acceptability

Acceptability is a psychometric term that describes the quality of the data. It is assessed by completeness of data and score distributions.

## Clinical Reference Group

The Heavy Menstrual Bleeding Audit's Clinical Reference Group comprises representatives of the key stakeholders in heavy menstrual bleeding care. They advise the Project Team on particular aspects of the project and provide input from the wider clinical and patient community.

## Clinician

A healthcare professional providing patient care, such as a doctor or nurse.

## Cohort

A group of people sharing some common characteristic (such as patients with the same disease) followed up in a study for a specified time period.

## Construct validity

The extent to which an instrument measures the construct it purports to measure. There are several different forms of construct validity (see convergent validity, discriminant validity, criterion-related validity and known groups validity).

## Content validity

The extent to which a measure represents all facets of the construct it purports to measure. Construct validity is evaluated qualitatively.

## Convergent validity

The extent to which a construct is correlated with measures of the same or similar constructs.

## Criterion-related validity

The extent to which a measure is correlated with a 'gold standard' measure of the same construct. Criterion-related validity can be evaluated concurrently or predictively.

## Discriminant validity

The extent to which the construct is not correlated with measures of a different construct. Discriminant validity is usually assessed using correlations.

## Endometrial ablation

A medical procedure that is used to remove (ablate) or destroy the endometrial lining of a woman's uterus.

## EQ-5D™

A standardised instrument for use as a measure of health outcome. EQ-5D™ is applicable to a wide range of health conditions and treatments. It provides a simple descriptive profile and a single index value for health status.

## Heavy menstrual bleeding (HMB)

Excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms.

## Health-related quality of life (HRQoL)

A person's quality of life as it is affected by their health condition. There is no universal definition of health-related quality of life, but it is usually taken to mean a multidimensional construct including physical, psychological and social functioning, often including the ability to perform usual roles within each of these domains. General health perceptions and opportunity for health, pain, energy, independence, environment and spirituality are also sometimes included.

## Hospital Episode Statistics (HES)

Hospital Episode Statistics is the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. Hospital Episode Statistics is the data source for a wide range of healthcare analysis for the NHS, government and many other organisations and individuals.

## Hysterectomy

The surgical removal of the uterus.

## Internal consistency

See reliability.

## Interquartile range

The difference between the value of a variable below which lie 25% of the population, and that below which lie 75%: a measure of the spread of the distribution.

## Known groups validity

The ability of a scale to differentiate known groups; assessed by comparing scores for subgroups who are expected to differ on the construct being measured.

## Levonorgestrel-releasing intrauterine system (LNG-IUS)

A T-shaped plastic device placed in the uterus that steadily releases small amounts of levonorgestrel, a progesterone hormone.

## Psychometrics

The field of study concerned with the rigorous measurement of unobservable constructs such as cognitive abilities, attitudes and, in the health domain, health-related quality of life.

## Reliability

Reliability is the extent to which an instrument is free from error. Test–retest reliability refers to the extent to which the measure is stable over time (assuming no events or interventions). Reliability is usually assessed using an intraclass correlation. Internal consistency is a form of reliability that refers to the extent to which items in a scale all measure the same construct (that is, the homogeneity of the scale). Internal consistency is assessed using Cronbach’s alpha.

## Responsiveness

The ability of an instrument to detect change in relation to a treatment of known efficacy.

## SF-12v2®

SF-12v2® is a shorter version of the SF-36v2® Health Survey that uses just 12 questions to measure functional health and wellbeing from the patient’s point of view. It is a well-established gold standard measure that is available in multiple languages.

## Test–retest

See reliability.

## Uterine Fibroid Symptom and Quality of Life Questionnaire (UFS-QOL)

A uterine-fibroid-specific questionnaire developed to evaluate the symptoms of uterine fibroids and their impact on health-related quality of life.

## Validity

The accuracy or truth of the data and findings that are produced and, in the context of measurement, the extent to which the instrument measures what it purports to measure. Validity can be assessed in a variety of ways. See, for example, content validity, convergent validity, discriminant validity and known groups validity.

# Foreword

I am pleased to introduce the first annual report of the National Heavy Menstrual Bleeding Audit and congratulate the hospitals and women that have contributed. To date, 200 hospitals are contributing to the audit of patient-reported outcomes, and it is excellent to see their enthusiasm and dedication to this essential audit even in times of structural change and uncertainty within the National Health Service (NHS). It is especially remarkable that 100% of outpatient gynaecology clinics returned an organisational survey.

Justification for this audit comes from large local variation in treatment modalities. In some areas, newer treatments such as levonorgestrel-releasing intrauterine systems and endometrial ablation may not be used as first-line treatment.

The National Institute for Health and Clinical Excellence and the RCOG have guidelines for the care of women with heavy menstrual bleeding. These guidelines recommend that NHS acute trusts create local referral pathways between primary and secondary care and provide gynaecological outpatient services that enable prompt access to hysteroscopic assessment or treatments. Trusts are encouraged to provide a dedicated one-stop menstrual bleeding clinic with appropriate diagnostic facilities, including comprehensive patient information.

The results of the organisational audit presented in this report highlight some positives and some negatives with regard to the adoption and implementation of these recommendations. Most hospitals have the appropriate range of facilities. However, only a minority of hospitals reported having a local written protocol, which is key to ensuring that primary care and secondary care are working together efficiently so that local resources are used to their best potential. A minority of hospitals also reported having one-stop clinics. This recommendation is aimed at streamlining care for the benefit of women but also to reduce the burden on other gynaecology services.

To help local NHS services improve quality of care and clinical outcomes for this group, the College has supported full participation in the audit. This audit will quantify women's quality of life related to their heavy menstrual bleeding and, in so doing, will allow us to appreciate the effect that this common and devastating condition has on so many women.

The College looks forward to future reports which will offer the first national information on patient-reported outcomes for women with heavy menstrual bleeding. We look forward to working with all participants over the next 3 years.



Dr Tony Falconer  
President, RCOG

# Executive summary

Heavy menstrual bleeding (HMB) is a common condition affecting 20–30% of women of reproductive age. HMB is estimated to be the fourth most common reason women are referred to gynaecological services and, each year, approximately 28,000 women undergo surgical treatment for HMB.

National guidelines regarding the treatment of heavy menstrual bleeding have been published by the National Institute for Health and Clinical Excellence (NICE)<sup>1</sup> and the Royal College of Obstetricians and Gynaecologists (RCOG).<sup>2</sup> These guidelines reflect the substantial changes in the management of HMB over the last 10 years, with a wider range of medical therapies and the introduction of newer minimal-access surgical procedures such as endometrial ablation. However, information about how the National Health Service (NHS) has responded to this new clinical evidence and guidelines is currently lacking.

The RCOG is conducting the National Heavy Menstrual Bleeding Audit, which began on 1 February 2010. The overall aims of this 4-year audit are to describe the care received by women with HMB referred to NHS outpatient clinics in England and Wales and to assess women's outcomes and experience of care. Specific audit objectives are to investigate the extent of differences among NHS organisations in England and Wales in terms of:

- the severity of menstrual problems experienced by women referred to NHS outpatient clinics
- the care received by women with HMB in the 1st year after their initial outpatient consultation, taking into account the severity of their symptoms and the effect these have on their health and quality of life
- the effect that treatments received in the 1st year after their outpatient visit have had on women's health and quality of life.

The audit consists of two principal components:

- **An organisational audit** of acute NHS trusts in England and Wales to describe the organisation of hospital gynaecological services, current referral patterns and local protocols with reference to the management of HMB.
- **A prospective audit of patient-reported outcomes** of women who attend outpatient gynaecology clinics with HMB symptoms for the first time between 1 February 2011 and 31 January 2012. These women will be followed up after 1 year to collect information on the treatments received since their outpatient visit and on patient-reported outcomes.

The organisational audit was part of the work undertaken by the audit in its 1st year. An analysis of Hospital Episode Statistics (HES) to look at regional variations in treatment and a pilot study of administering the patient questionnaire were also undertaken in the first year.

## Analysis of regional variation in treatment for HMB

An analysis of Hospital Episode Statistics was conducted, which demonstrated that between 1 April 2006 and 31 December 2009:

- The age-standardised annual rate of surgery for HMB in English NHS trusts was 152 procedures/100 000 women. This was a slight increase from the previous 3-year period, which mainly reflected an increase in the rate of endometrial ablation.
- Surgical rates across the ten strategic health authorities varied significantly from 70 to 255/100 000 women.
- There was also wide variation in rates within primary care trusts, ranging from 14 to 392 procedures/100 000 women.

## Organisational audit

The NICE HMB guideline and the RCOG's *Standards for Gynaecology* describe specific organisational requirements for hospitals relating to the management of heavy menstrual bleeding, including the development of protocols that address the unique circumstances of local services and the importance of women having access to information on treatment before their outpatient appointment.

All NHS acute trusts with outpatient gynaecology departments in England and Wales were sent a questionnaire on issues related to the availability of facilities, local treatment protocols and patterns of care in both primary and secondary care. Responses were received from 221 hospitals (100% response).

The results of the audit were as follows:

- 38.4% of responding hospitals reported that they had a dedicated menstrual bleeding clinic.
- The majority of hospitals reported the availability of ultrasound (80.0%), hysteroscopy (87.3%) and endometrial biopsy (97.7%) as well as a wide variety of surgical procedures and appropriate levels of investigations at the initial consultation.
- 76.0% of hospitals provided an HMB-specific information leaflet for women, 8.3% referred women to a website for information and 19.8% did not provide written information.
- Only 29.9% of hospitals reported that they had a local, written protocol regarding the care and management of women with HMB.

## Preparation for the prospective audit

A pilot study was conducted to test the procedures for the enrolment of women into the audit and the administration of the baseline patient questionnaire, and to develop the patient questionnaire. A focus group and interviews with women and clinicians identified issues around the staffing required, the timing of the questionnaire distribution, the need for privacy when completing the questionnaire and secure storage. These issues were incorporated into the audit procedures manual and communicated to staff at regional briefings.

The patient questionnaire was developed to capture information on women's demographics, menstrual symptoms, obstetric history, potential related conditions and health-related quality of life (HRQoL). Items were selected after a review of the literature and consultation with the Clinical Reference Group. The European Quality of Life-5 Dimensions was selected as the generic HRQoL instrument.<sup>3</sup> There was no widely used disease-specific measure of HRQoL, and after a comparison of available tools, the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire was selected subject to its successful adaptation for a UK population of women with HMB.<sup>4</sup> Suitable words to describe HMB and to replace US English were identified using interviews with women and clinicians, and the adapted UFS-QOL instrument was psychometrically evaluated at 11 sites (96 women participated). The adapted instrument demonstrated acceptable levels of reliability and validity.

## Conclusion

In summary:

- The HES analysis showed that large regional variations in the surgical treatment of HMB persist across English regions.
- The organisational audit demonstrated that the majority of hospitals have recommended facilities for the tailored care of women with HMB. However, few hospitals have written local protocols and the provision of patient information is variable. This potentially highlights limited implementation of the NICE *Heavy Menstrual Bleeding* guideline published in 2007.
- The pilot phase demonstrated that the main patient audit to begin on 1 February 2011 was feasible.

The national picture of how women experience their HMB and relevant care, as well as the services available to women with HMB, will be greatly enhanced by full participation in the audit of patient-reported outcomes. Since 1 February 2011, eligible trusts have been recruiting women to complete the patient-reported questionnaire. The results of the baseline questionnaire will be available in the second annual report (June 2012).



# 1 Introduction

## 1.1 National Heavy Menstrual Bleeding Audit

Heavy menstrual bleeding (HMB) is a common condition affecting 20–30% of women of reproductive age. There are various treatments available for women with HMB and the condition can be effectively managed within primary care. However, medical therapies may not be tolerated or prove ineffective, and it is estimated that in England and Wales, each year about 80 000 women with HMB are referred for the first time to secondary care and approximately 28 000 undergo surgical treatment.

Clinical guidelines on the treatment of HMB have been available in England and Wales since 1995 and have been regularly updated, taking account of changes in the available treatment options. The National Institute for Health and Clinical Excellence (NICE) published its latest guideline, *Heavy Menstrual Bleeding*, in 2007,<sup>1</sup> while the Royal College of Obstetricians and Gynaecologists (RCOG) published standards specific to HMB in its 2008 *Standards for Gynaecology*.<sup>2</sup> However, studies have persistently found significant regional variations in practice patterns within the UK with respect to the number of women referred to secondary care and the type of treatment that they receive. These variations raise concerns about inequality of access and availability of treatment.

