



Short report

An assessment of economic measures used in menorrhagia: A systematic review



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ABSTRACT

'Menorrhagia', or heavy menstrual bleeding, is a common problem affecting women. The principal driver for treatment is women's experience of its interference in their lives, so a measure of quality of life (QoL) is increasingly used as the primary outcome to assess treatment success. QoL measures need to accurately reflect women's concerns as these measures are often used to inform resource allocation decisions within the healthcare service. Healthcare decision-makers often advocate the use of generic measures so as to achieve consistency when making decisions. Generic measures, by definition, have a broad focus on QoL in contrast to disease-specific measures that focus on dimensions of health relevant to the condition. We report a systematic review of studies that have either used or assessed economic outcome measures in menorrhagia, and present criteria for assessing which measure is the most appropriate. Studies including women presenting with menorrhagia, and using or assessing economic measures were sought by searching nine electronic databases.

Fifty-six eligible studies were identified. A narrative synthesis was most suitable to the review question. Eleven studies assessed the psychometric properties of the outcome measures, twelve studies applied the measures in an economic evaluation, and thirty-three used them in effectiveness studies. Mixed results on the psychometric properties of the instruments were observed. Studies were often found to include both a disease-specific and a generic measure. We found no consensus on the most appropriate economic outcome measure to use when assessing the cost-effectiveness of treatment for menorrhagia. This is an important finding as QoL is the primary focus for treatment decisions. The cyclical nature of the condition has a large impact on the reliability and validity of outcome measurement. Alternative measures, such as willingness-to-pay, which embrace more than health and avoid standard recall periods should be explored.

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Introduction

'Menorrhagia', or heavy menstrual bleeding, can be defined as "excessive menstrual blood loss which interferes with the woman's social, emotional, physical and material quality of life" (NICE, 2007). As one of the most common gynaecological problems, it puts a considerable strain on healthcare resources, resulting in 1 in 20 women, aged between 30 and 49, consulting their general practitioner each year (Coulter, Kelland, Peto, & Rees, 1995; Rees, 1991). The principal driver for treatment is women's experience of its interference in their lives. Objective measures of volume of blood loss are considered to be unsuitable, and a woman's

subjective assessment of her ability to cope and the perceived impact on her quality of life (QoL) is increasingly used to assess treatment success.

A broad range of measures are available to assess QoL, including those specific to particular conditions, and those that are generic. Economic evaluation is used by decision-making bodies such as the National Institute for Health and Care Excellence (NICE) to help with decisions about resource allocation. Economic evaluations represent a framework used to compare the costs and benefits/outcomes of alternative options for resource use (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005). NICE explicitly recommend the use of generic outcomes to achieve a level of consistency when making resource allocation decisions across healthcare conditions. Specifically, NICE recommend the use of the 'quality-adjusted life year' (QALY) (NICE, 2008) as the unit of outcome. The QALY reflects changes in both the quantity and QoL

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and is constructed using information from generic utility-based QoL questionnaires (referred to as instruments), such as the EuroQoL-five dimension (EQ-5D) (Drummond et al., 2005). The patient's QoL is measured on a 0–1 (utility) scale where 0 represents death and 1 full health. The utility value is combined with information on quantity of life to estimate QALYs.

A 'welfarist' approach to measuring outcomes assumes a broad valuation space, which can include health and non-health benefits, in contrast, an 'extra-welfarist' approach measures outcomes which primarily focus on health-related QoL (Birch & Donaldson, 2003). There are a range of extra-welfarist generic utility-based QoL instruments available that can be used in all conditions. These measures are used in economic evaluations and the two most commonly used measures are EQ-5D and Short Form-6 dimension (SF-6D). To generate SF-6D utility scores the non-utility based Short Form-36 (SF-36) or SF-12 is mapped on to SF-6D (Drummond et al., 2005).

Disease-specific utility-based measures also exist such as the Menorrhagia Multi-attribute Scale (MMAS) (Shaw, Brickley, Evans, & Edwards, 1998). These are typically anchored by full health and the worst possible state for the condition rather than full health and death as in generic measures. Despite the disease-specific measure being referred to as utility-based, it cannot be used in the recommended economic evaluation because the methodology used departs substantially from theoretical approaches to generating QoL scores (for details see Drummond et al., 2005).

