Experience with shared decision making in gynaecological practice: treatment decisions in patients with dysfunctional uterine blood loss

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study evaluated the use of a blood loss chart for women complaining of excessive blood loss and diagnosed as suffering from dysfunctional uterine bleeding (DUB). Women were asked to fill out a blood loss chart during one menstrual cycle, and the chart was then used to help make the best choice of treatment. The comparator was to choose the best treatment without the aid of a blood loss chart. The treatment options were expectant management, levonorgestrel-releasing intra-uterine system (LNG-IUS), endometrial ablation, and hysterectomy.

Type of intervention
Management of treatment choice.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women between the age of 35 and 52 who were complaining of excessive menstrual blood loss and who had a medical history that suggested menorrhagia. The women had to have a uterus of less than 12 cm (seen on the ultrasound), a follicle-stimulating hormone level of less than 15 U/L, a normal uterine cavity, normal cervical cytology, no wish to be pregnant, and no fibroid uterus or any fibroids less than 1 cm.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness data were from the periods 2000 to 2001 and 1998 to 1999. The dates for the resource evidence were not given. The price year was not given.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Resource use was obtained from the prospective (chart) arm of the study. The costs were derived from national guidelines and formulary.

Study sample
No power calculations were reported. A total of 95 patient records were evaluated for inclusion in the retrospective (no
chart) group. Of these, 36 met the inclusion criteria and were selected. For the prospective arm, all patients referred as an outpatient to the clinic were screened for participation in the study. Sixteen of the 30 patients assessed were included. Reasons for the exclusion of the other 14 patients were reported.

**Study design**
This was a single-centre comparative study with a historical control. It would appear that all patients who were included in the final study groups were considered at analysis. The patients were followed up for 12 months.

**Analysis of effectiveness**
The primary outcome of the clinical study was the patients' SF-36 scores for physical functioning, vitality, pain and health perception. The study was also used to derive the probabilities that were used to populate the decision tree. The comparability of the two patient groups was not shown. It appears that there has been no adjustment for confounding factors.

**Effectiveness results**
The SF-36 scores for the intervention group (chart) were presented for the different the treatment options chosen. No SF-36 scores were available for the control group (no chart).

In addition, the authors presented the probabilities that were used as model inputs:

- the probability of selecting either of the four possible treatment modalities (expectant management, LNG-IUS, endometrial ablation and hysterectomy), with and without the decision aid chart; and

- the probability of no re-treatment within 1 year for each of the treatment modalities, with and without the decision aid chart.

**Clinical conclusions**
Use of a blood flow chart was associated with less re-treatment during the 1 year of follow-up, although the result was not statistically significant.

**Modelling**
For the purpose of comparing therapy selection with and without the decision-making chart in terms of the costs and quality of life, a decision tree was constructed using TreeAge software. The time horizon of the model was 1 year. A graphical representation of the model was presented in the paper.

**Measure of benefits used in the economic analysis**
The measure of benefit used was the quality-adjusted life-years (QALYs). Prior publications were used to assign a utility to the different health states that were assessed. The authors did not explain how the utility weights were used to estimate the QALYs. The authors did not use the information gained from the SF-36 data in the estimation of utilities or QALYs.

**Direct costs**
Discounting was not carried out as the costs were incurred during 1 year and it was therefore not relevant. Unit costs were given for an outpatient visit and the various medical procedures (i.e. the total cost of having an LNG-IUS, an endometrial ablation, or a hysterectomy). The quantities and the costs were not analysed separately. Resource use was derived from the prospective (chart) study group. The unit costs were based on data obtained from the national formulary and Netherlands national cost guidelines. No price year was given, but it was likely to have been 2000 to 2001.
Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were estimated.

Currency
Euros (EUR).

Sensitivity analysis
All probabilities used in the model were varied in one-way sensitivity analyses. The ranges over which they were varied were presented in the paper. In addition, the change in utility resulting from symptom control after hysterectomy and symptom control not resolved were also varied over plausible ranges. The authors also varied the cost of outpatient visits and the cost of hysterectomy.