The RCOG is conducting the National Heavy Menstrual Bleeding Audit, which was established in February 2010 to examine the care received by women with HMB and to assess patient outcomes and experience of care. Its work focuses on the care provided by National Health Service (NHS) acute trusts in England and Wales and consists of two principal components:

- an **organisational audit** of acute NHS trusts in England and Wales to describe the organisation of hospital gynaecological services, current referral patterns and local protocols with reference to the management of HMB
- a **prospective audit** of patient-reported outcomes of women with HMB symptoms who attend outpatient gynaecology clinics between 1 February 2011 and 31 January 2012.

In this first annual report, we describe the work undertaken in the first year of the audit. This includes the results of the organisational audit of NHS acute services in England and Wales and the results of the pilot study of the prospective audit. In addition, we describe current patterns of surgical treatment for women with HMB.

## 1.2 An overview of treatment options for women with heavy menstrual bleeding

In the majority of women with HMB, the cause is not known, although the HMB may be related to abnormalities such as fibroids or adenomyosis. Medical therapies are the recommended first-line treatment for HMB in women without pathological abnormalities.<sup>1</sup> If long-term treatment is required, the levonorgestrel-releasing intrauterine system (LNG-IUS) is considered the most effective therapy. Alternative medical therapies include antifibrinolytic

drugs (such as tranexamic acid), non-steroidal anti-inflammatory drugs (such as mefenamic acid) and hormonal drugs (such as combined oral contraceptives).

Surgical treatment is indicated when HMB severely affects quality of life or when medical therapies are not tolerated or prove ineffective.<sup>1</sup> The principal procedures are hysterectomy and endometrial ablation. Hysterectomy ensures the cessation of menstruation but is associated with potentially serious postoperative complications in around 3% of women. Endometrial ablation is less invasive and has been shown to be a safe and effective alternative to hysterectomy. However, a proportion of women will require repeat ablation procedures and some will eventually have a hysterectomy.

Since the introduction of endometrial ablation in the 1990s, there has been a steady shift in the pattern of surgical care for HMB in England. The number of endometrial ablation procedures has increased steadily while the number of hysterectomies has declined.<sup>5</sup> This change reflects the increasing evidence base on the effectiveness of endometrial ablation and the development of new techniques. First-generation techniques (hysteroscopic endometrial resection and rollerball endometrial ablation) required significant training and experience. Newer, second-generation techniques have proved to be equally effective but are easier to perform and require less training time and experience to achieve the appropriate competences. The second-generation techniques include thermal balloon ablation, impedance control ablation, microwave ablation, free fluid thermal ablation and endometrial cryotherapy ablation.

The choice of treatment will depend upon various factors, including the severity of the symptoms, the woman's preferences, plans to conceive and contraindications. Because of the range of medical and surgical treatments available, the provision of patient information is recognised as an important aspect of the management of HMB. Providing information enables women with HMB to understand the condition, improves self-management and helps support decisions about the treatments that are appropriate for them.<sup>1</sup> This active involvement in clinical decision making leads to better adherence to medical therapies and improved satisfaction.

### 1.3 Service organisation and policy in England and Wales

Women with HMB without structural or histological abnormalities will often begin medical treatments in primary care. Women may be referred for a gynaecological outpatient consultation if there is a history of a structural or histological abnormality or if the pattern of symptoms suggests that examination by a specialist gynaecologist and other investigations (such as ultrasound) should be performed. Women may also be referred if medical therapies prove ineffective or they have a preference for surgery.

NHS acute trusts are recommended to create local referral pathways between primary and secondary care and to provide gynaecological outpatient services that enable prompt access to hysteroscopic assessment or treatment.<sup>2</sup> Trusts are encouraged to provide a dedicated one-stop menstrual bleeding clinic with facilities within the clinic for diagnostic gynaecology, including hysteroscopy and ultrasound.<sup>2</sup> Services are also recommended to provide patient information leaflets to women before they attend for diagnostic or operative hysteroscopy, including information on treatment options for menstrual problems and the services available.<sup>2</sup>

# 2 The National Heavy Menstrual Bleeding Audit

## 2.1 Background to the audit

Previous studies have observed significant regional variation in the treatment patterns of HMB.<sup>6-8</sup> In primary care, studies reported variation in prescribing patterns and referral rates, suggesting inconsistency in the assessment of menstrual problems, the consideration of patient preferences and the reasons for referral. For example, referral rates in the Somerset Morbidity Project ranged from 24% to 52%.<sup>6</sup>

In secondary care, there is also evidence of variation in practice. For example, a recent study showed that, between 2004 and 2006, the annual rate of surgery for women with HMB ranged from 52 to 230/100 000 women across the strategic health authorities (SHAs) in England.<sup>9</sup> The study also reported substantial variation in the ratio of hysterectomy to endometrial ablation procedures.

Such variation may reflect differences in levels of morbidity, women's preferences and differences in the availability of services and clinical judgement.<sup>10</sup> Clinical guidelines to inform practice have been available since the mid-1990s,<sup>1,11-13</sup> but it is unclear to what extent the reported variations in practice still exist and to what extent they are associated with differences in women's outcomes. A problem with existing routine data is the lack of information about women's symptoms that would put observed patterns of care within a clearer clinical context.

## 2.2 Aims and objectives

The overall aim of the National Heavy Menstrual Bleeding Audit is to examine the care received by women with HMB referred to NHS outpatient clinics in England and Wales and to assess women's outcomes and experience of care. Specific audit objectives are to investigate the extent of differences among NHS organisations in England and Wales in terms of:

- the severity of menstrual problems experienced by women referred to NHS outpatient clinics
- the care received by women with HMB in the first year after their initial outpatient consultation, taking into account the severity of their symptoms and the effect these have on their health and quality of life
- the effect that treatments received in the first year after their outpatient visit have had on women's health and quality of life.

By so doing, the audit will provide comparative information for clinicians, highlight whether the care received by women with HMB is consistent with recommended practice and identify where improvements could potentially be made. The audit also supports other initiatives by:

- providing information on the uptake of the NICE guideline<sup>1</sup> and RCOG *Standards for Gynaecology*<sup>2</sup> across England and Wales

- generating a source of national information that commissioners can use to refine their purchasing strategy
- exploring whether outcome indicators collected through this audit could be used to support revalidation of clinicians as prescribed by the General Medical Council<sup>14</sup>
- informing the development of national quality matrices through the use of patient-reported outcome measures
- producing information on the impact that new patient-centred arrangements may have on the current service delivery model, treatment patterns and patient experience as detailed in the Department of Health project *Delivering care closer to home*.<sup>15</sup>

## 2.3 Design of the audit

The audit is funded by the Health Quality Improvement Partnership as part of the National Clinical Audit and Patient Outcomes Programme. The audit is led by the RCOG's Office for Research and Clinical Audit, which is a collaboration between the RCOG and the London School of Hygiene & Tropical Medicine. On this project, the Office for Research and Clinical Audit team is working in partnership with Ipsos MORI, a leading opinion and market research organisation. Additional team members from the Department of Health Services Research and Policy at the London School of Hygiene & Tropical Medicine are providing expertise in questionnaire development and outcome measurement.

The audit began on 1 February 2010 and will run for 4 years. It has two main components: an organisational audit and a patient-based prospective audit of the patterns and outcomes of care.

### Organisational audit

The aims of the organisational audit were to describe the provision of gynaecological services for women with HMB at NHS acute trusts in England and Wales and to examine important structural issues that influence the care received by individual women. The organisational audit collected information on the local organisation of services, access to diagnostic and therapeutic facilities and the availability of patient information. Trusts were also asked to send their local protocols to the Heavy Menstrual Bleeding Audit to allow for a review of how NHS trusts had responded to NICE guidance and the RCOG service standards.

### Audit of patient care and patient-reported outcomes

The main component of the Heavy Menstrual Bleeding audit is a prospective audit of the care received by women with HMB and their patient-reported outcomes. All women in England and Wales who receive a new referral for HMB to an outpatient gynaecology department will be eligible to participate. Women who have visited a gynaecological outpatient clinic for HMB within the past 12 months will be excluded.

Recruitment of women into the audit is taking place between 1 February 2011 and 31 January 2012. Consenting women will be asked to complete a questionnaire that includes questions on the severity of their condition, the impact its symptoms have on their quality of life and the treatments they received in primary care before referral. Owing to the personal nature of the questions, women will be required to complete questionnaires on their own. Therefore, women with insufficient English comprehension or a cognitive or visual impairment that precludes self-completion will be excluded.

One year after recruitment, women will be sent a follow-up questionnaire to gather information on their treatment history, their care experience and their symptoms and quality of life at that time. This patient-reported information will be linked to information from routine administrative databases to give a rich description of patient care and outcomes.

## 2.4 Annual reports

An annual report will be published in each year of the audit. This first report describes the work performed from February 2010 to January 2011 and summarises the patterns of surgery for HMB using data from Hospital Episode Statistics, the results of the organisational audit and the results of the pilot study for the prospective audit.

The second annual report will be published in June 2012 and will describe patterns of care and the characteristics of women at the first outpatient visit. The third annual report will be published in June 2013 and will focus on patterns of treatment during the year after the initial visit and women's 1-year outcomes. The final report will be published in 2014 and will provide an overall summary of the 4-year audit and recommendations for taking forward the results.

# 3 Patterns of surgical treatment for women with heavy menstrual bleeding

Many women with HMB will receive surgical treatment either because the condition severely affects their quality of life or because medical therapies were not tolerated or proved to be ineffective. The principal surgical alternatives are hysterectomy and endometrial ablation. Hysterectomy ensures the cessation of menstruation but is increasingly being replaced by endometrial ablation, which is less invasive.

In this chapter we describe patterns of surgical treatment for women with HMB. The analysis covers the period between 1 April 1997 and 31 December 2009 in English NHS trusts. We first describe trends in the use of endometrial ablation and hysterectomy. We then describe regional surgical rates from 1 April 2006 onwards, comparing the results with the rates previously reported for the period between April 2003 and March 2006.<sup>9</sup>

The analysis used data from Hospital Episode Statistics, an administrative database that captures all inpatient admissions and day cases in English NHS acute trusts. We restricted the sample to women aged between 25 and 59 years at the time of surgery and included the first surgical procedure only. A woman was defined as undergoing surgery for HMB if the first diagnosis field indicated ‘excessive, frequent and irregular menstruation’ (International Classification of Diseases and Related Health Problems, 10th edition [ICD-10] codes N92.0, .1, .4–.9) or ‘other abnormal uterine and vaginal bleeding’ (ICD-10 codes N93.8, .9) and if any procedure field described either an abdominal or vaginal hysterectomy (Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision [OPCS-4] codes Q07 and Q08, respectively) or an endometrial ablation (OPCS-4 codes Q16 and Q17).

Age-standardised procedure rates were derived for SHAs by dividing the observed number of procedures by the number that would be expected if the region had the same age-specific rates as England, and then multiplying this ratio by the English procedure rate. SHA rates were standardised using 5-year age bands. Reference female populations were aggregated from the 2007 Super Output Area population figures and all rates are expressed per 100 000 women/year.

The amount of excess variation (i.e. non-random) between age-standardised procedure rates was estimated using multilevel Poisson regression. A variance components model was used to describe the variation between the SHAs (level 2) and between the primary care trusts (PCTs) within each SHA (level 1). The variation was assumed to follow a normal distribution at both levels. All statistical calculations were performed in STATA 11 and the maps were produced in ArcGIS 9.2.

### 3.1 Characteristics of women with heavy menstrual bleeding

Between April 1997 and December 2009, 703 596 women were admitted to hospital with HMB as their primary diagnosis. The median age of the women was 41 years (interquartile range: 34–46 years). For those women with a recorded ethnicity group, 89.5% were white, 4.7% Asian, 3.3% black and 2.6% of other ethnic background. About 25% of the records did not contain information on ethnicity.

Although 45% of the women had HMB codes only in their diagnosis, a significant number of women also suffered from dysmenorrhoea (6.8%), abdominal and pelvic pain (5.4%), uterine fibroids (4.6%), hypertrophy of the uterus (3.5%) and polyps (3.1%).

### 3.2 Patterns of surgical treatment over time

Among the 703 596 women admitted with a primary diagnosis of HMB, 265 355 women (37.7%) received surgical treatment. There were a total of 33 926 vaginal hysterectomies, 102 995 abdominal hysterectomies and 128 434 endometrial ablations between April 1997 and December 2009. The number of endometrial ablations increased significantly in the last decade, accounting for 65% of all procedures for HMB in 2009 compared with only 22% in 1997/98 (Figure 3.1). About 25% of all hysterectomies were vaginal hysterectomies, with the proportion decreasing slightly over time from 27% in 1997/98 to 24% in 2009.