Within the welfarist paradigm where the valuation space for outcomes is broader, an alternative approach known as contingent valuation, takes the form of 'willingness-to-pay' (WTP) which can be used to value the utility change that occurs as a result of treatment. As the measure of benefit in WTP is derived in terms of monetary values, and not health utilities, WTP is used in an economic evaluation known as cost–benefit analysis. For a summary of the instruments see Supplementary Box 1.

As well as the need for consistency in methods to inform resource allocation decisions, for menorrhagia, the suitability of utility measures is more important because it is the primary measure of treatment effectiveness. This alongside the recent finding that utility values are the main cause of uncertainty in an economic evaluation, means that a review of outcome measures used to evaluate treatment options for menorrhagia is vital (Roberts et al., 2011). Until the evidence on the utility values associated with menorrhagia is strengthened, robust recommendations made on the basis of economic evidence cannot be provided. In this paper we provide a narrative review of all economic measures, extra-welfarist and welfarist, (utility-based QoL and contingent valuation) that have been used to evaluate treatment options for menorrhagia and provide an assessment of their psychometric properties and clinical utility.

Methods

In January 2012 we electronically searched nine databases and reference lists from relevant studies. We included studies where menorrhagia was the presenting complaint. The search terms included heavy menstrual bleeding **or** menorrhagia **and** questionnaires **or** quality of life **or** outcome assessment **or** psychometry **or** psychological tests **or** psychometrics **or** interview **or** instrument. We categorised the literature firstly based on relevance of title and abstract, and then by reading the full text of relevant papers (see Supplementary File).

Included studies are broadly categorised into two groups; those that assessed the psychometric properties and the feasibility of economic outcome measures and those that used the measures. For the full criteria used to judge the psychometric properties of the instruments see Supplementary Table 1. Briefly, the instruments were assessed according to the *validity*, whether the instrument measures what it is designed to measure, *reliability*, defined as the ability to provide consistent scores and *sensitivity*, the extent to which the measure captures clinical changes. A narrative synthesis of data was taken and therefore a discussion regarding the instruments use is provided.

Results

A full break down of the number of studies identified and included in the review is provided in Supplementary Fig. 1. Fifty-six papers were included in the review. Eleven papers assessed the psychometric properties of the outcome measures, twelve papers applied the measures in an economic evaluation or a cost study, eight and twenty-five effectiveness studies used the measures as a primary and secondary outcome, respectively. The results are described according to the type of instrument assessed. Particular psychometric properties are not reported for all instruments if there were no relevant studies. Table 1 summarises the main findings and presents those studies that assessed psychometric properties and feasibility. Remaining studies are discussed in the text.

EQ-5D

Where EQ-5D was used as the single outcome measure, there were no studies reporting on the psychometric properties of the instrument. We found some psychometric properties reported when it was used alongside the MMAS instrument, the disease-specific measure which has been shown to be reliable and valid in menorrhagia (Pattison, Daniels, Kai, & Gupta, 2011; Shaw et al., 1998). With respect to the construct validity we identified one case where the overall score for EQ-5D had a poor correlation with MMAS (Pattison et al., 2011) which led to the authors suggesting

Table 1
Judgement on properties of instruments.

Instrument	n	Validity			Reliability	Sensitivity	Feasibility/utility
		Content	Face	Construct			
EQ-5D	3	None	None	Pattison et al., 2011	None	(Clark & Gupta, 2004)	Kilonzo et al., 2010
<i>Judgement</i>		<i>Insufficient evidence</i>	<i>Poor^a</i>	<i>Poor</i>	<i>Insufficient evidence</i>	<i>Insufficient evidence</i>	<i>Mixed</i>
SF-36	9	None	Jenkinson et al., 1996	Garratt et al., 1993	Jenkinson et al., 1996; Garratt et al., 1993; Ruta et al., 1994	Coulter et al., 1994; Garratt et al., 1994; Habiba et al., 2010; Hehenkamp et al., 2008	Brown et al., 2006; Bongers et al., 2005
<i>Judgement</i>		<i>Insufficient evidence</i>	<i>Poor</i>	<i>Mixed</i>	<i>Mixed</i>	<i>Mixed</i>	<i>Mixed</i>
WTP	1	None	None	None	(Ryan & San Miguel, 2000)	None	(Ryan & San Miguel, 2000)
<i>Judgement</i>		<i>Insufficient evidence</i>	<i>Insufficient evidence</i>	<i>N/A</i>	<i>Poor</i>	<i>Insufficient evidence</i>	<i>Insufficient evidence</i>

^a Comments on the face validity of SF-36 can be applied to EQ-5D.

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