

**MEDICAL MANAGEMENT OF HEAVY MENSTRUAL BLEEDING:
UNDERSTANDING WOMEN'S EXPERIENCES**

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Medical management of heavy menstrual bleeding; understanding women's experiences

Abstract

Introduction: Heavy menstrual bleeding is known to impact on health, wellbeing and social functioning. There is limited research examining women's experiences of treatment for this complex condition. This longitudinal qualitative study explored women's experiences of medical treatment for heavy menstrual bleeding with particular reference to women's treatment preferences, quality of life and cultural variation.

Methods: Data were generated by a series of two semi-structured interviews conducted with women who had either consented to participate in a randomised controlled trial (investigating effectiveness of levonorgestrel intra-uterine system [LNG-IUS] compared with standard medical treatments) or had declined due to an expressed treatment preference. The sample was purposefully selected to include a wide range of demographic characteristics and medical treatment options. Interviews were audiotaped and transcribed verbatim before being coded. A grounded approach to analysis was used with concepts emerging from coded data. Data generation and analysis were iterative and continued until theoretical saturation was reached.

Findings: Twenty-seven women were selected and consented to the interview study, ten of whom expressed a treatment preference. A broad range of demographic characteristics and treatment options was achieved. In addition to physical aspects of heavy menstrual bleeding, most women described maintaining the societal norm of concealment of menstruation distressing. Expectations of positive treatment outcomes were high, but the experience of most treatment did not, in the initial stages, meet

women's expectations. After one year, women using LNG-IUS felt less restricted in their daily activities and described feeling less distress about their heavy menstrual bleeding. Many women who were using other treatments had discontinued them, several opting to manage their heavy menstrual bleeding by adapting coping behaviours rather than seeking alternative treatment. Treatment preferences appear to be influenced by knowledge gained from peers with LNG-IUS being the most preferred treatment. For many women in this sample the impact on quality of life was determined by their perceived ability to continue with their roles and responsibilities both at home and in the workplace. A conceptual model was developed when descriptive themes emerging from coded data were overlaid with recorded treatment outcomes. The model illustrates the complexity of heavy menstrual bleeding and highlights common feelings and experiences could be aligned to particular treatment trajectories.

Conclusion: This study adds understanding to women's experiences of medical treatment for heavy menstrual bleeding, preferences for treatment and how quality of life changes over time. The conceptual model developed highlights the complexity of this condition and might be used to improve communication between women and health professionals.

Declaration

Except where acknowledged I declare that this thesis is entirely my own work and is based on research carried out in the School of Graduate Entry Medicine and Health, University of Nottingham and in collaboration with the University of Birmingham and the Birmingham Clinical Trials Unit as a component of the ECLIPSE Trial.

Ethical approval was sought by the ECLIPSE Trial Management Group as a substantial amendment to the ECLIPSE Trial protocol, the amendment being co-written by myself and Birmingham Clinical Trials Unit. Funding for this study was sourced from within the original research grant for the ECLIPSE Trial.

Possible participants to the study were initially identified by General Practitioners and Gynaecologists collaborating on the ECLIPSE Trial. Purposeful selection and recruitment to this study was carried out by me. All data collection was carried out by me.

Some assistance was given with transcription of interviews by an administrator within the Division of Primary Care and also by an independent professional transcription company. All transcripts were then rechecked by myself to ensure consistency and accuracy of verbatim transcription. All coding and analysis of the data was done by me.

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Dedication

This thesis is dedicated to the memory of Sarah Louise Hill (1970-1995)

Publications arising from this thesis

Prileszky, G. (2010) *Medical Treatment for Heavy Menstrual Bleeding: Understanding women's experiences* [Conference presentation] Society for Academic Primary Care National Annual Scientific Meeting. University of East Anglia, UK, July 2010

Prileszky, G. (2010) *Medical Treatment for Heavy Menstrual Bleeding: Understanding women's experiences* [Invited speaker] University of Manchester Seminar; Showcasing qualitative research in action. University of Manchester, UK, April 2010

Prileszky, G. (2010) *Medical Treatment for Heavy Menstrual Bleeding: Understanding women's experiences* [Conference presentation] Society for Academic Primary Care Trent Regional Spring Conference, University of Nottingham, UK, March 2010

Prileszky, G., Kai, J., Gupta, J. (2008) Mirena coil for heavy menstrual bleeding [comment] *British Journal of General Practice* 58(577):886, author reply 886-887

Table of contents

	Abstract	ii
	Declaration	iv
	Acknowledgements	v
	Dedication	vi
	Publications	vii
	Table of contents	viii
	List of figures and tables	xv
Chapter One	Introduction	1
1.0	Heavy menstrual bleeding	1
Chapter Two	Review of the literature	6
2.0	Literature review methodology	6
2.1	Diagnosis of heavy menstrual bleeding	8
2.2	Heavy menstrual bleeding and health	13
2.3	Experiences of heavy menstrual bleeding and medical management of this condition	15
2.4	Psychosocial impact of heavy menstrual bleeding	17
2.4.1	<i>Psychological impact</i>	17
2.4.2	<i>Social impact</i>	18
2.5	Medical treatments for heavy menstrual bleeding	19
2.5.1	<i>Tranexamic acid</i>	20
2.5.2	<i>Oral contraceptives</i>	21
2.5.3	<i>Injected progesterogen</i>	22
2.5.4	<i>Norethisterone</i>	22

2.5.5	<i>LNG-IUS</i>	22
2.5.6	<i>Surgery</i>	24
2.6	Treatment preferences	27
2.7	Most appropriate place for treatment; primary or secondary care	30
2.8	Cultural and social responses to menstruation	33
Chapter Three	Methodology	40
3.0	Introduction	40
3.1	Aim of the study	40
3.2	Study objectives	40
3.3	Study design	41
3.4	Ethical approval and safety of participants and researcher	41
3.5	Sampling	43
3.6	Recruitment and consent	47
3.7	Data generation and analysis	50
3.8	Validation	60
Chapter Four	Findings: Descriptive themes and factual data	61
4.1	Introduction	61
4.1.1	<i>General demographic characteristics</i>	62
4.1.2	<i>Factual data relating to treatment outcomes</i>	62
4.2	Descriptive themes relating to psychological factors	65
4.2.1	<i>General perceptions of menstruation</i>	65
4.2.2	<i>Information and the experience of first menarche</i>	66

4.2.3	<i>Maternal support and communication with others</i>	70
4.2.4	<i>The last taboo</i>	73
4.2.5	<i>Stoic silence</i>	75
4.2.6	<i>Concealment of menstruation</i>	78
4.2.7	<i>Illness or condition?</i>	82
4.3	Descriptive themes relating to relationships and sexuality	84
4.3.1	<i>Heavy menstrual bleeding and sexuality</i>	84
4.3.2	<i>The influence of significant others</i>	88
4.4	Descriptive themes relating to the impact of heavy menstrual bleeding on life and work	90
4.4.1	<i>Quality of life relating to roles and responsibilities</i>	90
4.4.2	<i>Impact on roles and the decision to seek treatment</i>	92
4.5	Descriptive themes relating to fertility and womanliness	94
4.5.1	<i>Normal menstrual period or amenorrhea?</i>	94
4.5.2	<i>The association with aging</i>	96
4.5.3	<i>Fertility</i>	97
4.5.4	<i>Attachment to the uterus</i>	100
4.6	Descriptive themes relating to clinical signs	101
4.6.1	<i>Is my bleeding abnormal or not?</i>	101
4.6.2	<i>The experience of heavy menstrual bleeding</i>	104
4.6.3	<i>Key symptoms to be dealt with</i>	107
4.6.4	<i>Clinical signs impacting on quality of life</i>	110

4.7	Descriptive themes relating to confounding factors	111
4.7.1	<i>Physical confounding factors</i>	111
4.7.2	<i>Fear of pathology</i>	113
4.7.3	<i>Treatment setting; primary of secondary care</i>	114
4.7.4	<i>Communication and the gender of the health professional</i>	117
4.7.5	<i>The expertise of the health professional</i>	118
4.8	Descriptive themes relating to previous knowledge and experience of treatment	120
4.8.1	<i>The influence of family history</i>	120
4.8.2	<i>Previous experience of treatment</i>	123
4.8.3	<i>Expectations of a positive outcome</i>	124
4.8.4	<i>Experience of LNG-IUS</i>	127
4.8.5	<i>The fitting of LNG-IUS</i>	132
4.8.6	<i>Experience of standard treatment</i>	135
4.8.7	<i>Discontinuing treatment</i>	140
4.8.8	<i>The development of treatment preferences</i>	142
4.8.9	<i>Sources of information about treatment preferences</i>	144
4.8.10	<i>Communication about preferences with health professionals</i>	146
4.8.11	<i>The experience of the preferred treatment</i>	148
4.9	Descriptive themes relating to time	150
4.9.1	<i>Estimated time to menopause</i>	150
4.9.2	<i>Duration of heavy menstrual bleeding</i>	151

Chapter Five	Development and exploration of a conceptual model ELMA	152
5.0	Introduction to Experiences of life with heavy menstrual bleeding – aid to communication (ELMA)	152
5.1	Conceptual model development	152
5.2	Parameters within ELMA	158
5.2.1	<i>Psychological factors / self esteem</i>	158
5.2.2	<i>Relationships / sexuality</i>	158
5.2.3	<i>Impact on work and life</i>	159
5.2.4	<i>Fertility / womanliness</i>	159
5.2.5	<i>Clinical signs</i>	161
5.2.6	<i>Confounding physical factors</i>	161
5.2.7	<i>Previous knowledge and experience of treatment</i>	161
5.2.8	<i>Time (years)</i>	162
5.3	Exploration of ELMA	163
5.4	Testing the model using case studies	172
Chapter Six	Discussion	176
6.0	Introduction	176
6.1	Discussion relating to psychological factors	176
6.2	Discussion relating to sexuality and relationships	186
6.3	Discussion relating to impact on life and work	188
6.4	Discussion relating to fertility and womanliness	190
6.5	Discussion relating to clinical signs	193

6.6	Discussion relating to confounding factors	196
6.7	Discussion relating to knowledge and experience of treatment	201
6.8	Discussion relating to time	208
6.9	Discussion relating to the conceptual model ELMA	209
Chapter Seven	Conclusion and recommendations	212
7.0	Conclusion	212
7.1	Psychological factors and self esteem	213
7.2	Relationships and sexuality	214
7.3	Impact on life and work	215
7.4	Fertility and womanliness	216
7.5	Clinical signs	217
7.6	Confounding factors	217
7.7	Knowledge and experience of treatment	218
7.8	Time	220
7.9	Conceptual model ELMA	221
7.10	Strengths and limitations of this research	221
7.11	Recommendations for further research	224
7.12	Implications for practice	225
References		228
Appendicies		245
I	Study protocol	245
II	Sample matrix	253
III	Poster for education	257
IV	Participant information sheet	258
V	Consent to contact form	263
VI	Consent form	264

VII	Demographic data collection form	265
VIII	Topic guide	267
IX	Demographic data in detail	272
X	Open, axial and selective coding examples	284
XI	Validation correspondence	287
XII	Study schema	292

List of figures and tables

Table A	Medical treatments recommended by NICE (2007)	20
Figure 1	Sample Matrix	46
Figure 2	Analysis process	57
Table B	Summary of demographic characteristics	62
Table C	Treatment outcomes for sample population	64
Figure 3	Draft conceptual model	154
Figure 4	Conceptual model ELMA	157
Figure 5	ELMA used for assessment of condition	164
Figure 6	ELMA illustrating experiences associated with more minor intervention	167
Figure 7	ELMA illustrating experiences associated with more moderate intervention	169
Figure 8	ELMA illustrating experiences associated with more major intervention	171
Figure 9	Poster for education	257
Figure 10	Study sample age distribution curve	273
Figure 11	Study sample parity distribution curve	274
Table D	Annotated demographic characteristics	283
Figure 12	Qualitative study schema	292

1.0 Heavy menstrual bleeding

Heavy menstrual bleeding is a significant problem for many women, impacting on many aspects of health and wellbeing (Chapple 1999). Heavy menstrual bleeding can be an extremely debilitating condition yet the experience of this disorder has not been widely researched. Most women seek treatment in Primary Care where the most acceptable forms of treatment involve medical management, including the use of medications such as tranexamic acid and the levonorgesterel releasing intrauterine system (LNG-IUS). Generally the understandings of the effects and acceptability of medical treatments have not been fully investigated and are considered to be poorly understood (Santer 2008). This study sought to examine women's experience of heavy menstrual bleeding and medical management of this condition using a qualitative approach.

There is a broad range of treatments available including surgical and medical options. Quantitative research has been used to compile guidelines for the treatment of heavy menstrual bleeding (NICE Guideline 44. Heavy Menstrual Bleeding 2007) published by the National Institute of Clinical Excellence (NICE), endorsed by The Royal College of Obstetricians and Gynaecologists (RCOG).

The ECLIPSE Trial (www.eclipse.bham.ac.uk) is an ongoing randomised controlled trial that is comparing the use of LNG-IUS with standard medical treatment for heavy menstrual bleeding. The trial aims to find out which treatments are effective in reducing menstrual blood loss with the least side effects. LNG-IUS has been found to be effective in the reduction of menstrual blood loss but women have reported progestogenic side effects.

Studies have not shown significant differences in terms of quality of life issues such as satisfaction with treatment or improvements in perceived quality of life (Lethaby, Hickey and Garry, 2005a) when compared to surgical treatments. Following the publication in 2007 of NICE Guideline 44 recommending LNG-IUS as the first line treatment for heavy menstrual bleeding it became important to question the fact that women appear to report no differences in quality of life following treatment with LNG-IUS. In addition there is little published work comparing quality of life issues when LNG-IUS is used compared to standard medical treatments. The ECLIPSE Trial data will redress this issue when the self completed questionnaires are analyzed, however the depth of communication and the richness of data collected is restricted by the fact that ECLIPSE is a large quantitative study.

This qualitative study was able to collect much more detail about a smaller sample of women's experiences of heavy menstrual bleeding and its treatment, in parallel to the quantitative data obtained by ECLIPSE. Whilst the qualitative data could not be extrapolated to fit the entire population it may help to inform practice and promote discussion amongst health professionals and the general population.

Although there is some evidence comparing effectiveness of various treatments for heavy menstrual bleeding, there has been much less interest in examining women's experiences of heavy menstrual bleeding and its treatment. Several studies have indicated the impact of society and culture on the perception of the severity of menstrual disorders (O'Flynn 2006, O'Flynn and Britten 2004, Chapple 1999). Women who were interviewed by O'Flynn (2006) highlighted the management of menstruation including its concealment to conform with societies norms. Many women studied had experienced a change in their menstruation and required further explanation from sometimes dismissive doctors who were

preoccupied with volume of blood loss rather than impact on the woman's health and well being (O'Flynn and Britten 2004, O'Flynn and Britten 2000). In addition, research has suggested cultural differences both in the experience of treatment for heavy menstrual bleeding (Chapple 1999). Chapple's study highlighted the individuality of heavy menstrual bleeding to each woman, and also differences in health care professionals recognition of the condition and its treatment. The author suggested that some of this sample might have participated because they had experienced difficulty in obtaining effective treatment for their heavy menstrual bleeding.

The studies that have been published indicate that large proportions of women who require treatment for heavy menstrual bleeding have predetermined expectations and preferences for a particular treatment (Vuorma, Teperi, Hurskaninen *et al.* 2003, Sculpher, Dwyer, Browning *et al.* 1998, Coulter, Peto and Doll 1994). Expectations and preferences appear to be influenced by diverse factors such as employment status, as well as the more predictable severity of symptoms (Vuorma *et al.* 2005, Coulter *et al.* 1994). The development of personal expectations about treatment prior to consultation has obvious implications for the medical professional who is required to prescribe the most appropriate treatment in accordance with published NICE / RCOG guidelines. Previous personal experience and lay knowledge can affect compliance and therefore the efficacy of the treatment.

It would be beneficial if the voices of women could be heard alongside the evidence from randomized controlled trials when treatment guidelines are reviewed, something that this qualitative study was able to achieve. Taking the experiences of women into account could improve clinical practice in two ways. Firstly it could improve the understanding of women's

experiences of heavy menstrual bleeding and its treatment, which may improve the communication between doctor and patient. Secondly understanding the factors influencing women's experience, treatment preferences and decision making may encourage greater concordance amongst patients, reducing the need for repeat visits for different treatments.

The study objectives were to explore and develop understanding of both women's experiences and their expectations of medical treatments. In addition the study explored views, beliefs, attitudes and decision making in relation to treatment preferences. Women were followed over a time period of up to eighteen months in order to explore changes in treatment preferences and why they may have occurred. With the increasing use of assessment tools, the study also sought to explore women's perception of quality of life in this context and of the effects of medical treatment. Finally this study sought to explore cultural variation in relation to women's experience of medical treatment for heavy menstrual bleeding.

Chapter Two presents an overview of the literature published in this field to date, focusing on women's experiences of heavy menstrual bleeding and also on current medical treatments. Methodology and study design including purposeful sampling will be discussed in Chapter Three.

Chapter Four presents the data. In Chapter Four the sample population is described briefly along with factual data relating to treatment journeys. Qualitative findings presented in Chapter Four include descriptive themes within eight core categories that are presented and explored through illustrative quotes. Chapter Five relates to the development of a conceptual model **E**xperiences of **L**ife with Heavy **M**enstrual Bleeding; **a**id to communication (ELMA). The model is illustrated and explored through three case studies. Chapter Six contains discussion of the study findings,

including the conceptual model, comparing and contrasting with the published literature. There are also suggested possible reasons for the study findings with reference to wider societal influences. In addition there is some discussion about how this might impact on women in the future.

Conclusions are drawn, including the limitations of this research, with implications for further research and clinical practice suggested in Chapter Seven.

CHAPTER TWO

REVIEW OF THE LITERATURE

2.0 Literature review methodology

Between November 2007 and June 2008 several searches of five electronic databases (Medline, PubMed, CINHALL, British Nursing Index and PsychINFO) were performed in order to identify research into heavy menstrual bleeding. Initial searches included abstracts from clinical trials, quantitative and qualitative studies. From abstracts obtained the literature search was then focused on two main topic areas, namely qualitative research into women's experiences of heavy menstrual bleeding and medical treatment of heavy menstrual bleeding. In addition two other sources of information (Cochrane Library and NICE) were used to collate recent research on current recommended medical treatments. The preliminary literature review was used to describe the rationale for proceeding with this study and can be seen in the Study Protocol included in Appendix I on page xxxx.

As data collection and analysis progressed further searches were undertaken in 2008, 2009, 2010, 2011, and 2012 following the same initial search criteria and sources of information. These literature searches were driven by descriptive themes emerging from the data in line with grounded theory methodology. Several key searches were performed in order to identify research focused on concealment of menstruation, communication about menstruation and cultural differences in the experience of menstruation. Searches were limited to English language, but not by publication date. Key research papers identified from abstracts were ordered as full text pdf files or physically sourced by hand from the

relevant journal. During the writing up phase of the thesis the key literature searches were revisited to ensure all contemporary relevant literature had been included. This chapter represents the information gathered from all literature searches conducted throughout all stages of this research, from the initial study design through data collection and analysis, discussion of findings and the drawing of conclusions.

The publication of National Institute for Health and Clinical Excellence (NICE) Guidelines for Heavy Menstrual Bleeding (HMB) in 2007, which recommends levonorgestrel releasing intrauterine system (LNG-IUS) be considered as first line treatment for heavy menstrual bleeding, has created a debate amongst health care professionals treating the condition. Santer (2008) suggests that the NICE guideline could lead to an improvement in patient care, however she also highlights a lack of published evidence regarding the efficacy of LNG-IUS compared to medical treatments, and also the complexity of issues for women regarding treatment choices for this particular condition. There is a recognised need to explore treatment effects on quality of life from women's perspectives. This need is underlined by the NICE. There is ongoing research that seeks to address this lack of evidence. The ECLIPSE Trial (www.eclipse.bham.ac.uk) is an ongoing randomized controlled trial comparing the effectiveness and cost-effectiveness of LNG-IUS with standard medical treatments for heavy menstrual bleeding. While LNG-IUS is effective in reducing menstrual blood loss, a number of studies have not shown significant differences in satisfaction with treatment or improvement in perceived quality of life (Lethaby, Cooke and Rees, 2005b) when compared to surgical treatments.

Given the gaps in the research to date, and in particular a need to understand the impact of medical treatments on quality of life (Santer

2008), this study seeks to provide further understanding of women's perspectives to contextualize evidence from ECLIPSE and other trials of treatments in this field in order to improve the information available to health professionals and women themselves. Provision of information and detailed discussion to clarify treatment expectations and preferences has been associated with lower rates of subsequent surgery, improved patient satisfaction and, possibly, quality of life (Kennedy, Sculpher, Coulter *et al.* 2002; Protheroe, Bower, Chew-Graham *et al.* 2007).

2.1 Diagnosis of heavy menstrual bleeding

There are a number of terms in use relating to abnormally heavy menstrual bleeding including menorrhagia. Heavy menstrual bleeding is the term used in this thesis, (as it is the term currently used by NICE and the Royal College of Obstetricians and Gynaecologists). Heavy menstrual bleeding can be defined as defined as excessive menstrual blood loss that impacts on a woman's quality of life, either physically, emotionally, socially or materially (NICE 2007).

There are a number of different terms and definitions used internationally to describe abnormal menstrual bleeding, causing some confusion and inconsistency within the medical profession treating women and researching heavy menstrual bleeding (Woolcock, Critchley, Munro, *et al.* 2008). The International Federation of Gynaecology and Obstetrics (FIGO) recommend not using terms such as menorrhagia or dysfunctional uterine bleeding (Fraser, Critchley, Broder *et al.* 2011), so the term heavy menstrual bleeding is appropriate and up to date. Even the prevalence of heavy menstrual bleeding is difficult to determine as it is often not reported by women, or due to the confusion over terminology and definitions, may

be recorded as something else. Prevalence of heavy menstrual bleeding is currently estimated at between 10 – 30% (Nelson and Teal 2007), this spread being representative of individual interpretations of the range of terminology in use internationally. The fact that many women do not seek treatment suggests that prevalence data is probably underestimated as women may also have difficulty recognising that their menstrual bleeding is abnormal.

A postal survey conducted in Scotland (Santer, Wyke and Warner 2007) suggested that 30% of women reported heavy menstrual bleeding with an additional 5% reporting very heavy periods. However only 22% of these reported that their heavy menstrual bleeding was a marked or severe problem. The reporting of heavy menstrual bleeding was associated with pain and very heavy blood loss and also longstanding illness. Hormonal contraceptives were associated with lighter menstrual bleeding. The authors suggested that heavy menstrual bleeding was a common experience but that the reporting of this condition was as likely to be due to menstrual pain as heavy bleeding and that the medical professions preoccupation with blood volume does not reflect the epidemiology of menstrual disorders. This was a well designed study but further insight could be gained by using interviewing rather than a postal survey as a means of data collection. Interviewing may have enabled the researchers to identify relationships between comorbidities and the reporting of heavy menstrual bleeding and explore reasons why only 22% of women determined their heavy menstrual bleeding to be a marked or severe problem.

Santer *et al.* (2007) also interviewed a subset of 32 women in order to analyse menstrual symptoms and problems. This methodology was more appropriate. For the women in this sample, pain was cited as most

problematic followed by heaviness of bleeding, tiredness, and irregularity. Each of these was influenced by the social context for that individual, for example effect on working life or other responsibilities. Women were also unsure about defining their menstrual bleeding as heavy and this was determined by difficulty in containing bleeding and changes in bleeding patterns. This study highlighted the need for medical practitioners to clarify the impact of heavy menstrual bleeding for each woman and to provide help and advice for the determined specific problem, for example analgesia may be sufficient in some cases.

Santer (2008) suggests that historically clinicians have focused on actual blood loss and may be concerned about not diagnosing underlying pathology if addressing the impact of symptoms regardless of the actual blood loss volume. Indeed in a study (Hurskainen, Teperi, Aalto *et al.* 2004) cited in the NICE Evidence Table (2007) that was used to inform the published clinical guideline, LNG-IUS was compared with hysterectomy and the authors stated that the most important outcome predictor was volume of menstrual blood loss. Lukes, Muse, Richer, *et al.* (2010) attempted to correlate subjective and objective assessment of treatment efficacy by identifying a minimum reduction in menstrual blood loss that was acceptable to women. This approach may be useful for health professionals but it is unlikely to be relevant to the women themselves, as their experience of heavy menstrual bleeding is very complex. It has been suggested that a proportion of women present with heavy menstrual bleeding actually have menstrual blood loss that is within the medical definition of normal (O'Flynn and Britten 2004). It is also thought that the measurement of menstrual blood loss is very subjective and not generally perceived to be useful when considered in isolation. Yet a large number of referrals to secondary care cite blood loss (in terms of volume) as a major

factor leading to a surgical outcome (Warner, Critchley, Munro, *et al.* 2004).

The most interesting aspect of Warner's' research is the disparity between the women's perception of the main clinical sign prompting the decision to seek treatment and the medical practitioners reporting of reason for referral. Only 38% of women reported the volume of blood loss as a severe problem at the initial consultation, however 60% of women and 76% of General Practitioners stated that it was the reason for referral to secondary care. The authors suggest that during the primary care consultation menstrual problems tend to be reclassified as heavy menstrual bleeding at the time of referral and then during subsequent management. This could lead to some women being treated inappropriately. This may be occurring as it is an established mechanism to facilitate access to secondary care, where the impact of pain may be underestimated as the woman's social or employment context is perhaps less obvious.

When considering the objective measurement of menstrual blood loss heavy menstrual bleeding has been defined as menstrual loss greater than 80mls per cycle, although a diagnosis based on volume of blood loss is now considered to be obsolete. A cohort study objectively measured menstrual blood loss in two groups of women - those seeking treatment for heavy menstrual bleeding and those who considered their menstrual bleeding to be normal (Higham and Shaw 1999). Only 49% of women who were seeking treatment for heavy menstrual bleeding (n=207) had more than 80ml measured menstrual blood loss. These women also reported longer menstrual duration and increased sanitary protection requirements, subjective information which was accurately reflected by the objectively measured blood loss. These findings add to the argument that the

objective measurement of menstrual blood volume should not be the principal determinant when diagnosis of heavy menstrual bleeding is made.

Following on from the accepted medical preoccupation with menstrual blood volume other clinical signs may have been underestimated in both their prevalence and impact on women who seek treatment for heavy menstrual bleeding, with irregular vaginal bleeding and irregular cycles being reported in 46% of 736 women identified with heavy menstrual bleeding (Shapely, Jordan and Croft, 2007). In addition this study found that irregularity was present in 73% of 138 women who had sought treatment due to an increase in menstrual bleeding.

The aetiology of heavy menstrual bleeding is more difficult to ascertain and as yet science has not been able to ascertain a definitive answer. For some women heavy menstrual bleeding is apparent from menarche and for others a change in menstrual pattern occurs as they age. Anecdotal evidence from women themselves would suggest that a perceived increase in menstrual blood flow is seen as part of the aging process and may signify approaching menopause. Correlations between hormone concentrations and menstrual bleeding patterns demonstrate something different, with a change in the timing of each menstrual period (longer or shorter menstrual cycles) being associated with anovulatory cycles related to changes in hormone levels. Heavy menstrual bleeding was not found to be associated with hormonal changes as menopause approaches (Van Voorhis, Santoro, Harlow, *et al.* 2008).

2.2 Heavy menstrual bleeding and health

Heavy menstrual bleeding and other changes in menstrual experience can impact on many aspects of health, wellbeing and social functioning for women (Chapple 1999).

A systematic review of health related quality of life measurement in women with common benign gynaecological conditions found that questionnaires are commonly used to assess health status, but that these tended to be either standardised instruments or generic tools. Questionnaires tended to be disease specific - very few were generated from interviews with patients who had the disease and very few evaluated subjective health status (Jones, Kennedy and Jenkinson, 2002).

In 1998 Shaw, Brickley, Evans, *et al.* conducted interviews with women consulting with heavy menstrual bleeding in order to assess the impact of the condition on health and to develop an assessment tool or scale that could be utilised clinically. In this study women cited the following components of health as most affected; family life, physical health, work life, psychological health, practical difficulties and social life. A clinical scale was then developed to calculate a final health state utility to assist and clarify the impact of heavy menstrual bleeding for each individual. This scale is now accepted and is widely used for quantitative research into heavy menstrual bleeding and is the primary outcome measure for the ECLIPSE Trial.

In addition to the Shaw Menorrhagia Scale (Shaw, *et al.* 1998) outlined above, de Souza, Camargos, Ferrira *et al.* (2010) attempted to assess quality of life using quantitative methodology, and found haemoglobin levels predicted quality of life for women undergoing treatment for heavy menstrual bleeding. This study perpetuates the medical professions preoccupation with physical, measurable parameters that do not give the

whole picture of the possible impacts of heavy menstrual bleeding for women.

Many women are uncertain about seeking treatment for heavy menstrual bleeding due to a range of issues such as the recognition of their condition as requiring treatment or the unwillingness to discuss menstruation with medical practitioners. When a patient presents seeking treatment for a condition with medically unexplained symptoms (such as heavy menstrual bleeding) there is a high risk of dissatisfaction with the consultation unless the medical practitioner is a particularly skilled and trained communicator (Frostholm, Fink, Oernboel, *et al.* 2005a). The satisfaction with the consultation process can be predicted by the illness perceptions of the patient and is influenced by feelings of uncertainty and negative emotional involvement in the condition. Women seeking treatment for heavy menstrual bleeding commonly express both of these illness perceptions.

Each individual's perception of their health will have an impact on the decision to seek treatment or advice from their medical practitioner and also on the use of health care provision. Increased access to health care is associated with numerous self-reported clinical signs, worry or concerns about consequences of illness, perceived length of illness and emotional distress (Frostholm, Fink, Christensen, *et al.* 2005b).

Following a systematic review and meta-ethnography of qualitative studies Garside, Britten and Stein (2008) proposed a lay model of heavy menstrual bleeding to counter the perceived dominance of the medical disease model (focused on volume of blood loss). The lay model outlined physical characteristics such as type of loss, associated symptoms, the use of sanitary protection; all familiar from the Shaw Menorrhagia Scale (Shaw *et al.* 1998), but also included changes in symptoms and comparison with other women, thus moving away from the issue of blood loss in terms of

volume. In addition the patient illness model included impact on life, both in terms of physical problems such as staining clothing and psychological impact for example feelings of embarrassment. The patient illness model is very useful in highlighting the complexity of this condition and will undoubtedly be helpful when health professionals are discussing heavy menstrual bleeding with their colleagues or patients, however it does not assist either party in determining the appropriate course of action regarding treatment.

2.3 Women's experiences of heavy menstrual bleeding and medical management of this condition

Although there is still much work to be done several authors have begun to explore the experiences of heavy menstrual bleeding from the perspective of women themselves rather than from a predominantly medical model or perspective.