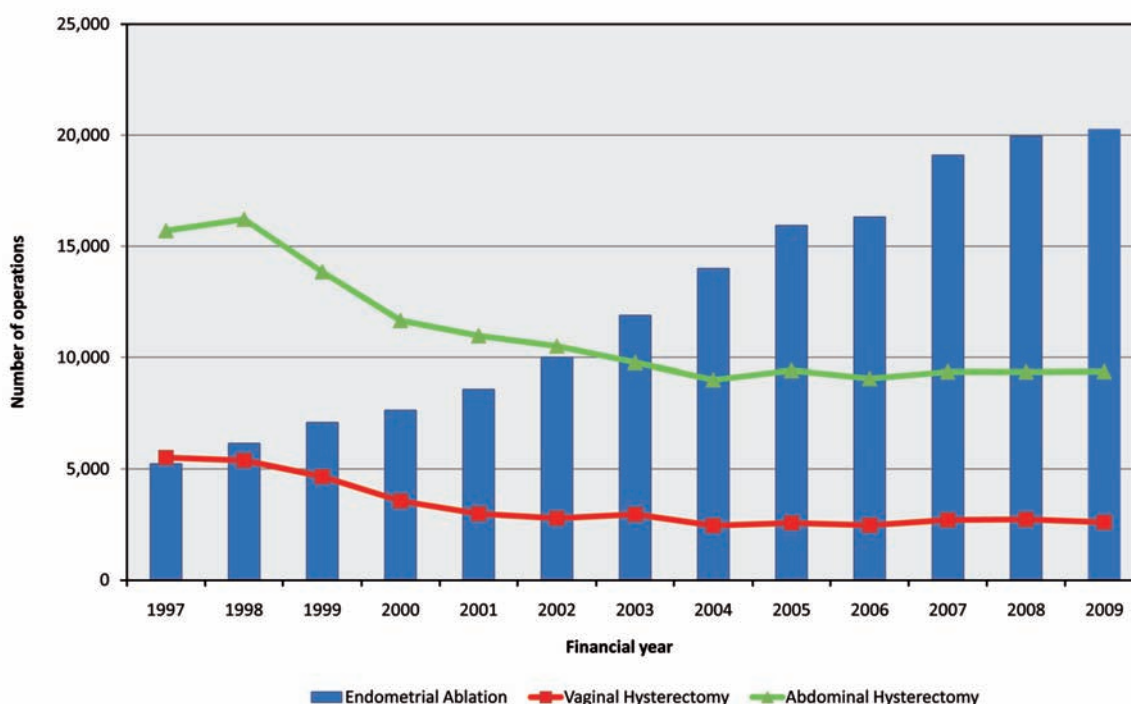


Figure 3.1 Number of surgical operations for women with HMB in English NHS trusts between 1 April 1997 and 31 December 2009

Figures for 2009 are based on 9 months of data

Overall, between 1997 and 2009, the rate of surgery decreased in women under 40 years of age, falling by around 50% in women under 35 years of age (Table 3.1). By contrast, rates of surgery among older women have been increasing.

**Table 3.1** Annual rate of surgery for women with HMB, by age group, between 1997 and 2009 in English NHS trusts

Age group (years)	Rate/100 000 women							
	1997/8–1999/2000		2000/1–2002/3		2003/4–2005/6		2006/7–2009	
	EA	HYS	EA	HYS	EA	HYS	EA	HYS
25–29	6.1	26.6	8.0	13.9	9.7	8.5	10.8	5.8
30–34	24.1	102.4	30.7	58.7	40.6	38.0	44.0	22.9
35–39	52.5	186.2	73.1	118.0	108.4	80.7	125.1	57.8
40–44	84.2	246.2	109.2	157.2	181.4	119.0	231.2	94.4
45–49	75.2	193.9	100.1	119.7	171.5	95.1	224.9	82.7
50–54	29.1	64.3	36.6	38.1	58.3	29.3	77.6	26.8
55–59	5.8	12.0	7.6	7.8	7.8	5.0	8.3	3.9

Populations to calculate the annual rates by age group were derived from the resident female population estimates for 1998, 2001, 2004 and 2007 published by the Office for National Statistics.

EA = endometrial ablation; HYS = hysterectomy.

Women living in the most deprived areas of England were more likely to have hysterectomies than women living in the least deprived areas, while women in the least deprived areas were more likely than women in more deprived areas to have endometrial ablations (Appendix 3).

### 3.3 Regional variations in surgical treatment in English NHS trusts

In the period between April 2003 and March 2006, the annual rate of surgery for women with HMB was 143 procedures/100 000 women (95% CI 142–144). Among the 10 SHAs, the annual surgical rates ranged from 71 to 220 procedures/100 000 women. There was also substantial variation in surgical rates among PCTs (Figure 3.2a).

Surgical rates for women with HMB between April 2006 and December 2009 showed a few changes in particular figures, but there was no significant reduction in the level of variation among either SHAs or PCTs (Figure 3.2b):

- The annual rate of surgery for English NHS trusts was 152/100 000 women. The increase was predominantly in the rate of endometrial ablation.
- Across the 10 SHAs, the annual surgical rates ranged from 70 to 255 procedures/100 000 women.
- The annual surgical rates across PCTs ranged from 14 to 392 procedures/100 000 women, an increase on the range observed between April 2003 and March 2006.

The geographical distribution of relative rates of surgery for English PCTs after April 2006 is shown in Figure 3.3. The pale areas have rates of surgery that are significantly lower than expected, while in the dark areas rates are higher than expected.

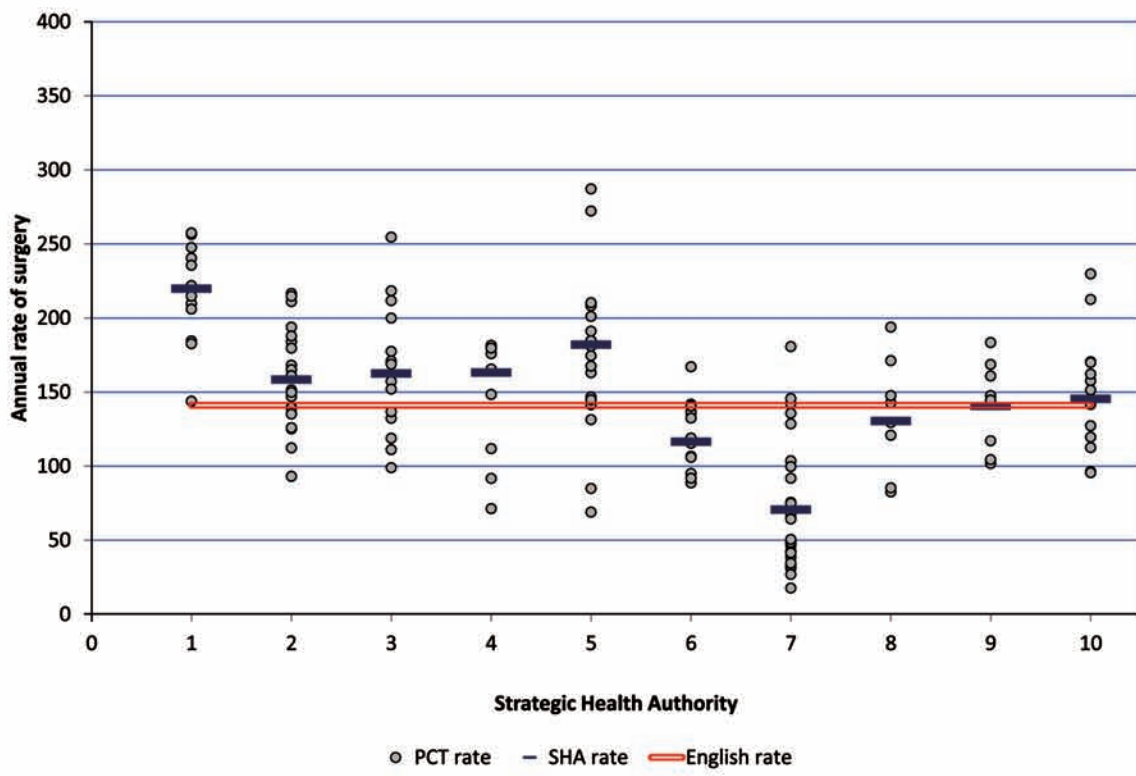


Figure 3.2a Annual rates of surgery at level of PCT, SHA and England for women with HMB admitted to English NHS trusts between 1 April 2003 and 31 March 2006

Rates are expressed per 100 000/year and are standardised for age.

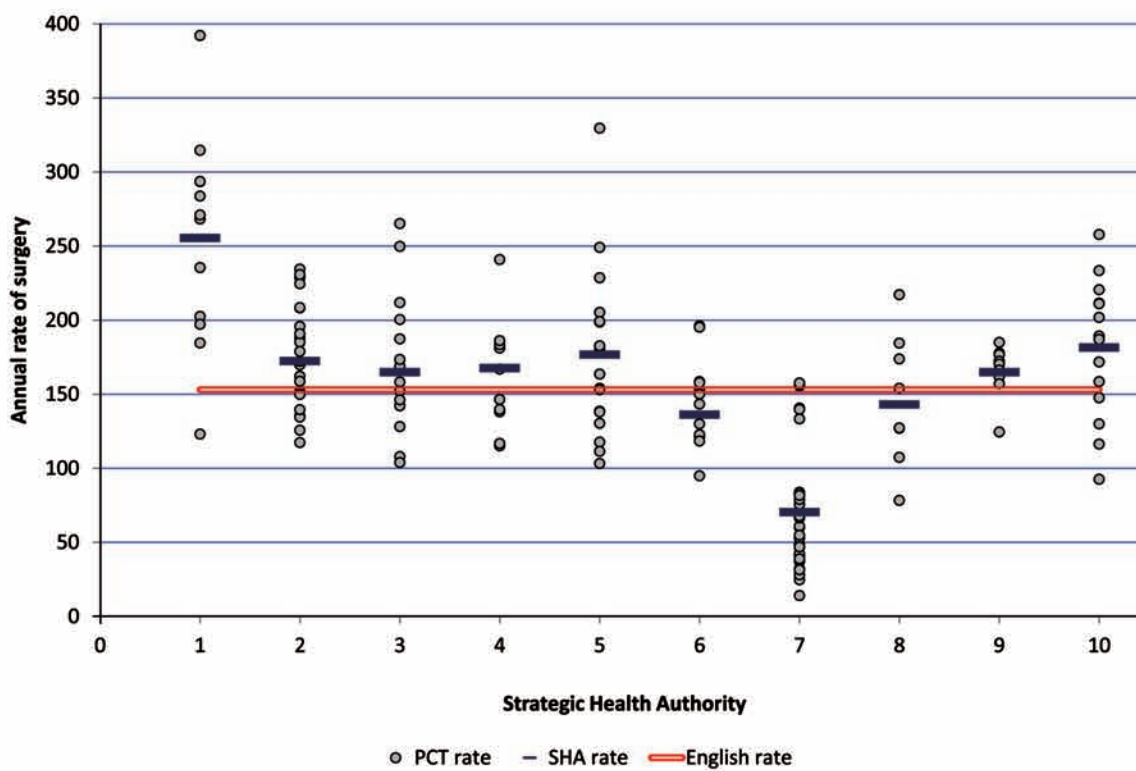


Figure 3.2b Annual rates of surgery at level of PCT, SHA and England for women with HMB admitted to English NHS trusts between 1 April 2006 and 31 December 2009

Rates are expressed per 100 000/year and are standardised for age.