Estimated benefits used in the economic analysis
The authors did not give the increase in QALYs resulting from the use of a blood flow chart. However, they stated that the use of the chart resulted in a slightly higher expected value of utility (0.70) in comparison with no chart (0.67).

Cost results
The cost per patient was EUR 1,469 in the chart group and EUR 1,530 in the no chart group.

Synthesis of costs and benefits
The use of a blood flow chart resulted in a cost of EUR 2,110 per QALY gained. This compares with a cost of EUR 2,273 per QALY gained when no chart was used. The authors did not fully explain how these results were obtained.

The authors stated, but did not demonstrate, that these results were robust to changes in the costs of outpatient visits, the impact of the chart on initial therapy choice, and the impact of persisting problems and of hysterectomy on quality of life. When the cost of hysterectomy fell below EUR 1,700, there was no difference between the cost-utilities of the two strategies. If the effect of the chart on the probability of re-treatment fell by 0.04 (calculated value 0.07), then the cost per QALY gained of using the blood flow chart was greater than if no blood flow chart had been used.

Authors’ conclusions
The use of a blood flow chart for women suffering from dysfunctional uterine blood loss (DUB), as an aid to selecting the best treatment, is practical and leads to better results for the women. It leads to less need for re-treatment and is less expensive per quality-adjusted life-year (QALY) gained for a wide range of cost and effectiveness outcomes.

CRD COMMENTARY - Selection of comparators
The choice of the comparator, no blood flow chart in helping make treatment decisions for patients with DUB, was justified by it being current practice in many settings. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was a single study. The observational nature of the study design has limitations, many of which might have been overcome through the use of a randomised controlled trial. Given that the patient


groups received the different treatments at a different time, and the authors did not show that they were comparable, it is difficult to know whether the results obtained were due to the chart or to chance. Whilst the provision of SF-36 scores for the chart group may be useful to some, not having these same outcomes for the comparator group in the paper makes the usefulness of this information for the intervention group debatable. In addition, it was unclear whether the patient sample receiving the treatment was representative of the study population because many of the patients satisfying the inclusion criteria did not want to participate in the study. The analysis of effectiveness was not handled credibly in that the only clear way of comparing the two patients groups was the probability of choosing a particular treatment option, and the probability of no re-treatment. The authors ascribed differences in outcomes to the fact that the second group was using a blood flow chart, but the differences in outcomes could be due to differences in the patient groups or differences over time in the way the treatments were carried out. Overall, the internal validity of the estimates obtained is likely to be low.

Validity of estimate of measure of benefit
Utility values obtained from published sources were used to value the change in outcomes caused by the treatment, and then used to estimate QALYs as a measure of benefit in the economic analysis. However, it was not entirely clear how the authors derived the QALY outcomes.

Validity of estimate of costs
From the cost perspective adopted (i.e. the health system) it was unclear whether all the costs were included. Resource use was based on the prospective chart group and unit costs from relevant national sources. However, resource use was not presented and it was not entirely clear whether treatments would have remained exactly the same over the different time periods. Although the authors were concerned to show that the chart was designed to give women more control over their lives, they did not attempt to include the cost to the patient or productivity losses. The impact these might have had on the findings of the analysis is unclear. No statistical analysis of the prices was carried out. The authors carried out some sensitivity analyses on the prices, such as the costs of outpatient visits and hysterectomies. The price year was not reported and this may hinder any future reflation exercises.

Other issues
The authors made some comparisons of their results with those of other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively, but they did not present sufficient study details to enable the reader to make clear comparisons between the two patient groups. The authors reported several limitations of their study. For example, the small number of patients enrolled, the use of historical controls, and the 1-year follow-up. In addition, the authors hypothesised that a longer follow-up might lead to different results.

Implications of the study
The authors concluded that the use of blood loss charts in DUB patients led to a better choice of treatment and to less re-treatment within 1 year. Further research, which avoids the deficiencies of the research in the current paper, is necessary to back up this view.

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