For some women the option of treatment for heavy menstrual bleeding is not considered for some time if at all. This group of women are under-represented in the literature to date, probably because most research has been focused on treatment efficacy (i.e. the medical perspective) rather than psychological, emotional or social impact of heavy menstrual bleeding. A proportion of women who do seek treatment are content with the treatments they receive, however there is a significant proportion of women who seek treatment for heavy menstrual bleeding and are disappointed by their General Practitioners (GP) response (Chapple 1999). It has been suggested that some GPs in the past have not recognised the need for appropriate treatment and when asked by the women for referral to a gynaecologist, they have been slow to concur that a secondary referral might be necessary (Chapple 1999). It is possible that this has occurred

due to concern over high rates of hysterectomy for heavy menstrual bleeding and the cost that this involves both financial and in terms of morbidity. This is a complex issue, as the expectations of women to be referred to a specialist may not reflect the GPs belief that heavy menstrual bleeding can be treated without a secondary care referral.

Qualitative studies done in London by O'Flynn (2006) recruited women from the primary care setting both through GPs and directly from primary care settings and the community. The most prominent theme to emerge from the constant comparative analysis of this data was the management of menstruation in order to conform with the powerful need to conceal any and all evidence of menstruation, deemed to be a normal social construct. Often the onset of a change in menstrual bleeding proved difficult to manage and continue to conceal and this resulted in stress, influencing a decision to consult a medical practitioner or to seek treatment. This study would seem to suggest that heavy menstrual bleeding has psychological aspects as well as physical, and that these are aligned to societal expectations. The context of this study should be retained, as there are likely to be different societal constructs in other countries and cultures.

The uncertainty of women when assessing their own menstrual bleeding and defining it as abnormal has been highlighted in a meta-ethnography of qualitative studies (Garside *et al.* 2008). The authors suggest that this may be a reason why some women seek medical treatment for heavy menstrual bleeding whilst others do not. They suggest that women believe that women's suffering is normal, heavy bleeding is cleansing and normal and this might be perpetuated by influential others undermining the validity of the women's experience. This opinion is influenced by the work of Chapple (1998), Chapple *et al.* (1998), whose studies suggested this view,

particularly for women of ethnic minority backgrounds. The lack of research into the experience of White British women's attitudes may have influenced this finding in the meta-ethnography analysis.

2.4 Psychosocial impact of heavy menstrual bleeding

2.4.1 Psychological impact

Whilst Santer (2008) has highlighted the relationship between heavy menstrual bleeding and psychiatric illness is the same as other physical conditions, other psychological factors such as anxiety or psychological distress may have an influence on the perception of heavy menstrual bleeding and the interpretation of what that blood loss might represent.

The relationship between psychological distress and heavy menstrual bleeding has been suggested in previous research (Gath, Osborn, Bungay, *et al.* 1987). Women with psychological distress appear more likely to report heavy periods (Shapley, Jordan and Croft, 2003a), and women presenting with heavy menstrual bleeding appear more likely to have psychological disturbance than those consulting other illness, for example respiratory tract infection (Shapley, Jordan and Croft, 2002). The question remains whether the psychological disturbance was present before the onset of heavy menstrual bleeding (often in childhood) or whether heavy menstrual bleeding had precipitated psychological disturbance. However it is clear from this research that the measurement of psychological distress is difficult and complex and often multi-factorial in origin and consultation behaviour is often influenced by the impact of heavy menstrual bleeding on daily life (Shapely *et al.* 2002). The effect of menstrual bleeding on mood suggested as a strong factor influencing women's inability to continue life as normal (Shapley, Jordan and Croft, 2003b).

The presence of other menstrual symptoms such as pain, mood changes and irregular bleeding also has an influence on the perception of the severity of heavy menstrual bleeding (Warner *et al.* 2004; Santer *et al.* 2007) a point that is highlighted again in Santer's editorial in the British Journal of General Practice (Santer 2008). A relationship between life changes and perception and experience of menstrual disorders has been suggested (Gordley, Lemasters, Simpson, *et al.* 2000). However, the wider context for women who present to services with change in menstrual experience resulting in treatment for 'heavy menstrual bleeding' has not been explored. It may be that during a period of life when many women experience other major transitional events a change in menstrual pattern could result in women seeking treatment for something that they may have been able to cope with in the absence of other stressors.

Many women studied had experienced a change in their menstruation and required further explanation. Research has shown that onset of heavy menstrual bleeding does not indicate the onset of menopause. Heavy menstrual bleeding did not correlate with steroid hormone concentrations and was less likely to be associated with anovulatory cycles. (Van Voorhis, Santoro, Harlow *et al.* 2008). Previous research has suggested that health professionals appear preoccupied with volume of blood loss rather than addressing patients' concerns or impact on women's health and well being (O'Flynn and Britten 2004, O'Flynn and Britten 2000).

2.4.2 Social impact

In terms of the impact of heavy menstrual bleeding on wider society there has been little data collated about the impact of this condition on the working lives of women and on the economy. A survey conducted in the United States measured work loss (absence from paid employment) associated with heavy menstrual bleeding in a sample of 3133 women, 373

of whom had self-reported heavy menstrual bleeding (Cote, Jacobs and Cummings, 2002). The survey found that several factors were associated with absence including the perception of health and of menstrual bleeding, age, education, marital status and family size. The women who reported heavy menstrual bleeding were generally likely to be in paid employment but were likely to be absent from work because of their condition. Cotes *et al.* (2002) estimated the cost of absence from work due to heavy menstrual bleeding to be \$1692 annually, representing a significant economic impact on the workplace in the United States of America.

Social factors have been identified as influencing both the perception of menstrual bleeding and the ability of the individual to cope with changes in menstrual pattern (O'Flynn 2006). Much of this work is focused on maintaining the societal norm of concealment of menstruation and the stresses that this brings if a woman has or perceives that she has heavy menstrual bleeding. Women have discussed management of menstruation including its concealment to conform to societal norms (O'Flynn 2006). In many cultures, including British, it is established behaviour amongst women to take great steps to conceal menstruation. A change in pattern or amount of bleeding often caused significant stress in that it caused difficulties in management of menstruation particularly related to concealment.

2.5 Medical treatments for heavy menstrual bleeding

There are a number of medical treatments recommended by NICE (2007) for heavy menstrual bleeding as shown in Table A on page 20. A brief description of each medical treatment option is included as knowledge of treatment options and the evidence around them was needed to aid analysis and understanding of women's accounts of their experience.

Recommended order	Treatment
First line	LNG-IUS
Second line	Tranexamic acid
	Non steroidal anti-inflammatories
	Combined oral contraceptives
Third line	Oral progestergen (norethisterone)
	Injected progestergen

Table A Medical treatment options recommended by NICE (2007)

2.5.1 Tranexamic acid

The use of tranexamic acid has been suggested by NICE (2007) as a second line treatment choice for heavy menstrual bleeding, with the recommendation that if there is no improvement in the condition the drug should be discontinued after three cycles. As an antifibrinolytic drug Tranexamic acid has no contraceptive effect and no impact on future fertility. It can be used whilst investigations are ongoing. It has been recently suggested as a well tolerated, long-term treatment for heavy menstrual bleeding (Muse, Lukes, Gersten *et al.* 2011).

When antifibrinolytic drugs were compared to other oral medical treatments (placebo, non-steroidal anti-inflammatory drugs, and oral luteal phase progestagens) they have been found to have a greater effect on reducing heavy menstrual bleeding, with fewer side effects or reported adverse events, however there a very small number of trials on which these findings are based (Lethaby, Farquhar and Cooke, 2004). Control of menstrual bleeding and sex life were found to have improved following treatment with tranexamic acid but the evidence on other quality of life outcomes have not been assessed. The ongoing ECLIPSE Trial will provide

more evidence with 571 women randomised, half of whom have been prescribed standard medical treatment options including tranexamic acid (personal communication, ECLIPSE Trial Management Group 2009).

Tranexamic acid is often prescribed in combination with a nonsteroidal anti-inflammatory drug, typically mefenamic acid. It is thought that non steroidal anti-inflammatory drugs have a modest effect on reducing heavy menstrual bleeding but are not as effective as other medical management options such as tranexamic acid, norethisterone or LNG-IUS (Lethaby, Augood, Duckitt, *et al.* 2007b). There is a clear indication for prescribing mefenamic acid in the case of a woman for whom menstrual pain is a significant part of the problem.

2.5.2 Oral contraceptives

The use of combined oral contraceptives has been suggested by NICE (2007) as a second line choice of medical treatments for heavy menstrual bleeding. The drugs are effective due to their prevention of proliferation of the endometrium. They do have a contraceptive effect but have no long-term impact on future fertility.

The evidence base for evaluating the effectiveness of combined oral contraceptives for the treatment of heavy menstrual bleeding is insufficient at present (Iyer *et al* 2006). In spite of this lack of evidence NICE has recommended the use of combined oral contraceptives as a second line treatment for heavy menstrual bleeding. Anecdotal evidence from medical practitioners and women might suggest that combined oral contraceptives could be beneficial as a number of women report lighter menstrual bleeding whilst taking combined oral contraceptives. Given that the average age of women seeking treatment for heavy menstrual bleeding is over forty, combined oral contraceptives are going to be contra-indicated on the basis of thromboembolic risks and so it is not a practical option for

the majority of women on that point alone, regardless of the lack of evidence base to recommend it as a treatment. More research is needed into the effects of combined oral contraceptives on heavy menstrual bleeding.

2.5.3 Injected progestogen

The use of a long acting injected progestogen has been suggested by NICE (2007) as a third line treatment for heavy menstrual bleeding due its action in preventing proliferation of the endometrium. It has a contraceptive effect and no effect on future fertility.

2.5.4 Norethisterone

The use of norethisterone has been suggested by NICE (2007) as a third line treatment for heavy menstrual bleeding with efficacy related to prevention of proliferation of the endometrium.

Cyclical progestogens (norethisterone) have been found to be less effective in the treatment of heavy menstrual bleeding than tranexamic acid and LNG-IUS (Lethaby, Irvine and Cameron 2007a). In addition to this finding a significant number of women found the treatment unacceptable due to the side effects noted above. Lethaby *et al.* (2007a) suggest that norethisterone has a limited short-term role in the treatment of heavy menstrual bleeding.

2.5.5 Levonorgestrel containing intrauterine system (LNG-IUS)

The use of LNG-IUS has been recommended by NICE (2007) as the first line treatment for heavy menstrual bleeding. It reduces menstrual bleeding by preventing proliferation of the endometrium due to the slow release of progesterone directly into the uterine cavity. It is an effective contraceptive that has no long-term effect on fertility. It has been suggested that treatment with LNG-IUS results in an improvement in quality of life and

sexual functioning (Bastianelli, Farris and Benagiano, 2011). This was a small quantitative study assessing 156 women, so although statistical analysis was used, the sample size is too small to obtain statistical significance, so it may not be appropriate to extrapolate these results to the general population. Indeed when LNG-IUS is compared to hysterectomy a small randomised controlled trial has shown that LNG-IUS does not have such a positive effect on sexual functioning (Halmesmaki, Hurskainen, Teperi, *et al.* 2007).

A small randomised controlled trial compared outcomes for patients who were treated with LNG-IUS and those treated with thermal balloon ablation (Shaw, Symonds, Tamizian, *et al.* 2007). The main outcome measures were determinants of reduction in menstrual blood volume using pictorial blood loss charts scores, with haemoglobin and serum ferritin also being monitored for nine months. In addition data was collated on hysterectomy rates at two years post treatment. Both LNG-IUS and thermal balloon ablation did significantly reduce menstrual blood volume with the greatest effect seen in the LNG-IUS group. However at two years more women were seeking alternative treatment from the LNG-IUS group (39.8% compared to 23.1% in the ablation group) with prolonged or irregular bleeding being the most common reason for discontinuing LNG-IUS. There were also higher rates of hysterectomy in the LNG-IUS group (20.7% compared to 13.3% in the ablation group). Although the sample size in this study was small, the findings raise issues about the acceptability of the side effects of LNG-IUS and it will be interesting to compare these findings with the much larger ECLIPSE Trial when it is completed. These findings concur with another small clinical trial (Soysal, Soysal and Ozer, 2002).

When compared to norethisterone, LNG-IUS was significantly more effective in reducing heavy menstrual bleeding (Lethaby *et al.* 2005b). Short term side effects were higher in the LNG-IUS group but women were more likely to continue with the LNG-IUS treatment. There is evidence to suggest that LNG-IUS is well tolerated and seen by women as a long term option, with 87.9% of premenopausal women deciding to use a second device after the first five year LMG-IUS had expired (Lete, del Carme Cuesta, Marin, *et al.* 2011).

There is also some question among health professionals around the use of LNG-IUS for nulliparous women due to difficulties with fitting the device. Research has suggested (as have the manufacturers of LNG-IUS) that it is appropriate and practical to fit LNG-IUS in nulliparous women, but that more local anaesthesia may be useful (Bahamondes, Hidalgo, Bahamondes, *et al.* 2011).

2.5.6 Surgery

Surgical options for the treatment of heavy menstrual bleeding with no uterine abnormality are suggested to be a last option, following the unsuccessful attempt to treat the condition with one or possibly two medical treatments (NICE 2007). Surgical options are either hysterectomy or endometrial resection or ablation. The research evidence to date would suggest that surgery; particularly (and unsurprisingly) hysterectomy reduces heavy menstrual bleeding more than standard medical treatment (Marjoribanks, Lethaby and Farquhar, 2005). Endometrial resection has been found to be more effective at reducing heavy menstrual bleeding than oral medication with fewer side effects at four months. The surprising findings to emerge from the Cochrane review written by Marjoribanks *et al.* (2005) is the fact that there was no significant differences found in satisfaction with treatment or quality of life between surgery including

hysterectomy, which is a major operation, and treatment with LNG-IUS. At present there is a lack of evidence regarding long term comparisons between medical and surgical management of heavy menstrual bleeding as long term follow up of clinical trial participants is challenging.

When endometrial ablation is compared to hysterectomy again the greatest improvement in health domains such as energy, pain, and general health, is seen in women who undergo hysterectomy although adverse events were more likely following hysterectomy (Lethaby, Shepperd, Farquhar, *et al.* 2009). Again the evidence relating to quality of life reported no difference between surgical groups and similar satisfaction rates (Lethaby *et al.* 2005a), possibly due to the fact that although hysterectomy is a more invasive intervention it does provide a permanent solution. There was more likelihood of the need for repeat surgery following ablation and this did impact on the cost difference between the two procedures over the long term.

For women who are considering surgical options the information regarding this treatment option must be carefully delivered as this treatment option has an irreversible effect on fertility. Communication within the bounds of a consultation is generally challenging due to the doctor – patient dynamic and also due to the constraints of the system itself. Although the majority of women are reportedly happy with their decision to undergo surgery a small minority of women reported shortcomings in the decision making process and doubts about the appropriateness of the hysterectomy that they had already had (Skea, Harry, Bhattacharya, *et al.* 2004). This study also raised the issue that some of these women had given a positive response to a patient satisfaction questionnaire and these concerns were only expressed during a post-operative interview. This is an important finding when considering the methodology used for future research into

patient satisfaction and experiences of treatment. Clearly there was different information to be gained from a qualitative interview study than the quantitative questionnaire results suggested and this would suggest that for exploration of complex issues such as decisions to proceed to hysterectomy, interviewing might be the most appropriate method of data collection.

The relationship between psychological distress or anxiety in women who present with heavy menstrual bleeding has been documented (Shapley *et al.* 2003a) and given the anxiety surrounding decision making regarding surgery highlighted by (Skea *et al.* 2004) it is interesting to see the impact of surgical treatment on anxiety and depression. In a prospective cohort study 59% of women undergoing endometrial ablation for heavy menstrual bleeding were found to have clinically significant anxiety or depression (psychiatric morbidity) (Wright, Gannon, Greenberg, *et al.* 2003). One year following ablation only 21.8% of women in this study still had significant psychiatric morbidity. The women who had the best psychiatric outcomes were those who had a measured menstrual blood loss greater than 80ml or low pre-operative psychiatric morbidity. Low menstrual blood loss pre-operatively was associated with poorer psychiatric morbidity post-operatively. These findings concur with the earlier work of Wright, Gannon and Greenberg, (1996) who suggested that endometrial ablation might provide better psychological outcomes than hysterectomy.

2.6 Preferences regarding medical management of heavy menstrual bleeding

Several studies have found that many women who require treatment for heavy menstrual bleeding have predetermined expectations and preferences for a particular treatment (Vuorma *et al.* 2003, Sculpher *et al.* 1998, Coulter *et al.* 1994). With the current treatment evidence base built upon a small number of trials with relatively small sample sizes no one particular treatment can be said to be better than the others in all cases. Due to the individual experience of this condition and expectations of treatment, women's preferences and choices should be taken into account when decisions about treatment are being made (Protheroe 2004). Expectations and preferences appear to be influenced by diverse factors such as employment status as well as severity of symptoms (Vuorma *et al.* 2003, Warner, 1994, Coulter *et al.* 1994). Moreover, they may reflect contraceptive preferences, attitudes to hormonal treatments, 'the pill' or 'coil' and the presence of other symptoms such as menstrual pain. Individual expectations about treatment prior to consultation have obvious implications in discussing treatment options. The publication of a numbered ranking system for treatment (NICE 2007) does not take patient preferences into account and this may well lead to problems with concordance and therefore efficacy of treatment.

A survey conducted in Hong Kong sought to elicit women's knowledge and preferences surrounding treatment for heavy menstrual bleeding. 62% of the women recruited from a gynaecology clinic returned their questionnaire (n=200); of those 90% had limited knowledge of treatment options (Leung, Ng, Tam, *et al.* 2005). Medical management was by far the most preferred initial treatment option (87%) and in contrast to similar data

from European research (Vuorma *et al.* 2003), none would consider hysterectomy as an initial treatment option, a reflection of different cultural attitudes towards surgery in general perhaps. If the initial medical treatment was not effective LNG-IUS was a popular preferred option (53.6%), with 19% reporting a preference for endometrial ablation, 16% declining any further treatment and only 5% reporting a preference for hysterectomy. It would be interesting to compare hysterectomy rates between a hospital in Hong Kong and a hospital of similar size in the UK to see if the Chinese women's desire to avoid surgical intervention is reflected in the numbers of hysterectomies performed for heavy menstrual bleeding. Unfortunately data on hysterectomy rates in China is not available. The vast majority of women in this survey sought a normal menstrual period not amenorrhea. As this was a quantitative study the researchers could not explore the relationship between the desire to avoid surgery (retaining the uterus) and to seek a normal period and perceptions of fertility and womanliness in Chinese culture.

Cooper, Grant and Garratt (1997) assessed the use of a partially randomised patient preference design along side a randomised controlled trial to evaluate alternative treatments for heavy menstrual bleeding. The main treatments compared were endometrial resection and medical management, with the main outcome measure being the Short Form 36 and clinical outcomes. More women participated in the patient preference design with equal proportions of women randomised in both the randomised controlled trial and the patient preference design. The implications of the uneven samples might be that large numbers of women may have developed a treatment preference before joining the trial. Partial randomisation may not have reduced the impact of preference as a confounding factor in the analysis process. Women who had a preference

for medical management had less previous experience of treatment and better general health and their menstrual bleeding had less of an impact on their lifestyle. Those women who preferred surgical options had all tried medical treatment previously and had higher bleeding scores. For women who had chosen medical treatment there was higher degree of satisfaction and willingness to continue with their preferred treatment than those who were allocated to medical treatment. Interestingly satisfaction rates were highest following endometrial resection, whether it was the preferred or allocated treatment.

When treatment preferences have been examined, hysterectomy and conservative (including no) treatment have been equally preferred (Vuorma *et al.* 2003). Preference for hysterectomy was associated with a completed family, pain and irregular menstruation and age. In addition women who had a preference for hysterectomy were also more likely to have a lower education level, be unemployed and have consulted a gynaecologist in a secondary care setting. The influence of clinical signs and fertility are unsurprising however it is of concern that this study also suggested that socioeconomic factors and the setting at which the consultation took place was more influential in the development of a preference for hysterectomy. In addition this study found that half of study population had not received any previous treatment for heavy menstrual bleeding.

The impact of a decision aid booklet on treatment outcomes and costs over twelve months was evaluated in a randomised trial and cohort study in Finland (Vuorma, Teperi, Aalto, *et al.* 2004). All participants in this trial had an improvement in health related quality of life, and clinical signs with improvement in anxiety and psychosomatic outcomes also noted following medical and surgical treatment. There was however no improvement in

sexual health. When the intervention group was compared to the control group small differences were recorded, the intervention group having more frequent courses of treatment and less indecision about treatment choices, but these were not statistically significant. In terms of cost, including costs related to absence from paid employment, the intervention group had significantly lower costs over twelve months but no difference in terms of cost of treatment. The authors concluded that the use of a decision aid booklet did not increase the use of health services or treatment cost, or improve the health outcomes or satisfaction with treatment. It is interesting to consider whether the intervention, which in this case was knowledge about heavy menstrual bleeding and treatment options, did have an effect on women's ability to cope psychologically or otherwise at work. This could possibly explain the lower productivity costs in the intervention group.

2.7 Most appropriate place for treatment; primary or secondary care

Heavy menstrual bleeding has been successfully treated both in the primary care and secondary care setting with geographical variation in the medical practitioners preferred management setting.

Julian, Naftalin, Clark, *et al.* (2007) developed a specific pathway that was designed to better integrate the services offered by the primary and secondary care setting when considering the management of heavy menstrual bleeding. The general practice led model of integrated care; the Bridges pathway, when compared to a consultant led one stop menstrual clinic was found to significantly reduce outpatient attendance, with an improvement in the quality of the patient's experience. There were no differences in surgical or medical treatment rates indicating that quality of

care was maintained and no difference seen in the use of appointments in the primary care setting.

The results from this study are in contrast to the earlier findings of the Somerset Morbidity Project (Grant, Gallier, Fahey, *et al.* 2000) that suggested a significant correlation between referral to secondary care and operative management in spite of effective management in primary care. The difference in the findings of these two studies may reflect individual variation between primary care setting and individual medical practitioners, something that the publication of National Institute for Health and Clinical Excellence has sought to address with the publication of Guideline 44 Heavy Menstrual Bleeding (NICE 2007) by publishing a care pathway standardising medical treatment options for use in both primary and secondary care.

Approximately one third to half of women who are referred to the secondary care setting (gynaecology outpatients clinic) seeking treatment for heavy menstrual bleeding request hysterectomy (Echlin, Garden and Salmon, 2002). These women tended to describe their clinical symptoms as catastrophic, including the impact on daily life, criticism of previous treatments or possible future treatment options. They often sought corroboration from others who had attended the consultation with them. These emotive consultations were more likely to result in a decision to proceed to surgery; an option influenced largely by the women's mode of communication rather than the gynaecologists themselves. The conclusions reached by Echlin *et al.* (2002) have been questioned due to the fact that the consultations that were transcribed were predominantly between women and trainee gynaecologists. Only one of the 59 consultations involved a consultant gynaecologist. The decision to proceed to surgery may have been influenced by the possibility that the consultant was basing

the treatment decision on the clinical signs as reported to him / her by the trainee gynaecologist (Bewley 2003). It is also possible that the women were perhaps aware of the medical practitioners inexperience and became more insistent about their condition in response. The biggest question arising from this study is why were these women not seen by a senior gynaecologist?

Further work on the response of medical practitioners to patient requests for treatment has indicated that medical practitioners in primary care were more likely to prescribe medical treatment or to refer to secondary care for investigation or treatment if the patient 'elaborated' the clinical signs that they experienced. If a patient expressed psychosocial difficulties they were less likely to be prescribed medical treatment or to be referred to secondary care (Salmon, Humphris, Ring, *et al.* 2006). This study also concluded that patient demand for a treatment would not in itself influence the medical practitioners course of action. The contrast between the findings of Echlin *et al.* (2002) and Salmon *et al.* (2006) could be explained by the experience of the medical practitioners, as the primary care medical practitioners could well have been more experienced, or by the assumption by the gynaecologists that women have been referred because the General Practitioner feels that a surgical option may be a more beneficial option in the case of that individual.

The gender of the health professional may influence the experience of consultation for heavy menstrual bleeding. However communication style may be more influential than the actual gender of the health professional, even in the gynaecology setting (Christen, Alder, Bitzer, 2008). When gender is considered alongside ethnicity of the health professional, again gender made very little difference to the satisfaction with the consultation (Babitsch, Braun, Borde, *et al.* 2008). Interestingly Babitsch *et al.* (2008)

assessed satisfaction with the consultation from the health professional's perspective. The findings may have been different if the researchers had asked focused on the patient's perspective.

When medical practitioners who have received specific communication training relating to shared decision making conduct a consultation, the usefulness of that consultation to the patient increases (Longo, Cohen, Hood, *et al.* 2006). This is related to the enhanced communication attributes - specifically the 'doctor listens', easily understood information, shared treatment decision and longer consultation attributes. This trial was conducted in primary care but the findings could be applied equally to the secondary care setting. There is however increasing pressure on medical practitioners due to consultation time constraints relating to the numbers of patients to be seen.

2.8 Cultural and social responses to menstruation

Societal norms and culture impact on women's perception of severity of menstrual disorders (O'Flynn 2006, O'Flynn and Britten 2004, Chapple 1999). When considering the attitudes of young women towards menstruation the societal pressures to conceal menstruation are pronounced, particularly at school (Burrows and Johnson 2005). Girls felt that menstruation was embarrassing and shameful and should remain hidden. In addition the authors found that normal menstruation was construed as an illness, a worrying finding considering the age of the girls from whom this data was obtained (12-15 years of age). The authors suggested that the negativity found was related to physical change and the impact of socio-cultural representations, again the influence of a broader social attitude is reflected on the attitudes of young women.

Stubbs (2008) highlighted the mixed messages contained within menstrual education for young women; that is the fact that menstruation is a normal natural event but it should be hidden. This leads to negative perceptions and shame. Negative early menstrual experiences are also thought to influence the perception of current menstruation and attitudes to menstruation in general (Chang, Hayter and Wu, 2010, McPherson and Korfine 2004). Social and cultural factors have been found to play a part in how menstrual knowledge and understanding is transmitted (Orringer and Gahagan, 2010).

Strange (2001) explored the historical context of discussion of menstruation between the 1920s and 1960s. Before the 1920s the menstruation was seen as pathological and disabling and was cited as a reason why women could not compete with men, particularly in relation to education and employment. Between 1920 and 1970 narrative accounts changed this view suggesting the normal menstruation was not disabling or pathological. However the women who collated these accounts remained tied to the societal norm of discretion about menstruation, which perpetuated the taboo around menstruation (Strange 2001).

The idea that menstruation is bothersome or unclean has been established for a very long time. It is an idea that is reflected in various cultures and is often associated with religious teaching about menstrual etiquette (Rothbaum and Jackson 1990, Ben-Noun 2003). A quantitative study assessing the impact of religious training in Orthodox Jewish Mikvah attenders, Orthodox Jewish Mikvah non-attenders, Protestant and Catholic women found that although religious training relating to behaviour during menstruation was apparent and differed between the religions. The authors tested the hypothesis that the effects of this training would have an impact on menstrual attitudes, expectancies and symptoms and found their

hypothesis to be weakly supported (Rothbaum and Jackson 1990). It is possible that the methodology used in this study may have influenced the quality of the result. The challenge of exploring and understanding the complex nature of the relationships between religion and a taboo subject such as menstruation, is perhaps better suited to qualitative research techniques.

Reference to a menstruating woman being unclean dates back to biblical times. Ben-Noun (2003) examined biblical passages that discussed vaginal bleeding and found clear instructions about hygiene during menstruation or 'pathological' vaginal bleeding. Sexual intercourse during menstruation (and for seven days before and after) was forbidden, as the woman was 'unclean'. It would be interesting to see if abstinence during menstruation is still practiced by women today.

The concealment of menstruation is known to have an impact on seeking treatment for endometriosis as well as heavy menstrual bleeding. Seear (2009) highlighted the reluctance to disclose menstrual problems as a significant (and neglected) factor in seeking treatment for endometriosis in twenty Australian women. That author suggested that concealment of menstrual problems may have been more influential in delaying seeking treatment than difficulty distinguishing between normal and abnormal menstrual cycles. It is possible that the concealment and non disclosure of menstrual problems influences women's ability to recognise abnormal menstrual bleeding and then has a further impact on the decision to speak out and seek treatment.

One step further is the idea of menstrual suppression (continuous use of medication to achieve amenorrhea) put forward by the pharmaceutical industry and a small number of the medical profession. There has been clinical rationale for menstrual suppression published (Lin and Barnhart

2007) in which the authors state that not only would menstrual suppression be of benefit for women with menstrual disorders but that the 'elimination' of the menstrual cycle would be an attractive option for many women with active and busy lifestyles due to greater convenience. A study examining the discourse surrounding menstrual suppression in the lay press in which twenty two articles published in America and Canada were analysed, indicated that menstrual suppression was not only advocated for women with menstrual disorders but also generally for convenience (Johnston-Robledo, Barnack and Wares, 2006). The lay press described menstruation as unhealthy and unnecessary as well as messy and inconvenient, with advocates of menstrual suppression being quoted twice as often as opponents. The authors concluded that coverage of menstrual suppression in the articles studied was biased and insufficient and that this reinforced both the medicalisation of normal female physiology and the concept of menstruation as a distasteful taboo to be concealed from society.

Young women are more likely to have higher levels of critical thoughts about their bodies, both in terms of closer surveillance and increased shame than men (Rees, 2007). In a qualitative study, (Rees, 2007) female medical students were less likely to have a positive attitude towards peer physical examination and were more likely to feel objectified and fear critical or teasing comments from the opposite sex than the male medical students. This is thought to be due to objectified body consciousness; a feminist theoretical concept in which men and women experience their bodies differently, possibly related to the portrayal of the 'perfect female' in popular culture. These findings concur with earlier work on the relationship between objectification of the female body and the media portrayal of feminine beauty (Roberts and Waters 2004). The authors suggested that in

a sexually objectifying culture, menstruation, above all other bodily functions should be concealed and controlled. This could be related to the commonly expressed view that women should not be sexually active during menstruation, a concept that has a biblical origin but has not been explored in the modern context in the literature to date.

Women in many cultures experience menarche as a rite of passage from childhood to adulthood (Estanislau do Amaral *et al.* 2011 {research conducted in Brazil}) and the rite of passage have positive associations in that culture. Both Roberts and Waters 2004 and Estanislau do Amaral *et al.* 2011 agree that the women's focus is on body changes and image, however in contrast to the Brazilian study, most of the women in the western study were unhappy with the changes they were experiencing and the different status that menarche brought. The key difference between the two study populations appears to be the amount of knowledge that the women had prior to first menarche. Christler and Zittel's (1998) and Estanislau do Amaral *et al.* (2011) suggest that the provision of information and support from the mother of the menstruating girl made the difference between a positive experience and a negative one and that this coloured the woman's experiences of menstruation for the rest of their menstrual lives. Whilst Christler and Zittel's 1998 study population described feeling fear, anxiety and embarrassment, there were also feelings of pride, happiness and being more valuable, mature and more beautiful.