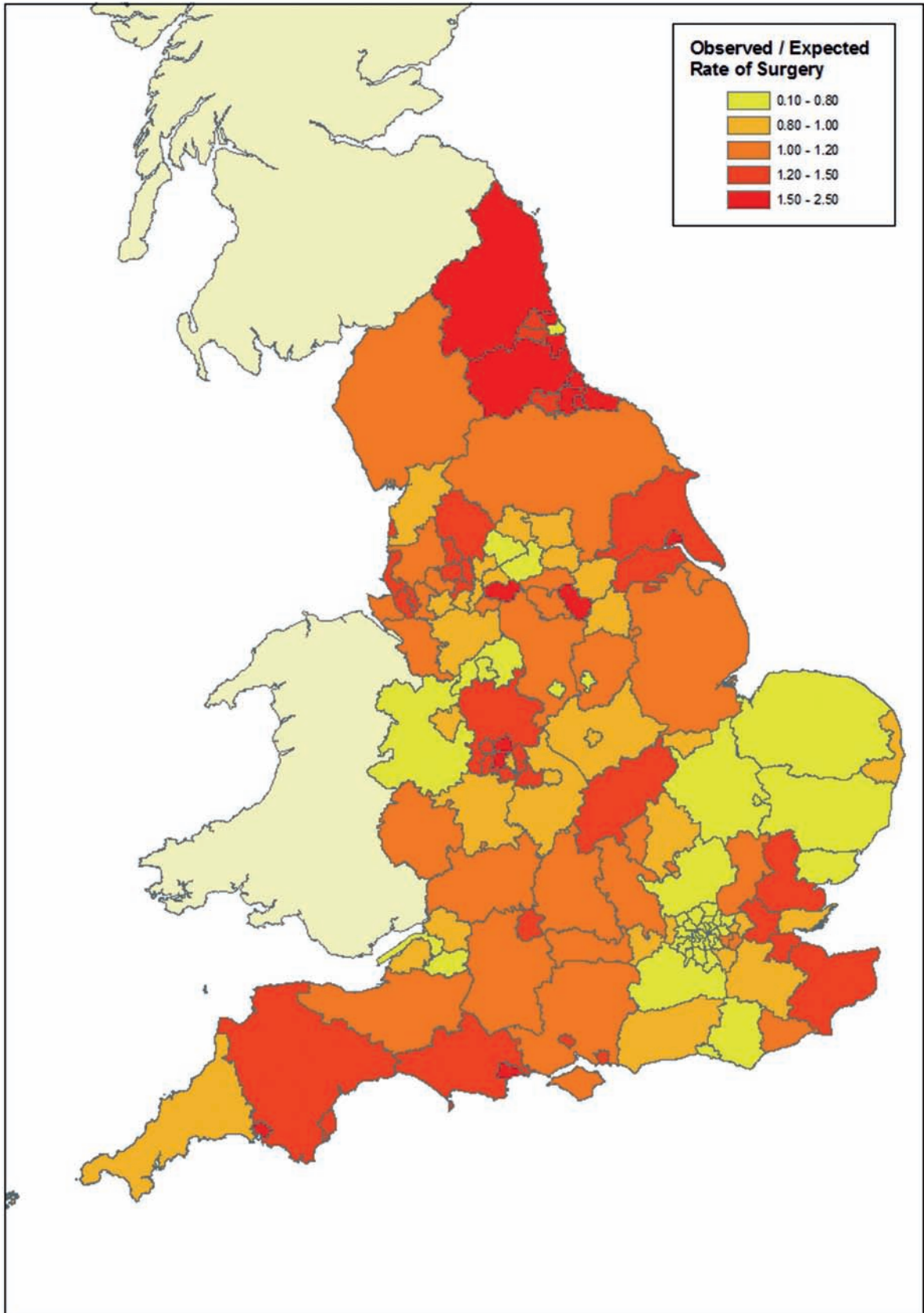


Figure 3.3 Relative rates of surgery for women with HMB in English PCTs between April 2006 and December 2009

Rates are expressed as observed divided by expected.

Between April 2003 and March 2006, the proportion of women having surgery who underwent endometrial ablation ranged from 46% to 75% within the 10 SHAs. After April 2006, endometrial ablation accounted for more than 60% of all procedures across the 10 SHAs. Nonetheless, the proportions varied from 64% (East Midlands) to 82% (North East).

### 3.4 Conclusions

The analysis in this chapter highlights the fact that regional variations in surgical rates for HMB persist. The most recent data show that, within England, the annual surgical rates varied by a factor of four among SHAs and by a factor of 28 among PCTs. This level of variation is similar to that observed previously, although the actual rate of surgery has increased slightly, with more women having endometrial ablation. Some variation may legitimately reflect differences in population demand and clinical uncertainty owing to the lack of precise treatment indications. It is unfortunate that the routine data available from Hospital Episode Statistics gives only a limited amount of information about the women's condition. The collection of patient-reported symptoms and quality of life data in the prospective part of this audit will provide greater detail about the women and enable a clearer interpretation of these patterns of surgery.

# 4 An organisational audit of services for women with heavy menstrual bleeding

The organisational audit was conducted to understand the current arrangement of clinical services for women with HMB in the outpatient departments of NHS acute trusts in England and Wales. The aim of the audit was to describe the provision of diagnostic and therapeutic services, current referral patterns and local protocols for the management of HMB and, where possible, to evaluate the extent to which these met the national recommendations in the 2007 NICE guidance<sup>1</sup> and 2008 RCOG standards.<sup>2</sup>

All hospitals in England and Wales that provide secondary care through outpatient gynaecology departments were eligible to participate. These hospitals were identified from various sources, including the RCOG database of clinical directors. Hospitals were approached through the clinical directors of obstetrics and gynaecology and, in some cases, the clinical audit departments, who then nominated an appropriate person to complete the questionnaire. The organisational questionnaire was available in both paper and web-based formats.

All eligible hospitals returned the organisational questionnaire (response rate of 100%). The final population included 221 hospitals comprising 154 trusts (Appendix 1). Data completeness was very high, with only 1–3% missing values for the majority of questions reported here.

Results are presented for individual hospitals and geographical regions. Welsh hospitals were analysed using the new structure for NHS trusts as of 1 October 2010. For the regional analyses, we used the current English SHAs and, given its similar size, Wales as a whole. All analyses used descriptive statistics to summarise responses to the survey. Significant differences across regions were evaluated using chi-square tests.

## 4.1 Secondary care characteristics

### Local protocols

The RCOG *Standards for Gynaecology* emphasises that ‘Every organisation should clearly set out specific requirements relating to the management of excessive menstrual blood loss which interferes with a woman’s physical, social, emotional and material quality of life.’<sup>2</sup> Particular standards for HMB include:

- care pathways for women with HMB who have abnormal histopathological results
- locally agreed referral pathways between primary and secondary care.

Given these standards, and the recent recommendations in the guidance from NICE, respondents were asked whether their hospital had a written local protocol and, if so, to send a copy to the audit team.

Overall, only 64 hospitals (29.9%) reported that they had a written local protocol on the management of women with HMB (seven hospitals did not respond to this question). Twenty hospitals sent in protocols (Table 4.1). Three hospitals (1.4%) had protocols which were summaries of either the NICE or RCOG documents and nine hospitals (4.2%) had locally developed protocols. The locally developed protocols were derived from multiple sources and included consideration of local systems and circumstances.

**Table 4.1** Description of local HMB protocols

Local HMB protocol	Number of hospitals (214 responses)	Percentage*
Summary of RCOG standards	1	0.5
NICE guidelines (or summary)	2	0.9
Care pathway flowchart only	8	3.7
Locally developed protocol (multiple sources cited)	9	4.2
Reported having a protocol but did not send a copy	44	20.6
No protocol	150	70.1

\*Percentages were calculated after removing non-respondents.

## Available facilities

The RCOG *Standards for Gynaecology* states that ‘there should be a dedicated one-stop menstrual bleeding clinic with facilities within the clinic for diagnostic gynaecology, including hysteroscopy and ultrasound.’<sup>4</sup>

Eighty-four hospitals (38.4%) reported that they ran a dedicated menstrual bleeding clinic (Table 4.2) (two hospitals did not respond to this question). Of these 84 hospitals, 72 described the clinic as a ‘one-stop’ clinic (a clinic that provides both diagnosis and treatment plan at the same appointment).

**Table 4.2** Available facilities within gynaecology departments

Facility	Number of hospitals	Percentage*
‘One-stop’ clinic (provides both diagnosis and treatment plan at the same appointment)	72	32.9
Dedicated menstrual bleeding clinic	84	38.4
Ultrasound (transvaginal scanning in the clinic)	177	80.0
Hysteroscopy (outpatient-based)	193	87.3
Day-care diagnosis (inpatient-based) hysteroscopy plus endometrial biopsy	210	95.0
Endometrial biopsy (outpatient-based)	216	97.7

\*Percentages were calculated after removing non-respondents.

Hospitals reported what facilities were available within the department to investigate women with HMB (Table 4.2). The majority of hospitals had ultrasound, hysteroscopy and endometrial biopsy. In addition, 210 hospitals (95.0%) reported that they had available day care diagnosis, which is inpatient-based hysteroscopy plus endometrial biopsy.

### Treatment and services in secondary care

Respondents were asked what investigations are considered at the initial consultation in their clinic for women with HMB being referred for the first time. In general, the responses followed the national recommendations.<sup>1,2</sup> An objective measure of blood loss was considered ‘never’ or ‘rarely’ in most hospitals (data not shown). An abdominal and pelvic examination was considered ‘mostly’ or ‘always’ by almost all hospitals (data not shown).

### Waiting time from primary to secondary care

Respondents were asked about their department’s average waiting time between referral from the general practitioner (GP) and the first outpatient appointment for women with HMB. Reported average waiting times ranged from 2 to 24 weeks, with the majority giving an average figure around 6 weeks.

### Available surgical and management options

Almost all hospitals reported that abdominal and vaginal hysterectomy were available surgical options at their hospitals (97.3% and 95.9%, respectively); laparoscopic-assisted hysterectomy was available at 82.4% of hospitals. Most hospitals (93.7%) offered one or more second-generation ablation technique, in line with the good practice point in the NICE guidance.<sup>1</sup> Of these various techniques, fluid-filled thermal balloon ablation was the most commonly available. Over 70% of hospitals still offered the first-generation rollerball ablation technique, but only 5% of hospitals offered this as their only ablation option. The availability of myomectomy (72.9%) and uterine artery embolisation (49.4%) was also assessed in the survey as these surgeries are sometimes performed in the treatment of fibroids. Figure 4.1 shows the availability of the various surgical options.

Respondents were asked to estimate the approximate percentage of women with HMB who had the following management options after their initial appointment in the gynaecology clinic:

- reassure and send back to GP
- offer medical treatment and send back to GP for follow-up
- insert an LNG-IUS
- put on waiting list for endometrial ablation
- put on waiting list for hysterectomy.

In general, the options for which hospitals reported the highest proportions were: offer medical treatment and send back to GP for follow-up; insert an LNG-IUS; and put women on a waiting list for endometrial ablation.

The hospital-estimated proportion of women who had an LNG-IUS inserted varied by hospital and region. In Wales and the North East of England, the majority of hospitals reported this was an option for 50% or more of women. Conversely, most hospitals in South Central England and the West Midlands said this was an option for only 0–20% of women.

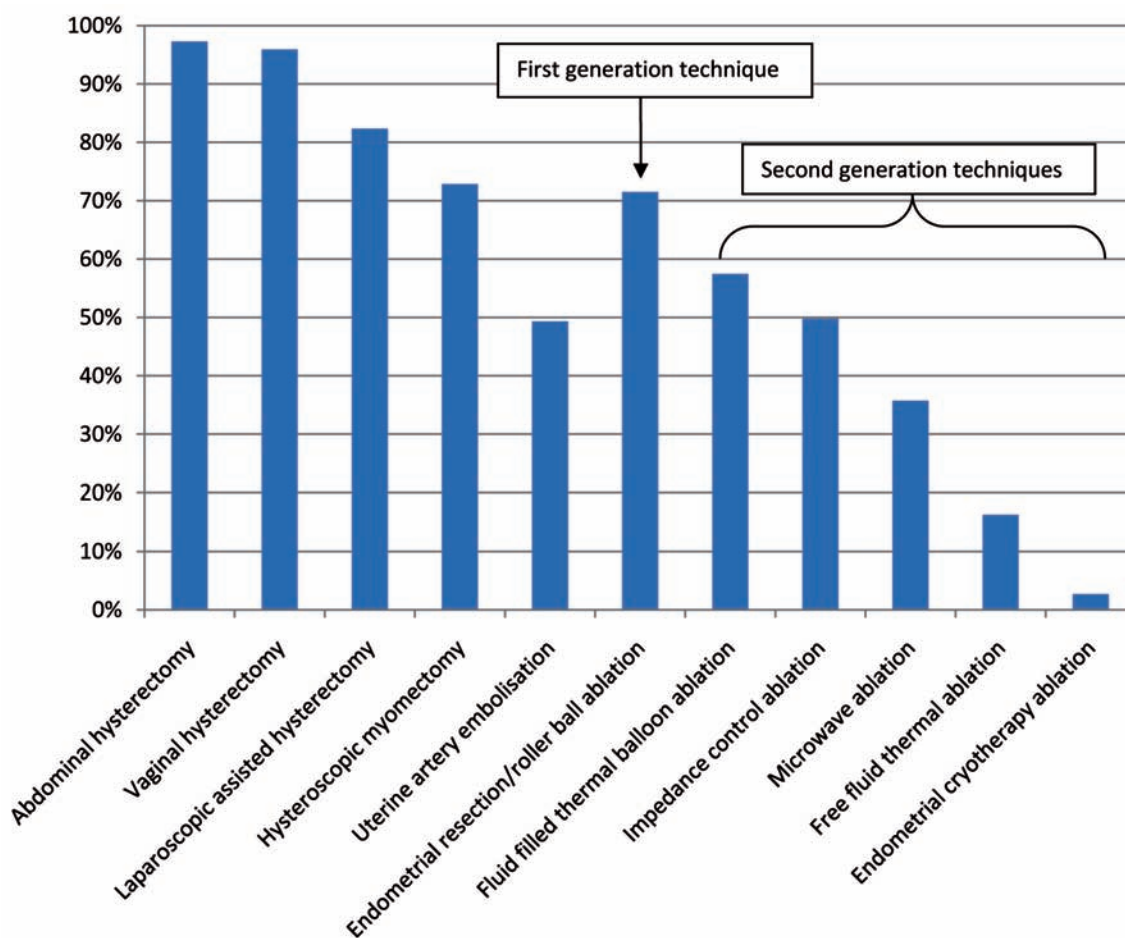


Figure 4.1 Available surgical options for women with HMB at NHS hospitals in England and Wales

## Patient information

RCOG standards state that services should provide information leaflets to women that include a description of each treatment option for HMB, together with outcome and complications.<sup>2</sup> The NICE guideline similarly states that ‘a woman with HMB referred to specialist care should be given information before her outpatient appointment.’<sup>1</sup>

Of the responding hospitals, 76.0% provided an information leaflet, 8.3% referred women to a website for information and 19.8% did not provide written information.

