

# A multicentre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia

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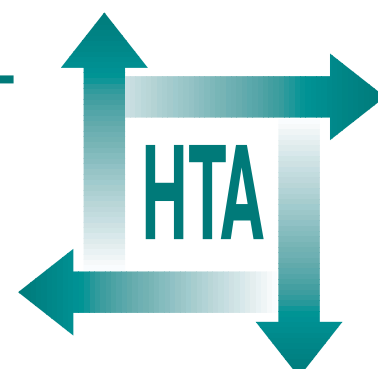
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## Executive summary

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## Executive summary

### Objectives

To develop decision aids to provide evidence-based information and formal preference elicitation for women with menorrhagia; and to evaluate their effects on patient outcomes, patient management and cost-effectiveness.

### Design

The development of the interventions was based on a series of activities including a systematic review of published literature on available treatments, their effectiveness and their impact on quality of life; surveys of treatment patterns and women's treatment-related preferences; and focus groups with women experiencing menorrhagia or who had undergone treatment for the condition.

The interventions were evaluated using a pragmatic, parallel group, multicentre, randomised controlled trial with 2 years of follow-up. Women were randomised to one of three arms:

- control (usual practice)
- information only
- interview plus information.

### Setting

Six hospitals in south-west England.

### Participants

A total of 894 of 1301 women referred to one of 28 consultant gynaecologists with a new episode of uncomplicated menorrhagia.

### Interventions

The interventions consisted of an information pack, including a booklet and complementary video, and a preference elicitation interview with a research nurse. Women randomised to the information and interview groups were sent the information pack 6 weeks prior to their initial

outpatient appointment. The interview group also underwent a structured interview with a research nurse immediately prior to the initial consultation with their gynaecologist. The control group received standard practice.

### Main outcome measures

The primary outcome was health status, measured using the 36-item short-form general health survey (SF-36) instrument. Secondary outcomes included women's treatment preferences, treatments undergone and satisfaction. In the economic analyses, health outcomes were measured in terms of quality-adjusted life-years (QALYs) based on women's responses to the EQ-5D (EuroQol-5 dimensions) instrument.

### Results

#### Health status

The interventions had no consistent effect on health status compared with controls.

#### Preference formation

In comparison with the control group, women were more likely to hold a treatment preference in both the information (adjusted odds ratio (OR) 1.87; 95% confidence interval (CI), 1.25 to 2.80) and interview (adjusted OR 2.51; 95% CI, 1.66 to 3.79) groups post-consultation. The interview also influenced preferences towards individual treatments, where women were less likely than controls to want hysterectomy (adjusted OR 0.54; 95% CI, 0.35 to 0.85) or drug therapy (adjusted OR 0.44; 95% CI, 0.24 to 0.82).

#### Treatments undergone

After 2 years of follow-up, women in the interview group were less likely to have undergone hysterectomy than controls (adjusted OR 0.60; 95% CI, 0.38 to 0.96) and women who were only given information (adjusted OR 0.52; 95% CI, 0.33 to 0.82).

#### Satisfaction

The results of the satisfaction analyses were mixed. At short-term follow-up, the information group was significantly more satisfied than controls with the

opportunities that they had been given to be involved in treatment decision-making (adjusted OR 1.39; 95% CI, 1.04 to 1.86). At long-term follow-up the interview group rated both these opportunities (adjusted OR 1.49; 95% CI, 1.11 to 2.01) and the results of their treatment (adjusted OR 1.44; 95% CI, 1.03 to 2.01) higher than women in the control group.

### Cost-effectiveness

There is a high probability that information provision in conjunction with preference elicitation is cost-effective; even under a range of sensitivity analyses this result does not change. The probability that interview is the most cost-effective form of management, assuming decision-makers are willing to pay £30,000 per additional QALY, is 78%, and 55% under sensitivity analysis.

### Conclusions

Neither intervention had a major impact on health outcomes relative to control. Information plus interview gave major additional benefits compared with the information pack on its own. It helped women form preferences, reduced hysterectomy rates and increased long-term satisfaction. The interview also had the highest probability of being cost-effective.

### Implications for healthcare

- Information alone is not sufficient: patients need help in using the information to clarify their preferences, which then need to be communicated to their clinician.

- The results of this study suggest that the use of decision aids, consisting of evidence-based information along with formal preference elicitation, can actually reduce health service costs as well as improving patients' satisfaction.
- The effects in terms of preference formation, patient management and cost-effectiveness can be generalised to the treatment of uncomplicated menorrhagia in primary care.
- The reduction in hysterectomy rate is consistent with trends observed in other studies looking at conditions where patients have a choice between conservative and radical surgical options.

### Recommendations for future research

- Approaches to training clinicians in patient-centred decision-making.
- Practical methods of clarifying and eliciting a patient's treatment-related preferences and communicating them to clinicians.
- Scenarios of clinical decisions under which these methods would prove most effective and cost-effective.

### Publication

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# NHS R&D HTA Programme

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Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme continues to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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