In India women may be subject to many cultural and social practices and restrictions during menstruation. Kumar and Srivastava (2011) conducted a mixed method study exploring cultural, religious and social beliefs with 117 young women and 41 mothers from a range of urban and rural settings. They found that young women were not well informed about

menstruation and this impacted negatively on their experience of menarche. Restrictions during menstruation were many and varied according to religion, socio-economic status, and education and family background. For example Muslim women were not permitted to touch religious books and Hindu women were restricted from religious practice during menstruation. In a wider social context most women refrained from cooking and attending to guests; the inference being that a menstruating woman is unclean or impure (Kumar and Srivastava 2011). For many women restrictions made menstruation unwelcome. Interestingly education reduced the restrictions on menstruating women. The authors suggested that improving understanding of menstruation would improve the health and well being of young Indian women, particularly those living in rural areas.

There is a paucity of published research exploring ethnic variation in the western context. One study, that included 13 women of South Asian origin, suggested that cultural perceptions of heavy menstrual bleeding in South Asian women may lead to reluctance to request treatment and higher levels of iron deficiency anaemia in this population. Beliefs included positive views of heavy menstrual bleeding as menstrual blood is thought to be impure, reduced menstrual blood loss is thought to increase abdominal weight gain and menstrual pain. In addition cultural beliefs around dietary intake compound the effect of heavy menstrual bleeding, as certain foods should be avoided if menstrual blood flow is heavy. Communication is another important factor for South Asian women with very few medical practitioners speaking their language and interpretation often done by family members. There is also a reluctance to discuss menstruation with a male doctor (as is the case for the majority of women regardless of ethnicity) and this barrier to communication is increased if

the interpreter is also male. (Chapple 1998, Chapple, Ling and May 1998). Chapple (1998) highlighted the need for more understanding of ethnic variation in perceptions of heavy menstrual bleeding. Whilst this study gives valuable insight into cultural variation it is limited by the small sample size and the relationship between the participants. It would be useful to follow up on the findings of this study with a wider sample, perhaps exploring South Asian menstrual culture in more depth or exploring a range of ethnicities and the impact of living in a western country on traditional menstrual beliefs. Some other cultures also believe that heavy menstrual flow is healthy and delay seeking treatment for heavy menstrual bleeding for this reason (Haththotuwa, Goonewardene, Desai *et al.* 2011).

Prior to examining the women's perspectives the perceptions of General Practitioners were also examined by Chapple *et al.* (1998) with specific reference to women of South Asian descent. This study found that GPs were aware of the possibility that South Asian women might be more at risk of anaemia due to heavy menstrual bleeding. The perception of GPs was that the gender of the medical practitioner and interpreter, both in the primary and secondary care settings, would be a factor in the reluctance to seek treatment. Male GPs were found to be unable to obtain consent for internal examinations and so would refer to secondary care if there were no female GPs at the practice, where the lack of female gynaecologists would present the same problem. Anecdotal evidence would suggest that the gender of the medical practitioner is sometimes a barrier for women regardless of their ethnicity and an increase in the number of female medical practitioners both in primary and secondary care settings would help communication on this complex condition.

3.0 Introduction

This is a qualitative longitudinal interview study nested within a randomized controlled trial, designed to explore heavy menstrual bleeding from the women's perspective.

3.1 Aim

To explore, and enhance understanding of the experiences, decision making and impact on quality of life of women receiving medical treatments for heavy menstrual bleeding.

3.2 Objectives

1. To explore and develop understanding of women's experiences and expectations of medical treatments for heavy menstrual bleeding.
2. To explore women's views, beliefs, attitudes and decision making relating to treatments for heavy menstrual bleeding, including treatment preferences, how they may change over time and why.
3. To explore women's perspectives on indicators of quality of life in the context of heavy menstrual bleeding and the effects of treatment on their symptoms and quality of life.
4. To explore potential cultural variations in women's experiences, contexts and decision-making in relation to medical treatments for heavy menstrual bleeding.

3.3 Design

Qualitative study with purposeful sample of women accepting or declining different medical treatments recruited from the ongoing ECLIPSE Trial, generating data by series of semi-structured interviews, with grounded approach to data analysis.

3.4 Ethical approval and safety of participants and researcher

Ethical approval was sought from the Multi-Centre Research Ethics Committee and this was granted in July 2008. In addition approval was sought from each primary care or hospital trust's Research Governance officer in order to comply with each area policy. These consents were granted July 2008 and August 2008. At all times the rights of the individual interviewees were acknowledged and respected and the detailed consent forms were designed to reflect this. The study researcher was careful to remain objective and neutral when recruiting women and collecting data. In all cases anonymity was maintained with only the interviewer aware of the identity of the woman on each digital recording. All files and information either paper or digital were securely stored as per ethical approval.

Procedures were put in place to minimize harm to participants. These included the development of a comprehensive participant information sheet (Appendix IV on page 258) detailing the study and the participants' course of action in the event of a complaint. The information was given to women more than twenty-four hours before verbal consent to visit was obtained. Written consent to participate in the interviews was only obtained after discussion of the participant information sheet and the research process. Care was taken to try to ensure that no participant was under the influence

of medication or alcohol when consenting to participate in this study. In one case the interview was rescheduled as consent could not be obtained, as the participant had taken morphine-based analgesia for knee surgery and was drowsy. In one other case the interview was stopped to protect both participant and researcher as family members began to smoke an illegal substance in the house during the interview.

The researcher was aware of the possibility of raising emotional issues during the interviews so a small leaflet was prepared detailing some women's support groups and sources of health information such as NHS Direct. These were handed to participants as deemed necessary. Care was taken to provide a safe and private interview environment with careful negotiation of the presence of partners or others in the room at the time of the interviews. If a partner insisted on being present then prompt questions were tailored to suit the reactions and behaviour of both the participant and the attending partner. In two cases interviews were rescheduled by women at their request for times when their partners would not be present. The women's safety and comfort were considered paramount.

Interviews were conducted at various times of the day, evening and weekends to fit in with the women's schedules. This flexibility on the part of the researcher enabled women to feel much more relaxed during the interviews as they had chosen a time when they were least likely to be interrupted or disturbed. There is no doubt that the quality of the data obtained was positively influenced by this. The safety of the researcher was compromised by this arrangement with travel to and from interviews being undertaken at night. A safety sheet was drawn up for each interview, with addresses, contact details and expected times of arrival and departure listed. This was retained by one designated member of the research team

and formed part of a system of checking in order to promote researcher safety. Following the safe departure of the researcher from each interview these records were destroyed.

Verbal consent was obtained from women at the end of the first interview to contact them in due course to arrange a second interview. For those who consented (the whole sample of twenty-seven women) this contact was limited to five attempted phone calls plus five attempted email contacts in order to prevent participants feeling harassed. Follow-up interviews were arranged within one phone call for all participants with three exceptions, two of whom had five attempts at contact via telephone and email. There was one exception to this as one participant had disclosed a history of domestic abuse and made clear that she may move house during the study period without leaving contact details. Only two attempts to contact her were made (one phone and one email).

3.5 Sampling

A purposeful sample of women willing to participate in this study was selected from women consulting health professionals about heavy menstrual bleeding who have been identified as eligible and approached for inclusion to the ECLIPSE trial, and who have subsequently agreed to be randomized to treatment arms or have declined to participate in the trial because they had a strong treatment preference for a particular medical treatment, which they have then been prescribed.

Sampling included women of varying demographic (age, social and educational background, ethnicity) experiencing different medical treatments for heavy menstrual bleeding, of differing treatment duration, seeking a purposeful range (Mason, 1996) of respondent characteristics

and contexts in relation to the study objectives. Two sample matrices was designed at the project planning stage in order to assess the possible number of women who might need to be interviewed in order to capture as many of the treatment and experience variables as possible (see Appendix II on page 253).

From the literature published to date, it was suggested that age, ethnicity and parity have a strong influence on women’s experience of menorrhagia and expectations for treatment. The experience of treatment will also be strongly influenced by the treatment itself and whether that was the choice of the patient, of both the patient and clinician together or a random choice as in the case of women participating in the randomised controlled trial. As many of the recommended treatment options for menorrhagia have a contraceptive effect then parity is likely to be influential particularly amongst those women who decline randomisation.

Purposeful selection criteria

<i>Primary criteria</i>	<i>Secondary criteria</i>
Age	Employment status / education
Ethnicity	Treatment duration / change
Treatment prescribed	Life events / transitional stage
Treatment preference	Relationship status
Parity	

Other variables that may be influential include education and employment. However life events such as completing a family, children starting school or leaving home, a change within a significant relationship may be more influential on attitudes and decision-making than has been previously

thought. For this reason it would be important to conduct second interviews with women who may discuss transitional events during the first interview to consider how the perception of treatment efficacy changes over time. In terms of relationships, it is not just the relationship with a husband or partner but also the relationship with female family members, such as mothers, sisters and daughters, who may also have experienced heavy menstrual bleeding or the treatments offered, such as the LNG-IUS. Their experiences may well have an impact on the views of the sample selected. This kind of information is not available prior to obtaining consent to interview so has not been included in the sample matrix.

When recruitment began the sample matrices shown in Appendix II on page 253 proved to be unwieldy and so a much simpler sample matrix was devised as shown below. This matrix aimed to capture simply the range of treatment options available and key variables such as age, ethnicity and parity.

Characteristic or treatment option	Number of women
LNG-IUS	5-10
Tranexamic acid	5-10
Oral contraceptive	2-3
Contraceptive implant	2-3
Noriheterone	1-2
Ethnic minority background	2-4
Nulliparous	2-4
Age under thirty five years	2-4

Figure 1 Sample matrix used to aid purposeful selection

In addition the demographics of the sample populations for both the randomized controlled trial and the interview study were tracked and compared to ensure that they were comparable when it came to drawing conclusions. As recruitment continued participants were selected under two main criteria; firstly the range of treatment options recommended by NICE and RCOG was captured within the sample population and secondly that each interviewee would add a different angle to the findings already emerging from ongoing analysis. In this way comparison could be made constantly with findings either validated or refined throughout the data

collection process. Women were considered under the following inclusion criteria; aged between twenty-five and fifty years, seeking treatment for heavy menstrual bleeding, and not intending to become pregnant within five years. Exclusion criteria included the presence of any significant pathology, for example gynaecological carcinomas and if a woman was unable to give informed consent. These criteria matched the inclusion and exclusion criteria for the randomized controlled trial running concurrently. As the study progressed and descriptive themes began to emerge deviant cases were sought and this was a particularly important phase of testing and refining the conceptual model.

3.6 Recruitment & consent

Access to participants was through GP practices and gynaecology clinics participating in the ECLIPSE trial. Once ethical approval had been granted for the interview study, each of the 134 ECLIPSE Trial collaborating GPs and Gynaecologists was visited by a member of the ECLIPSE Trial Management Team to deliver up-to-date trial and qualitative study documentation and to teach collaborators about the interview study recruitment process. This was facilitated by means of posters (see Appendix III on page 257) and one to one training relating to the documentation specific to the interview study. Practitioners identified potential participants at the time that interest in participation in the ECLIPSE trial was discussed, and trial participation accepted or declined. Permission was sought to pass contact details to the study researcher (part of the trial research team) by the use of the Consent to Contact form (see Appendix V on page 263). The qualitative study was rolled out in the final year of the recruitment phase of the ECLIPSE Trial (RCT), when more than 80% recruitment to the RCT had been achieved. There were approximately

one hundred women recruited to the ECLIPSE Trial during the qualitative study recruitment process. It is not known how many women were asked about participating in the interview study, as records were not kept of women who declined to complete the Consent to Contact form. All collaborators were trained to ask women about the interview study, but the returned Consent to Contact forms indicated that some collaborators made more effort to recruit than others. This was also the case when recruiting to the RCT.

There were advantages and disadvantages to nesting this qualitative study within the ongoing ECLIPSE Trial. The major advantage was access to the established framework of GPs and gynaecologists who were ECLIPSE Trial collaborators. This provided a network of doctors that were interested in understanding heavy menstrual bleeding and motivated to identify potential study participants via the Consent to Contact form. The ECLIPSE Trial collaborators covered a very large geographical area and so were able to identify potential study participants from diverse backgrounds with different demographic characteristics. The framework of the ECLIPSE Trial also gave this study credibility and support with administrative tasks such as printing of study documentation.

There was only one major disadvantage to nesting this study within the ECLIPSE Trial and that related to the recruitment of women from a variety of ethnic backgrounds. Recruitment to the study was restricted to women who presented to the ECLIPSE Trial collaborators requesting treatment for heavy menstrual bleeding. Fewer women from ethnic minority backgrounds presented seeking treatment, which in turn reduced the ethnic diversity captured in this study sample population. As this study was nested within the ECLIPSE Trial the researcher could not use snowballing or other targeted techniques to specifically recruit women of diverse ethnicity. This

then limited the amount of data relating to the effect of ethnicity on women's experiences of heavy menstrual bleeding.

A total of fifty-two Consent to Contact forms were received and all of these women were contacted to discuss their participation in the interview study. One woman was ineligible, as within one month of her consultation she had undergone a hysterectomy as a private patient. During the first three months of the recruitment process six women declined to participate in the interview study, as they had not fully understood what participation in the study would mean to them. This identified a retraining need in two of the GP practices and one of the secondary care clinics from which the potential study participants were drawn. Following retraining of these collaborators this problem ceased to occur and the remaining forty-five women who signed the Consent to Contact form were all willing to be interviewed. From the forty-five, twenty-seven were finally selected according to the criteria outlined above. The other women were all telephoned and thanked for their interest.

The study researcher sent study information via a patient information letter and verbal consent was obtained to visit the participant in order to conduct an interview. Text was found to be a useful means of communication with several women and email was also popular but most contact to arrange the interviews was conducted by telephone. Discretion was always maintained with the women being offered a more convenient or appropriate time for telephone contact. Over the course of the study period most telephone contact was conducted in the evenings or at weekends as the majority of the women worked during office hours.

On arrival at the participants home time was allowed for questions and conversation to establish the women's understanding of the research process and study participation. Only if both researcher and participant

were satisfied with each other's understanding of general research process and specifically the interview process was written consent to participate obtained using the Consent Form (Appendix VI on page 264). On one occasion the interview had to be rescheduled as the potential interviewee had taken prescription medication (analgesia) following knee surgery and the researcher felt that true informed consent was not achievable due to the slight drowsiness of the potential participant. An alternative date was agreed for one month later and this woman was then able to give full informed consent.

3.7 Data generation and analysis

In addition to qualitative interview data, sample characteristics data was also collected. This data aimed to ensure that the sample selected reflected a wide range not only of general demographic characteristics but also of different treatments and outcomes. The tool used to collect the demographic data was a questionnaire that the interview participants completed themselves and can be seen in Appendix VII on page 265. This questionnaire was designed to be simple and quick to administer and so tick box options were included for information such as education and ethnicity. The section on ethnicity was designed with reference to the British Census (Office of National Statistics 2001) as this has been an established framework for collecting data relating to ethnicity in previous qualitative studies.

Information was collected on age, parity, occupation, education, ethnicity and marital status on the proforma. This information gathering was done at the beginning of each interview as the researcher found that giving the interviewer the form to complete after gaining written consent created a

'beginning' to the interview process. The proforma was handed to each participant to complete themselves and this gave the researcher a few minutes to prepare the physical equipment for the interview ahead. The proforma was then filed with the consent form in an envelope before beginning the interview proper. The approach described above allowed the researcher to have a few minutes to observe the participant and prepare the recording equipment. Once this form had been completed the interview process moved into a more informal phase and conversation flowed much more freely. Filing the demographic form away coincided with a change in both the interviewer and the participant's body language and conversational flow and this was recognised as a cue for deeper engagement between the two.

This is in contrast to other published qualitative work when demographic data was collected at the end of the interview process (Cluett and Bluff 2000) but suited the personal style and 'ice breaking' techniques of the researcher involved. It also lengthened the time between meeting the participant (usually for the first time at the first interview) and beginning the digital recording; a point that was sometimes associated with nervousness on the part of the interviewee in the early interviews. Introducing the proforma early and allowing the participant to complete the form themselves did not have a negative impact on the quality of demographic data collected, with all participants completing all fields. An assumption was made by the researcher that all fields were answered honestly.

Semi-structured face-to-face interviews were conducted at respondents' convenience. A pilot study was conducted prior to commencing this study with volunteers who had experienced heavy menstrual bleeding. In keeping with grounded theory methodology the initial literature review was brief

and so the pilot study was performed with the aim of developing a topic guide for the qualitative study. Four interviews were conducted with four volunteers in order to develop and refine a topic guide before commencing the qualitative study. The data from these interviews was not included in the study findings. In addition the pilot study provided an opportunity to identify the strengths and weaknesses of the researcher particularly relating to interview techniques and led to further training on in-depth interviewing before the qualitative study commenced. The pilot study also allowed the researcher to explore her personal attitudes and beliefs about heavy menstrual bleeding and increased researcher reflectivity and objectivity.

Disclosure of the researcher's background and expertise was limited to a brief description of professional nursing and midwifery qualifications and experience with direct reference to her role on the qualitative study. Personal information was not included. If the interviewee asked a direct personal question this was answered honestly but very briefly and techniques used to deflect the interviewee from asking further personal questions of the interviewer. In several interviews it became apparent that the interviewee had made assumptions about the researcher (usually relating to having experienced heavy menstrual bleeding personally). In these cases the researcher remained neutral, neither confirming nor refuting the assumptions made and again using deflective techniques to return the focus of the interview back to the participant. Some interviewees asked for explanation or advice during the interviews. If the interviewee required a simple explanation of an aspect of heavy menstrual bleeding or their medication then this was given following the interview. If the interviewee asked for advice on further treatment or a professional opinion this was declined. The researcher did not offer any advice during

the interviews or throughout the study period and referred the interviewee back to their health professional.

The topic guide used for the first interviews can be seen in Appendix VIII on page 267. This topic guide was utilized throughout the data collection although questions were adapted to suit the communication style of each interviewee. The order of the questions asked was altered in response to the flow of each woman's narrative with an individualised natural order becoming apparent during each interview. Interviews were conducted in the respondent's home unless preferred elsewhere by respondents. None of the interviewees requested an alternative venue and so all interviews were conducted at the interviewees' homes on a date and time to suit them. The researcher remained flexible about working hours and a significant number of interviews were conducted during evenings and weekends. Provision was made for interviews to be conducted in the participant's mother tongue via an interpreter, but this service was not required.

Where possible, two interviews were conducted with each participant. The first interview was conducted within three months of the initial medical treatment, and a second interview between twelve and eighteen months following commencement of treatment. The purpose of a second interview was to explore changes in experience, views and decision-making that may have occurred during the treatment process over time. Of particular interest were those patients who have requested or undergone a change of treatment from their initial allocated treatment plan. It was anticipated that varying the interval at which participants were interviewed would allow for the possibility of collecting data on the experience of a change of treatment contemporaneously and this did happen in several cases. This enabled the researcher to capture more detailed information about the reasons behind the decision to change their treatment whilst it was still recent and well

remembered. This second interview was also conducted in the participant's home.

Interviews were digitally recorded and transcribed verbatim. Some professional administrative support was utilized during the transcription process with the agreement of the study team and project supervisors. Each transcription was checked on completion in its entirety by listening to the whole digital recording at the same time as reading the transcription by the interviewer to ensure complete accuracy of the verbatim transcription. This approach enhanced the understanding and familiarity of the researcher with the data prior to coding. The subsequent interviews followed broad topic areas based upon the study objectives, using a topic prompt modified and refined following each interview, with participants encouraged to discuss their perceptions and experiences freely. Willingness to be approached again to participate in a second interview was assessed following the first interview. The interviewing researcher also kept contemporaneous field notes, in order to enhance recording of interview context and researcher reflexivity.

Field notes were written both during and immediately following each interview, prior to transcription. The researcher took minimal notes during the interview, only documenting timing of interruptions or of heightened emotion. Each interview was then reviewed via headphones on the same day it was recorded and detailed field notes were written from the brief notes documented at the time. Field notes allowed the recording of many variables not captured on the digital recording. Some of these variables could have influenced the responses of interviewees to certain questions and certainly this was found to be the case in a small number of interviews. The most influential factor impinging on interviewee response was the presence of someone else at the interview, namely their husband

or partner and wherever possible it was suggested to the women that they might be more comfortable without their partner present due to the intimate nature of the discussion. Only one man stayed throughout the whole interview, most left the room a short time after the researchers arrival, once they were comfortable with her presence in their home. When there was a man present during all or part of the first interview the researcher made sure that the second interview was conducted at a time when the woman could be alone. This approach worked well as by the second interview each interviewee was comfortable with the interviewer.

A proportion of women had young children present during the interviews and again the recording of field notes was particularly useful in maintaining the quality of data captured during noise generated by the children. Children themselves did not seem to affect the responses of interviewees, probably due to their youth; most were pre-verbal toddlers, nor did they change the emotional intensity of the interviews, although the interviews conducted with young children present were slightly shorter than those conducted without children present.

Field notes also allowed the researcher to capture emotional responses to questions. As the recorded interviews were reviewed almost immediately following each interview, it was easy for the researcher to recall body language and other non-verbal cues to heightened emotions and document the same. This information was very useful when coding the data as the field notes and transcription together were used to determine the impact of and strength of feeling about the condition and the experience of treatment. In order to maintain confidentiality field notes were written under each interviewee's study number and the notebook stored in the same manner as the interview transcripts in line with ethical approval.

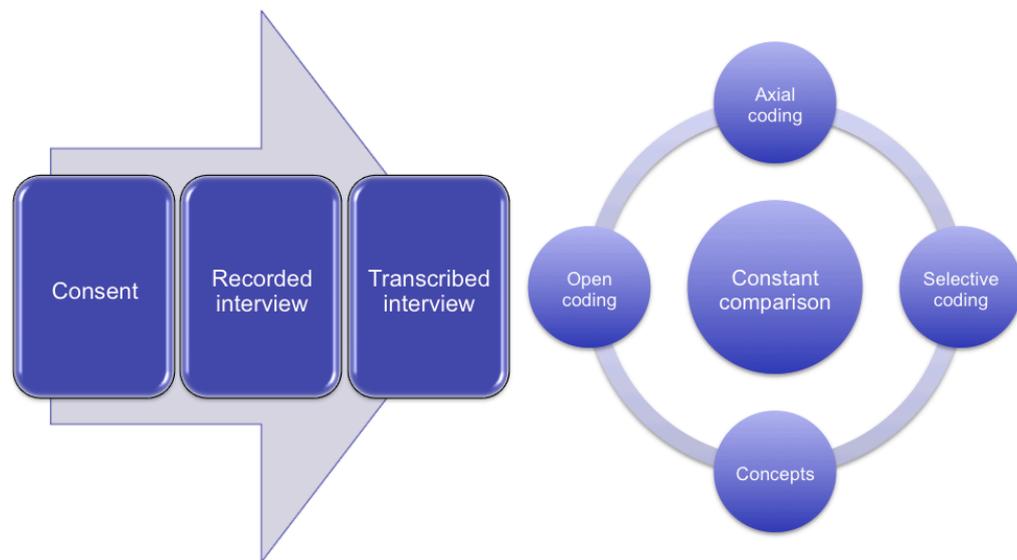
When considering the impact of participating in the study on women's experiences of heavy menstrual bleeding it became apparent that the interview process itself did influence some aspects of experience for some women. A number of women found that having someone to listen to their story had a therapeutic benefit and also clarified their own thoughts and attitudes towards heavy menstrual bleeding. Although the researcher was always neutral and objective, these women had had very little opportunity to talk openly about their condition with anyone, including their health professional in a relaxed setting with minimal time constraints. They were also positively affected by the fact that there was a research project in progress and the knowledge that there were other women who were also coping with heavy menstrual bleeding. The impact could have been reduced by an alternative approach to data collection, for example an anonymous questionnaire but the data obtained would have been far more restricted. It was determined during the protocol development that in-depth interviewing would provide detailed data that could, through a grounded theory approach to analysis allow the researcher to explore this complex condition in full.

A grounded theory approach to data analysis was utilized in this study as this methodology was best suited to the exploration of a complex condition of unknown aetiology and multifaceted impact. In addition previous research has highlighted a number of social and political ideologies impacting on women's experiences of menstruation and of menstrual disorders. The grounded theory approach of gathering emergent theories of social action through identification of analytical categories and the relationships between them enabled the researcher to follow the interviewee's lead and discuss a much broader topic base than was initially suggested by a preliminary literature review. This approach also captured a

holistic perspective, with significant data being defined by the interviewees rather than the researcher. Data was analyzed using constant comparison (Strauss and Corbin 1990) by the study researcher, with research colleagues of different disciplinary and professional backgrounds (namely the project supervisors; a clinical primary care academic and General Practitioner and an academic midwife both of whom have qualitative experience) contributing to development of the analysis and conceptual development to maximize theoretical sensitivity. Figure 2 on page 57 outlines the data analysis process.



Data analysis process



Adapted from Strauss and Corbin (1990)

Figure 2 Analysis process

The coding process was detailed and consisted of open coding of all transcribed data. Data was examined line by line to get as many codes as possible. This initial coding was done using NVivo. Following the open coding of the first five interviews, axial coding began, linking open codes and determining relationships between codes. At this point five core

categories were identified. With further data collection and the addition of abstract and theoretical elements, selective coding drew analytical categories and descriptive themes out of the coded data. Finally the descriptive themes were further analysed to develop the conceptual model by means of constant comparison. Axial and selective coding was aided by application of NVivo software to organize and manage the coded data. Axial codes were set up as tree nodes and the open coded transcripts were imported into the NVivo file. Data generation and analysis were iterative, each informing the other, with the seeking of deviant cases (Mason 1996) and further theoretical sampling and data collection to extend and challenge earlier data and interpretation. This tested the integrity and credibility of the analysis, until no new categories or descriptive themes emerged suggesting theoretical saturation. Examples of open, axial and selective coding can be seen in Appendix X on page 284.

Grounded theory was chosen because this methodology suited the principle of finding out women's perceptions of their condition, in that the researcher approaches the question with an open mind and seeks answers that emerge from the data. This approach kept the voices and experiences of women central to the data analysis process. Although data analysis followed the sequence and methodology described by Strauss and Corbin (1990), situational analysis (Clarke 2005) was also used to develop the conceptual model. Situational analysis is a grounded theory approach that utilizes diagrammatic mapping to further enhance understanding of the social action emerging from the data. The researcher drew a series of situational maps, relating to the descriptive themes for individuals and for the whole sample, which laid out the themes and the relationships between them. Visualizing the findings in the form of diagrams was helpful to the researcher particularly as the amount of data and the number of variables

impacting on women's experiences increased. The use of situational analysis also helped to 'replace' themes within an individual context for each woman and draw out themes that were significant to the majority. Situational analysis helped to define what variables were most likely to be affecting each women's experience of heavy menstrual bleeding and treatment. From these diagrams the researcher was able to draft the conceptual model, which was then tested through ongoing data collection and analysis.

A total of twenty-seven women participated in the first interviews with twenty-four of these also participating in the second interview. No women declined to participate in the second interview but three women could not be traced at twelve months following the start of treatment. Due to the wording of the Consent to Contact forms signed by the study participants the researchers means of contacting these women was limited to telephone, email or address so contact through NHS numbers or medical records was not available. This was a limitation of the study design as tracking through medical records would have been more successful as all three of these women had moved home during the interim period. However it is possible that these women did not want further participation, as they also did not respond to telephone messages or email correspondence.

In total fifty-one interviews were conducted and recorded, ranging in length from twenty-seven minutes (stopped by the researcher for safety reasons) to one hour and twenty-five minutes. Theoretical saturation was reached with the initial twenty-seven interviews. Follow-up interviews focused on collecting qualitative data relating to treatment outcomes, changes in treatment expectations and experience over time. The follow-up interviews also provided additional investigation of descriptive themes and the opportunity to develop, test and refine the conceptual model ELMA.

3.8 Validation

Findings were fed back and reviewed with a range of interview study participants who were willing to be approached again. This was conducted by digitally audiotaped telephone interview following distribution of written summaries. The summary can be seen in Appendix X on page 284. Respondents were asked to consider and comment on the findings, enabling the research team to confirm or further refine data interpretation and analysis if appropriate. A sample of six respondents was asked to participate in the validation process. This process consisted of a summary of the study findings, including the conceptual model, being sent out to the validation group with key prompt questions added. Interviewees were asked to post back their responses or to participate in a telephone interview. All six participants in the validation group responded, two by post and all six by telephone. The findings from the validation process were consistent with the study findings and no major changes were made to the analysis of findings following validation.

FINDINGS: FACTUAL DATA AND DESCRIPTIVE THEMES

4.0 Introduction

Findings are presented within eight core categories, each relating to a specific aspect of heavy menstrual bleeding. Examples of open, selective and axial coding can be seen in Appendix X on page 284.

Within the core categories descriptive themes are presented and illustrated with quotes from interviewees (with the interviewer's voice in italics). For each descriptive theme the majority view is represented and also the range of coded data is represented by a quote detailing the minority or individual experience. During data analysis themes were generated by interpretation of the majority view, followed by testing in further interviews and by the seeking of deviant cases. The terminology relating to the number of women who shared the same experience for this thesis is as follows:

- 'almost all' = all except one or two participants
- 'the majority' = well over half of the participants
- 'a number of' = about half of the participants
- 'some' = under half but more than a quarter of the participants
- 'a few' = one or two participants

This section of the thesis details and discusses the findings from the research study and there are three chapters; Chapter Four details the study findings, including factual data and descriptive themes. Chapter Five then follows and this chapter describes the development and examination of the conceptual model 'Experiences of life with heavy menstrual

bleeding; aid to communication' (ELMA). Chapter Six discusses the qualitative findings.

4.1 Factual data relating to demographic characteristics and treatment outcomes

The factual data collected can be divided into two categories:

- general demographic characteristics such as age, parity, education and ethnicity
- factual data relating to treatment outcomes

4.1.1 General demographic characteristics

Table B on page 62 details the general demographic characteristics for the twenty seven women selected to participate in the interview study.



Demographic data

	LNG-IUS	Standard Treatment
ECLIPSE	8	9
ECLIPSE Decliners	6	4

Characteristic	Range
Age	25 to 51 years
Parity	0 to 4 children
Duration of HMB	<2 to >20 years
Treatment	Range of medical treatment (NICE 2007)
Education	No qualifications to postgraduate diploma
Occupation	Range of professional and non professional roles
Ethnicity	Limited ethnic variation
Care provider	8 care settings across 6 counties

Table B Summary of sample characteristics

Through purposeful selection this sample included women from a wide range of age, parity, education and occupational characteristics. This sample included women with a range of different experiences of heavy menstrual bleeding, both in terms of severity and duration of their condition. Positive and negative experiences of all of the recommended treatment options were captured. There were few women from different ethnic backgrounds, largely due to the constraints of recruiting from within the established ECLIPSE RCT. Further detail and discussion of the demographic characteristics of the sample population can be found in Appendix IX on page 272.