## 4.2 Primary care characteristics

All but one hospital (99.5%) reported that women were referred for HMB to their outpatient clinics by GPs. Other methods of referral were also reported, with many hospitals reporting more than one referral route, including accident and emergency department referral (59.1%), referral by other NHS professionals (58.6%) and other triage or PCT systems (23.6%). Only four hospitals (1.8%) reported that women could self-refer.

The majority of hospitals (83%) reported that over 50% of their patients had received some treatment in primary care (three hospitals did not respond to this question). Nonetheless, 37 hospitals (17.0%) reported that most or almost all of the women referred for HMB did not receive any treatment in primary care.

The RCOG standards indicate that 'guidelines should be in place for direct referral to imaging services from primary care.'<sup>2</sup> Almost all hospitals (99.1%) responded that GPs in their area could refer directly to imaging services. It was less common for GPs to be able to refer directly to pathology (42.7%) and other diagnostic procedures (21.8%). Only one hospital said that GPs could not refer directly to any services.

# 5 Preparation for the prospective audit

## 5.1 Rationale for the pilot study

An important aspect of the 1st year of the audit was to run a pilot to examine the practicality of patient enrolment and the administration of patient-reported questionnaires in gynaecology clinics. The prospective audit is a large-scale undertaking and posed various logistical issues. The participants will be women who present at outpatient clinics, which substantially increases the number of eligible women compared with an audit based only on inpatient care. The time available for staff to enrol women is also much shorter and enrolment to be carried out around the time of the outpatient consultation. Another feature of the audit is that data are primarily collected from the women themselves rather than from information held in medical records.

The other crucial aspect of the preparatory work was to develop the patient questionnaire and, in particular, identify a suitable instrument of disease-specific health-related quality of life (HRQoL) for use with women with HMB.

## 5.2 Eliciting women's and healthcare professionals' views about the feasibility of administering patient-reported questionnaires in routine gynaecology clinics

The audit approached a selection of gynaecology departments in England and Wales with different characteristics and invited them to participate in the pilot study to assess the logistical issues of the prospective audit. Five pilot sites agreed to help with the qualitative study.

The first phase of the pilot involved a qualitative study of clinicians' and women's views. Coordinators from the pilot sites were asked to distribute letters to clinicians and all women with HMB attending outpatient clinics inviting them to either a focus group or an interview about all aspects of the audit process. Participating clinicians and patients returned a signed consent form and provided contact details for us to arrange a mutually convenient time for interview. Members of the audit's clinical advisory group were also invited to take part. In total, we recruited seven gynaecologists, one nurse and three women with HMB for this phase of the pilot. All participants in this phase were also invited to take part in a de-briefing interview after the trial administration of the patient questionnaire. Five local pilot-site coordinators and seven additional women were interviewed after the trial questionnaire administration.

All of the interviews and the focus group were facilitated by a member of the audit team and were conducted using a semi-structured topic guide. This guide covered a range of topics about the process of being asked to participate in the study and completing the patient-reported questionnaire. Interviews lasted between 20 and 60 minutes and notes were transcribed. The focus group lasted just under 2 hours and was audio-taped and transcribed verbatim.

Thematic analysis was applied to all the data using a coding framework developed by two coders (members of the audit team) to ensure emerging themes were clearly understood.

## Lessons learned

In general, the qualitative data suggested that women were willing to talk about their HMB and were sometimes relieved that they had been asked about it. Some participants also mentioned ways of helping women to stay motivated enough to complete the follow-up questionnaire. Women seemed to be reassured about taking part in an audit if a clinician was involved. Nonetheless, women did not want their completed questionnaire to become part of the clinical consultation. Women also had a strong need for privacy and to have their individual needs respected. They felt that the outpatient waiting time was a good time to complete questionnaires.

Hospital staff identified various logistical issues, including:

- the need for a process to take account of the variability of outpatient clinic resources and facilities across hospitals
- identification of appropriate staff to distribute questionnaires
- provision of sufficiently private space for participants to complete the questionnaire
- perceived difficulties in the time required for staff to identify eligible participants
- practical issues of storing and managing data.

Women and staff both identified the need for straightforward and easy-to-understand written materials.

The solutions adopted by the audit to address the issues identified in the qualitative phase are summarised in Table 5.1. We developed a detailed procedures manual (Appendix 4) and frequently asked questions sheet and invited each participating hospital to attend a regional briefing session. It was also clear that a single method of administration would not necessarily work for every hospital and there would have to be some local adaptation.

### 5.3 Development of the baseline patient questionnaire

The questionnaire to be completed by women at their first outpatient visit was developed in stages, reflecting the various aspects of its content. First, questions were developed to capture data on a woman's demographics, menstrual symptoms, obstetric history and potential related conditions. Potential questions were identified from previous audits and other large-scale studies such as the VALUE<sup>16,17</sup> and MISTLETOE<sup>18</sup> studies. The importance of risk factors was rated by a consultant gynaecologist and the clinical reference group, after which a final selection was made.

Second, a systematic review of the published literature was conducted to identify a disease-specific HRQoL instrument for women with HMB. The instrument needed to:

- describe HMB-specific quality of life
- be applicable during any stage of the care pathway and
- be reliable, valid and responsive (psychometrically robust).

The PubMed, Embase, PsycINFO, and CINAHL Plus abstracting databases were searched for relevant articles (scope from beginning until 27 November 2009). The search strategies are available upon request. The search located 342 articles from which five disease-specific HRQoL instruments were identified:

- Menorrhagia Outcomes Questionnaire (MOQ)<sup>19</sup>

**Table 5.1** Practical recommendations to address feasibility issues in routine clinics

Issue raised in qualitative data	Proposed solution
Need for a dedicated nurse locally	Procedures manual/regional briefings
Questionnaires wrongly used as part of clinical encounter or not self-administered (questions read out)	Procedures manual/regional briefings
Need for specific training in introduction and administration of questionnaire	Procedures manual/regional briefings
Variation in clinic resources and facilities	Procedures manual/regional briefings/provision of local teaching materials/podcast
Importance of private space	Procedures manual/regional briefings
Questionnaire best administered before consultation	Procedures manual/regional briefings
Need for clear, simple information	Procedures manual/regional briefings/conduct a reading-level test for written materials
Women's need for assurances of confidentiality	Procedures manual/regional briefings
Raising awareness among women with HMB	Posters/other visual reminders
Sustaining clinic interest/commitment over 12 months	Posters/other visual reminders for staff
Sources of help/information for staff	Helpline
Motivating units to take part	Telephone contact with local staff leading up to and at regular intervals during the audit
Continuity of staff (especially among junior medical staff)	Extra support to units from Ipsos MORI at particular times
Changes of address before follow-up	Addresses will be checked through the personal demographics service

- Menorrhagia Questionnaire<sup>20</sup>
- Multi-Attribute Utility Assessment (MAS)<sup>21</sup>
- Menstrual Distress Questionnaire (MDQ)<sup>22</sup>
- Uterine Fibroid Symptom and Quality of Life questionnaire (UFS-QOL).<sup>4</sup>

None of the measures identified met all of the selection criteria (Table 5.2). The MOQ<sup>19</sup> was psychometrically strong but was designed for postoperative use only. The Menorrhagia Questionnaire<sup>20</sup> was also reasonably strong psychometrically but had restricted content validity as many items described symptoms rather than quality of life per se. The MAS<sup>21</sup> was developed to derive a utility score and again had limited coverage of quality of life domains. The MDQ<sup>22</sup> had only moderate psychometric properties.

Table 5.2 Psychometric properties of identified disease-specific HRQoL measures for HMB

	UFS-QOL (Spies et al., 2002)	Heavy Menstrual Bleeding Audit Adaptation of UFS-QOL (2010)	MOQ (Lamping et al., 1998)	Multi- attribute Utility Assessment (MAS) (Shaw et al., 1998)	Menorrhagia Questionnaire (Ruta et al., 1995)	MDQ (Moos, 1968)
Construct measured	HRQoL	HRQoL	Outcomes postsurgery	Health utility	Health status	General menstrual cycle symptoms at any point of menstrual cycle
Item reduction/ development	+++	(+++)	+++	++	+++	++
Reliability: internal consistency	++	+++	++	0	++	0
Reliability: test–re-test reliability	+++	++	+++	0	+++	++
Validity: content validity	++	(++)	+++	+	++	++
Validity: criterion- related validity	0	0	++	0	0	0
Validity: construct validity – within-scale analyses	++	0	++	0	0	++
Validity: construct validity – convergent	++	+	++	0	++	+
Validity: construct validity – discriminant	0	+++	+++	0	0	+++
Validity: known groups differences	+++	++	++	+++	++	++
Validity: other hypothesis testing	+	0	0	0	0	0
Responsiveness	0	0	+	+	+	0
Acceptability	0	++	+++	0	0	0

Psychometric criteria: 0 = not reported or no evidence in favour; + limited evidence in favour; ++ some acceptable evidence in favour, but some aspects fail criteria or not reported; +++ acceptable evidence in favour.

Of the five candidates, the UFS-QOL was the only instrument that could be used throughout the care pathway, measured HRQoL and was psychometrically strong. The main disadvantage was that the UFS-QOL was originally developed for fibroids, although a significant proportion of women with HMB do also have fibroids. It was therefore decided to select the UFS-QOL subject to its successful adaptation for a UK population and the adapted version performing acceptably in a psychometric evaluation. Permission for the adaptation was obtained from the Society of Interventional Radiology Foundation.

The final aspect of the patient questionnaire was the selection of a generic HRQoL instrument. Generic HRQoL measures have the advantage of enabling direct comparison of results across conditions. We therefore selected the generic European Quality of Life-5 Dimensions (EQ-5D) measure because this is the instrument recommended by the Department of Health and allows us to compare the results of the audit directly with other national studies, such as the Patient Reported Outcome Measures study of common elective surgical procedures.<sup>3</sup>

The final patient questionnaire is presented in Appendix 5.

## 5.4 Quantitative (psychometric) analysis of adapted UFS-QOL

### The UFS-QOL

The UFS-QOL consists of 37 items (eight symptom items and 29 HRQoL items). The symptom items are scored to produce a severity subscale and the HRQoL items are scored into six subscales (concern, activities, energy/mood, control, self-consciousness and sexual function). These HRQoL sub-scales can be either used separately or combined into an overall HRQoL score.

### Adaptation of UFS-QOL

To determine suitable alternative words to describe HMB and to identify any words that were not clearly understood in UK English, we conducted semi-structured interviews with women ( $n = 7$ ) and clinicians ( $n = 5$ ) and a mini focus group ( $n = 3$ ) with local Heavy Menstrual Bleeding Audit coordinators. This resulted in the following changes:

- we changed the wording to refer to ‘heavy menstrual bleeding (i.e. heavy periods)’ rather than ‘fibroids’
- we changed six specific words so that they were appropriate for UK English rather than US English (changed ‘checking’ to ‘ticking’ in the introduction; changed ‘soiling’ to ‘staining’ in Q26; changed ‘soiling’ to ‘staining’ in Q33; changed ‘blue’ to ‘low’ in Q35; changed ‘wiped out’ to ‘exhausted’ in Q36; changed ‘soiling’ to ‘staining’ in Q43).

### Evaluation of adapted UFS-QOL

In the second phase of the pilot study, 11 hospitals around England and Wales used the draft audit patient questionnaire over a 4-week period in their outpatient clinics. Women aged 18 years or over were approached to take part and those who consented completed a questionnaire. Participants were also asked if they would be willing to receive a second questionnaire 2 weeks later to allow the test–retest reliability of the adapted UFS-QOL to be assessed. In total, 96 women completed a questionnaire and 23 completed a second questionnaire 2 weeks later.

The women ranged in age from 19 to 57 years (mean = 41 years). Participants were mainly white (62.6%), but the sample included a sizeable number of black or black British women (19.8%) and Asian or Asian British women (14.6%). One-third had experienced their HMB symptoms for more than 5 years and a further 46% had experienced symptoms for between 1 and 5 years. Nearly 75% had received some form of previous treatment for HMB (73%): 46% of women had received previous medical treatment, 33% had been prescribed the pill and 15% had an intrauterine system such as an LNG-IUS.