4.1.2 Factual data relating to treatment outcomes

Table C on page 64 outlines the treatment outcomes for the twenty seven women included in this study. A number of women underwent a change of treatment, several women changing treatment more than once. The majority of women who were initially prescribed standard treatment had discontinued their treatment at the time of the second interview. Women prescribed LNG-IUS initially were more likely to still have LNG-IUS at the time of the second interview. Similar treatment outcomes were seen for women with an expressed treatment preference.

	Initial Treatment	Treatment preference	Outcome (>1 year)	Subsequent treatment 1	Subsequent treatment 2
2	Depo provera	Randomised	Change of treatment	LNG-IUS	
5	LNG-IUS	Randomised	No change		
7	Tranexamic acid	Randomised	Change of treatment x2	LNG-IUS	Hysterectomy
11	LNG-IUS	Preference for LNG-IUS	No change		
15	LNG-IUS	Preference for LNG-IUS	No change		
12	LNG-IUS	Preference for LNG-IUS	No change		
9	Tranexamic acid	Preference against LNG-IUS	Change of treatment x2	No treatment	Tranexamic acid
16	LNG-IUS	Randomised	No change		
18	Tranexamic acid	Randomised	Change of treatment	LNG-IUS	
25	Depo provera	Randomised	Change of treatment	No treatment	
22	Tranexamic acid	Preference against LNG-IUS	Change of treatment	LNG-IUS	
19	Tranexamic acid	Preference against LNG-IUS	Change of treatment	No treatment	
30	Tranexamic acid	Randomised	Change of treatment	No treatment	
23	LNG-IUS	Preference for LNG-IUS	No change		
31	Norethisterone	Randomised	Change of treatment	No treatment	
27	Tranexamic acid	Preference against LNG-IUS	Change of treatment	No treatment	
28	LNG-IUS	Randomised	Change of treatment	No treatment	
29	LNG-IUS	Randomised	No change		
26	LNG-IUS	Randomised	No change		
37	LNG-IUS	Randomised	No change		
43	Contraceptive pill	Randomised	Change of treatment	No treatment	Contraceptive pill
39	LNG-IUS	Randomised	No change		
42	LNG-IUS	Randomised	No change		
32	Tranexamic acid	Randomised	No change		
10	LNG-IUS	Preference for LNG-IUS	Not known		
8	Tranexamic acid	Randomised	Not known		
51	LNG-IUS	Preference for LNG-IUS	Not known		

Table C

Treatment outcomes for study sample population

4.2 Descriptive themes relating to psychological factors and self esteem

4.2.1 General perception of menstruation

Descriptive themes:

Negative attitudes prevalent with all menstruation seen as problematic

Negative attitude predated changes in menstrual pattern

Most of the women in this study had negative attitudes towards heavy menstrual bleeding related to its negative impact on their lives but also towards menstruation in general.

"Nobody wants to be on their period. Not one woman I know wants to be on her period." 10A

"When I die and I go to heaven I am going to take the great Lord creator, whoever you may believe he is, to one side and say why? Why? I started my periods at 11, I could well go on until I am 60, who needs 49 or 50 years of child bearing years? How many children do you want me to have? Please stop it and make it shorter. God is definitely a male being, a male entity somewhere because no woman would do this to her fellow woman." 18B

This was particularly noticeable in the women who had experienced a change in menstrual pattern. However the negativity of the women when describing a previously normal menstrual pattern was surprising, as there

was little difference in the depth of feeling expressed about lighter menstrual bleeding in the past and their current heavy menstrual bleeding. It is possible that the perceived change in menstrual bleeding was not actually that great and that these women had always had a degree of heavy menstrual bleeding that was not recognised; or the women's negative attitude towards menstrual bleeding in general had increased over time and was altering their perception of their menstrual blood loss.

The women in this sample population clearly described distinct changes in menstrual bleeding citing measurable clots and more frequent incidences of increased blood flow causing leaking as well as increased use of sanitary towels and the increased costs involved. Whilst this evidence is subjective and cannot accurately determine how much of a change in menstrual bleeding had occurred, the women perceived their blood loss to have increased. In addition several women became anaemic, another indicator that an actual change in menstrual bleeding had occurred.

4.2.2 Information and experiences at first menarche

Descriptive themes:

First menarche traumatic

Lack of information and support influenced negativity

Strong pressure to conceal regardless of background

The majority of women in this study had negative views on menstruation that seemed to be present from menarche and even before. First experiences of menstruation were described in detail by a number of women, including evidence of distress and the use of emotive language.

For many interviewees the first experiences of menstruation were easier to recount than recent events perhaps indicating a degree of psychological trauma sustained at the time. Several women were moved to tears when recounting difficulties with menstruation at school or in their homes as teenagers. Most of the women interviewed also described a lack of knowledge about menstruation either before or around the time of menarche and feelings of isolation due to the perceived reluctance of their mothers to discuss what was happening to them.

"She said I am eleven I am going up to senior school 'you are going to get a bit of blood on your pants, don't worry about it, it's quite normal. And don't you go lading it!'

Lading it? [understood as becoming sexually active]

I had no idea, this is how my mum spoke. Her next sentence made even less sense 'don't you come back dirtying my doorstep'. I thought what the hell is she on about so I thought I am not going to school because they will sit me on a spike or something, what the hell you know, you have no concept what she was on about and my sisters again 'under this roof you do not' so they knew but wouldn't say anything." 7A

"I remember when I started, because I says, I says oh mum I'm bleeding and she went oh, you know, you've started your period and she'd given me like a sanitary towel and I had to go up the shop and get them. Get them myself, so that was embarrassing like going in to, to get them.

Why do you think your mum didn't tell you before?

I don't know she's never really been one for telling us anything. So and it's like me two sisters like I would tell them about, you know, when they start. So no my mum really didn't say anything." 8A

"I ended up with the thickest bricks you've ever seen and she used to say you'll have to carry one of these with you, just in case, from the age of eleven and I'm thinking just in case what? Not very open my mum. You didn't talk about those things." 27A

There were a number of women, having no understanding of their normal female physiology, sought to conceal menstrual bleeding from even their mothers, believing that they might have injured themselves.

"The first time I had a period I thought I'd cut myself...I remember thinking 'oh I've got blood in my pants, oh I've cut myself'. It was only a little bit. Then the next month I thought I'd cut myself even more and I thought how have I cut myself? And my mum came and said 'oh you're bleeding' and I thought she was going to tell me off because I'd cut myself." 19A

The women who did this described a range of emotions including guilt and shame and there was the perception that they were defiled, although the sexual connotation was unclear to them at the time. This was the case not only for women coming from a strong religious background but also from those who were not aware of a religious influence in their lives. Women described hand washing underwear and bed sheets, stealing sanitary towels from mothers or older siblings, for several months (in one case a year) before their mothers became aware that they were menstruating.

"We never talked about such things when I was growing up. Even to the point that I think when I had my first period I had periods for about 12 months before I actually told my mum that I had started

periods because I didn't feel that I could talk to her about it ... to the point that I remember she went out to work one day and I had got blood on the sheets and I whipped my sheets off, washed them and hung them on the line and made sure I got home and took them off the line and put them back on the bed before she came home so I wouldn't have to be embarrassed about that. Because I was embarrassed about it but it's not like she was a horrible mother or a strict mother so I don't know what I thought she would have said or done." 37A

A few women did have a limited knowledge and awareness of menstruation, usually this information was provided by an older sibling.

"I was about 12 years old when I started my periods and I kind of knew what to expect because I have got an older sister." 2A

Even the few women who had been given some information about menstruation before first menarche still expressed negative attitudes and the perception that this is normal.

"I can remember being a little bit disgusted and scared and I think that girls still these days find the whole thing quite revolting because I teach year six and we have the nurse comes in and shows them all about sanitary towels and tampons and all sorts of things and girls still think that a horrible thing is going to happen to their bodies." 11A

4.2.3 Maternal support and communication with others

Descriptive themes:

Perceived lack of maternal support

Practical management learnt by trial and error and peer information

Minimal information given by other adults

Very little psychological support given

The majority of the interviewees described a lack of support particularly in their early menstrual history. They had very limited communication with their mothers; a fact reflecting societal norms that anecdotally appears to have persisted through several generations of women. Not only did they experience a lack of psychological support, through explanation and discussion of menstruation but they also described a lack of help with learning how to use sanitary towels and how to care for their bodies during menstruation. Practicalities were learned by trial and error and by discussion with peers.

Often it was someone outside of the family who explained menstruation to the women in this sample, predominantly school teachers or school nurses. Whilst they gave facts they were not in a position to provide sufficient emotional support due to constraints of time and the nature of the professional relationship. The factual information was often brief and the teacher or nurse referred these women back to their mothers as a primary source of information. Unfortunately the majority of women in this sample

did not gain any further detail from their mothers, even after being prompted by the events and conversations that had taken place at school.

"When it was explained to me that this is the beginning of your body is going to change and this happens to all women, it happens to your mother as well. I was thinking 'well really my mother has never told me this'. So I was a bit distrusting of what the gym teacher was saying... I will never forget her [mother] face when I told her and I showed her my underwear and the sanitary towels the teacher had given me and she didn't want me to discuss anything with my other sisters." 39A

Several women thought that increased education in schools, with greater emphasis placed on factual information and practical management of menstruation for all young girls would be beneficial.

Within family groups there were a number of women who had an older sister and this often had a positive impact on the woman's experiences. Although there was a similar lack of information, the older sibling was able to provide tips on how to use sanitary products and guide the women through the societal norms expected particularly in relation to concealment of menstruation. Most of the women in this sample learnt about sanitary protection including the different types and how to use them by trial and error and with some information from their peers. They also learnt behavioural norms and how to cope with the physical aspects of menstruation from 'mistakes' and observing their peers rather than through communication their mothers or peers. The exception to this was in the one or two cases where an older sister took on a 'maternal' role, often due to her own negative experiences at menarche.

"She [younger sister] and I shared a room and shared a wardrobe together... and she had seen my sanitary towels and protection and she would say 'what's that' and I would explain it to her what it was. I didn't see any shame... When my middle sister started her periods I was glad it was a Saturday. She was crying in her room. I went in and chatted with her and she was in shock because no one had explained it to her." 39A

The striking finding relating to maternal support and communication was the difference that the women described in relation to their own children. They were much more open with their own daughters and had prepared them for first menarche by providing both practical information and the offer of emotional support. Concealment was discussed and maintained.

"My mum never spoke to me about periods ever and her mum didn't but I do with mine you know. They perhaps don't want to because again it is [pause], but I will ask them questions you know because I know how much I suffered so I wouldn't want them to quietly suffer and think there was nothing that could be done and that it was acceptable." 27B

Sons were treated differently though, receiving little information about menstruation.

In all cases there was a perceived lack of psychological support for these women, many of who were very emotionally distressed by menarche. There was no celebratory aspect described (as in rite of passage into womanhood as there is in some cultures) for these women. This led to predominantly negative memories of menarche and negative associations with menstruation in general. This was then compounded by the onset of heavy menstrual bleeding, whatever age it occurred.

4.2.4 The last taboo

Descriptive themes:

Menstruation still a taboo subject

Maintaining taboo had negative impact on experience and quality of life

Dishonesty sometimes preferable to breaking taboo

Running throughout accounts was still a strong societal pressure to remain silent about menstruation; menstruation remains taboo.

"I think in society it's quite a taboo subject. I work in an all female environment with one man who is obviously married, who has got children but if we were actually talking about periods we would stop if he came into the room." 11B

This appears to be particularly true for women experiencing heavy menstrual bleeding.

"It makes me feel not so much like a normal woman really when I have a heavy period because you feel like you're the only one that's having a heavy period. Obviously there are hundreds of women out there that are having them but it's not common knowledge that a lot of women are having heavy periods like I did, I kept it quiet."

15A

The taboo exists within families, amongst friends, is strongest in the workplace and even persists within consultation with a health professional.

"A lot of women don't like to go [to the GP] because it's this taboo subject, so it has to start somewhere other than a GP. It's got to start somewhere that you know that it is acceptable to have a problem, there isn't a right and a wrong." 27B

Women are so tuned to maintain the societal norm that they will deny their problems, lie to employers and withhold information from their doctors in order to stay silent about heavy menstrual bleeding.

Maintaining the societal norm of not speaking about heavy menstrual bleeding (and menstruation in general) had a negative impact on most women's quality of life.

"I had gone to the doctors a few times and somebody had asked me and I wished somebody had asked me earlier and perhaps if you talk about it then somebody perhaps at work might actually well I am doing this, this and this and then you are more confident then to seek help." 26B

Even the women who had developed coping behaviours and mechanisms that relied on help from other people had often not discussed their menstrual difficulties in detail but had given superficial information. In some cases the support people were not aware of way their support was needed. They often agreed to help without question due to the close bond between them and the interviewee.

Over the period of time that the study was running a few of the younger women thought long and hard about the social taboo of not discussing menstruation and had changed their attitudes.

"Just fight and shout and don't be afraid to speak to people it's not a taboo subject, it's not a dirty word, it's nothing to be ashamed of,

it's a medical condition and unfortunately is taboo because nobody likes talking about it. Well the more people who start talking about it the less of a taboo it becomes and then women can be open about it and takes one of the pressures off." 18B

This is one of the ways that participation in the interview study did influence the women's experience of heavy menstrual bleeding. Few women had ever discussed their menstruation in such depth with a neutral and interested non-judgemental person and many women found the interview process cathartic. It is a measure of how much distress the taboo around menstruation causes when the simple action of listening is in itself therapeutic.

4.2.5 Stoic silence

Descriptive themes:

Women should put up with heavy menstrual bleeding

Silence linked with strength and resilience

Stoic silence part of wider female role

There was also not only a lack of knowledge about treatment for heavy menstrual bleeding but a strong sense that women should 'put up' with heavy menstrual bleeding and not complain about it.

"There's no point whinging and moaning about it because there's nothing you can do so I just get on with it." 15A

"I am sure there are thousands of women that suffer from menstrual problems you know if you have got somebody that you

can sit and talk to because everybody thinks they are on their own, everybody thinks it's just me and another thing that I find wrong and people it's dismissed oh well it's just your monthlies and you expect it because you are a woman." 27B

The majority of the interviewees expressed this viewpoint, even though they had recognised a need and desire to seek treatment. Indeed they all had approached a health professional and commenced on a course of treatment. The decision to seek treatment and therefore break the silence was seen as a weakness or failure and was often associated with reduced self-esteem.

"And you just feel a bit, not worthless because worthless is the wrong word but you think some people must think you are one of these women that you have just got a heavy period get on and sort of deal with it but you can't physically get on unless you have actually been through a phase of having heavy periods you can't and I am the same because I didn't understand when people said they had really heavy periods because I never had them before."

26B

The women suggested that maintaining a stoic silence was a positive sign of internal strength of character and resilience. There was value attached to this idea. When women described older family members, including their mothers and grandparents, who had not disclosed their own heavy menstrual bleeding, they spoke of maintaining silence with respect and reverence. The women also indicated that they felt themselves to be less strong as they had disclosed their heavy menstrual bleeding to others or when seeking treatment.

"I do sometimes say to them, boys, I am not really up to it I am not feeling too well. I don't want them to feel it's a pattern that mum's oh mum's always not well you know, every few weeks mum's not so well because it makes me look weak and I don't want that to happen." 28A

There was a perception that this was important to an older generation, yet the majority of women interviewed still had difficulty discussing menstruation and all of them adopted behaviours to maintain concealment.

"I couldn't understand the need for secrecy. I think it was just part of her background because coming from the Caribbean they are quite [pause] 'blinkerred'. My mother is from a different generation where certain things you are not taught to talk about openly. You do not talk about sex, babies, boys or things like that; anything that is intimate with a woman's body you do not talk openly about." 39A

The women suggested that this was a societal norm; the inference that suffering was a women's lot. Only one woman made specific reference to the biblical context, however many interviewees discussed negative aspects of menstruation and the pain of childbirth something punitive; a negative aspect of being female.

"It's just one of those things in life that you are a woman. I am born in this shell, I have to get on with it but try and live my life as comfortably as I possibly can." 39A

Many women also said that men would not 'put up' with menstrual pain and discomfort but would have determined an effective treatment. The inference was that men are either more worthy of treatment or men control that access to treatment and the treatments themselves. When this was questioned further there also appeared to be individual feelings of low

self esteem for a number of women in this sample, as well as the perception of women being less valuable in society. This was expressed across the education spectrum and also by women who were very successful in their working lives.

4.2.6 Concealment of menstruation

Descriptive themes:

The need to conceal menstruation was paramount

Feelings of low mood and low self-esteem were influenced by not being able to conceal menstruation

Women developed complex behavioural mechanisms to cope with and conceal menstruation

The most often described aspect of heavy menstrual bleeding affecting women was the need to conceal menstruation and the difficulties that heavy menstrual bleeding caused with this. Most women described complex behaviours and coping mechanisms to enable them to both manage their menstrual bleeding and to conceal their condition, not only from work colleagues and friends but also from family members. These behaviours and adaptations to routine enabled them to continue with daily life and improve their quality of life during menstruation and included: those that related to preparation for menstruation, those that related to avoidance of activities during menstruation and those that related to substituting someone else for that woman during menstruation.

Preparatory coping behaviours included carrying extra sanitary protection at all time, frequent changes and checking of blood loss and having a spare change of clothes (sometimes two).

"It was every handbag had some sanitary wear in it just in case... I always knew it was best to stock up at that time ready for next time." 29B

"Just to show you as well [interviewee getting item out of handbag] if I go out anywhere this is my small bag, that is my large bag I take this with me at work.

For the benefit of the tape this what you call the 'survival kit' is it?

This is it. I can't go out without sanitary protection, lots of sanitary protection, medication to take with me, a change of underwear and wet wipes to clean myself. I have to walk with this every single day so that the embarrassing or the awkward things I have to go to the toilet whilst I am at work you know instead of having to lug my large handbag with me I just discreetly take this, put it under my arm and just push past everybody and go. I do get the odd looks from other women where is she going with that you know so to speak ... my smaller one is a bit more compact, so if I went out say for example a meal with colleagues, friends or my husband. If we went to the pictures or somewhere where I know there are toilet facilities I will carry this in my smaller bag and I am only out of my home for a few hours" 39B

Women also thought of verbal explanations for frequent trips to the toilet or for having changed clothes in the middle of the day.

"I had gone to work to work in say a red outfit and then had to change in to a blue outfit or whichever they would say 'well why have you got changed' and although you could say 'oh I spilt tea down me or coffee down me', if you then got changed again, and sometimes I was having to change two or three times, 'why have you got changed again you can't have spilt coffee down you again'. It would just impact on what I thought they were thinking of me. Did they think I had wet myself or something?" 26B

Avoidance coping mechanisms and behaviours included rescheduling activities at home and at work, cancelling meetings both social and professional, taking time off sick from work and remaining at home (avoiding leaving the house) during menstruation. Substitution coping mechanisms and behaviours included having someone else take care of children, or having someone else take a woman's place at work, either for a short time or for a longer time such as a shift or working day.

These coping mechanisms and behaviours served firstly to allow the woman to rest (indicating the degree of illness that they felt) and secondly to ensure that their menstrual difficulties remained concealed from the wider population. In some cases even the people who substituted for women were unaware of the reason why their colleague, friend or relative was unable to participate in their normal daily activities.

If these coping mechanisms or behaviours failed almost all of the women reported feeling embarrassment, guilt and shame, particularly if other people needed to help them. They often became distressed and upset.

"It was on our staff party [date] it was and it was mid afternoon and I just didn't quite understand, I just thought I need to go to the ladies but what I had not realised was it was only when I got to the

ladies toilets and unclothed myself as it were to you know as you do to go to the toilet, I had wet my, soiled my trousers, my underwear was saturated through and the pain and the contractions were really bad and it was just pouring out of me and thick lining was coming out as well. I was there in the ladies I was too embarrassed to come out and, you know basically with women coming in and out of the ladies toilets and what have you because I had been gone a while and it was a colleague who came looking for me and you know I had to beg this colleague, I was crying as well. And they went in and sorted out some sanitary protection for me and brought my supervisor as well and I just felt really mortified and embarrassed about it." 39B

They clearly described feelings of embarrassment, guilt and failure if their menstrual blood loss became evident. Often the development of low mood and was influenced by incidences of leaking and menstruation becoming evident. This was accompanied by feelings of shame and failure and ultimately low self-esteem. The language that women used to describe the effect of incidences of leaking was emotive and included the use of many words that may indicate clinical depression. This may be why some health practitioners consider antidepressant treatments for women when they consult for heavy menstrual bleeding.

Whilst most women did not question the concealment of menstruation in society, one woman did.

"It would be upsetting I think if it [menstruation becoming evident] happened when you are out and about but what can we do hopefully people will see it as a natural thing and these things happen you know why is it any different to somebody perhaps cutting their arm or their leg and then bleeding from their wound

there? It's probably just as natural as that but then if you look at it in terms of the way I was brought up they probably won't see it that way." 28B

4.2.7 Illness or condition?

Descriptive themes:

Clear descriptions of being physically unwell

Societal pressure to deny being unwell during menstruation

Women were unclear about health status when menstruating and used 'condition' rather than illness to describe their health status

The women were unclear about whether heavy menstrual bleeding was an illness even though they were very unwell in some cases. They almost all listed a catalogue of clinical signs and how unwell they felt.

"You just don't want to do anything and you know there have been times when I have just lain on the sofa with something over me because I just felt so ill almost. I just felt that my body can't move, my stomach hurting, my back hurting." 2A

They felt pressure to continue as normal because their physical symptoms were related to menstruation.

"Everybody said to me I look drained which has an impact on you because if people tell you that you look pale and you don't look well then you kind of think oh yeah I don't think I feel very well even though it wasn't an illness as such I just felt down I suppose." 37A

Most women used the term 'condition' to describe their heavy menstrual bleeding with no one using the term 'illness'. The denial of illness or disease extended to discussion about treatment in that women were not seeking a cure for a disease but relief from symptoms of their 'normal' condition.

"I don't know if there is a cure because it's part of who we are isn't it? It is part of who we are, I don't think it's about curing it I think it's our attitude to it and our attitude to when somebody says I am feeling really low, I am feeling really tired to actually hear that and say well I have heard you say that a few times you know let's look at that you." 19B

All women clearly described being unwell and several used the words 'ill' or 'sick' particularly when relating to time away from the workplace (or being sent home from work) but then denied they were sick when relating to visiting the GP surgery or Gynaecology clinic. Interestingly people around them openly acknowledged that the women were unwell and acted accordingly.

"The day before I was due in [to the gynaecology clinic] I was having a bad episode, very painful episode and I could feel 'oh no I know my period is going to be starting soon' and I was sitting at my desk and my colleague said you look awful we thought you were going to collapse and I was told to go home early and it was a good thing." 39A

There was a dichotomy in play through the data between definitions of health and illness in relation to heavy menstrual bleeding posed by the women themselves.

4.3 Descriptive themes relating to relationships and sexuality

4.3.1 Heavy menstrual bleeding and sexuality

Descriptive themes:

Heavy menstrual bleeding had negative impact on sexuality and sexual relationships

Women did not feel sexual and avoided sexual contact during menstruation

Women reported partner frustration at the lack of sexual contact

Most women found that heavy menstrual bleeding has a negative effect on sexual relationships with the majority suggesting this was related to self-image rather than their partners' views.

"I feel very self conscious making love to my husband with; you know remotely bleeding for that period of time, that's just not nice."

9B

"I think psychologically it's just makes me feel kind of a bit old and (pause) and in terms of how I see myself with my husband and you know of course he just wants me to be healthy and happy. So he is not going to trade me in for a younger model or anything but it just makes me feel really uncomfortable." 9B

All of the women in this sample described avoiding sexual contact during menstruation due to a combination of feeling physically unwell, not feeling sexy and wishing to avoid the practical difficulties of having intercourse whilst menstruating. They implied that the decision to avoid sexual contact rested with them.

"When I split up with my partner we hadn't been sexually active for years before that, it could have been [related to heavy menstrual bleeding]. Where I didn't even want, it didn't even interest me and I wasn't even interested in sex in fact I used to go to bed late so as to avoid it. I just hadn't got those feelings for it." 43B

There was also some inference that sex during menstruation would not be satisfying and would even be unpleasant. There was also the inference that their partners would find sex during menstruation distasteful. Some women assumed that their partner would not be interested in sex during menstruation but had not discussed this in detail.

"You don't really feel like doing anything that week anyway and we don't live together so I can always say don't come and stop that week and he is alright anyway. He would rather keep away I think."
51A

There was also a consensus that it was normal not to have sex during menstruation. It was commonly expressed that they would not have sexual contact with their partners during this time and when this was explored further the women who held this view thought it was the norm (that no woman would have sexual intercourse whilst menstruating). There was also the inference that it would be shameful or inappropriate to have sex during menstruation.

"[He might think] 'I am not going anywhere near you, you dirty cow'. And then you know your name is mud round everywhere, sorry but I can't have my name blinking mud [name of interviewee and job title] you know like [name of interviewee] likes to have sex on her period." 23A

"It hasn't changed our closeness or spending more time, although you know we don't have any intimacy during that time any way we just wait until it has completely passed and then we can get close then." 28B

Around a third of the women did however state partners' frustration as influencing the decision to seek treatment. This was expressed by men in a number of ways from teasing to outright statements.

"[name of husband] is really, really good when I have got my period, he is very understanding and he is very, he never pressures you in to anything, everything goes at my pace so from that aspect it doesn't really have that much impact, other than he might say something like, what does he say, he might make a comment and I will say you are only saying that because I have got my period and he says 'yes I haven't got to be nice to you because I am not going to have sex', or something like that and he doesn't mean it nastily he is just making a joke you know. And he will say 'oh I am going to watch one of my films tonight, you can go to bed early' sort of thing' and he will say things like 'you are no good to me tonight'."
26B

*"What was it that led you to initiate the conversation with your GP?
My husband really, because I didn't know where I was with my periods at all, it was quite erratic ... He said to me I don't*

understand why you don't go to the doctors and he thought that I was quite hormonal as well ... I think probably if I am honest with you that [negative impact on sex life] was more of the reason why he wanted me to go to the GP's about it because I didn't know where I was with it and then I think I wasn't on and then suddenly I was. In actual fact it almost if sexual intercourse took place it almost bought it on." 37A

"I just don't like sex anymore I hate it I absolutely hate it with a passion [laughs], wrong sort of passion. He is very understanding but there comes a point, he has got a bit shirty with me at times and he said you know that is the one thing he had said "you really need to see a doctor because this isn't right" you know. He has even felt that I haven't loved him and that is terrible that is you know I do, I do but I just can't bear it." 2A

A minority of women felt that side effects of treatment had in fact had a detrimental effect on sexuality due to the irregular bleeding experienced. Childcare was also affected in many cases with family activities being restricted during menstruation and more extended family involvement in childcare.

Successful treatment had a significant impact on sexuality and the women's perceptions of themselves as sexual beings.

"Its made me feel as though, yeah, I wanted to meet someone else and now its nice that I have got a relationship, a sexual relationship that I never wanted before. I mean a year ago it didn't bother me if I never had sex again but its nice if you meet someone and you can be intimate." 43B

4.3.2 The influence of significant others

Descriptive themes:

Communication with significant others was not difficult

Men were perceived as lacking empathy

Some women were contradictory when discussing their partners understanding and support

Most women in this study found communication about heavy menstrual bleeding with their (male) husbands and partners was not difficult in itself, although there was a strong perception that a man would not be able to understand or empathise.

"I don't feel as though, you are not getting any help there; nobody has any sympathy for you.

Why is that?

I think it's because they can't actually see anything and they just think you are being a bit paranoid about how you are feeling. You know it's [pause] I can't really explain this it's just, how you are feeling inside they just put it down to you are having a bad day when all the time you are suffering and they just can't understand it and just nobody gives you any sympathy." 43B

There were no women in this sample who were in a lesbian relationship and it would be interesting to know how a same sex relationship would impact on this finding. The women were able to express their problems with menstruation with their partners, all be it in oblique terms, using

euphemisms and indirect references. Incidentally many of the women talked about their experiences with heavy menstrual bleeding in the third person and also used euphemisms and indirect references to describe their own experiences. This again highlights the depth of the need to maintain the societal taboo when discussing menstruation.

"He just, I don't know, I think men in general don't have a clue. I think they are more clued up nowadays about certain things but he just hasn't got a clue. He doesn't know what I have to put up with, he says stuff like 'have you got the painters in?' that sort of mentality really. He doesn't understand, I wouldn't expect a man to understand because they don't go through it do they. He just sees what I am going through, he knows that I am not happy. I have told him I am doing this [participating in the study] and he says 'good'." 30A

One woman having treatment with LNG-IUS had a negative impact on her relationship. She described a lack of understanding of the reasons for having LNG-IUS fitted by her then partner and the issues that this raised.

"You have been using protection and you say well I have got the coil fitted now so you don't have to [use a condom], oh [expletive deleted] no, no I'm not doing that. I am not doing that because you try explaining to a bloke you have been sleeping with for fifteen months, you don't have to use a condom now. He probably thinks I'm a liar and I want him to get me pregnant so he doesn't leave me...I ain't in a relationship with him anymore due to the fact that I honestly believe that was his thinking" 23A

There may have been other issues within this relationship but this was the one that this woman felt had ended it.

4.4 Descriptive themes relating to impact of heavy menstrual bleeding on life and work

4.4.1 Quality of life relating to roles and responsibilities

Descriptive themes:

Heavy menstrual bleeding dominated women's lives, negatively affecting quality of life

Quality of life defined by ability to fulfil roles and responsibilities

Successful treatment had a positive impact on overall quality of life

Heavy menstrual bleeding had a negative impact on all areas of women's lives. Managing physical symptoms and maintaining societal norms of silence and concealment dominated women's lives during menstruation. Almost all of the women described being anxious about menstruation throughout their cycle and described dreading the onset of menstruation.

"I would say it's not trivial. You know to them it may be something that you know if they are a gynaecologist and they are dealing with it may be the least of someone's problems but to that woman it is the butt of her problems you know and it has an impact on her whole being her whole holistic being revolves around that one thing." 27B

Quality of life for the women in this study was most often related to their ability to function effectively in their daily roles; to be able to cope well

with their responsibilities at home, at work and within their relationship with their partner, during menstruation.

"I gave up my job to have my children. I love having children ... I don't want to go to work until [name of third child] is at school and I enjoy it but that [menstruation] makes me feel like a she devil I can't bear it." 2A

The negative impact on roles and responsibilities was influential in the decision to seek treatment.

"I have to wear a star wars head piece with a phone so that wherever I am in the building I can answer my phone, I just press a button on the side, so that I'm always contactable, obviously if somebody needs me they have got my direct number. But I could be in the toilet and me phones going and that make you anxious because you're thinking, that could be a client wanting a train time or a taxi and I'm trying to clean myself up to go and then carry on with my job... if I get my period on a Monday and it lasts until Friday, they must think 'bloody hell, how many more times does she have to go to the toilet?' ... It makes you try to hold off as long as you can but then by doing that you just keep flooding." 26A

Women who had a positive experience of treatment with LNG-IUS described overall improvement in their quality of life and these women were the majority. Conversely women who were treated with standard treatment did not have such improvement in their quality of life and this was influential in their decisions to discontinue treatment.

When treatment was successful there was a major improvement in women's perceived quality of life.

"It just sort of gave us I suppose my bit of life back, my bit of independence back that I could do, you know carry on without thinking you know have I leaked." 26B

4.4.2 Impact on roles and the decision to seek treatment

Descriptive themes:

Negative impact on roles and responsibilities (quality of life)
influenced decision to seek treatment

High impact on women in professional roles

Control over working environment reduced impact of heavy
menstrual bleeding

Heavy menstrual bleeding appeared to impact more on professional / career orientated women as they expressed more concern about work, describing more complex coping mechanisms.

"I had got chronic stomach pains to the extent I thought I might be going to faint. I had just had one [client group] leave and then I got a gap and he [manager] came around and bring cups of tea and I said 'oh I am going to have to go to the toilet' and I actually thought I might stand up and bleed everywhere. He said 'I will give you permission to go to the toilet' and I said 'no I actually have to go to the toilet.' He was joking but [pause]" 11B

Women were concerned about the impact of taking frequent sick leave on their current employment and future employment prospects.

"I had lost a lot of time because of this problem off work. I was advised I was being made redundant so I was really worried ... I had lost about four or five weeks in total over the year and I was thinking if there are people going for jobs with me I am going to have to be honest on the application. One girl I did work for was offered the job provisionally and then three weeks later they phoned her up and said they couldn't take her on because of the time she had lost but they didn't check why. So I did put down that it was a medical condition, I put down the actual name of my condition... I was honest and I think I was very lucky [to get a job]."

42B

When treatment was successful this concern was lifted and women felt much more secure in their employment, including their relationships with their colleagues.

"Because it's not an issue anymore I have lost no more time from work. Before it was a problem every month I was losing time because of this condition. Unfortunately, I think we did discuss this before, even though, even with other women that they just assumed that it was just a period but for me it wasn't just a period it was a nightmare." 42B

A few women had more flexibility and control over both workload and their working environment possibly due to seniority and self employment and this made a considerable difference to their quality of life. It also influenced treatment choices, with opting for no treatment more prevalent in this group.

"If I didn't have that flexibility and I had to work and be more mobile and restricted as to when I you know could change and swap

then yes I think maybe I would have looked at it differently and dealt with it differently.” 28B

4.5 Descriptive themes relating to fertility and womanliness

4.5.1 Normal menstrual period or amenorrhea?

Descriptive themes:

Definition of positive outcome varied

Normal period seen as sign of non pregnant state

Normal period associated with fertility

Women not wanting children sought amenorrhea

There was some variation regarding the idea of a successful outcome with some women seeking amenorrhea and others wanting a 'normal' period.

"I never bleed again ever, ever, ever, ever and that's the biggest one, that's it. Everything else stems from that, lack of energy, feeling unclean, having to worry about where I am going on certain days; that it will all just stop." 18B

This was often linked to fertility and childbearing. A number of women who had older children and considered their families to be complete would were seeking amenorrhea.

"I am at a stage in my life where I don't want any more children I feel that I have passed that point in my life so I don't actually need

my periods to continue and I just see them as just a blight really now. The perfect solution for me for them to stop.” 37B

Women with young children and those with no children were more likely to be seeking a normal period, suggesting that menstrual blood was an indicator of reproductive potential.

“I know that periods are a fact of life and I don’t want them stopped completely. Great if you can stop them completely but and then can you guarantee that I can have kids in the future if they stop.” 23A

Some women were seeking a normal period as reassurance that they were not pregnant.

“I would be worried thinking oh my god I am pregnant, because the only time you don’t have a period is when you are pregnant, so even if you know you are using contraception, you have been really careful, you still think I haven’t had a period, I am pregnant.” 51A

A small number of women were concerned about the consequences of amenorrhea and displayed a lack of understanding of menstrual physiology. They had questions about what would happen if they did not menstruate.

“It would be nice if I didn’t have a period at all but, how can I say it? If it is going to stop you having a period anyway, where would all the blood and everything go?” 31A

“I think women have to go through this process and then you have got the thing about hormones changing and everything and I was like if I don’t have a period how does that affect your hormones, how does that affect the rest of your body, where does all this that comes out what happens to all of that, where does that go, does it

get clogged up? I know it doesn't, but what happens to all those things? You do have various processes inside you that you have to go through and so that kind of, [pause] that was a deep thought and maybe I thought too much. I don't know, but I didn't want to do anything whereby I would cause myself problems." 28B

Most women wanted relief from whatever aspect of heavy menstrual bleeding troubled them the most, be that physical, psychological or social and this was clearly stated in the interviews.

"If it's heavy then I am quite happy with it being heavy for seven days, I have dealt with that for god knows how long, I just want regular. I just want normal regular periods" 23A

4.5.2 The association with aging

Descriptive themes:

Change in menstrual pattern was associated with the aging process

A number of women believed that heavy menstrual bleeding signified menopause

The majority of women who had experienced a change in menstruation associated the onset of heavy menstrual bleeding with the normal aging process. Whilst most of the women were not afraid, they did resent the aging process and all felt they were not ready to embrace middle age. The erroneous association of heavy menstrual bleeding with becoming 'middle aged', intensified their negative feelings about themselves and their bodies.

"I assume it is any sort of time from 45 to 55 you know and I thought, plus I, sometimes I do feel unexpectedly hot and I didn't think that was just down to being overweight and my memory is getting worse but maybe it's just old age but I did have some blood tests and supposedly the menopause isn't on it's way yet." 29A

Some women believed that heavy menstrual bleeding might signify approaching menopause and this belief added to the perception that there was no point in seeking treatment.

"I am very conscious of my age and I don't think of it in a morbid sort of way but I do realise that people start, and as they get older [pause] we all get older and we all know people who are starting to become ill and have problems, and you realise your own mortality I suppose." 16B

Again the association of the menopause and aging was made and the prospect of being middle aged was fiercely resisted.

4.5.3 Fertility

Descriptive themes:

Fertility was a significant issue

The desire to retain fertility was not related to age or parity

Even women who had been sterilised or considered their family complete still sought to retain the potential to conceive

There was a belief expressed that being sterilised would improve heavy menstrual bleeding

Fertility was an important issue for many women regardless of their age or the number of children that they had and most wanted to preserve the uterus.

"I went quite for a bit and she became hesitant and I looked at her and I said you are going to say the H word aren't you and she said well a hysterectomy is a possibility of a form of treatment as such but she said she didn't know how I would feel about that.

How do you feel about that?

Erm [long pause, interviewee distressed and tearful] I know I have slowly come to terms with it, I was very upset at the time

Are you still very upset?

I am upset yes, resentful. The thing is around the time when I received this news I have got a sister and she is a year younger than me, I am [age of interviewee mid-forties] she is [age of interviewee's sister mid-forties] and she is pregnant for the first time ... It does hurt, it does hurt [interviewee upset] you know I am happy for them all and all the rest of it you see but [pause] oh god!" 39B

This view was also related to being female and the individuals' sense of identity as a woman.

"My ideal scenario would be not to be going through the experience I am going through, the coil to be doing what we all hoped it was supposed to do, help curb the heavy periods, less pain and without a shadow of a doubt know I will still be able to have children, with my womb still intact within me." 39B

Several women in this sample had been sterilised and two women stated that they believed that being sterilised would somehow improve their heavy menstrual bleeding. Both acknowledged that they did not fully explore this thought with the health professional at the time of the sterilisation but they did associate the loss of fertility with a reduction in menstrual bleeding.

"I made my decision I didn't want to have any more children so it seemed like the best alternative but again I feel I was, not misinformed maybe I didn't ask the right questions but I also thought that this might help my periods by being sterilised and it didn't. It made no difference at all." 42A

"I don't know why but I thought being sterilised would stop my periods. No one explained to me honestly, no one said this will not stop your periods. I know that sounds really stupid and naïve now but you think if you can't have children you are not going to have a period." 10A

Some women struggled with the rational decisions they had taken regarding long-term contraception and the question of needing hysterectomy for heavy menstrual bleeding.

"I am being irrational and illogical because I have only got one ovary and because I had an ectopic and during my last caesarean I was sterilized so it's not as though I am going to have ten babies anyway, but it [hysterectomy] takes away the maybe, maybe one day you could reverse the procedure [sterilization] they do it with a clip so its not completely final but of course with a hysterectomy it is... it's more of a feeling of knowing that you are still a woman and you could perhaps." 9B

4.5.4 Attachment to the uterus

Descriptive themes:

Retaining the uterus was associated with a sense of being female

Younger women were less attached to the uterus in terms of defining who they are

Most of the women in this sample, particularly the women who were over thirty five had a strong attachment to their uterus. They sought to retain it and viewed the uterus as an essential part of them. This was the case for older women whether they had borne children or not. This view was related to being female and the individuals' sense of identity as a woman.

"I wouldn't like to go down that route [hysterectomy] my mum did and I'd rather not.

Why is that?

I think it takes away a bit of your identity, your feminine identity away. I don't know, its part of my womanly identity... It's not like I'm going to have anymore kids. Maybe it's more psychological than anything else." 30B

For the younger women the uterus was seen as less important in their conceptualisation of themselves. They were much more likely to refer to activities or employment to define them. For those younger women who already had children, this was even more pronounced with the function of the uterus being accomplished and therefore not necessary anymore.

"I haven't got that much of an attachment to mine [uterus] as it has served its purpose. I have had my children and they are healthy and fantastic; for me it is a pain in the arse and needs to be got rid of." 27B

"You see people walking around you don't know who has got a womb and who hasn't. I don't think it's a factor in being a woman. They could be pushing a pram but you are not knowing it's not their baby because they haven't got a womb. It doesn't make me feel more of a woman because I have got a womb, it's more trouble than it's worth sometimes." 15B

4.6 Descriptive themes relating to clinical signs

4.6.1 Is my bleeding abnormal or not?

Descriptive themes:

Difficulty recognising heavy menstrual bleeding as abnormal even following a change in menstrual pattern

Lack of information available on which to judge heavy menstrual bleeding

Perception that heavy menstrual bleeding might be psychosomatic

Many women had difficulty recognising that their heavy menstrual bleeding was abnormal. This may be related to a lack of information and associated with the inference that talking about menstruation is still taboo.

"If I had read somewhere that sign of heavy periods is having big chunks I think I would have realised I have heavy periods, But I just didn't realise I came into that category." 19A

"They have got even heavier but [I was] not talking about it, not realising that wasn't necessarily normal." 29A

The women described a lack of information about menstrual blood flow on which to make a judgement about their own.

"There has got to be some sort of benchmarks really. You have got to say what is acceptable and what isn't. To come on and be a bit heavy is quite normal but to stand up and pour down your legs is not. It is difficult because every woman is different, they all obviously have their own periods and what they feel is acceptable is different." 42A

Discussions with peers and female relatives were not detailed and problems not clearly articulated. In addition no women were able to access information about blood flow in written or pictorial form from any other source. An idea put forward by the interviewees was the development and wide dissemination of a pictorial or descriptive scale to enable women to assess their menstrual pattern and verify problematic menstrual bleeding. Women suggested printing this information on sanitary protection packaging, and also publishing it in nightclub or other public toilets.

If a number of women in the same household were affected by heavy menstrual bleeding then the comparison (in the rare circumstance that one was made) enforced the view that excessive blood loss was normal. The first indication that their menstrual blood flow was excessive for a number of women was a diagnosis of anaemia and discussion about possible causes with a health professional. Some interviewees were aware that their

mothers or aunts had undergone a hysterectomy but not that the surgery was to treat heavy menstrual bleeding. Often this information would emerge following the interviewees' initial treatment and feelings of frustration were not uncommon if they discovered that a family member could have helped them to identify heavy menstrual bleeding sooner.

This difficulty in recognising heavy menstrual bleeding was also related to conversations about perceptions of health professional's views on menstrual bleeding.

"When do people go to their doctors about their periods really? The only time I went was because I was having very very heavy periods and I was losing livery bits which made me feel ill... I wondered if that was normal because I had asked about that and apparently they don't worry how much blood you lose it's only if you lose in between your periods. So I would probably never have gone to the doctors about it but I go regularly for blood pressure and in the toilets at the doctors was the sign" [detailing the ECLIPSE Trial] 32B

Even women who had experienced a change in menstrual pattern had difficulty deciding their heavy menstrual bleeding was abnormal.

"As the years have gone by they have gradually got I have noticed more lining, more heavier, lining instead of just regular blood.

Do you mean clots?

Yes, the clots and I thought well that's alright, that's just part of the process so to speak but between then and now I would say then and up to a year ago the clots have gotten much worse, much bigger, much painful." 39A

A number of women thought that their condition might be psychosomatic and that they were simply exaggerating their psychological responses to what may be a 'normal' menstrual period. This was related to two factors, firstly the lack of information about what was normal and secondly their experience of the attitude of some health practitioners, who were perceived to assert this belief.

"Is it in my head? You know? No one else must be getting them [heavy periods], so it must be in my head, so it made you think that it was probably in your head. Then you go back to the doctor because [pause] but you just get on with it because they reckoned it was in your head anyway...It ain't [in my head], they ought to see how many pairs of knickers I have to wash." 8A

In addition to the misconception that their heavy menstrual bleeding might be psychosomatic some interviewees were concerned about being diagnosed with depression. This was the case for several women who had been treated for depression in the past.

"You tell them [doctors] how you feel but they always just want to put you on anti-depressants but I am not depressed. I want something sorted out with my periods not depression. I need something for my periods and I am not depressed in that way. I am depressed because of my periods if you know what I mean." 51A

4.6.2 Experience of heavy menstrual bleeding

The data would suggest that the majority of women in this sample do have heavy menstrual bleeding. Although the assessment of menstrual blood flow in this study is derived from subjective descriptions of blood flow there is strong evidence to suggest above average volumes of menstrual blood and evidence of rapid blood flow. This conclusion is drawn from length of

menstrual cycle in terms of days of bleeding, the amount and flow rate of blood as determined by the women themselves.

"From the minute they started they have just been horrendous. In so much as they are just for the first two or three days of the period I am literally pouring. A box of tampons a day. I wake up in the morning and it is just running down my legs it is just a nightmare so I can't go out, I don't want to do anything." 18A

Menstruation varied from five days to fifteen days of which half of the days were described as heavy bleeding. Most women had a twenty five to twenty nine day menstrual cycle. The women described blood flow in graphic language and amount of menstrual blood seen.

"They would be so bad that I would probably bleed for 10 or 12 days ... It's been horrendous, go to the toilet and use super plus tampons and a sanitary towel. One day at work I went to the toilet and did that and before I got out of the toilet the tampon was literally falling out because it was soaked." 10A

Most women described large blood clots being passed, ranging in size from coin size to the size of a fist, often in conjunction with extremely heavy flow and episodes of leaking. Some women described using hand or bath towels and infant nappies in place of sanitary towels as sanitary towels did not cope with blood volume or flow rate.

"They've always been very heavy, very clotted, liverish clots. Very long time, I seem to have a long period, I have like a thirty seven day cycle, where eight of them are the bleed, four of them I'll be very heavy and three of them would be the tailing off and finishing."

27A

"I started to lose clots of blood and it made me feel ill because it was like liver." 32A

In addition descriptions of number and types of sanitary towels used per day and per menstrual cycle were also used to subjectively assess amounts of menstrual bleeding. Only one woman in this sample routinely used tampons in place of sanitary towels and her primary complaint was leaking and displacement of the tampon. She regularly used two tampons simultaneously in order to reduce the risk of leaking but found that even this was unsatisfactory. The majority of women used a combination of 'super' or maternity sanitary towels often wearing two at a time sometimes with a tampon as well, but still described experiences of episodes of leaking when their protection was not able to cope with menstrual flow rate or volume. Sanitary towel changes were frequent with women changing up to half hourly through the day and at several times at night.

Less than half of the women in this sample had noticed a change in menstrual flow within two years of seeking treatment. Perceptions of blood loss may be influenced by long-term use of oral contraceptive pill in a minority of cases (two cases only), although the description of excessive blood flow and volume was consistent with the other women in this sample suggesting that they did have heavy menstrual bleeding.

A third of the interviewees have experienced heavy menstrual bleeding for more than ten years. This group of women had experienced heavy menstrual bleeding since first menarche and the time they had heavy menstrual bleeding was directly associated with their current age, that is the women who were over forty stated that they had heavy menstrual bleeding for more than twenty five years. They described similar accounts of blood loss but also described coping mechanisms and behaviour to

enable self management of their condition more often than the women who had experienced a change in menstrual pattern.

4.6.3 Key symptoms to be dealt with

Descriptive themes:

Other clinical signs more important than blood volume

Pain significant for most women

Regular menstrual cycle crucial for management of heavy menstrual bleeding

Most of the women in this sample listed a number of clinical signs that were of concern to them in relation to heavy menstrual bleeding. These included pain (cramping period pain), fatigue, anaemia, irritability, low mood, joint pain, lack of energy and headaches. The key clinical signs that were of concern were highly individual and a combination of problems was usually stated. Most women did not think of their menstrual bleeding in terms of blood volume (in contrast to the medical professions outcome measures for successful treatment) but were far more concerned about rate of blood flow, the presence of blood clots and controlling this flow in order to maintain concealment of their menstrual state.

"It's a strange sensation because its coming away from you and you have no control over it... I have blood clots sometimes the size of a fist and it's awful" 15A

For the majority of women pain was the most significant clinical sign that they wished to address. The most often described pain was uterine cramps, followed by backache.

"You can cope with the amount of blood loss but it's the pains." 43A

"But it wasn't the actual bleeding part, it was more the pain ... doubled over with the pain." 5A

Many of these women felt this pain to be severe and debilitating and were completely unable to continue with their normal daily activities during menstruation. These women were more likely to take time off work due to sickness than those who experienced less pain.

"Then the last year they have got worse with pain and having to have time off work for a couple of days ... It always felt like my insides were dropping out the pain on the first 2-3 days and I was constantly needing to go and sit on the loo. My mood as well the week before PMT week I had noticed I am snappier and a lot moodier." 5A

All of the women in this study who felt they had severe pain were using regular analgesia, mostly self-medicating without consultation with a health professional. They did not seem worried about the side effects or long term usage of analgesia, which contrasted sharply with their views on taking oral medications to treat their heavy menstrual bleeding. There was a view expressed that because the analgesics were available to buy without a prescription they must be safe to use as required, for years in some cases. Most common analgesics used were paracetamol, ibuprofen paracetamol preparations with caffeine, aspirin and codeine preparations. The majority were taking a combination of tablets and some were routinely

exceeding recommended doses. A few were taking analgesia that had been prescribed for another condition or for another person.

"Because my mum has got [disease] she has got her own personal pharmacy in there, so it was cocodemol and ibuprofen strong dosage which literally take it, it knocks you out." 23A

There was evidence to suggest that the question of long term effects and potency of drugs was directly related to the fact that medications for the treatment of heavy menstrual bleeding were dispensed by prescription.

All of the women interviewed stated that one of the key issues for them was maintaining a regular menstrual cycle. The majority did have regular menstrual periods and would calculate when they were due to occur. This was fundamental for the women to plan ahead and organise management strategies to facilitate coping with heavy menstrual bleeding. Most aspects of life were planned around the menstrual cycle, particularly in relation to family events, holidays and patterns of childcare. This extended to sexual activity as well and many partners were aware and supportive of the planning of their sexual activity. For women who had control over their working environment (those in senior positions or who were self employed) this was even more important, as they were able to schedule their important business commitments for times when they were not menstruating. The women who did this thought that their colleagues were probably not aware of this as it did not seem to be an issue in the workplace. Women in more subordinate positions in the workplace had much more difficulty and were frequently off sick from work, to their detriment.

4.6.4 Clinical signs and their impact on quality of life

Descriptive themes:

Menstrual pain had a significant impact on quality of life

Symptoms of anaemia impacted negatively on quality of life

Rate of menstrual flow caused difficulty with concealment of menstruation

In clinical terms many women found pain in particular and other clinical signs such as tiredness and the presence of blood clots to be more distressing than the volume of blood. Of all of the clinical signs described pain was the one that causes most distress to the women in this sample. Several different types of pain occurring in different parts of the body were described, along with numerous pharmacological and non-pharmacological methods of dealing with the pain. Blood clots were very distressing for women. This was in part related to difficulties with controlling blood flow and maintaining concealment of menstruation when leaking occurred. For some women flooding and leaking through clothing was a regular occurrence, in spite of the use of multiple sanitary products at once. It was also related to feeling squeamish when larger blood clots were seen and women described a predisposition to disliking the sign of blood.

Whilst the volume of blood lost was not of primary importance to women the result of excessive menstrual blood loss, namely anaemia was. Anaemia was also an important clinical indication to seek treatment for heavy menstrual bleeding and for some was the first time that treatment was suggested or considered.

4.7 Descriptive themes relating to confounding factors

4.7.1 Physical confounding factors

Descriptive themes:

A concurrent unrelated health problem had an impact on heavy menstrual bleeding

Gynaecological problems had the most negative impact on heavy menstrual bleeding and treatment experience

The presence of another unrelated health issue was reported by a number of women in this sample, including hypertension, irritable bowel syndrome and migraines. Women felt that the other condition or illness had an impact on their experience of heavy menstrual bleeding, even if the co-morbidities were unrelated. This often related to concerns about how medications for one condition might interact with medications for the other.

"The tranexamic that you were prescribed did you start taking that straight away?"

No not straight away I think there was a gap, I am just trying to think how many months gap there was because at the time I had just started to take some (pause) something for my migraines and for my ulcerative colitis as well so yes I wanted that to settle down."

19B

Although the concurrent medical condition was usually unrelated and medications were compatible, women did not perceive this to be the case

and so a concurrent health issue become a physical confounding factor in their experience of heavy menstrual bleeding, and it's treatment.

For women who had a gynaecological problem, including infertility treatment, the concurrent health issue become much more influential and had a negative impact on women's experiences particularly with treatment. Their situation became more complex both in terms of developing or maintaining coping behaviours and accessing successful treatment.

"I went and saw him and I had a prolapse so they said that was causing problems as well and they stopped the tablets and said "Go and have a [Mirena] coil." ... then I had to go back within 3 months and it was about June/July and I'd had such a heavy period that the coil had come out. And he says "Well we can do... an ablation". So he was going to take me in and give me this ablation and I went for the day treatment and I was quite nervous. I forgot to take my tablet first thing in the morning. He said take this one now but the prolapse had got worse. So I was all drugged up, legs in the air, not very lady-like or dignified and he says "Whilst you're this bad we may as well give you a hysterectomy". And I thought "What now?" 7B

Surgery was recommended for the three women in this sample with a gynaecological problem. This had a negative impact on physical and psychological health and well being, especially for the nulliparous women in this sample.

4.7.2 Fear of pathology

Descriptive themes:

Most women did not associate heavy menstrual bleeding with threat of pathology

Family history or media reporting influenced fear of pathology

Fear of pathology was more often expressed by women treated in secondary care

Most of the women did not believe that their heavy menstrual bleeding was a sign of life threatening pathology. For some women there was some thought given to this possibility arising from knowledge of someone else's pathology. A few women suggested the possibility of pathology and linked their ideas with current newspaper items about a young minor celebrity's public battle with cervical cancer and her subsequent death. In one or two cases there was a family member who had been recently diagnosed or treated with cancer.

"The main reason I went was because obviously there is cancer in the family, my aunt has cervical cancer, she has had breast cancer. My mum has had bowel cancer, my dads got prostate cancer so you are always worried something is wrong." 43A

Interestingly all of the women who expressed concern about the likelihood of pathology such as cancer were all seen in the secondary care setting in a hospital outpatient gynaecology clinic by a consultant gynaecologist.

4.7.3 Treatment setting: primary or secondary care

Descriptive themes:

Primary care setting more comfortable and convenient for women

Known health professional more prevalent in primary care

Secondary care setting associated with increased anxiety

Expertise of health professional recognised in secondary care

The treatment setting did seem to have a bearing on the women's experience of treatment overall. The primary care setting was described in more favourable terms than hospital outpatient gynaecology clinics. Women found it easier to travel to a known place for both the consultation and treatment. The location of the primary care surgery was often more practical and closer to the interviewees home and this reduced stress associated with travelling to an unknown and complicated location such as a hospital. Facilities were often less intimidating with smaller numbers of staff and friendlier environments in primary care compared to secondary care.

"Doctors are bad enough, hospitals are worse."

Why?

"Whenever I go to the hospital it's for something bad. When you go to the doctors that's because you are poorly so it's all bad things really. I always think hospitals are worse than the doctors surgery, that's just how I feel about it." 51A

The most beneficial part of treatment in the primary care setting was the doctors themselves and pre-existing relationship that had built either directly with the woman or with members of her family or close friends.

"He is an old fashioned doctor if you see that makes sense, what I would consider to be an old fashioned family practitioner. Where he takes concern of not just what you go to that minute but everything else as well.

Does that change the relationship between you and the doctor?

Yes I have absolutely no fear, I can go to him about anything, absolutely anything and also now he is my daughter's doctor as well. I know he would do his absolute damndest by me and by her, there is no messing about." 18B

Whilst the expertise of gynaecologists in the hospital setting was recognised the lack of pre-existing personal relationship did impact on the women's experience. The women had different views about the health practitioners with the two settings though, with individual health practitioners commended and criticized by women in both settings.

The secondary care setting also introduced two important additional sources of anxiety or distress for women. The first was the idea that they might have a significant pathology because they had been referred to a specialist. Almost all of the women recognised that their heavy menstrual bleeding did not indicate significant pathology but for some the referral to secondary care introduced doubt. The second was the association between hospital (specific or general) and traumatic events such as the death of a parent or serious accident experiences by themselves or their family and friends.

The expertise of the gynaecologist in the secondary care setting was recognised and appreciated.

"I did find them lovely at the hospital because it was; it was just about heavy bleeding and women's problems. They were really, really lovely and perhaps when you go to the doctors there is so many different things he is seeing and you know the patient before and the patient after perhaps whereas if you are seeing somebody that is just dealing with all these perhaps they get a bit more, I don't know perhaps they are a bit more dedicated because they see the same people with the same problems." 26B

There was a more clinical emphasis perceived by a few women in this sample. Some women felt that the health professionals in the secondary care setting were more concerned with the physical aspects of heavy menstrual bleeding, such as blood loss, and did not take a holistic or individualised approach.

"I think sometimes the gynaecologists are dealing with the problem as opposed to the woman and that is the mistake; that is the mistake." 27B

Women who experienced this approach were dissatisfied with the consultation process and expressed reluctance to seek further treatment. This impersonal approach made communicating about psychological or practical aspects of heavy menstrual bleeding, such as impact on sexuality, difficult to disclose and impossible to discuss. Women felt undervalued by their health professional.

4.7.4 Communication and the gender of the health professional

Descriptive themes:

Communication was influenced by gender

Women requested female health practitioners more than male

Female health professionals were perceived to be more empathic and understanding than male health professionals

Communication with health professionals, work colleagues and family and friends was influenced by gender, with most women feeling uncomfortable discussing heavy menstrual bleeding with men including male doctors.

"I personally couldn't talk to a male doctor about it. I personally wouldn't feel comfortable." 15A

"I do feel when you are talking to a male doctor about women's problems no matter what they are, they don't always listen or understand, it's just 'well you have to put up with it' or that is the impression I get. Whereas when you speak to a female doctor, because they go through periods and other things you have gone through, they just seem to empathise with you a bit more than a male doctor." 12B

This view was the most commonly expressed but a few women held the opposite view.

"I have no hesitation talking to any male doctor about it, they would be more likely to be completely impartial because it has never happened to them." 9A

Women requested female health practitioners more than male.

"There are lots of male GPs and I definitely didn't want one, I just don't think they understand. I specifically wanted a female [GP], but there is one female in particular ... I just felt she was more in tune with what I am trying to say." 2A

Female health professionals were perceived to be more empathic and understanding than male health professionals.

4.7.5 Expertise of the health professional

Descriptive themes:

Greater professional expertise was associated with perception of increased knowledge and understanding

When communicating with health professionals the perceived level of expertise and understanding of the health professional was also influential. A few women had the perception that their GP would have limited knowledge about heavy menstrual bleeding and in one case this was suggested by eight years of treatment for anaemia before being asked about menstruation as a result of the ECLIPSE Trial publicity.

"What a cheek! I've been sat here for a few years now saying how chronically tired I am. I'm just amazed that he pulled off the shelf the research and said you can go for some investigative procedures. I mean that, and he's such a good GP and has sent me for other investigative procedures. I mean that, that's the thing that amazed me that he's actually, he's sent me for colitis, he's sent me for chronic headaches that come out the blue for an MRI scan on my

head, you know, he has sent me for other treatments, but blow me he never asked that.

Why do you think he didn't ask that?

Because he hasn't got that awareness of periods having that kind of effect, having that effect on you." 19A

The individual health professional's personal communication skills impacted on the women's experience of the consultation. An open style of communication with a genuine interest in the women's own perceptions was welcomed. In other words a 'good bedside manner' generated confidence in the health professional, who was then perceived as being knowledgeable and understanding. Less accomplished interpersonal skills had the opposite effect, regardless of the actual training and expertise of the health professional involved.

In the secondary care setting the title of the health professional also added to the perception of knowledge and understanding of heavy menstrual bleeding. Women had confidence in 'professors' or 'consultants' and were sometimes disappointed if they were then seen by someone other than the professor or consultant.

4.8 Descriptive themes relating to previous knowledge and experience of treatment

4.8.1 Influence of family history on perceptions and treatment expectations

Descriptive themes:

Unawareness of family menstrual history

Following maternal treatment journey

During the study about half of the women in this sample become aware of a family member who also had heavy menstrual bleeding. This was predominantly their mother and in one or two cases a sister. There was also a clear inference from some participants that heavy menstrual bleeding must be hereditary.

"My mum said her mum had been the same, and she was the same so it's probably hereditary isn't it, I should imagine." 30B

The majority were unaware of their family menstrual history at the time of the first interview but during conversations about their participation in the research their relative disclosed their own menstrual history and treatment experiences. It was apparent that close family members had not discussed this issue outside of the context of the study and for such long periods of time, years in some cases. It is remarkable how this lack of discussion has endured, requiring something out of the ordinary to provoke it such as research participation – which perhaps made it easier and gave families permission to discuss more. A number of women stated that they were aware of 'women's problems' within the family but that the nature of the

problems were never discussed openly. When explored further this finding was related to maintaining the societal norm of silence about menstruation. Interviewees felt disappointed that a valuable source of information and support was closed to them in order to maintain the societal norm of silence. The mothers of the women in this sample were reflecting stronger messages of silence than those that persist today, as interestingly the women interviewed had communicated or were preparing to discuss menstruation with their own children in a much more open and supportive way.

For the women who were aware of their mothers menstrual history there was a view held that they would follow the same treatment journey as their mother.

"If your mother went through, if ever your mother, your aunt and elderly relative went through similar problems and what have you it is very likely that, as a blood related relative, you are going to be following that course or process. It might not be severely or you may have the worst experience what your mother, your sister or your cousin may have had because everybody's bodies are slightly different." 39B

This view was held whether the interviewee had known for a while or had only just discovered their mother's menstrual history.