The psychometric evaluation of the adapted UFS-QOL was conducted on its predefined scales using standard psychometric methods to evaluate acceptability, reliability and validity (convergent, discriminant and known groups).<sup>24-26</sup> Full details are available on request.

In summary, the psychometric results were as follows:

- Acceptability: all subscales except two (sexual functioning and, consequently, overall HRQoL) had less than 5% missing data.
- Internal consistency: all subscales met criteria for item-total correlations (>0.2) and Cronbach's alpha (>0.7).
- Test-re-test reliability: five subscales (concern, activities, energy/mood, self conscious, overall HRQoL) met criteria (correlation between scores >0.7); symptom severity had a value of 0.67; control had a value of 0.53; and sexual functioning had a value of 0.58.
- Convergent validity (tested using correlations with SF-12v2,<sup>27</sup> expected  $r = 0.5-0.6$ ): all subscales showed correlations in the right direction; severity scale,  $r = -0.41$ ; overall HRQoL scale,  $r = 0.40$ ; all other subscales,  $r$  ranged from 0.20 to 0.47.
- Discriminant validity (tested using age): all subscales demonstrated discriminant validity as none was correlated with age.
- Known groups validity (tested differences in scores between women with and without chronic pelvic pain): severity subscale showed good known groups validity (statistically significant difference for all four tests). Overall HRQoL showed statistically significant difference for two out of four tests (as did subscales energy/mood and self conscious). The differences in the group averages for subscales of concern, activities, control and sexual functioning were not statistically significant.

Overall, the symptom severity subscale and the HRQL subscale demonstrated the strongest psychometric properties. We propose to use these two subscales to report the audit data. The scoring algorithm allows for imputation of missing data which will to some extent address the issue of slightly higher missing data on the overall HRQL subscale.

## 5.5 Preparing local staff members for the patient questionnaire phase of the audit

During the 1st year, the audit team has communicated at regular intervals to ensure eligible hospitals were aware of the audit and to provide information about its aims and timescales and how patient data would be collected. In May 2010, introductory letters were sent to the medical directors of all 10 SHAs in England and the chief executive of NHS Wales to tell them about the forthcoming main-stage audit and secure their support.

From July 2010, the process of registering units to participate in the prospective audit was begun. Contact was made with the clinical directors of gynaecology departments at each NHS trust identified as having hospitals with outpatient gynaecology departments or clinics to:

- ask them to register each eligible department/clinic and nominate staff who would act as contact points
- invite the nominated staff to attend forthcoming regional briefings.

The following staff were requested to be nominated:

- audit clinical lead: audit lead for the unit – often a consultant gynaecologist
- audit coordinator: responsible for managing the day-to-day administration of the audit in the unit, ensuring that procedures are followed so that eligible women are identified and offered a questionnaire
- outpatient gynaecology nurse: responsible on a day-to-day basis for identifying patients and handing out and gathering back completed questionnaires
- Departments could also nominate a clerk or administrative officer to provide additional support.

Twelve regional briefings for eligible hospitals and units were held during October and November 2010. One briefing was held in each of the 10 English SHAs and two briefings were in Wales: one in Cardiff, covering health boards in south Wales, and one in Aberystwyth, covering health boards in mid and north Wales.

At the briefings, the audit team presented information about the audit and explained the practical issues involved with recruiting women. Over half of eligible hospitals attended these briefings. The remainder were sent the materials presented at the briefings and were contacted by telephone to talk through the materials and answer any questions they had.

Communication with units has also involved other related and continuing activities. This has included regular email communications with nominated staff to send them the latest information about the audit and remind them of key dates and deadlines, as well as publishing audit information and materials online. Both the Ipsos MORI and RCOG websites feature pages dedicated to the audit ([www.ipsos-mori.com/researchspecialisms/socialresearch/specareas/nhspublichealth.aspx](http://www.ipsos-mori.com/researchspecialisms/socialresearch/specareas/nhspublichealth.aspx) and <http://www.rcog.org.uk/orca/audit>). A helpline for patients and local staff members is available 24 hours a day or by email ([nationalhmbaudit@ipsos.com](mailto:nationalhmbaudit@ipsos.com)).

## 6. Discussion

The work carried out so far in the Heavy Menstrual Bleeding Audit has demonstrated that, although hospital staff members report that timely and tailored care is available for women with HMB, there is still significant variation in procedure rates across English regions. Some variation may legitimately reflect differences in population demand and clinical uncertainty owing to the lack of precise treatment indications. However, the regional variation is sufficiently large to suggest that there is scope for improving the management of HMB within England.

It has been suggested that the introduction of endometrial ablation has lowered the threshold for surgery, and it is possible that this lower threshold has increased differences among gynaecologists as to when surgery is indicated. The recent NICE guideline recommends that endometrial ablation be offered as first-line treatment if HMB has a severe impact on quality of life, and that ablation is preferable to hysterectomy for women with a uterus that is no bigger than a 10-week pregnancy and where HMB is the only symptom. Hysterectomy is recommended only when other treatment options have failed, are contraindicated or are declined by a woman.

Widespread compliance with the new NICE guideline may reduce regional variation, but the guideline does not provide clear criteria for what constitutes a ‘severe impact on quality of life’; this might be one reason for the lack of obvious change in regional variation. Greater consistency will require the routine measurement of symptom severity and quality of life.

The organisational audit revealed some potential explanations for variation in procedure rates. For example, the RCOG *Standards for Gynaecology* states that ‘adequate facilities and trained individuals should be available for the insertion of a levonorgestrel-releasing intrauterine system in the outpatient clinics and in primary care settings.’<sup>22</sup> Yet, the organisational audit found that the option of inserting an LNG-IUS varied significantly by region.

One part of the organisational audit was an analysis of local written protocols to assess reasons behind local and regional variation in management and treatment practices. This did not prove possible to undertake. Only a minority of hospitals reported that they had a written protocol relevant to the management of women with HMB. This suggests a low level of implementation of the NICE HMB guidelines published in 2007.

In brief, the NICE guideline and the RCOG standards have contained the following key recommendations:

- For clinical purposes, HMB should be defined as excessive menstrual blood loss which interferes with the woman’s physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. Any interventions should aim to improve quality of life measures.
- Every organisation should clearly set out specific requirements relating to the management of excessive menstrual blood loss which interferes with a woman’s physical, social, emotional and material quality of life
  - Hospitals are reminded of their responsibility to develop and put in place protocols that address the unique circumstances of local services.

- A women with HMB referred to specialist care should be given information before her outpatient appointment.
- Hospitals are reminded of their responsibility to provide patients with appropriate information. The NICE information for patients is available at [www.nice.org.uk/CG044publicinfo](http://www.nice.org.uk/CG044publicinfo).

## 7. Conclusion

The NICE guidelines and the RCOG *Standards for Gynaecology* have established standards for managing and treating women with HMB in England and Wales. Despite the fact that these standards have been available for 2–3 years, there is still evidence of significant regional variation in outcomes for women with HMB. Equally as important, women's experience of care has also been reported as variable. There are concerns that women may not always be sufficiently involved in treatment decisions or have the information to make informed choices.

A prospective audit of women presenting to outpatient gynaecology clinics (who have not been treated within the previous 12 months) will be undertaken in the coming years, with women being enrolled between 1 February 2011 and 31 January 2012. This cohort of women will be followed up at 1 year using questionnaires that will assess HRQoL, diagnosis, treatment and complications. This will allow an in-depth exploration of women's experience of HMB and how management and treatment of HMB affects their quality of life.

The results presented in this first annual report have informed the patient questionnaire phases of the prospective audit, particularly with respect to the development of training sessions for local staff members, procedures manuals and questionnaire development. Future annual reports will provide progressively greater information as the results of the prospective audit phases (baseline and 1-year follow-up) are presented in subsequent years.

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Aneurin Bevan Health Board	Chelsea and Westminster Hospital NHS Foundation Trust
Ashford and St Peter's Hospitals NHS Trust	Chesterfield Royal Hospital NHS Foundation Trust
Barking, Havering and Redbridge University Hospitals NHS Trust	City Hospitals Sunderland NHS Foundation Trust
Barnet and Chase Farm Hospitals NHS Trust	County Durham and Darlington Foundation Trust
Barnsley Hospital NHS Foundation Trust	Colchester Hospitals University NHS Foundation Trust
Barts and The London NHS Trust	Countess of Chester NHS Foundation Trust
Basildon and Thurrock University Hospitals NHS Foundation Trust	Cwm Taf Health Board
Basingstoke and North Hampshire NHS Foundation Trust	Dartford and Gravesham NHS Trust
Bedford Hospital NHS Trust	Derby Hospitals NHS Foundation Trust
Betsi Cadwaladr University Health Board	Doncaster and Bassetlaw Hospitals NHS Foundation Trust
Birmingham Women's NHS Foundation Trust	Dorset County Hospital Foundation NHS Trust
Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	Dorset Primary Care Trust
Bradford Teaching Hospital NHS Foundation Trust	Ealing Hospital NHS Trust
Brighton and Sussex University Hospitals NHS Trust	East and North Hertfordshire NHS Trust
Buckinghamshire Hospitals NHS Trust	East Cheshire NHS Trust
Burton Hospitals NHS Foundation Trust	East Kent Hospitals University NHS Foundation Trust
Calderdale and Huddersfield NHS Foundation Trust	East Lancashire Hospitals NHS Trust
Cambridge University Hospitals NHS Foundation Trust	East Sussex Hospitals NHS Trust
	Epsom and St Helier NHS Trust

Frimley Park Hospital NHS Foundation Trust

Gateshead Health NHS Foundation Trust

George Eliot Hospital NHS Trust, Nuneaton, Warwickshire

Gloucestershire Hospitals NHS Foundation Trust

Guy's and St Thomas' NHS Foundation Trust

Harrogate and District NHS Foundation Trust

Heart of England NHS Foundation Trust

Heatherwood and Wexham Park Hospitals NHS Foundation Trust

Hereford Hospitals NHS Trust

Hinchingbrooke Health Care NHS Trust

Homerton University Hospital NHS Foundation Trust

Hull and East Yorkshire NHS Trust

Hywel Dda Health Board

Imperial College Healthcare NHS Trust

Ipswich Hospital NHS Trust

Isle of Wight PCT

James Paget University Hospitals NHS Foundation Trust

Kettering General Hospital NHS Foundation Trust

King's College NHS Foundation Trust

Kingston Hospital NHS Trust

Lancashire Teaching Hospitals NHS Foundation Trust

Leeds Teaching Hospitals NHS Trust

Lewisham Healthcare NHS Trust

Liverpool Women's NHS Foundation Trust

Luton and Dunstable Hospital NHS Foundation Trust

Maidstone and Tunbridge Wells NHS Trust

Mayday Healthcare NHS Trust

Medway NHS Foundation Trust

Mid Cheshire Hospitals NHS Foundation Trust

Mid Essex Hospital Services NHS Trust

Mid Staffordshire NHS Foundation Trust

Mid Yorkshire Hospitals NHS Trust

Milton Keynes Hospital NHS Foundation Trust

Newham University Hospital NHS Trust

NHS Manchester PCT

Norfolk and Norwich University Hospitals NHS Foundation Trust

North Bristol NHS Trust

North Cumbria University Hospitals NHS Trust

North Middlesex University Hospital NHS Trust

North Tees and Hartlepool NHS Foundation Trust

North Wales NHS Trust

Northampton General Hospital NHS Trust

Northern Devon Healthcare NHS Trust

Northern Lincolnshire and Goole Hospitals NHS Foundation Trust

Northumbria Healthcare NHS Foundation Trust

Nottingham University Hospitals NHS Trust

Oxford Radcliffe Hospitals NHS Trust

Pennine Acute Hospitals NHS Trust

Peterborough and Stamford Hospitals NHS Foundation Trust

Plymouth Hospitals NHS Trust

Poole Hospital NHS Foundation Trust

Portsmouth Hospitals NHS Trust

Queen Victoria Hospital NHS Foundation Trust

Royal Berkshire NHS Foundation Trust	Swindon and Marlborough NHS Trust
Royal Bolton Hospital NHS Foundation Trust	Tameside Hospital NHS Foundation Trust
Royal Cornwall Hospitals Trust	Taunton and Somerset NHS Foundation Trust
Royal Devon and Exeter NHS Foundation Trust	The Hillingdon Hospital NHS Trust
Royal Free NHS Trust	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Royal Surrey County Hospital	The Northwest London Hospitals NHS Trust
Royal United Hospital Bath NHS Trust	The Princess Alexandra Hospital NHS Trust
Salford Royal NHS Foundation Trust	The Queen Elizabeth Hospital King's Lynn NHS Trust
Salisbury NHS Foundation Trust	The Rotherham NHS Foundation Trust
Sandwell and West Birmingham Hospitals	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Scarborough and North East Yorkshire Health Care NHS Trust	The Royal Wolverhampton Hospitals NHS Trust
Sheffield Teaching Hospitals NHS Foundation Trust	The Whittington Hospital NHS Trust
Sherwood Forest Hospitals NHS Foundation Trust	Trafford Healthcare NHS Trust
Shrewsbury and Telford Hospital NHS Trust	United Lincolnshire Hospitals NHS Trust
South Devon Healthcare NHS Foundation Trust	University College London Hospitals
South London Healthcare NHS Trust	University Hospital of North Staffordshire NHS Trust
South Tees Hospital NHS Foundation Trust	University Hospital of South Manchester NHS Foundation Trust
South Tyneside NHS Foundation Trust	University Hospitals Bristol NHS Foundation Trust
South Warwickshire NHS Foundation Trust	University Hospitals Coventry and Warwickshire NHS Trust
Southend University Hospital NHS Foundation Trust	University Hospitals of Morecambe Bay NHS Trust
Southampton University Hospitals NHS Trust	University of Leicester NHS Trust
Southport and Ormskirk Hospital NHS Trust	Walsall Hospitals NHS Trust
St Helens and Knowsley Hospitals NHS Trust	Warrington and Halton Hospitals NHS Foundation Trust
Stockport NSH Foundation Trust	West Hertfordshire Hospitals NHS Trust
Surrey and Sussex Healthcare NHS Trust	West Middlesex University Hospital NHS Trust