"I thought about the contraceptive pill again. I just thought well I would rather suffer a week of this [heavy menstrual bleeding] than get unduly cross with my children. I mean my mum was and I keep harping back to my mum but she, just before her period had major temper, you know she would chase you round the house with a table leg on one instance or a hair brush. She [mother] would throw

things at my dad so when I did take the pill and I found myself inside probably getting cross, you know, I am not going down that road. I am not going to become my mother and children are gorgeous and I will deal with them with as much patience as I can muster. I don't need any help to be impatient so that's why I have got an issue with that [contraceptive pill] and don't want to do it."

9A

The maternal history had a strong influence on treatment choices and the development of treatment preferences. In some cases this confirmed the women's own feelings about treatments and in some cases it was a powerful motivator to consider treatment and sometimes to seek an alternative treatment.

"She had terrible a bit like myself heavy, heavy periods that would go on for 3 or 4 weeks and then she would stop for a few days and then start again. She was really miserable, she kept going back and oh you know it's just your age and bla, bla, bla and all this. Eventually it got the stage where she had to have a full hysterectomy, she was it was 1996 or 97 so she was 52 maybe 50, 52 when she had her full hysterectomy and then she, but the endometriosis by then had spread to other places so she still has problems with you know her various other things ... So I was just determined I am not going down that road, I am not leaving it for years that she got left, I am just not going to have it." 18A

This was particularly true of hysterectomy. The majority of women's mothers who had heavy menstrual bleeding had undergone a hysterectomy and there were mixed narrative accounts of the success of this procedure in improving quality of life. Even though surgical techniques have improved over the last twenty years and the operating surgeon would be different,

the women believed that hysterectomy would have the same consequences for them as it had for their mothers. Almost no consideration was given to advances in surgical techniques when considering hysterectomy. When questioned they could not rationalise this viewpoint but held it none the less.

This was also found in the case of the 'coil'. Little differentiation was made between the intrauterine device and LNG-IUS when making these assumptions. The first hand accounts from a very close relative or witnessed outcomes were more powerful when considering these two options than any other form of information. This finding was inconsistent with the educational level of some of the women in this sample.

Most women who had daughters believed that they too would eventually have heavy menstrual bleeding and need treatment in the future.

"If you have got problems make sure you talk to your children don't let them suffer quietly, because these things do run in families."

27B

For some this was a strong motivating factor in their decision to participate in this research; in order to expand on current medical knowledge and understanding and to improve treatment options before their daughters needed treatment.

4.8.2 Previous experience of treatment

Descriptive themes:

Knowledge and experience of previous treatment varied

Wide range of previous treatment experienced

Most reported unsuccessful treatment in the past

A large proportion of women, particularly those who had a long history of heavy menstrual bleeding did have previous experience of at least one medical treatment option in the past. There were also a few of women who had never considered or experienced treatment in the past.

The previous treatment options were widely spread, and this is consistent with the treatments having been prescribed before the publication of the NICE guideline in 2007. There was a large degree of individual variation in the knowledge and experience of previous treatment. A negative experience of previous treatment was a powerful influence on treatment preferences and expectations.

"When they prescribed the tranexamic acid I thought been there, done that, it didn't work." 7A

Some women found these treatments to be unsuccessful in terms of lack of effect and some found the side effects intolerable.

4.8.3 Expectations of a positive outcome

Descriptive themes:

High expectation of positive outcomes

Treatment preference influenced high expectations

Short time frame made expectations unrealistic for some

Expectation that positive treatment would improve all aspects of life

The women interviewed had high expectations of a positive treatment outcome.

"I would never have to worry again, it might be the miracle cure that I am after." 18A

"I am hoping for miracles with this tablet." 32A

There were numerous external and internal factors that influenced the expectations of women. External factors included the information they were given by their friends who were their principal information source. Women suggested that only positive information was shared about heavy menstrual bleeding. Accounts from friends were upbeat and used emotive positive language. The accounts from friends were backed up by reports of the success of a certain treatment, (namely LNG-IUS) published in the lay press that coincided with the publication of the NICE guideline recommending LNG-IUS as a first line treatment for heavy menstrual bleeding.

The development of a treatment preference had a significant impact on treatment expectations. There was a strong sense that if a treatment was chosen by the woman herself (most often before consultation with a health professional) that it would be successful. Along with this expectation was the expectation that side effects would not be experienced.

Most women expected to see an improvement in their heavy menstrual bleeding within a very short time of starting treatment. Even though they were counselled that they would need to persist before treatments would be effective, the majority felt that they should have their expected

outcome within two or three menstrual cycles. This view was held by the majority of women regardless of which treatment option they were prescribed.

Many women interviewed had high expectations of a positive outcome from their treatment, and this was consistently expressed amongst women prescribed standard treatment and those prescribed LNG-IUS. Those who had a treatment preference or who were initially treated with LNG-IUS used more emotive language to describe their expectations. For a minority of women these expectations were unrealistic and this unrealistic level of expectation was more often expressed in women who had developed a treatment preference for LNG-IUS. Around two thirds of the interviewees thought that effective treatment for heavy menstrual bleeding would have a very significant impact on other areas of life such as career progression and relationship issues.

"Just feeling better, I just want to be happy ... I was hoping that if I felt better my relationship would be better." 43A

This finding highlights how heavy menstrual bleeding takes precedence and dominates women's lives. Women expected to see improvement in their working lives, domestic lives and relationships and there was little recognition of the possibility that factors other than heavy menstrual bleeding might be influential in the problems that some were experiencing at work or at home.

4.8.4 Experiences of LNG-IUS

Descriptive themes:

Most women had irregular bleeding in the first three months

Generally LNG-IUS tolerated well and considered to be successful

Progestogenic side effects problematic in a small number of cases

LNG-IUS was considered to be successful by the majority of women who were treated with it in this study.

"I had it [month and year]. It started working really well probably from [third month following fitting] and it was a very good year. No periods. I put all my big tampons away." 29B

"The best part of six months in from having the coil; things certainly seem to be what it says on the tin basically."

Which is?

Reduced blood flow. That is what I have noticed. Month after month the periods were getting lighter and lighter to the point where I hardly noticed I was even having a period." 39B

Successful treatment had a positive impact on many aspects of life.

"Well it's a joy really because initially I was quite anxious because I kept thinking that at some point they could come back or they could start or I could spot or whatever so I was and that did actually happen initially I was having spotting or a mild period pain and things like that but they just got less and less and now over the last

four months there has been absolutely nothing at all so I am actually, whether I should say that or not I feel 100% confident that it won't happen which is a joy in itself really." 37A

Generally the LNG-IUS was found to be problematic within the first three months of treatment with irregular bleeding being the most common side effect.

"It started off really, really excellent then we tended to have a bit of a dip where it was a bit hit and miss some months but now it seems to have settled back down again so I don't know whether that was just a fluke or perhaps whether I was a bit more stressed at work at the time and you know busy in my life that made an impact on that but now on the whole is the best decision I could have made." 26B

Most women in this sample considered removal of the LNG-IUS after one or two weeks but did not seek to do this partly because they were advised that their experience of treatment would improve over time and partly because they thought that the removal process would be difficult or they might not have an alternative treatment.

"The other day it [intermittent bleeding following treatment with LNG-IUS] drove me so mad somebody actually offered me pliers and I nearly took them [pause] you know." 27B

"I first went back for the check up it felt like everything was alright and I did say to him is this dribbling and drabbing going to settle down and he said oh yes of course you know. Which maybe it does for some ladies I don't know but no it hasn't and it doesn't but you know then I think what are they going to do if they take that out."

27B

Women did not ask for the LNG-IUS to be removed because they did not want to go through the process of revisiting the health professional and being subject to another vaginal examination with such a short time.

"Tell you the truth I did actually think about going back to the doctor because I thought from a point I thought perhaps there was something wrong perhaps the coil perhaps wasn't working properly or perhaps something had happened and it was sort of making it go a bit weird but then I never sort of got round to making an appointment and then the next month would come and it would be a bit better and then by the third or fourth month it seemed to have settled down anyway." 26B

Those who were seen in the secondary care setting saw this as a further barrier as returning to the hospital to see the gynaecologist was seen as more costly for them personally and for the health service too. The fact that the women expected a period of transition following the initial fitting of the LNG-IUS was a positive finding and reflects the detailed information given by most health professional about the initial side effects at the time the LNG-IUS was fitted. However the interviewees were surprised at the amount of disruption to their cycle or amount of irregular bleeding as it was more significant and disruptive than either their peers or health professionals had indicated. The women also had high expectations of this treatment in particular, and associated with the belief that their menstrual bleeding would cease completely was the belief that this would happen within a relatively short time scale, that is one or two months.

"It took a while, it didn't do much at the beginning, it took a while for it to do anything. I didn't think it was going to do anything at first but yeah, it took a while and I noticed it slowing down. That was the big thing for me. It didn't matter if it didn't stop or

anything, just slowing it down. It has done it in the same year, it has done it bit by bit, it slowed down and slowed down and now for the last two or three months I have not had anything, not a thing."

15B

When this belief was explored further it was linked to the finding that women who had a positive experience of treatment were more inclined to talk about it, whereas women who had had a negative experience of treatment stayed silent. The women in this sample persisted with the side effects of the LNG-IUS for longer than the women treated with oral medication, not seeking consultation about removal for three to four months compared to the women on standard treatment who stopped taking their medication after two to three months. In this sample only one woman had her LNG-IUS removed at four months citing pregnancy symptoms and irregular bleeding as her rationale. She had experienced heavy menstrual bleeding for more than ten years and decided to opt for no treatment, preferring to rely on coping behaviours rather than the side effects of the LNG-IUS.

"It was very similar to being pregnant and I did have lots of, I didn't actually feel sick with the coil but there were lots of feelings of just general lack of energy which I remember from early being pregnant ... I would rather have stuck with the heavy periods for a week once a month than feeling like absolute rubbish every [pause] every day. The consultant did say it would probably wear off but I stuck with it for I think I don't know whether it was two or three months and just felt that this is not, I can't live like this, I am too tired." 11B

One other woman had experienced seven weeks of irregular bleeding at the time of the first interview, which she described as moderate every day and she was undecided as to whether to continue with this treatment.

Unfortunately she was lost to follow up and her decision is not known. There was also one woman who was randomised to the LNG-IUS and who requested a change of treatment before her coil fitting could take place. This decision was made on the basis of information provided by a family member who was a pharmacist and was based on the fear of an indwelling device and that irregular bleeding would make her coping behaviours and mechanisms fail.

The majority of women persevered with the LNG-IUS and at twelve months most women were satisfied with this treatment and had experienced a significant improvement in their condition.

"It is such a relief, it really is after the pain that I used to have before and the tiredness and the flooding and the whole, it was almost like your whole life revolved around periods and being comfortable or uncomfortable and you know it was, it was awful and I was feeling constantly tired and thinking this is just you know that just awful and now that has all gone and it is just such a relief it really is." 16B

Most women with a LNG-IUS were happy to continue with this treatment long term. Several women had considered hysterectomy prior to commencing their treatment with LNG-IUS now no longer considered surgery as a viable option.

"What I have now is not worth going through an operation for... If it hadn't worked and I was still having heavy periods then I would think about it but no, not with the coil, no it's not worth having that done, taking up space in the hospital just to have that." 5B

4.8.5 The fitting of the LNG-IUS

Descriptive themes:

Fitting of LNG-IUS more difficult for women than expected

Same findings for nulliparous and multiparous women

Experiences were slightly better in primary care setting due to continuity of health professional

More psychological preparation needed before procedure

The majority of women who were treated with LNG-IUS found the coil fitting to be more distressing than anticipated and a number felt unprepared psychologically for the procedure.

"I suppose I was a bit naïve, I suppose a picture might have helped. I was thinking of like a smear test but they actually have to open you up a bit more and obviously that's not very pleasant." 29B

Whilst it is well documented that the LNG-IUS might be more difficult to fit in nulliparous women due to the cervix never having been changed by pregnancy and childbirth and many doctors did not recommend it for nulliparous women, but this study found that multiparous women had similar experiences.

"It really hurts when they put the [pause] the spectrum

The speculum

When it opens it really hurts and then I suppose she has got to open you more, the entrance at the cervix and she said I am going to do it a couple more times and I was holding the bed.” 29B (multiparous woman)

They recounted feeling pain and discomfort far in excess of other medical procedures within their previous experience and used emotive language.

“I had it done [LNG-IUS fitting] and it really hurt. I think you would really have to make that how do you sort of make that clear to somebody. Even if they have not even had a baby or something. It hurts for a short time I suppose. But you wouldn’t like, if you were doing that to somebody’s neck it would be classed as torture or something you know it really is nasty. You know a bit sort of medieval.” 29B

Some of this might have been related to the fact that it was an intimate gynaecological procedure and women find this kind of procedure psychologically difficult and therefore don’t relax their bodies.

“That was quite embarrassing for me because they kept saying relax, relax, relax and I am like it’s a bit embarrassing when you are on your back, your legs are in the air so to speak, you have no sort of control because they are strapped into these stirrups and you can’t really move and you are opened up for all the world to see and whilst the doctor was there trying to you know fit this coil and what have you, the most embarrassing thing I thought how can I relax I can feel a sensation in my bowel going on and the last thing I wanted to do was to pass wind in the doctors face so I couldn’t relax.” 39A

Some of it was also related to the fact that the health professionals taking consent for the procedure often down played the possible intensity of the pain and also the complexity of the procedure itself.

"She said it's going to be feeling like this, this, this and this, you are going to feel a little bit of pain and it should be over and done within like two minutes, okay right not a problem. Oh how very wrong she was. The little [nationality] nurse I was holding her hand and I had to let go of her hand because I would have broke her fingers because in the end it was literally gripping on to the sides of the bed, tears coming down my eyes, excruciating pain ... I felt sick, I felt giddy I just wanted to be sick and then she done it and the pain was just excruciating, she said you are going to have to wait like half an hour in here. I couldn't walk when I got off" 23A

The women had a strong sense of the fact that whilst this was a simple procedure for the health professional, it was not simple for them as a woman. It is not known whether any type of local anaesthesia was used as routine. A few women recounted being told to take oral analgesia before the procedure but many did not. In most cases women did not specifically mention local anaesthesia in their narrative and those that did were dissatisfied with it.

"I don't think she put any bloody numbing lotion there to be fair there is no way on this earth that she put anything to numb me because there was no numbness." 23A

The place that the fitting of the LNG-IUS took place made little difference to the women's negative experiences. Women who were treated in the hospital settings described more anxiety about the procedure but descriptive accounts of the duration and intensity of pain during the fitting

procedure were similar to those treated in the primary care setting. Women in the primary care settings did have less anxiety prior to the procedure due mostly to the pre-existing relationship that they had with their GP but still recounted similar levels of pain and discomfort.

4.8.6 Experiences of standard treatment

Descriptive themes:

Standard treatment less effective than LNG-IUS

Treatments discontinued after short time

Number and size of tablets cited for tranexamic acid

Oral medication seen as short term measure

Generally most women who were treated with standard medical treatment (tranexamic acid, depo provera, oral contraceptive pill) were less satisfied with their treatment and most had stopped taking the prescribed medication at twelve months.

This was particularly true for the women in this sample who were prescribed tranexamic acid and depo provera.

"I have been taking the iron tablets which help with the dizzy spells and things like that I did try the other medication [tranexamic acid] but I tried it and I felt no, I didn't feel anything changes much and therefore I thought is there any point taking another medicine if it doesn't make any difference. I still have the pain and I still felt the same and the blood flow seems to be no better so I haven't taken it again." 28B

"I was taking, I had got good at remembering to take them, take them just before and take the maximum dose and I thought they are not making much difference at all, I still can't get out of bed without hopping to the bathroom cross legged." 29B

"The course of treatment I started to have 12 months ago so that was the Depo injections. Which initially worked fantastic. Stopped bleeding almost straight away and I had no bleeding at all and it was fantastic I actually felt fine, [pause] a bit of weight gain but you expect that with hormones you know we will see how we get on. But then the end of the last one, so coming up to the end of the three months of my last injections [month of year] two weeks, three weeks before I was due to have it I started bleeding. So I had the injection in [month] I haven't stopped bleeding since, now it's not working and I am getting chronic migraines all the time. And I have ballooned in weight in the past three months so suddenly it just seems not to be working, not suiting me, I am not quite sure. I am changing my treatment as of next week." 18B

The experience of the few women who were prescribed oral contraception was also not satisfactory although this treatment was continued for other reasons such as familiarity, reversible contraceptive effect and lack of interference with other medical treatments.

There were however a few women who were satisfied with some aspects of standard treatment.

"My periods have really got better, I hardly have any periods, I think I have had two days of bleeding, don't get any pain but I do get a very bad week before my period is due, I get terrible like depression where I am always crying, I just feel dead depressed"

and I just let small things they just seem like big things and it's just when I am coming up to my period. But regarding you know having pain, I don't get that any more." 43B (oral contraceptive)

Women were dissatisfied with tranexamic acid although they did acknowledge some reduction in menstrual blood flow. This further highlights the findings that other aspects of heavy menstrual bleeding were more problematic than blood volume and also the finding that disruption to the menstrual cycle was unacceptable to the majority.

"If I take them it does keep the bleed you know under control. If I leave it a little bit too long before I take the next lot I am just like flooding again so it's, I am not really one to take tablets though, it's very hard, it's definitely, I have to get up in the morning and take two tablets and I can't make it until lunch time to take more. So I tend to take them as often as I can in the day and then when I get home if I have not got any more tablets left if I don't tend to sort of relax." 32B

In the case of tranexamic acid women were concerned about the physical size of tablets and the number that they had to take each day.

"It's like remembering to take X, Y, Z and the amount of tablets all the time, that can be a problem and you think "Hang on a minute, I've got to do this, hang on a minute, I've got to do that. Did I take these here? If you are at home you have a more structured life you are more level. When you've got chaos like this, remembering to take tablets and making sure there's the right spaces in the day between these tablet-taking that can be a problem in itself 'cos you might not be where your tablets are or you might be, you know,

hung on at work doing extra hours and that and it's all that and it's all that added stress that you don't really need." 7B

The majority who were treated with tranexamic acid were compliant with the prescription but did not see significant improvements in the short term and so stopped taking their medication with two to three months.

Many of the women who discontinued treatment elected not to try any other treatment, preferring to manage their condition themselves by changing coping behaviours and strategies. This was particularly true of the women who had a long history of heavy menstrual bleeding and those who anticipated the onset of menopause within the next few years.

Several women experienced a change in menstrual cycle whilst taking standard treatment, even when the treatment prescribed was not hormonal.

"For the first time in my life they actually upset my periods and I've had, I've been two and three weeks late and then I've been three weeks early and I don't quite know where I am at the minute."

27A

It is possible that the changes in menstrual cycle were not influenced by the medication but by hormonal changes occurring as women approached menopause, however this kind of experience was described across the whole sample including younger women who were prescribed standard treatment.

"I found that probably the first two months or so it seemed like a life saver it completely did change my life but then it seemed to kind of make it worse in a way that it was just so unpredictable. You know I kind of just thought I have got a normal period and

everything is fine and then I would be bending down or up at the shops and think argh it's obviously just worn off so it completely took me by surprise." 9B

The women who discontinued standard treatment did so for a number of reasons the one most often cited was the size and amount of tablets prescribed daily.

The women in this sample were not concerned about addiction but were concerned about the physical amount of tablets that they would have to take over the course of their remaining years of menstruation.

"I must admit that I don't like taking tablets so it turned me off and when I first started taking them I'd try to do without. But then it was silly I needed them so I say I think a maximum of eight and I definitely could have done with more. I took two at a time with maybe another three doses during the day to actually you know get through the day." 32B

"They [tranexamic acid] did work but I didn't like the quantity of tablets that I was taking." 18A

Most women disliked the thought of taking medication, and the majority voiced concerns about the long term effects of the medications prescribed. For some this was related to potential unknown side effects.

"I will probably go back to the doctor and get some more tablets... unless there was something else that they could try instead rather than stay on them long term. But in the short term, yes... I know they research them but they never know until years later the effects. It might not have an effect now but in years to come and

I'd rather not take the risk of causing anything long term. If I had a choice I would rather not take the tablets." 30B

4.8.7 Discontinuing treatment

Descriptive themes:

Initial compliance with prescription was good

Standard treatment was often discontinued with two or three cycles

No consultation with health professional before discontinuing

Number of women opted for no further treatment

Only three of the women in this sample were satisfied with the treatment prescribed at the initial stage in the treatment continuum (two LNG-IUS one standard treatment) that is within three months of commencing their prescribed treatment. Two of them described the physiological impact of commencing treatment as the main positive factor. Only one third of women had noticed a reduction in menstrual blood loss at this stage, however the majority of women in both treatment arms felt the perceived side effects of the medication (for example irregularity of the menstrual cycle, persistent bleeding following insertion of LNG-IUS) outweighed the reduction in menstrual flow at this stage.

In general daily compliance with the prescription was good but many women discontinued standard treatment for more after one or two menstrual cycles. This was often related to the expectation that the treatment would be very effective with a short time frame and these women who did not notice a significant improvement in quality of life

admitted that they quickly became less likely to adhere to the prescription and discontinued the medication during their next menstrual cycle.

All of the women who were dissatisfied with their treatment did not consult their health professional initially. This included women who stopped taking standard treatment and the women who were dissatisfied but persevered with the LNG-IUS. Some women expressed the feeling that the health professional might be judgemental, even punitive, or that there simply was not another alternative treatment.

"I felt, at the time I felt well if I don't take them and now if I go back to my GP she is probably just going to tell me that well you were prescribed the tablets, you have stopped taking them you know so and you don't want this treatment and you don't want to take these so at the end of the day there is not a great deal that you have left us that we can help you with so I can understand that as well." 28B

Women who discontinued standard treatment did not consult with any health professional at any time. The medication was within their control and they took the decision to discontinue treatment independently because of this. Also there was a perception that the health professional might be disapproving of the relatively short length of time that the treatment was taken for.

A significant number of women who discontinued standard treatment then opted for no further treatment, instead relying on coping mechanisms and behaviours as they had done prior to seeking treatment. For a third of the women this approach was no longer satisfactory and a consultation was sought in order to discuss alternative treatment options. This was more common with the women who had been seen by their GP in the primary

care setting and the request for a change of treatment often arose at an appointment booked for another reason. The inference from these women during the second interview was that the initial standard treatment may have been more effective than they had realised. It was only the return of the pre treatment level of menstrual blood flow that allowed them to appreciate the difference that the treatment had made. Only one woman returned to her original prescription for tranexamic acid though and she did so whilst on the waiting list for hysterectomy. The others opted for LNG-IUS, one opting for LNG-IUS then proceeding quickly to hysterectomy due to failure to fit the LNG-IUS due to uterine prolapse.

4.8.8 The development of treatment preferences

Descriptive themes:

LNG-IUS most common preference

Standard treatment preference expressed as preference against LNG-IUS

Women with preference tended to be educated professionals

Preferences were influenced by a woman's previous experience of treatments.

Of the ten women in this sub-sample six had a preference for treatment with LNG-IUS and four had a preference for standard treatment, all of whom were prescribed tranexamic acid. All of the women were prescribed treatment according to their preference. Interestingly the women who had a preference for standard treatment expressed this as a preference against

LNG-IUS rather than for tranexamic acid. A few of the women wished to retain their reproductive potential and one women had an objection relating to her religious upbringing and the sanctity of life and the moment of conception.

"They have shown the moments of conception you know when the sperm has gone through the egg and within a few days the cell sort of – I think the question might be about when does a fetus become an entity, a legal entity or something. Well I am not really bothered about legal entity, my bothering is about the spiritual aspect you know, when does a fetus become a spiritual being." 19B

The education level of these women was generally high with six having had a university education and only one having no educational qualifications at all. The educational achievement was reflected in the occupations of this sub-sample with the majority in professional employment.

Table E on page xxxx shows the treatment outcomes for the women who were prescribed their preferred treatment over the course of twelve to eighteen months. In two cases the outcome is not known as these women, (both had LNG-IUS), were unobtainable at the time of the second interview. Amongst the women who had a preference for LNG-IUS the majority were continuing with LNG-IUS at the time of the second interview, with only one woman discontinuing treatment with LNG-IUS. The women who had a preference for standard treatment were all prescribed tranexamic acid and had all discontinued treatment opting most opting for no further treatment and one opting for LNG-IUS by the time of the second interview.

4.8.9 Sources of information about treatment options

Descriptive themes:

Health professionals were not usually the primary source of information when developing treatment preferences

First hand accounts from friends was the most influential source of information

First hand accounts were almost always positive as unsuccessful treatment experiences were not discussed

Health professionals were not the primary source of information when forming preferences, although this was not the case for one woman.

"I have spoken to a couple of friends who have had it and they said go for it, it's the best thing....its not as if I've gone in there [the hospital] not knowing" 23A

"She [work colleague] has had the Mirena coil which she said has made a real difference...so I was thinking it will probably be easier if I had that " 11A

Information about treatment options was primarily gathered from first hand accounts from family and peers and this source of information seemed to be valued above all other sources for the majority of women in this sample, even if it was unclear or out of date.

"My mate has been having stuff examined on her [expletive deleted meaning gynaecology investigations] for god knows how long, she has been through it, she has been through the tablets, she has

been through the implants, she has been through the injections and she has had the coil fitted. The Mirena coil now for about eight months and she said it's amazing, it's fantastic, it changes your life." 23A

Several women recounted friends and relatives experiences but often the information about treatments was inaccurate or conflicting indicating either incorrect recollection during the narrative by the friend or errors in interpretation by the listener.

Few of the women in the study sample had sought information from other sources such as the Internet and all had a treatment preference prior to their medical consultation. Some women were unclear about where they had heard about LNG-IUS being prescribed to treat heavy menstrual bleeding although they were certain that it was not from a medical source.

The most requested treatment was the LNG-IUS, largely based on word of mouth information from peers and relatives. Women who expressed a preference for standard treatment did so because they specifically did not want LNG-IUS, due to its effect on fertility and also the invasive nature of the coil. Amongst the other women who rejected the LNG-IUS due to its contraceptive effect the majority strongly wanted to conceive a child. Interestingly all of these women were in their forties and they described the impression that they were considered to be past childbearing age by the health professionals that they saw. This was particularly true of the nulliparous women, both of whom had complex gynaecological histories but still had the desire to conceive and the belief that they would do so in the future.

The women often cited stories of positive outcomes with LNG-IUS from their peers or families. However when this theme was explored further it

emerged that most women had not heard anything negative at all about LNG-IUS. Women felt that if treatment were unsuccessful, the subject of heavy menstrual bleeding would remain taboo, so the negative experiences of treatment were far less common by virtue of simply not being told.

Communication about positive outcomes was more common than communication about negative outcomes. This included information from peers and also whether the women themselves communicated more openly about their treatment.

"I just said I had the Mirena coil fitted twelve months ago and I had it as part of a programme where I would be monitored over a few years and this is the follow up appointment and the class teacher said to me "oh really oh that sounds like the problems I have been having" but I have got to go because I knew it could be a huge conversation and I thought, I did actually think to myself this is really weird starting a topic of conversation about something so personal but being so blasé about it so I think if things hadn't gone to plan and it was perhaps messy then I probably wouldn't have, I would have said something else." 37B

"I was singing its praises to everybody who would listen." 29B
(LNG-IUS)

4.8.10 Communication about preferences with health professionals

Descriptive themes:

Women found communicating their treatment preference difficult

Treatment preferences were fixed before the medical consultation and did not change following discussion with the health professional.

Women found communicating their preference to the health professional difficult.

"It was like she was arguing with me to which I was trying to stay calm but arguing back with her and explained everything to her which meant I kind of bullied her into giving me the coil" 23A

Following successful treatment with LNG-IUS one interviewee recounted difficulty requesting the LNG-IUS two years earlier as the health professional at the time had concerns about the cost effectiveness of fitting the LNG-IUS in a woman whom he considered to be of childbearing age. This woman was not in a relationship and already had a child. She considered her family to be complete.

"My GP and I talked about it a couple of years before and my GP said it was an expensive treatment and it should only be done if there was no possibility of me wanting children in the near future because he didn't like the idea of me having one [LNG-IUS] then within a year or two, you know... so it wasn't seen as an option because he thinks of it as at least a five year thing and he doesn't want me having one and then changing my mind. So that was it and nothing else was offered. If he had told me how much it was at the time and if I had known how I feel now about it, I would have said here is the money, I want one, I can pay for it, because it has made such a difference to my quality of life." 16B

This paternalistic management by one particular health professional delayed this woman's successful treatment for two years.

Some of the interviewees raised the issue of the financial implications of different treatment options for the NHS.

"It does cost more to do one operation, now bear in mind that I am only [age of interviewee] so to have a coil [LNG-IUS] every five years for the next twenty years or so, that is four coils. I honestly believe that my GP takes financial reasons into account because he has to, because he is answerable to the PCT... but I think my doctor genuinely puts patient health care before anything else so he genuinely thinks this is the best option for me... There may be financial implications for him wanting to try it [LNG-IUS] but it wouldn't ever stop him trying something else if it called for it." 18B

Treatment preferences were determined prior to consultation with a health professional and this may be one of the reasons why communication between women and health professionals about treatment preferences was difficult. The first hand account from a known and trusted individual seemed to be more influential than both written medical information and information gained during the consultation with a health professional.

4.8.11 The experience of the preferred treatment

Descriptive themes:

LNG-IUS was the most preferred treatment and was tolerated well.

Positive outcomes for women who had a preference for LNG-IUS validated their preference.

Women who had a preference for standard treatment had negative outcomes and several opted for no further treatment.

Positive experiences of LNG-IUS validated decision making about preferred treatment with the majority not changing treatment after one year. Initial side effects were tolerated better as the women who felt ownership of the treatment choice were generally much more optimistic and positive about the potential for successful treatment with LNG-IUS than those in the study who were ambivalent about treatment options and stated no treatment preferences. Perceived control over decision making and the feeling of working in partnership with the health professional promoted better information seeking for problems that did occur during the first few months of treatment, particularly within the primary care setting when the health professionals were perceived to be much more accessible.

Only one woman with a treatment preference was dissatisfied with LNG-IUS treatment. Two months after commencing treatment she was experiencing what was to her an intolerable amount of breakthrough bleeding and was unsure about whether she would continue the treatment or not. She had high expectations of a successful outcome and felt some responsibility / blame that she had not been open minded about any other options when they were suggested by her doctor at her consultation. Part of her reason for persevering with the persistent daily bleeding for so long was the fact that she was embarrassed about returning to the doctor to explain that her preferred treatment was turning out to be unbearable. Unfortunately this woman was lost to follow up before the second interview so her final decision about continuing with LNG-IUS treatment was not known.

Those with preference for standard medical treatment were all dissatisfied with treatment after one year and had either requested a change of treatment or had stopped treatment altogether. Reasons for stopping

treatment were related to the quantity of medication when taken as prescribed and the perception that the medication did not have a significant impact on their heavy menstrual bleeding within a short timeframe. There was the sense that the women themselves were responsible for their choices and the consequence, that is a negative outcome from their preferred treatment, was also their responsibility. The decision not to consult with their health professional was related more to having already tried the treatment they considered to be most appropriate to them, than any feelings of having made an inappropriate treatment choice.