West Suffolk Hospitals NHS Trust  
Western Sussex Hospitals NHS Trust  
Weston Area Health NHS Trust  
Whipps Cross University Hospital  
NHS Trust  
Winchester and Eastleigh Healthcare  
NHS Trust  
Wirral University Teaching Hospital  
NHS Foundation Trust

Worcestershire Acute Hospitals NHS Trust  
Wrightington, Wigan and Leigh NHS  
Foundation Trust  
Yeovil District Hospital NHS Foundation  
Trust  
York Teaching Hospital NHS Foundation  
Trust

## Appendix 2

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## Appendix 3

### *Surgery for heavy menstrual bleeding in English NHS trusts*

Type of surgical treatment for women with HMB, by age group, between 1997 and 2009 in English NHS trusts

Age group (years)	Endometrial ablation		Vaginal hysterectomy		Abdominal hysterectomy	
	Number of procedures	% in age group	Number of procedures	% in age group	Number of procedures	% in age group
25–29	1846	39.4	858	18.3	1986	42.3
30–34	8142	38.6	3808	18.1	9145	43.4
35–39	22 851	46.0	7581	15.3	19 192	38.7
40–44	37 584	52.2	8675	12.0	25 786	35.8
45–49	31 899	55.9	5187	9.1	19 953	35.0
50–54	10 601	56.6	1416	7.6	6711	35.8
55–59	1435	52.7	224	8.2	1063	39.1

Type of surgery by deprivation quintile

Deprivation quintile*	Endometrial ablation		Vaginal hysterectomy		Abdominal hysterectomy	
	Number of procedures	% in age group	Number of procedures	% in age group	Number of procedures	% in age group
Q1: least deprived	20 720	55.6	4032	10.8	12 499	33.6
Q2	22 425	53.8	4706	11.3	14 579	35.0
Q3	22 870	51.4	5346	12.0	16 254	36.6
Q4	23 823	48.9	6129	12.6	18 770	38.5
Q5: most deprived	23 591	45.3	7290	14.0	21 149	40.6

\* Deprivation was derived from the 2004 Index of Multiple Deprivation rank of the English Super Output Areas. Women were allocated a category based on their postcode of residence.

# Appendix 4

## *Procedures manual*



Royal College of  
Obstetricians and  
Gynaecologists

Setting standards to improve women's health

# National HMB Audit Procedures Manual

Dear Staff Member,

We would like to thank you and your colleagues for participating in the National HMB Audit.

This Audit is extremely important to the treatment and care that patients will receive in the future. For it to be a success, we rely heavily on your cooperation. We are therefore extremely grateful to you for taking part.

This Procedures Manual is a guide to your role in the Audit. It outlines the things that you will need to do, offers some advice and answers any questions that you may have.

Thank you once again.

The HMB Audit Team

Royal College of Obstetricians and Gynaecologists  
London School of Hygiene & Tropical Medicine  
Ipsos MORI

If you would like any further information about the National HMB Audit,  
please contact us.

Staff helpline: 0808 238 5410 (you will get a response within two working days)

Patient helpline: 0808 238 5411

E-mail: [nationalhmbaudit@ipsos.com](mailto:nationalhmbaudit@ipsos.com) (staff and patients)

Write to:  
HMB Audit Team (Tomasz Mludzinski)  
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79-81 Borough Road  
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Visit our website: [www.rcog.org.uk/orca/audit](http://www.rcog.org.uk/orca/audit)

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## Quick Guide: What you need to do

### 1. Check that you have all the materials you need.

You should have received a supply of patient packs (i.e. large envelopes containing questionnaire booklets including tear-off consent forms and patient information leaflets), and the boxes in which to keep returned questionnaires and the padded envelopes in which to keep returned consent forms during the clinic. If anything is missing, please call us on 0808 238 5410.

### 2. Identify eligible patients.

This is best done before the consultation. Patients are eligible if they: are aged 18 or over, have been referred for a new outpatient appointment for heavy menstrual bleeding, and have not been seen in a hospital for heavy menstrual bleeding in the last 12 months.

Do not recruit patients who do not have adequate English, who cannot read the questionnaire (e.g. those who have a visual impairment) or those who have a cognitive impairment.

If you cannot identify eligible patient referrals before the consultation, then the clinician should ask eligible patients if they would be willing to take part and hand out the questionnaire at the end of the consultation. These patients should then complete the questionnaire before they leave clinic and return the consent form/questionnaire to the receptionist's desk.

### 3. Recruit patients (before the consultation if possible).

The following prompts might be helpful to introduce the study:

- *There is a national women's health study running called 'the National HMB Audit' that you are eligible to take part in.*
- *Please could you read this information about the study and there is a questionnaire to fill in.*
- *If you agree to take part, please sign the consent form and tear it off the questionnaire, then fill in the questionnaire.*
- *All the information that you provide will be treated confidentially.*
- *When you have finished, please put the questionnaire in the envelope and bring both the signed consent form and the questionnaire back to me.*
- *The information leaflet is for you to keep and take home.*
- *There is a patient helpline you can call and you will find the number on your information sheet. You can also e-mail the HMB Audit Team at the address provided.*

Ideally patients will complete the questionnaire while they are waiting.

### 4. Completed questionnaires/consent forms should be returned to you.

Store the completed questionnaires in the provided box and the completed consent forms in the provided padded envelope until the end of clinic. These should be kept close to a member of staff at all times.

### 5. Lock away the contents of the box and the padded envelope at the end of each clinic.

Completed questionnaires/consent forms will be collected by courier each month.

## 1. Background to the Audit

The Royal College of Obstetricians and Gynaecologists (RCOG) together with the London School of Hygiene & Tropical Medicine (LSHTM) and Ipsos MORI have been commissioned by the Health Quality Improvement Partnership (HQIP) to undertake a prospective audit of heavy menstrual bleeding (HMB) in women referred to NHS hospitals in England and Wales. The audit will focus on patient reported health-related quality of life as well as on case-mix and treatment. The data collection will be co-ordinated by Ipsos MORI, the independent opinion research organisation.

## 2. How long will the Audit last?

Data collection for the Audit will start on 1<sup>st</sup> February 2011 and continue in the clinic until 31<sup>st</sup> January 2012. Twelve months after each patient's attendance we will send a follow-up questionnaire to their home.

## 3. Your appointment as HMB Local Audit Co-ordinator (HMB LAC)

You are our main point of contact for your hospital. As the co-ordinator, you will be responsible for making sure that the patient packs are given out and that completed questionnaires and consent forms are stored safely and then collected by Ipsos MORI. Other members of your clinic team may also help, and the HMB Audit Team will be available to provide any support that you need. Please read the following sections of the manual before beginning the Audit:

- Setting up the Audit
- What does the HMB Local Audit Co-ordinator need to do?
- What does the patient need to do?
- Sending data back to Ipsos MORI
- What happens next?

There is also a separate sheet of frequently asked questions which you may find helpful.

## 4. Setting up the Audit – your materials

Before starting data collection you should have:

- Received the first set of patient packs (we will initially send enough materials for 6 months and will then send more as needed). These packs include:
  - large envelopes containing questionnaire booklets (including tear-off consent forms)
  - 12 boxes (one for each month) for storing the completed questionnaires during the clinic
  - 12 padded envelopes for storing the completed consent forms

- Decided which member(s) of the clinic team will be taking on each of the following roles and responsibilities:
  - co-ordinating the Audit locally within your unit
  - handing out and receiving returned questionnaires to/from patients
- Decided where completed questionnaires and consent forms will be safely stored after clinic before they are collected by Ipsos MORI. It is extremely important that these questionnaires and consent forms are stored safely. Only the staff who are involved in the HMB Audit in your hospital should have access to them.
- Made a plan to ensure continuity when the LAC is on leave or for other staff changes

**If you have not received any of the materials** mentioned above or if you have any queries, please contact us as soon as possible.

## 5. What does the HMB Local Audit Co-ordinator need to do?

We realise that there is a lot of variety in how clinics are run and what facilities are available. We have included suggestions for what we think is the best way to introduce the Audit to patients. However, we understand that every clinic is different and that what works for one clinic may not be possible for others.

As the HMB Local Audit Co-ordinator you may wish to ask other staff to help. However, you must make sure that any additional staff involved in the Audit are fully briefed and trained in all study procedures, including how to introduce the questionnaire and what to do with returned consent forms/questionnaires.

### 5.1 Patient recruitment

#### Identifying eligible patients

Ideally eligible patients should be identified from the referral letter in the patient notes before the clinic (but we realise that for some clinics this is not possible). You may find it helpful to put the patient pack ready in the notes of each eligible patient. Please stick the patient's sticky label on the top right hand corner of the front page of the questionnaire and fill in the date in the space provided. If no sticky label is available, please fill in the patient's NHS number in the space provided. NHS number is not mandatory.

Patients should be **included** if they are:

- aged 18 or over
- referred for a new outpatient appointment for heavy menstrual bleeding and have not been seen in secondary care for heavy menstrual bleeding within the last 12 months

Patients should be **excluded** if they:

- are under 18 years of age
- do not have adequate English to understand either the consent process or the questionnaire

- have a visual impairment that prevents them from reading the consent form and/or the questionnaire
- have a cognitive impairment that prevents them understanding either the consent process or the questionnaire
- have been previously referred to secondary care for heavy menstrual bleeding in the last 12 months

#### **When should patients be recruited?**

We strongly suggest that patients should be approached before their consultation and, if they agree to take part, they should complete the questionnaire while they are waiting.

If it is not possible to identify eligible patients before the consultation, then the clinician can ask them to take part immediately after their consultation. The patient should then complete the questionnaire before they leave the clinic.

### **5.2 Handing out questionnaires**

#### **Who should hand out the questionnaires?**

If you can identify patients referred for heavy menstrual bleeding before the consultation, then you as the HMB Local Audit Co-ordinator (or your delegate) should recruit patients before the consultation, and hand out questionnaires.

If the reason for referral is not available before the consultation, then at the end of the consultation the clinician should ask the patient if she would be willing to take part and the clinician (or you/your delegate) should hand out the questionnaire.

In this instance the patient should complete the questionnaire in the waiting room (or other suitable space), not in the consulting room.

#### **The questionnaire should not under any circumstances be used as part of the consultation.**

Whoever is responsible for recruiting the patients and handing out questionnaires must have full knowledge of the audit so they can handle any questions that may arise. This person must be able to:

- Explain the study and consent process clearly and simply. When introducing the study and where there is a possibility of being overheard, try not to mention any diagnosis such as “heavy menstrual bleeding” as some women would like to keep this private. Use a very brief description of what the patient would have to do. You may find it helpful to use the following prompts:
  - *There is a national women’s health study running called ‘the National HMB Audit’ that you are eligible to take part in.*
  - *Please could you read this information about the study and there is a questionnaire to fill in.*
  - *If you agree to take part, please sign the consent form and tear it off the questionnaire, then fill in the questionnaire.*
  - *All the information that you provide will be treated confidentially.*
  - *When you have finished, please put the questionnaire in the envelope and bring both the signed consent form and the questionnaire back to me.*

- *The information leaflet is for you to keep and take home.*
- *There is a patient helpline you can call and you will find the number on the information leaflet. You can also e-mail the HMB Audit Team at the address provided.*

- Listen to the patient and answer any queries
- Be sensitive to the patient's concerns. For example, a patient may not want to discuss the study if she feels she can be overheard. It may be possible to approach patients about taking part when they are in a more private setting, e.g. after having blood taken. Some hospitals may have separate rooms that can be used. If the only available space is the waiting room, try to use the receptionist's desk and perhaps speak in lower tones.
- Accept that some patients may not want to take part

### 5.3 Receiving back completed questionnaires and consent forms

Completed questionnaires and consent forms should be returned to you before the patient leaves the clinic. You need to:

- Check whether the patient has any questions about the Audit and answer these or refer to the patient helpline
- Ensure that the consent form has been filled in and signed and that it is separated from the questionnaire
- Place the completed questionnaire and the completed consent form in the box and padded envelope provided. At the end of the clinic, please make sure the contents of both the box and padded envelope are stored securely.