4.9 Descriptive themes relating to time

4.9.1 Estimated time to menopause

Descriptive themes:

Use of estimated time to menopause to make decisions about treatment options

The majority of women thought that heavy menstrual bleeding was a long term condition that they would have until menopause. The amount of time, in terms of number of years that remained until menopause, was an important aspect of their condition.

The estimated time until menopause was a significant factor in treatment decision making including discontinuing treatment and the exploration of other treatment options such as hysterectomy.

"I keep saying in the back of my mind that it's not long now, I am 43 nearly and maybe in a few years time it will start to calm down and if that's the case I won't have to take any medication at this point." 28B

"I would imagine that in eight years time I will have gone through the menopause so I don't think it is bad enough to go down that route and have the complications or side effects of having a hysterectomy." 29B

If the woman considered menopause to be several years away then she often preferred to continue to use behavioural coping mechanisms and strategies rather than rely on medication that they would need to continue for years and that may interfere with established coping behaviours.

4.9.2 Duration of heavy menstrual bleeding

Women who have experienced heavy menstrual bleeding for more than ten years were more pragmatic about the estimated time to menopause and the thought of managing heavy menstrual bleeding for a considerable number of years. These women had developed numerous practical coping mechanisms over time. For almost half of these women deciding that their blood loss was abnormal proved difficult and this was one factor that had facilitated the development of coping mechanisms and behaviours. Seeking treatment was usually triggered by a change in circumstances or in starting a new phase of life (children leaving home and returning to work) that would challenge their established coping behaviours. The more successful these coping behaviours were and the longer such behaviours were established, the less likely the woman was to either seek treatment or to persevere with a treatment that impacted on them.

CHAPTER FIVE

DEVELOPMENT AND EXPLORATION OF A CONCEPTUAL MODEL: EXPERIENCES OF LIFE WITH HEAVY MENSTRUAL BLEEDING – AID TO COMMUNICATION (ELMA)

5.0 Experiences of Life with Heavy Menstrual Bleeding – Aid to communication (ELMA)

This chapter describes the development of a conceptual model, discusses possible practical uses and explores effectiveness of the model in mapping the experiences of heavy menstrual bleeding and treatment journeys. This model evolved using data from the longitudinal accounts of twenty seven women and reflects their experiences and treatment journeys. While endorsed by women in this sample during second interviews and the validation process, further testing and refinement would be required before this model could be generalised and applied to other women with heavy menstrual bleeding. It may then be utilised as an aid to communication tool in general or gynaecology practice.

As the emerging model was developed with continuing data collection and analysis it became clear that, just as using a diagrammatic model was enhancing the researcher's understanding, it might also be used to enhance the understanding of health professionals.

5.1 Conceptual model development

Following further analysis of the descriptive themes emerging from the coded data, development began on a conceptual model that aimed to illustrate the descriptive themes and their interaction with each other. The model also aimed to reflect the complexity of heavy menstrual bleeding

and to highlight the impact on health and wellbeing from women's perspective. In addition, as treatment outcomes over time were overlaid onto the original concept, drawings and a pattern of physical and psychological parameters were mapped to the recorded treatment outcomes.

As part of the ongoing analysis process the women's experiences were plotted on a large piece of paper and grouped together into segments (parameters), leading to a first draft conceptual model drawn freehand. The first step in the model development process was to 'map' women's experiences (by drawing freehand models for each woman). These were individualised situational maps as described by Clarke (2005). The maps set out the context or situation for the woman and helped the analysis of links and relationships between themes emerging from the data. A composite situational map was then drawn, identifying aspects of living with heavy menstrual bleeding that were shared by all interviewees and those were collated to form the first draft conceptual model ELMA (Figure 10 on page 154).

This situational map of experiences was used to link descriptive themes and to help the researcher to understand the heavy menstrual bleeding as a condition and also from the perspective of individual's experiences. When new descriptive themes emerged these were cross referenced against the situational maps to ensure that the model reflected the qualitative data analysis. This ensured that the theory (the conceptual model) emerged from the data, in keeping with the principles of grounded theory methodology. The individual experience mapping led directly to identifying the range of experience within each parameter. The final step in developing the model was continued testing and refining through follow up interviews and validation feedback from participants.

A circular design was chosen as this format best suited to expressing the holistic nature of the themes emerging from the data, with each parameter; physical, psychological or practical closely aligned to another. The parameters most that had the most impact on women were placed at the top of the model; namely [impact on life and work](#) and [psychological factors / self esteem](#). Parameters that directly interacted with each other were placed on opposite sides of the circle:

- [clinical signs](#) interacting with [confounding physical factors](#)
- [previous knowledge and experience of treatment](#) interacting with [time](#) (estimated time until menopause / duration of heavy menstrual bleeding)
- [impact on life and work](#) interacting with [fertility and womanliness](#)
- [psychological factors / self esteem](#) interacting with [relationships / sexuality](#)

The interaction between parameters was determined from analysis of the narrative flow of the interviews. Women would discuss a subject then naturally flow onto a related subject without the use of a prompt question by the interviewer. This pattern was most obvious when women were discussing [psychological factors / self esteem](#) and [relationships / sexuality](#). It was also clearly illustrated with the parameters [previous knowledge and experience of treatment](#) interacting with [time](#), [impact on life and work](#) interacting with [fertility and womanliness](#). The parameters that this pattern was least obvious in was that of [clinical signs](#) interacting with [confounding physical factors](#) however this link was recounted by women with reference to the consultation with their health professional.

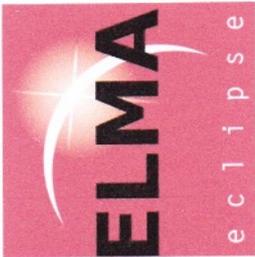
As further data were analysed factors were added into the parameters and a scale or range of these factors became evident. The factors with the least

impact in each parameter were placed on the outside of the model and the factors with the most impact were placed in the centre.

When treatment outcomes were overlaid onto the model, women whose experience closely aligned to the factors on the outside of each parameter were found to be having little or no treatment after twelve months. Women whose experience aligned to the factors in the middle of the model were found to require medical treatment usually with LNG-IUS and the women whose experience aligned with the factors in the centre of the model were found to need more radical treatment, which is surgical intervention.

The model can also be interpreted in another way, in that the women whose experiences aligned to the centre of the model had no space in their lives for anything other than the management of their condition, whereas the women whose experiences aligned with the outside of the model did have space for other aspects of life.

The conceptual model illustrates which combination of physical, psychological and practical parameters were likely to be associated with different treatment outcomes.



Experiences of Life with Heavy Menstrual Bleeding – Aid to communication

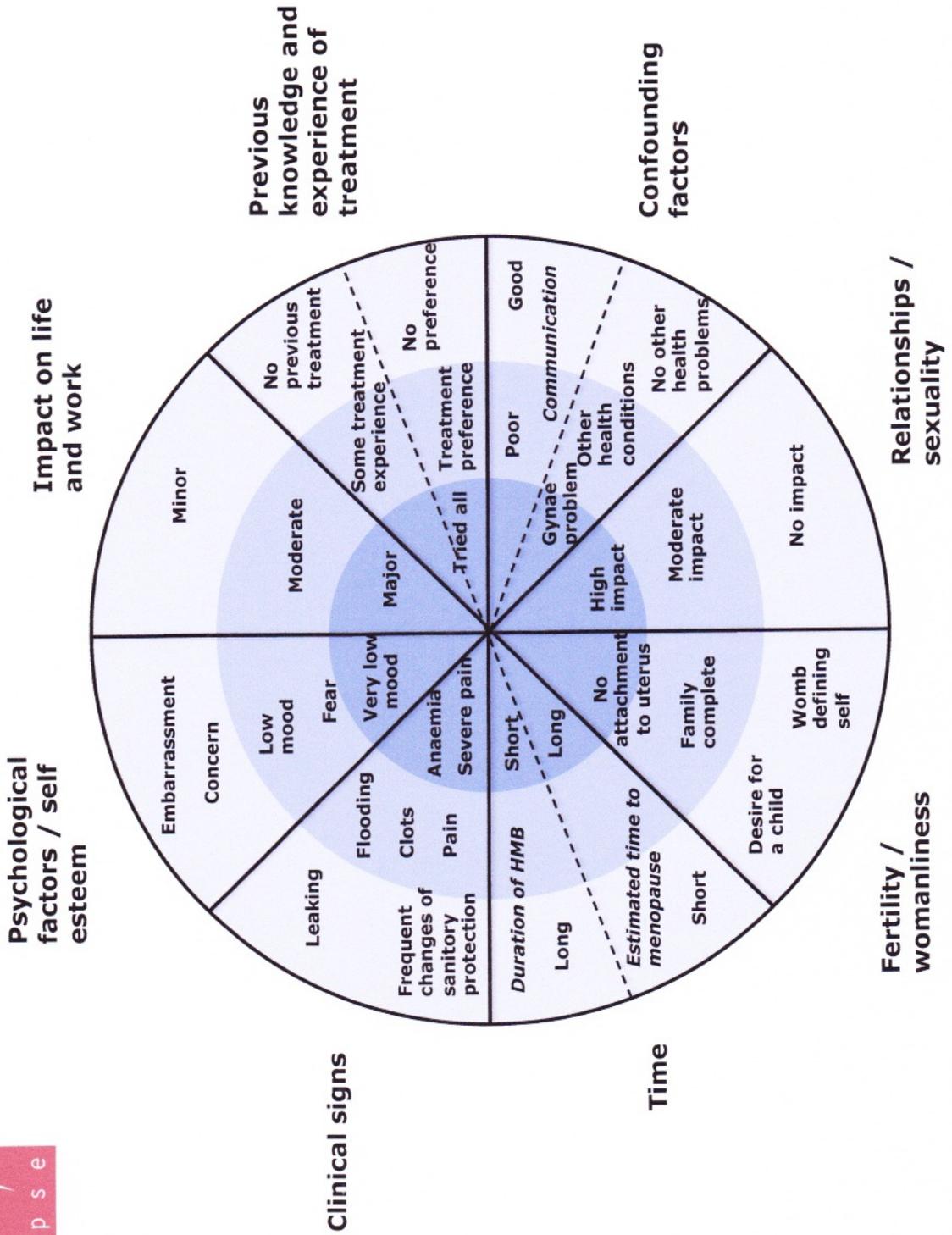


Figure 4

5.2 Parameters within the conceptual model ELMA

The model comprises eight parameters, each representing an aspect of women's experience of heavy menstrual bleeding. Within each parameter there is a range of experiences or impacts, increasing in severity along a gradient with the most severe impacts in the centre of the circle.

5.2.1 Psychological factors / self esteem

Psychological factors and self esteem were the most important impacts of heavy menstrual bleeding for women in this study. That is not to say that heavy menstrual bleeding is a psychological condition but that the greatest impact of heavy menstrual bleeding for women is on their sense of self esteem and psychological well being. This was primarily related to societal norms around menstruation including stoic silence and the concealment of menstruation. Whilst this aspect was the most important for the women in this study, it was not a common trigger for seeking treatment due to the societal norm of being stoically silent about menstruation. This aspect only came into decision making about seeking treatment when combined with other aspects of women's experiences such as impact on work and life. Being miserable due to heavy menstrual bleeding was acceptable long term, but being miserable and in trouble with your employer was not (for example), leading to consultation for treatment.

5.2.2 Relationships / sexuality

This was one of the most important aspects of heavy menstrual bleeding for women, yet this it was most often not discussed, either within families, peer groups and within consultation with health professionals. The range of impact varies from no impact to high impact and there was a continuum with women moving from different portions at different life stages. This

was influenced heavily by practical aspects of heavy menstrual bleeding and also by personal circumstances (for example the general quality of the relationship).

Of equal significance was the perceived reactions of significant others, particularly partners. This was a strong trigger for seeking treatment due to its negative impact on significant relationships. Many women described not feeling sexual due to heavy menstrual bleeding but again, in common with having a low mood, this was not a major trigger to seek treatment for the women themselves. The trigger for seeking treatment was out of consideration for the sexual needs of their partner. Successful treatment was seen as a way to reconnect with their partners through sex and thereby fulfil their roles as wife / lover.

5.2.3 Impact on work and life

The range of impact on life and work is simply defined as minor, moderate or major, as this was how women perceived it. The range of aspect was more of continuum with women fluctuating between different portions of the descriptor according to their roles and responsibilities at any particular time. Often this aspect of their experience was the trigger for seeking treatment as the perceived costs of frequent absence from employment or inability to care for children overran the perceived benefits of maintaining the societal norms of silence and concealment.

5.2.4 Fertility / womanliness

Many women in this sample had children and most were in a stable relationship. Four women had not had children, two of them by choice and two who had actively tried to conceive, including one who had undergone fertility treatment including in vitro fertilisation. The majority considered their families to be complete and about half had either been sterilised or

partners had had a vasectomy. It was therefore very surprising to find that several women still cited the desire for a child as the primary reason for retaining the uterus and rejecting surgical intervention. This was often related to aging and the reluctance to move onto the next stage of life as well as the genuine desire for another child.

The desire for another child was sometimes related to a change in circumstance, for example the youngest child starting school. The nulliparous women were slightly different in that two out of four were desperate to conceive and although in their early forties still had not given up hope of having a child. For them most of the medical treatments and all of the surgical interventions were unacceptable. They found it difficult to communicate as the health professional had often assumed that they had accepted their childless state due to their age but the interview data demonstrated that this was clearly not the case.

Upon further exploration of fertility with subsequent interviewees the concept of the uterus as a defining feature of being female also emerged. Several women held the view that if they were to have a hysterectomy they would be less of a woman.

Women under thirty felt less strongly about both fertility and retaining the uterus in order to feel like a woman. When questioned about this they were more likely to suggest adoption as a means of having (more) children. They were also more likely to cite secondary sexual characteristics such as breasts as defining womanhood. Women who were older had a much stronger desire to retain the uterus for both reasons and had a stronger aversion to surgery, suggesting that surgery was unnecessary as they did not have a life threatening pathology. They determined that the loss of either the potential to conceive or the sense of being a woman (in some cases both) was not worth undergoing surgical treatment.

5.2.5 Clinical signs

Women felt health professionals focused most on clinical features that did not have as much significance to the women themselves. There was a range of clinical signs that women described that related to perceived menstrual blood volume and rate of blood flow ranging from leaking to flooding. This was sometimes described in relation to the frequency of changes of sanitary towels. Other clinical signs were more significant to the women and the ones that caused most concern were menstrual pain and anaemia.

5.2.6 Confounding physical factors

A small number of women had other health issues, such as migraines and irritable bowel syndrome. These had greater impact if they concerned a long term illness or if it involved the gynaecological tract. One woman had a mild uterine prolapse and this impacted on her experience of consultation and the efficacy of the treatment she was prescribed. She progressed to hysterectomy after trying several medical treatments.

5.2.7 Previous knowledge and experience of treatment

A number of women in this study did have previous experience of medical treatment in the past and this had a bearing on treatment preferences and the experience of the current treatment. The influence of treatment preferences had quite an impact, although this was tempered when treatment had been personally experienced or whether treatment preference was developed by communication about the experience of others.

5.2.8 Time (years)

This not anticipated from the literature but was of great significance to the women themselves. There are two components. The first is the duration of heavy menstrual bleeding in terms of years of recognition of heavy menstrual bleeding as problematic. Women who had always experienced heavy menstrual bleeding, that is had more than ten years of experience did not rate the amount of time they had suffered as having high impact on their health and well being. The women who had recently experienced a change in menstrual bleeding described the amount of time that they had experienced heavy menstrual bleeding as highly significant and having a large impact even if this was less than two years. When treatment outcomes were super imposed on this parameter alone, women who had heavy menstrual bleeding for many years were more likely to opt for less invasive treatments as they had developed and established coping behaviours enabling them to continue to manage their condition indefinitely.

The second component is closely aligned to the duration of heavy menstrual bleeding (in years) and is the estimated time to menopause (in years). This component was frequently used by women to analyse costs and benefits when considering treatment options and also when considering the effectiveness of the treatment they experienced. The majority of women discussed the amount of time that they thought they had left before menopause and this was expressed in years and in relation to their age and also their mother's age at menopause.

Menopause was often spoken of as a discreet event that would happen at a specific age and this viewpoint was held even when information about the gradual natural process of menopause had been given by health professionals. Younger women who considered themselves to be twenty

years away from menopause were more likely to describe this concept as having a high impact on health and well being. Women who were older and considered themselves to be approaching menopause in the next five years considered this concept to have less of an impact and often cited this as a primary reason for discontinuing treatment.

5.3 Exploration of the Conceptual Model

The first draft of the conceptual model was developed six months prior to the end of data collection and was tested and refined through ten second interviews and six validation interviews. This model was positively received by the women themselves. They used the model to categorise their experience of heavy menstrual bleeding and also to assess the effectiveness of their treatment. Use of the model as a means of assessing treatment efficacy was not the intention of the researcher but was suggested by all of the sixteen interviewees who saw it.

The design of the model lent itself to a kind of scoring system, with women drawing dots in segments of the model to describe their initial experiences of heavy menstrual bleeding and then drawing different coloured dots to describe their experiences following treatment. Treatment success was determined if the second set of dots had moved towards the outside of the model. An example of this is shown in Figure 5 on page 164.



Experiences of Life with Heavy Menstrual Bleeding – Aid to communication

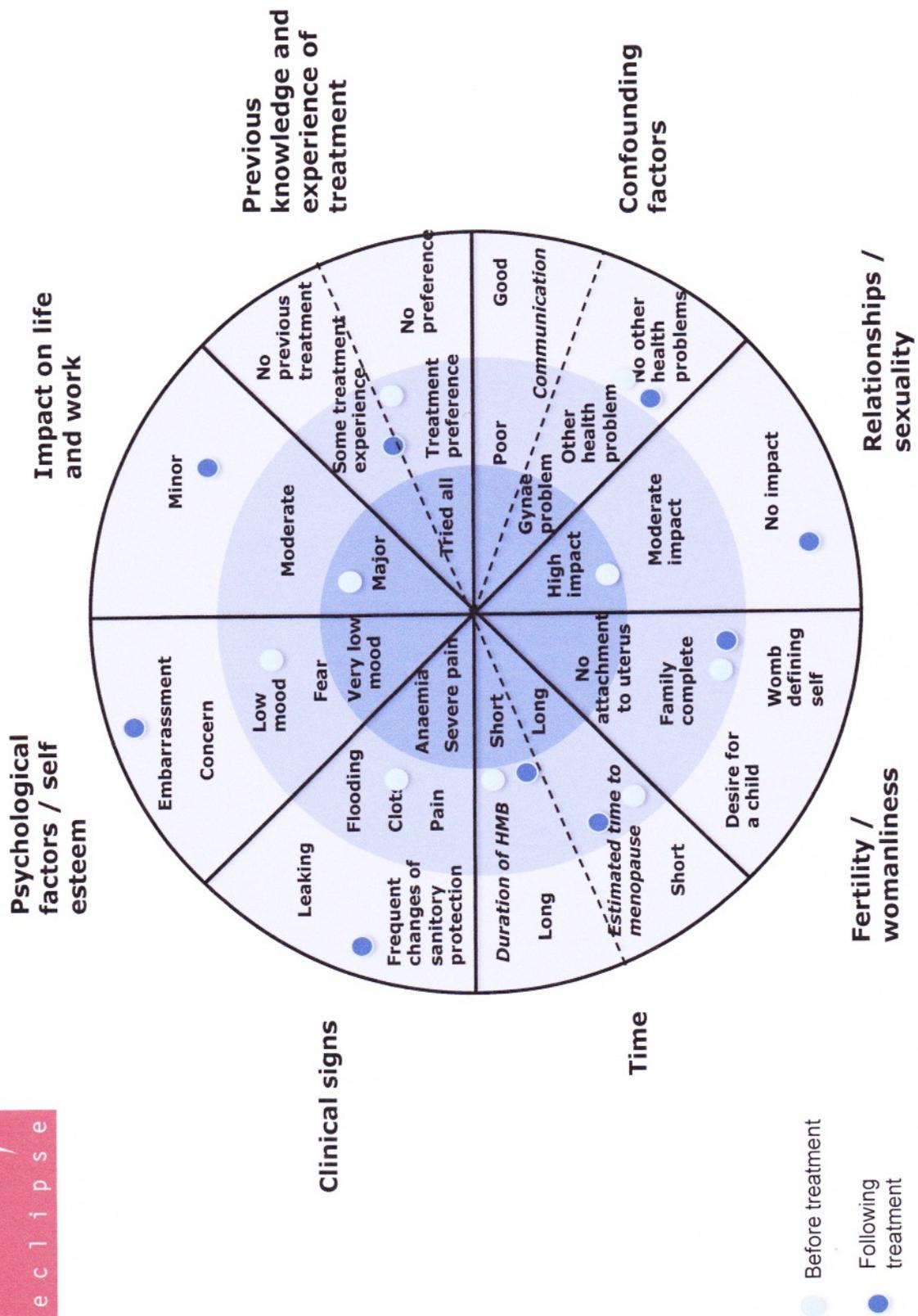


Figure 5

ELMA – used for assessment of condition

Whilst these results cannot be extrapolated beyond the sample, the women themselves were very excited about this potential application for ELMA. Further research might explore the feasibility of this conceptual model as not just an aid to communication during the initial assessment of a woman's experience of heavy menstrual bleeding but also potentially as a means of assessing the effectiveness of medical treatments in a more objective manner. In its present form it would be best utilised as an aid to communication, to promote discussion of individual experiences and impacts of heavy menstrual bleeding, along with possible treatment options. Some of the parameters change in response to successful treatment, such as impact on life and work, but others do not. In terms of assessment of treatment efficacy it may be useful to develop a revised model that only focused on parameters that change in response to treatment.

When discussing treatment options the use of the conceptual model ELMA may have a role in assessing possible treatment trajectories as certain experiences were associated with certain outcomes for these women. This is not surprising as the model was developed from their data but it is worthy of further testing to see if the experiences match treatment outcomes for a much larger sample of women.

The experiences associated with more minor intervention (oral medication taken during menstruation or more commonly no medical treatment at all) were as illustrated on the diagram below (Figure 6 on page 167). Women tended to have embarrassment and concern about heavy menstrual bleeding but this had little impact on life and work or on their relationship or sexuality. They were experiencing episodes of leaking but this was largely controlled by frequent changes of sanitary protection. They tended

to be in good health with no confounding physical factors and had not sought or experienced treatment for heavy menstrual bleeding in the past.

Interestingly they had often had heavy menstrual bleeding for a number of years (ten to twenty years) and considered themselves to be only a few years away from the menopause, although this was subjective as most were in their early forties. Secondly, in spite their age and suggestion that they were close to the menopause there was a strong desire to retain their fertility and in some cases the desire to conceive (another) a child. There was also a strong sense of the womb defining them as women.



Experiences of Life with Heavy Menstrual Bleeding – Aid to communication

Types of experiences that may respond to minimal intervention

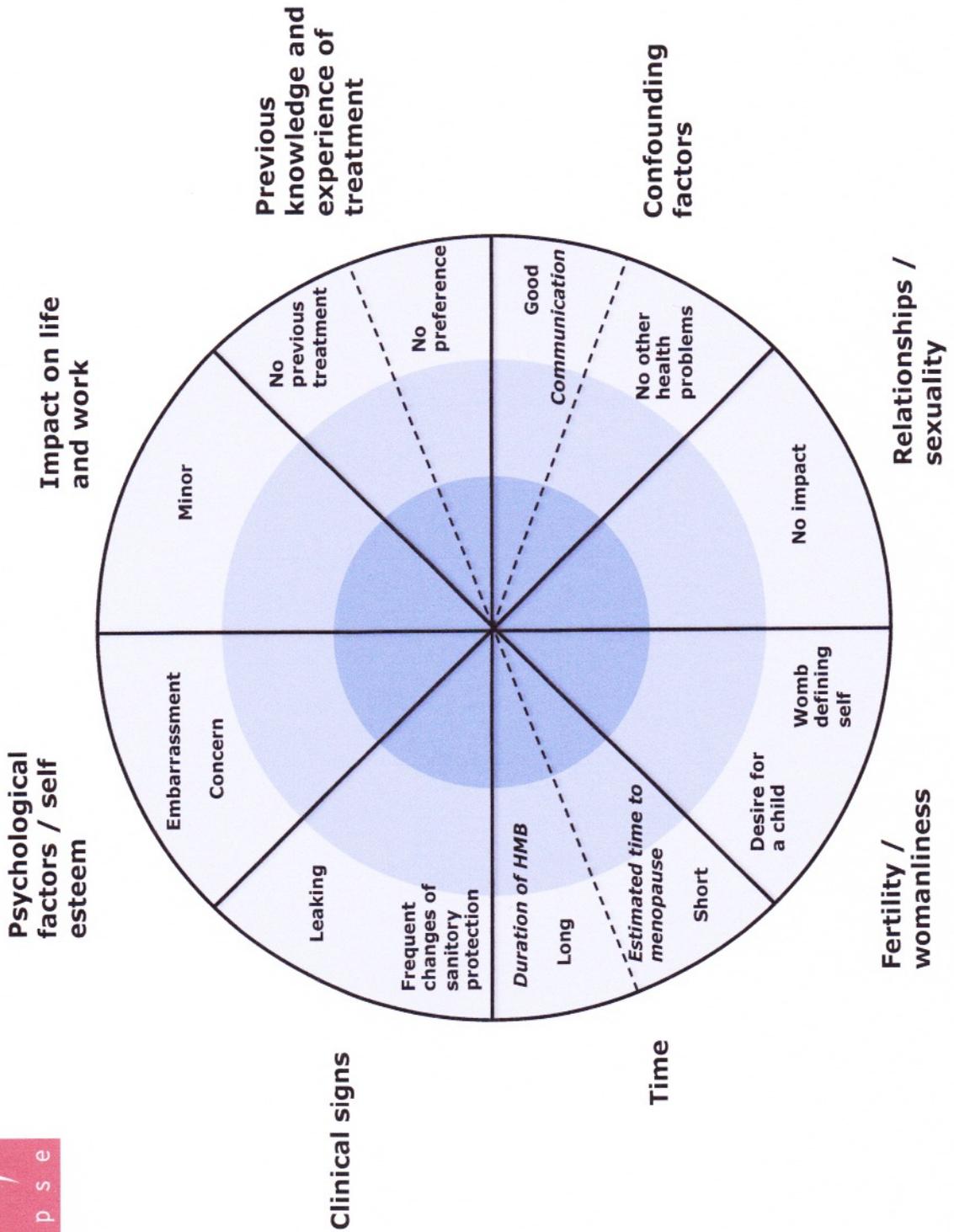
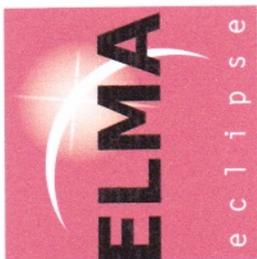


Figure 6

The experiences associated with moderate intervention (LNG-IUS) were as illustrated on the diagram below (Figure 7 on page 169). Women tended to describe fear of menstruation and low mood when thinking about heavy menstrual bleeding which was often. They would describe dreading the onset of menstruation each month. This had a moderate impact on life and work or on their relationship or sexuality and these would be absence from work and withdrawing physically and emotionally from their partners during menstruation. They were experiencing flooding, passing large clots and having significant pain.

Concealment of menstruation was extremely difficult with frequent episodes of leaking and staining of clothing. This could not be controlled by frequent changes of sanitary protection but with the use of multiple sanitary protection. They tended to be in general good health but some had confounding physical factors such as an unrelated medical condition or anaemia. These women had sought treatment and had some experience of treatment for heavy menstrual bleeding in the past. They were more likely to have developed a treatment preference. They had heavy menstrual bleeding for some years (two to ten years) and did not really think about menopause at all. The majority of these women considered their family to be complete and did not have a clear sense of the uterus defining womanhood, although this parameter had the widest range of experiences described and the weighing applied to this parameter varied according to the individual.



Experiences of Life with Heavy Menstrual Bleeding – Aid to communication

Types of experiences that may respond to moderate intervention

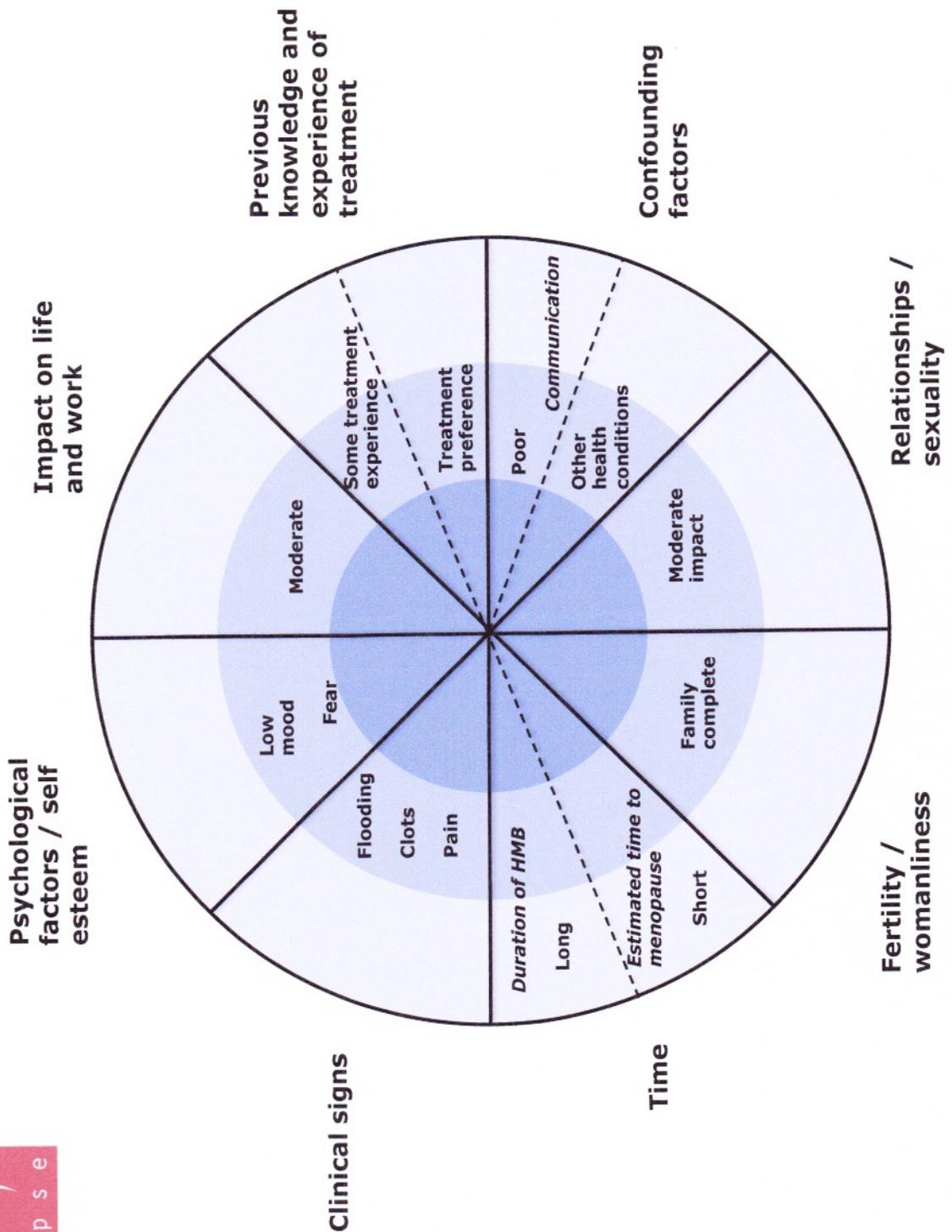
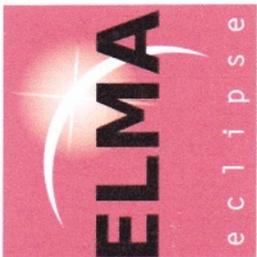


Figure 7 ELMA - experiences associated with more moderate intervention

The experiences associated with more major intervention (for example unsuccessful medical treatment and escalation to surgical treatment) were as illustrated below (Figure 8 on page 171). Women tended to have very low mood impacting significantly on life and work. These women described themselves as imprisoned at home during menstruation and were often reluctant to socialise or pursue activities at other times of their menstrual cycle also. They may have been offered or prescribed anti-depressants in the past. In terms of their relationship or sexuality, they were avoiding sexual contact describing themselves as not sexy at all, demonstrating low self-esteem. This had often led to problems within their relationships.