If the questionnaire was handed out by the clinician, the clinician should ask the patient to return the signed consent form and completed questionnaire to the receptionist (or other easily identifiable person). The receptionist should then follow the same steps as above.

## 6. What does the patient need to do?

If the patient is willing to take part then she should complete and sign the consent form and then fill in the questionnaire.

Patients should:

- tear off the completed consent form from the questionnaire,
- place the questionnaire in the envelope provided, and
- return both the consent form and the completed questionnaire back to you.

The patient should take the information leaflet home with them.

## 7. Sending questionnaires and consent forms back to Ipsos MORI

In order to minimise the burden on clinic staff we will arrange a courier service to collect completed questionnaires and consent forms from you on a monthly basis.

We will provide you with 12 boxes (one for each month of the data collection) and 12 large padded envelopes. These will be delivered to you with the patient packs.

Please use one box per month to store completed questionnaires and one envelope per month to store completed consent forms.

We will also provide you with security tape; please seal the box and padded envelope once they are ready to be collected.

Seven days before the monthly collection you will receive an e-mail reminder from Ipsos MORI, confirming the collection arrangements.

The courier service arranged by Ipsos MORI will call at each participating hospital unit on the first working day of each month to collect the box of completed questionnaires and the envelope of consent forms. Please ensure the box and envelope are ready for collection. The first collection will take place on 1<sup>st</sup> March 2011, and the final collection on 2<sup>nd</sup> February 2012.

## 8. What happens next?

You need to continue collecting the questionnaires and consent forms for 12 months. After that you do not need to do anything else. Ipsos MORI will send the follow-up questionnaires directly to patients at home.

**Thank you very much for your time and help with this Audit.**

# Appendix 5

## *Patient questionnaire*



Royal College of  
Obstetricians and  
Gynaecologists

Setting standards to improve women's health

**FOR OFFICE USE ONLY**

Place patient sticker here, with NHS number

If you do not have a patient sticker, fill in the patient's NHS number below.

--	--	--	--	--	--	--	--

Date of clinic visit 

--	--	--	--	--	--	--	--

# HMB: A National Audit

Dear Patient,

We are carrying out a survey to help improve health care for women with heavy menstrual bleeding (HMB). Some people might call this "heavy periods". Sometimes this type of survey is called an "audit". The best way for us to improve services is to ask women with heavy menstrual bleeding to tell us about their experience. Everyone who comes to a hospital outpatient clinic for heavy menstrual bleeding for the first time in the last 12 months will be offered a questionnaire.

We would be really grateful if you could complete this questionnaire while you are in the clinic today, and hand it back to a member of staff before you leave.

**If you are not here for heavy menstrual bleeding, or if you have been seen in a hospital for heavy menstrual bleeding in the last 12 months, please just give the blank questionnaire back to a member of staff.**

The enclosed patient information sheet describes in more detail why we are undertaking this survey and how we will use your answers to this questionnaire. Taking part is voluntary. You may find some of the questions sensitive. If you agree to take part, please complete and sign the consent form on the next page.

When you have completed the consent form and questionnaire, tear off the consent form. Please put the questionnaire in the envelope provided. The questionnaire (placed in the envelope and sealed) and the consent form (not in the envelope) should both be handed to a member of staff before you leave the hospital.

Thank you very much for your help.

The National HMB Audit Team

Royal College of Obstetricians and Gynaecologists  
London School of Hygiene & Tropical Medicine  
Ipsos MORI

In partnership with:



Ipsos MORI

Funding provided by:



12345678910

Barcode placement only.

08-027840-02

## Consent Form

**Complete, tear off and return with your questionnaire**

Please read the information, tick the relevant box and sign below.

**I have read and understood** the enclosed Patient Information Sheet.

**I understand** that patients who complete this questionnaire will not be identified by name in any published reports or papers.

**I understand** that I am free to withdraw from taking part at any time, without giving a reason.

**I understand** that all information I provide will be kept confidentially.

**I agree** to receive a second questionnaire by post in 12 months.

**I agree** that my personal details will be held and used by the National HMB Audit. These details will be used to send out the second questionnaire and to link the questionnaire to information that is routinely collected in other NHS databases (such as the hospital episode statistics databases).

**I understand** that the National HMB Audit will not release my personal details, unless required by law. In such an exceptional event, I will be told if any disclosure will take place.

**I AGREE** to take part in the National HMB Audit.

If you have agreed to take part in this Audit please write your name and address in CAPITAL LETTERS below so that we can send you a second questionnaire in 12 months' time.

Title

--	--	--	--	--

First Name

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Surname

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Address

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

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Postcode

--	--	--	--	--	--	--	--

Date of birth

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

(dd/mm/yyyy)

**Signature**

\_\_\_\_\_

**Name (in capital letters)**

\_\_\_\_\_

**Today's date**

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

(dd/mm/yyyy)

12345678910

The first few questions are about your symptoms, any treatment that you may have had and factors that may have influenced your treatment. Please indicate your answer by ticking (✓) the box or writing in the space provided.

**Q1. How long have you had symptoms of heavy menstrual bleeding?**

- 2 months or less  Don't know  
 More than 2 months, but less than 1 year  
 More than 1 year

**Q2. In the last year, how many times have you seen your GP about heavy menstrual bleeding?**

- None  Don't know  
 1-2 times  
 3-4 times  
 5-6 times  
 More than 6 times

**Q3. What previous treatment have you had for heavy menstrual bleeding?**

Please tick (✓) as many boxes as you need to.

- None  Don't know  
 The Pill (oral contraception)  
 Other medication (not The Pill)  
 Intrauterine system (for example Mirena)  
 Endometrial ablation (treatment to remove the lining of uterus or womb)  
 Other treatment

**Q4. Have you had any operations on the uterus (womb) or cervix? Please do not include endometrial ablation.**

- Yes  No  Don't know

**Q5. During the last 3 months, how much pain did you experience during your periods?**

- No pain  
 Very mild pain  
 Mild pain  
 Moderate pain  
 Severe pain  
 Very severe pain

**Q6. How many times have you been pregnant?**

- pregnancies  I do not want to answer this question

**Q7. How many babies have you had?**

- babies  I do not want to answer this question

12345678910

**Q8. Do you think you might want to become pregnant in the future?**

- Yes                       No                       Not sure  
 I do not want to answer this question

**Q9. Have you been told by a doctor that you have any of the following?**

Please tick (✓) as many boxes as you need to.

- |   |   |
|---|---|
| <input type="checkbox"/> Uterine fibroids   | <input type="checkbox"/> A bleeding disorder              |
| <input type="checkbox"/> Endometriosis  | <input type="checkbox"/> Adenomyosis                      |
| <input type="checkbox"/> Polyps of the uterus (womb) or cervix                              |   |
| <input type="checkbox"/> Heart disease (for example angina, heart attack or heart failure)  | <input type="checkbox"/> Depression                       |
| <input type="checkbox"/> High blood pressure  | <input type="checkbox"/> Thyroid disorder                 |
| <input type="checkbox"/> Lung disease (for example asthma, chronic bronchitis or emphysema) | <input type="checkbox"/> Kidney disease                   |
| <input type="checkbox"/> Diabetes   | <input type="checkbox"/> Cancer (within the last 5 years) |

**Q10. Overall, how would you say your health is?**

- |                          |                          |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Excellent                | Very good                | Good                     | Fair                     | Poor                     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

**Q11. If you were to spend the next 5 years with your heavy menstrual bleeding symptoms the way they are now, how would you feel about that?**

- |                          |                          |                          |  |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|--|--------------------------|--------------------------|--------------------------|
| Delighted                | Pleased                  | Mostly satisfied         | Mixed – about equally satisfied and dissatisfied | Mostly dissatisfied      | Unhappy                  | Terrible                 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Listed below are symptoms experienced by women who have heavy menstrual bleeding (heavy periods). Please consider each symptom as it relates to your heavy menstrual bleeding or menstrual cycle. Each question asks how much distress you have experienced from each symptom during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by ticking (✓) the most appropriate box. If a question does not apply to you, please mark “not at all” as a response.

During the previous 3 months, how distressed were you by...	Not at all	A little bit	Some-what	A great deal	A very great deal
<b>Q12.</b> Heavy bleeding during your menstrual period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q13.</b> Passing blood clots during your menstrual period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q14.</b> Fluctuation in the duration of your menstrual period compared to your previous cycles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q15.</b> Fluctuation in the length of your monthly cycle compared to your previous cycles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q16.</b> Feeling tightness or pressure in your pelvic area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q17.</b> Frequent urination during the daytime hours	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q18.</b> Frequent nighttime urination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Q19.</b> Feeling fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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The following questions ask about your feelings and experiences regarding the impact of heavy menstrual bleeding symptoms (heavy periods) on your life. Please consider each question as it relates to your experiences with heavy menstrual bleeding during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by ticking (✓) the most appropriate box. If the question does not apply to you, please tick “none of the time” as your option.

During the previous 3 months, how often have your symptoms related to heavy menstrual bleeding...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Q20. Made you feel anxious about the unpredictable onset or duration of your periods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q21. Made you anxious about travelling?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q22. Interfered with your physical activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q23. Caused you to feel tired or worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q24. Made you decrease the amount of time you spent on exercise or other physical activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q25. Made you feel as if you are not in control of your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q26. Made you concerned about staining underclothes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q27. Made you feel less productive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q28. Caused you to feel drowsy or sleepy during the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q29. Made you feel self-conscious of weight gain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q30. Made you feel that it was difficult to carry out your usual activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q31. Interfered with your social activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q32. Made you feel conscious about the size and appearance of your stomach?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q33. Made you concerned about staining bed linen?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q34. Made you feel sad, discouraged, or hopeless?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q35. Made you feel down hearted and low?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q36. Made you feel exhausted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q37. Caused you to be concerned or worried about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q38. Caused you to plan activities more carefully?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q39. Made you feel inconvenienced about always carrying extra pads, tampons, and clothing to avoid accidents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q40. Caused you embarrassment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q41. Made you feel uncertain about your future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q42. Made you feel irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q43. Made you concerned about staining outer clothes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

During the previous 3 months, how often have your symptoms related to heavy menstrual bleeding...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Q44. Affected the size of clothing you wear during your periods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q45. Made you feel that you are not in control of your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q46. Made you feel weak as if energy was drained from your body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q47. Diminished your sexual desire?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q48. Caused you to avoid sexual relations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions are about your health overall. By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

#### Q49. Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

#### Q50. Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

#### Q51. Usual Activities *(for example work, study, housework, family or leisure activities)*

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

#### Q52. Pain/ Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

#### Q53. Anxiety/ Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

**Q54.** To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the black box below to whichever point on the scale indicates how good or bad your health state is today.

**Please also write the number that represents your health today in the white boxes provided.**

**My health today**  
(write number between 0 and 100 here)

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Your own health state today

Best imaginable health state

100

90

80

70

60

50

40

30

20

10

0

Worst imaginable health state

**Q55. What is your current body weight?**

   kg

or

  stones   pounds

**Q56. What is your height?**

   cm

or

  feet   inches

**Q57. How old were you when you left full-time education (for example school, college or university)?**

 16 or under

 I do not want to answer this question

 17 to 18

 19 or over

**Q58. What is your ethnic group?**

Choose ONE section from A to E, then tick (✓) the appropriate box to indicate your ethnic group

**A White**

 British

 Irish

 Any Other White background

**B Mixed**

 White and Black Caribbean

 White and Black African

 White and Asian

 Any Other Mixed background

**C Asian or Asian British**

 Indian

 Pakistani

 Bangladeshi

 Any Other Asian background

**D Black or Black British**

 Caribbean

 African

 Any Other Black background

**E Chinese or Other Ethnic Group**

 Chinese

 Any Other

 I do not want to answer this question

**Thank you for completing this questionnaire.**

**Please check that you have given us your correct name and address so that we can send you a second questionnaire and then give this questionnaire back to a member of staff.**