They were experiencing episodes of leaking that could not be controlled and also had severe menstrual pain and clinical signs of anaemia. They tended to be in poorer health than the rest of this sample and reported gynaecological problems in addition to heavy menstrual bleeding. The majority had experienced treatment for heavy menstrual bleeding in the past.

Such women had often had heavy menstrual bleeding for a short time (less than two years), although this was not always the case. They saw themselves as having a long time to suffer before becoming menopausal (even if they were already in their forties) and found the thought of coping with heavy menstrual bleeding until menopause unbearable. These women had no attachment to the uterus or desire to have (another) a child, seeing their uterus only as a source of significant problems.



Experiences of Life with Heavy Menstrual Bleeding – Aid to communication

Types of experiences that may respond to major intervention

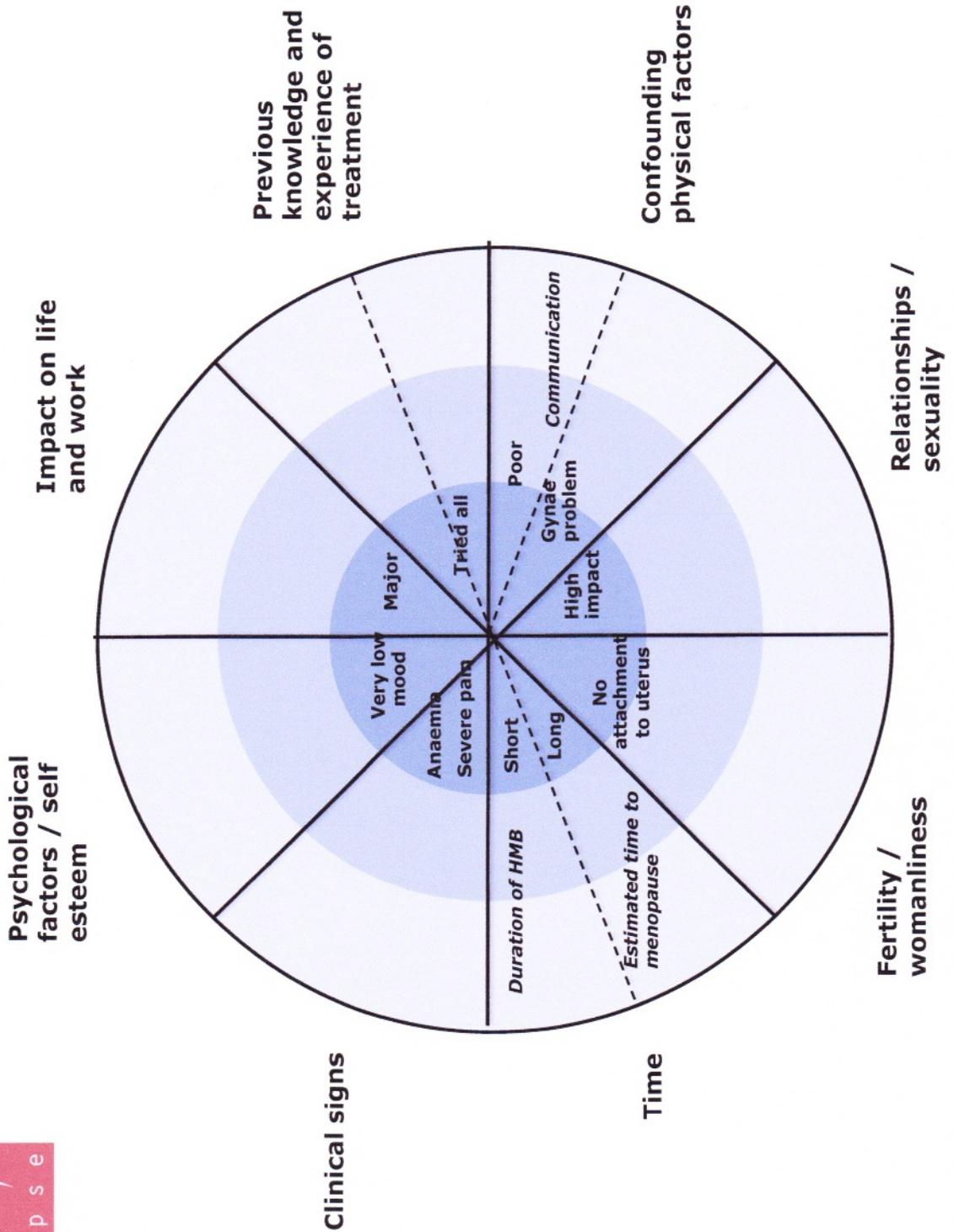


Figure 8

5.4 Testing of the model using case studies

In order to explore and test out the model more clearly the following three case studies were explored and used to illustrate the model further.

Case Study One

This woman identified herself as being in the outer ring of the conceptual model, with mild disruption to her lifestyle, who ultimately opted for no treatment at twelve months.

Anne (pseudonym), an ECLIPSE Trial participant was originally randomised to LNG-IUS but quickly decided not proceed with this treatment option for reasons relating to wanting to remain drug free and take a natural approach to her heavy menstrual bleeding. She had a long history of heavy menstrual bleeding and had developed complex coping behaviours that she was comfortable with and that proved to be effective for her. A well educated woman, Anne had researched her prescribed treatment and determined that the potential side effects would counteract her coping behaviours which she knew to be effective. She had a great deal of control over her working and family life, being a successful self employed business woman with excellent childcare systems and family support. Her husband was supportive of her both in terms of her decision to remain drug free and self manage her condition and in terms of his role in making sure that her coping behaviours worked. This influenced her ability to manage her heavy menstrual bleeding without treatment considerably. Anne had a clear sense of responsibility for her own health and being in her forties saw the menopause as not very far away. She felt confident that she would be able to continue to self manage her heavy menstrual bleeding until menopause. She had been treated in the primary care setting, and had a long standing

relationship with her female GP. She was open to the possibility of seeking treatment in the future but was confident that her coping behaviours would mean she didn't have to.

Case Study Two

Belinda (pseudonym) was a younger nulliparous woman at the start of a physically demanding, male dominated professional career. She lived with her parents and reported having heavy menstrual bleeding since puberty. Her heavy menstrual bleeding, whilst being physically very similar to Case Study One, had a much more significant effect on her working life. She had already experienced a significant lack of empathy from her predominantly male managers and colleagues and a detrimental impact on her ability to physically cope with her job. It also impacted greatly on her personal relationships and her perceived potential for family life in the future. In the first interview she stated that she would rather have a hysterectomy and have no children than continue having heavy periods. She had a strong preference for LNG-IUS after hearing accounts of its effectiveness from friends but found this difficult to communicate to her health professional due several factors relating to her previous health care experiences. Belinda found the fitting of the LNG-IUS particularly traumatic due to what she described as a lack of psychological preparation and physical pain.

The first three months of her treatment were difficult due to breakthrough bleeding but she did persist and at twelve months was very satisfied with the treatment outcomes she experienced. Her persistence with LNG-IUS was attributed to the fact that she had chosen the treatment herself and had faith in her friends' accounts of their own experience of breakthrough bleeding. Having initially placed herself in the middle ring of the conceptual

model, by the second interview she considered herself to have no place on the model at all due to her amenorrhea. She used the model as an assessment tool and was able to articulate her experience of treatment for heavy menstrual bleeding much more clearly using ELMA to pinpoint improvements in quality of life since having the LNG-IUS fitted. Interestingly a number of other aspects of her life had changed following successful treatment. She was more positive about her career, being able to cope well with the physical and emotional demands of her job better. She had moved out of the parental home and was confidently living independently. She was now in a stable relationship and was considering having children in the future. Both her physical appearance and her attitude and demeanour had improved markedly since successful treatment.

Case Study Three

This is an example of a woman who fitted into the centre ring of the conceptual model. Catherine's (pseudonym) heavy menstrual bleeding had a severe impact on her life and had been a factor in marriage breakdown and job loss in the past. She was an ECLPISE Trial participant who was initially randomised to tranexamic acid.

Whilst she was in equipoise for her randomisation she did have previous experience of most of the medical treatments before including tranexamic acid. Although she took her prescribed medication as directed she found no effect and returned to her health professional requesting a change of treatment. At this time she was prescribed LNG-IUS and was examined and found to have a slight uterine prolapse and small fibroids. The health professional still recommended LNG-IUS and fitting was attempted. During

the procedure it was determined that the uterine prolapse had worsened and that hysterectomy would be the best option.

A hysterectomy was performed twelve months following randomisation. When considering treatment options for Catherine, communication would have been improved using ELMA. The impact on quality of life was extreme and also Catherine had tried numerous medical treatments in the past without success. Added to that there were underlying gynaecological complications, namely fibroids and a uterine prolapse. The use of ELMA may have indicated that discussion about surgical treatment for heavy menstrual bleeding was indicated much earlier in this woman's journey. Interviewed post hysterectomy Catherine was satisfied with the surgical procedure. She questioned why she had needed to try so many other treatment options before her surgery, given that she had lost a husband and jobs because of heavy menstrual bleeding over the years and had additional gynaecological issues. She was accepting that health professionals had used correct clinical judgement at the time but felt that using ELMA to aid communication would have enhanced her ability to communicate the severity of her condition to her health professional.

This chapter has offered and discussed a conceptual model ELMA developed from women's experiences. The following chapter is focused on discussion of the findings of this study, including the descriptive themes and the conceptual model.

6.0 Introduction

This chapter discusses the findings from this research with reference to the published literature reviewed in Chapter Two.

6.1 Discussion relating to psychological factors impacting on experiences of heavy menstrual bleeding

All women interviewed had negative attitudes towards heavy menstrual bleeding and also towards menstruation in general.

As adolescents, the majority of the women had no idea that they would menstruate and there could have been many reasons for this. In a few cases there was the sense that their mothers were unaware of their daughter's progress through puberty and that menarche took both mother and child completely by surprise, but for most this was not the case. Women had very sketchy information either before or during first menarche. This finding is in contrast to Chrisler and Zittel (1998) who found that across four different cultures (Lithuanians, Americans, Malaysians, and Sudanese women) more than half of the women they studied reported being prepared for menstruation. In American and Malaysian women the figure was 89% and 90% respectively. For the women in this British study the discussion about menstruation, when it occurred, was generally not informative consisting of oblique references and unfamiliar, inaccurate terminology. The tone of the conversation was often reported as threatening or disapproving creating the impression that the women were somehow at fault or to blame for menstruating. This then

denied the women the opportunity to ask questions when they were frightened and also to seek comfort when they were in pain.

Women commonly described first menarche in vivid detail, indicating that this was a major life event for them. This is consistent with other work indicating that menarche is experienced by women as a rite of passage from childhood to adulthood (Estanislau do Amaral *et al.* 2011). This study found the women's focus was on body changes and image, however in contrast to the Brazilian study above, most of the women in this study were unhappy with the changes they were experiencing and the different status that menarche brought. The key difference between the two study populations appears to be the amount of knowledge that the women had prior to first menarche. In the current study few women had factual information about the physiology of menstruation and fewer still had either practical management of menstruation or psychological / emotional support. These positive emotions described by Estanislau do Amaral *et al.* (2011) and Christler and Zittel's (1998) were missing from the narrative account of first menarche for majority of the women in the current study. It is possible that this was related to the responses of significant family members such as mothers and reflect wider negative perceptions of menstruation in Britain, as social and cultural factors influence how menstrual knowledge is shared (Orringer and Gahagan 2010).

Lack of knowledge prior to menarche made for a frightening experience for the women in this study, but far more influential was the perceived lack of emotional and psychological support when it was sought. Women experienced their mother's reluctance or refusal to discuss menstruation in detail, adversely affecting the care (both physical and psychological) that their daughters needed and received. This established or confirmed the notion that menstruation was shameful and a negative experience. This

study suggests this negative experience of menarche remained with women and influenced their perception of heavy menstrual bleeding and their ability to manage their condition. That is not to say that heavy menstrual bleeding was psychosomatic as the women all clearly described excessive amounts of menstrual blood loss; but that the negative attitudes towards menstruation in general made coping with heavy menstrual bleeding even more difficult and the condition more psychologically debilitating.

Lack of knowledge appeared to influence experience of early menstrual history in a negative way. Women described strong feelings of fear and anxiety each time bleeding began and this was increased firstly by having no understanding of normal female physiology and secondly by the response of their mothers when they asked for help and explanation. Fear and anxiety that surrounded early menstrual experiences and the response of their mothers may have informed later negative attitudes towards menstruation in general as found in a survey of 327 women (McPherson and Korfine 2004). All of the women in this sample shared a negative attitude from early in their menstrual history, including those who did not experience heavy menstrual bleeding until much later in life.

One of the most surprising findings for the researcher was the reported lack of emotional and psychological support from women's mothers at first menarche. In contrast to possible lack of prior knowledge, possible lack of concern and care for their distressed child is harder to understand. Rather, this might be seen to reflect and underline the profound taboos surrounding menstruation. A few women had an awareness of other issues in their mothers lives which might have had an impact, such as being depressed or being in an abusive marriage. For almost all there was simply brief practical information followed by an immediate return to the societal

norms of silence and concealment. The behaviour of the mothers was then mirrored in the behaviour of the child, who quickly adopted the same need to remain silent and conceal menstruation as best they could on their own.

The societal pressure to conceal menstruation for young girls (of school age) has been suggested by Burrows and Johnson (2005) and the findings from this study echo this work. The average age of women was forty one, making the approximate age of their mothers between late fifties and early seventies. A number of the interviewees suggested that there was a generation gap and that older women, for example their mothers, were taught not to talk about female physiology including menstruation, pregnancy and childbirth. The older women in this sample population, although willing to talk about menstruation as part of this research talked about themselves in the third person and used oblique terminology, especially when describing either physical things like blood flow or clots, or difficult situations like incidences of leaking. In contrast, younger women talked about themselves and used accurate descriptors, although some tended to be dramatic, using more emotive language. A few women suggested their mother's reticence was related to religious beliefs or a religious upbringing (several different religions were mentioned). However even mothers who did not have a strong religious upbringing behaved in the same way because of the strength of the societal norms of stoic silence and concealment.

Family history, when it was known, also had a large impact on attitudes towards heavy menstrual bleeding, with many women believing that they would suffer as their own mothers did. The majority of women strove to copy the behaviours that their mother role modelled in terms of stoic silence. There was also a firm belief that they would follow their mothers

(or other female relatives) treatment journey with the same outcomes and consequences.

Women had great difficulty defining abnormal menstrual bleeding and there were several cited reasons for this. Many women did not seek treatment early in their menstrual history. This study suggests they either did not recognise that their menstrual bleeding was abnormal or did not think there was any treatment available. Much of this appeared influenced by the lack of communication within families and within society generally about menstruation. Women did not have any benchmark to determine what a normal menstruation was. This is arguably quite remarkable when 50% of the population either menstruate or have menstruated. There were suggestions put forward by interviewees as to how this issue could be tackled.

Several women thought that increased education in schools, with greater emphasis placed on factual information and practical management of menstruation for all young girls. This finding is consistent with Chang, *et al.* (2010), who suggest that the school nurse is an ideal person to educate women about menstruation. The consensus from the interviewees was that this currently rested with parents, specifically mothers, but their experience was that this was insufficient. Their mothers didn't tell them anything that was helpful. Steps would need to be taken to ensure that information about menstruation delivered in schools was accurate, balanced and not delivered in a negative way. This may be difficult to achieve given the long standing societal norm of restricting open communication about menstruation.

When shown the proposed ELMA conceptual model at the end of the second interviews women appeared excited by this and saw ELMA, not just as an aid to communication with their doctor, but also as a basic

assessment tool, fulfilling some of their own ideas about having a reference point by which to assess menstruation. They also thought it might be useful as a teaching aid and one woman brought her husband into the room to explain her experience of heavy menstrual bleeding to him.

Given that normal menstruation caused distress and was seen as a negative event by the majority of women, the impact of heavy menstrual bleeding can be seen as that much greater. So much so that it may dominate lives, not just because of the physical effects of pain and anaemia but also because of the strain of maintaining impossible societal norms of stoic silence and concealment.

Menstruation is a basic female physiological process that most women experience for many years and is a fundamental part of the process that ensures the continuation of the human species, yet it remains one of the last taboos in modern society. There is a strict set of societal norms in western and other cultures that restrict communication about menstruation and this marginalises this aspect of normal female physiology. The British societal norm is to be secretive about menstruation and to conceal evidence of menstrual bleeding from others both male and female. The power of this societal norm has been highlighted in previous research (Chapple 1999, O'Flynn and Britten 2004, O'Flynn 2006) and still persists for this sample population more than a decade after Chapple's (1999) findings were first published. The current study suggests that this is perpetuated by successive generations.

In addition, as suggested by Raftos *et al* (1998), it is enforced by the media and manufacturers of feminine hygiene products through advertising. In the last ten years sanitary towels have become ever smaller and thinner and are packaged in a way that suggests concealment ('discrete individual wrapping'). The use of tampons has increased and this

is the ultimate attempt to conceal menstruation, in that nothing is externally visible at all, an approach that is impossible for the women in this study due to their heavy menstrual bleeding. Whilst the materials used in the manufacture of sanitary towels are more technologically advanced, women feel pressured by aggressive marketing to select the smallest, thinnest, most 'invisible' sanitary towel possible and this may potentially be one of the reasons for the incidences of leaking and staining that the women in this sample experienced. The leaking may be related not to the volume of blood flow but to the flow rate and the presence of plasticised coating on the sanitary towels that are designed to direct blood flow but may impede the absorption of rapid flow and clots.

As the research by Raftos *et al* (1998) suggested, the women in this sample tended to blame failure of the sanitary protection on a poor choice of sanitary towel or lack of timeliness in changing towel on their part rather than the design of the product itself. Simes and Berg (2001) also highlight the role of media advertising of sanitary protection in heightening insecurities particularly in young women. They concluded that menstrual product advertisements reflect negative societal views of menstruation and once again perpetuate the societal norm of stoic silence.

The interviewees suggest that there was more pressure from other women to maintain silence and concealment than from men, particularly the men that these women shared their daily life with. Whilst concealment of menstruation around work colleagues and strangers is easier to understand, the concealment of menstruation (by the use of oblique terms and references) from close family members is more difficult to explain. Even more difficult to comprehend is concealing menstrual difficulties from health professionals even within the context of a consultation seeking treatment for heavy menstrual bleeding.

The extent of concealment of menstruation evidenced here can only be explained by the strength of the societal norms of silence and concealment, concurring with previously published research (Chapple, 1999, Garside *et al.* 2008). The findings in this research are based on the women's accounts of the consultation and it would be fascinating to observe consultations in progress in a further study. During the consultation process the responsibility for breaking down the societal norms of silence and concealment around menstruation should rest with the health professional. Some interviewees recounted this being done well, being put at ease to openly discuss the facts of their experience of heavy menstrual bleeding in plain language, but for a number this was not the case. It is unclear whether the health professionals who did not facilitate open factual conversations were not aware of the potential for deeper conversations about heavy menstrual bleeding or were unable to initiate them due to time pressures or interpersonal factors.

Whilst concealment is related to negative attitudes passed down from one generation to another, it is also felt more keenly in today's British society, obsessed as it is with perfection, sexuality and youth. A number of women in this study lied to maintain concealment yet would not consider deception about other aspects of life. It would appear that the stress of a fabricated reason or excuse for absence from work or social activities was less than the perceived stress of discussing the true reason for absence (problematic menstruation). Women did not really see this behaviour as dishonest. There was a lack of guilt or regret that would normally have been associated with telling a lie, indicating that this behaviour was seen as acceptable in order to maintain the societal taboos around menstruation. This gives an indication of the power of the messages learnt through childhood and adult experiences of menstruation, including modification of

behaviours, learnt mainly by observation of other women, to maintain the societal norms of silence and concealment and to cope with heavy menstrual bleeding in a socially acceptable way.

The maintenance of concealment was deemed to be imperative in every setting but more distress was evident when women recounted episodes of their menstrual state becoming evident at work. There was a great deal of anxiety about the prospect or possibility of this happening at work. Tying in with the idea that to be equal in the work place women need to be the same, physically, emotionally, mentally, as men, clear evidence of womanhood in the form of menstrual blood leaking or staining was seen as unacceptable. The inference was that a woman who could not successfully conceal her menstrual state could not successfully do her job, whatever that might be. There was very little acceptance of the fact that heavy menstrual bleeding is a recognised medical condition, even amongst women who sought treatment. There was a stated need and acceptance of medical treatment whilst denying there was a medical illness. Women stubbornly held the view that employers, whether male or female, would not understand this point. This was evidenced by the fact that only one woman out of twenty seven gave her employer a written letter from her doctor, stating she had heavy menstrual bleeding and some information about her condition after being repeatedly absent from work due to heavy menstrual bleeding. This is in contrast to other medical conditions such as severe food allergies, asthma or long term back pain, which are talked about openly. In recent times mental illness has lost some of its taboo status and is discussed in the workplace, with employers and within peer groups. The same cannot be said for menstrual disorders where there is clear evidence that the taboo still exists, and is perpetuated by both men and women.

All of the women in this sample felt unclean during menstruation and this was not related to ethnicity. Interestingly and in contrast to other work on cultural variation (Chapple 1998, Chapple *et al.* 1998) there was little difference in the perception of menstruation as being unclean between the Caucasian and South Asian women in this sample. This is possibly due to the fact that the South Asian women in this sample had lifestyles and beliefs that reflected British culture more than traditional South Asian culture and also that perceptions of menstruation generally have not been fully explored in White British women.

The concept of menstrual blood being unclean is present in many religious faiths, including Protestant, Catholic and Jewish faiths. It has been suggested that this may impact on women's perception of menstruation (Rothbaum and Jackson 1990). Analysis of passages of the bible suggested that a woman who is menstruating is unclean (Ben-Noun 2003) and the attitude of the White British women in this study would strongly suggest that this idea persists today, even in women who do not consider themselves to be religious.

It would appear that in British culture and society there is still a strong drive to conceal menstruation in agreement with O'Flynn's findings in 2006. This is a societal norm observed in a number of different cultures. For the British women with heavy menstrual bleeding in this study it was powerful and was both the primary cause of so much of their distress and the predominant barrier to seeking treatment. Concealment of menstrual problems and the subsequent delay in seeking treatment has also been highlighted in women with endometriosis (Seear 2009).

There was some evidence in this study that concealment of menstruation crossed cultural divides. There were discussions from several women with different religious and cultural backgrounds that had similarities with

regard to not talking about menstruation in front of men. One key difference for South Asian women in this study was that, although they were more secluded during menstruation there was a much stronger sense of sisterhood, support from other adult females, including support from older women (their aunts and older siblings and cousins) during their period of seclusion. This concept is also suggested in the work of Kumar and Srivastatva (2011) who explored cultural and social practices during menstruation in Indian women. The western women in this study often chose seclusion at home during menstruation (for fear of not being able to maintain the concealment of menstruation) but they had much stronger feelings of isolation.

It is possible that the maintenance of concealment is related to striving for equality by adopting characteristics of men and denying their own female physiology. However this is difficult to determine as the women themselves had never analysed why they behaved in this way and the majority were unaware of the true reasons why they felt compelled to conceal menstruation. This could be because of the additional difficulties relating to their heavy menstrual bleeding for this sample population. Simply managing concealment was challenging enough without analysing why they should conceal all evidence of menstruation. There is a sense that this viewpoint of equality by denial of female physiology is present in British modern society; the suggestion that the only way to succeed in a career (whether it is a male dominated profession or not) is to be a masculine as possible.

6.2 Discussion relating to relationships and sexuality

One of the aspects of life most affected by heavy menstrual bleeding was sexuality and sexual functioning, resulting in reduced quality of life. This was reportedly the least discussed both within family and peer groups and within the consultation with a health professional. The societal norm of not discussing sex and sexuality has been broken down in recent years and this may be linked to the increasing objectification of the female body through media portrayal of feminine beauty (Roberts and Walters, 2004). These authors suggest that the menstruating woman is not beautiful in a modern sexually objectifying culture and the findings for this sample population certainly suggest that this is a common perception.

However Ben-Noun (2003) suggests an even earlier influence. This author found that several biblical passages that referred to menstrual bleeding or pathological vaginal bleeding, suggested that sexual relations should be forbidden within seven days of menstrual bleeding beginning and for seven days after menstrual bleeding stops. The concept of having sex during menstruation as distasteful is clearly perpetuated today, even amongst women who did not consider themselves to be religious.

For most of the women in this sample there was a change in self image during menstruation from a sensual, sexual woman to an unclean, undesirable woman and so most avoided sexual contact during menstruation. Husbands and partners did not share the change in image, as a number of them were frustrated by the reduction in sexual activity during menstruation. The finding that the sexual frustration of a partner was a factor in the decision to seek treatment for some women is evidence of this.

Women who considered their treatment to be successful described an improvement in their sexual self image and in their sexual functioning. This was particularly true of LNG-IUS. This finding concurs with Bastianelli *et al.*

(2011) who found decreased intercourse related pain and increased sexual desire in women who had LNG-IUS for contraception with or without heavy menstrual bleeding.

The influence of significant others in determining quality of life was significant for a number of women. In contrast to general communication about heavy menstrual bleeding, women were able to communicate with their husbands or partners about this issue, (although they did continue to use unclear indistinct language). This was due to their involvement in facilitating coping mechanisms and behaviours and also due to physical proximity; they were simply the person who spent the most time with the women. The need for communication often arose because of an incident of leaking or staining and it impacting on both the man and the woman, for example if menstrual blood leaked and wet the bed sheets in the night.

Male partners were described as largely supportive. A few women contradicted themselves when discussing the attitude of their partner, saying they were supportive then giving an example of being ridiculed or belittled by them. This may have been a normal style of communication between the couple but it did suggest that the partners who did this were not quite as supportive as the women perceived them to be. Often partners made statements about the woman's health and wellbeing, suggesting that heavy menstrual bleeding was having a negative impact on the woman's quality of life (and their own too). This kind of discussion between the couple invariably included the men indicating that seeking treatment would improve the quality of life of both of them. The impact of heavy menstrual bleeding on sexuality has not been explored in the literature to date and the findings of this study suggest that it is a subject worthy of further exploration.

There were a few women who were doubtful about the LNG-IUS because of its primary function (and primary marketing) as a contraceptive device. These were women whose husbands or partners had undergone a vasectomy and the women raised the issue of not needing contraception and possible misunderstandings arising from them having a contraceptive device fitted. They raised the question of men becoming suspicious of infidelity if they were treated for heavy menstrual bleeding with LNG-IUS. This concern was not sufficient to prevent them being treated with LNG-IUS and most women were able to discuss this with their partners or husbands and discovered that their fear was unfounded.

6.3 Discussion relating to the impact of heavy menstrual bleeding on life and work

Quality of life and the impact of heavy menstrual bleeding on life and work, was directly related to ability to continue to perform self defined roles and responsibilities during menstruation. There was a strong trend to think of self worth in terms of employment by most of the women in this sample population. In some instances the woman's occupation was also used to describe and rationalise thought and behaviours. Most of the women who did this seemed proud of their 'occupational identity' and some attached more value to this than other ways of defining self (such as marital status or being female or being a mother). In male dominated occupations this was prevalent, indicating a cultural norm within that profession that has evolved over time. Almost all of these women may have been trying to compete with men as equals and one way of indicating their equality at work was to adopt this cultural norm.

At the opposite end of the spectrum were women who said they did 'nothing' because they weren't employed outside of the home. This had a totally different inflection, with women using this as an expression of low self-worth. These women were invariably raising young children but saw this an occupation not worthy of discussing, possibly a reflection of their perception that motherhood was associated with a lack of or loss of economic or employment status. There were a number of women somewhere in the middle, most of who worked part time or had taken a career break, and were raising children. Interestingly on many occasions the occupational title was given first, before the description of children's ages and names. This was even the case when women had chosen to take a career break to prioritise child rearing. Their first reference to self was as a working professional, yet their current primary role was that of mother and wife.

Given that the sample was purposefully selected and encompassed a wide range of age, educational achievement and occupations, it is reasonable this finding may be reflected more widely.

The decision to seek treatment for heavy menstrual bleeding was most often driven by reduced quality of life relating to the woman's inability to fulfil her self defined roles and responsibilities. Often there were external influences, such as family members or significant others who also influenced the decision to seek treatment. For the women in this sample the most common barrier to seeking treatment was being unable to ask for it. There was also the perception that they might be 'judged' by health professionals. Some women had experienced a dismissive attitude from a health professional but these were the minority. Most women had personally built up a barrier to seeking treatment due to the social conditioning of maintaining a stoic silence and concealing menstruation

primarily but also due to the lack of information about the recognition of heavy menstrual bleeding and possible treatment options. It is possible that large numbers of women in the general population have the same barriers to seeking treatment for heavy menstrual bleeding. The difficulties with recruitment to the ECLIPSE RCT bear this out, with recruitment taking far longer than expected as women were reluctant to discuss heavy menstrual bleeding or to seek treatment (Gupta personal communication 2009).

6.4 Discussion relating to fertility and womanliness

A number of women, who had experienced a change in menstrual bleeding pattern, associated this with becoming older and approaching menopause. It is difficult to determine where this idea came from given that discussion about menopause within families and peer groups was limited. Published research would suggest that heavy menstrual bleeding was not associated with hormonal changes in early perimenopause, but a change in cycle length was (Van Voorhis *et al* 2008). Almost all of the women were resistant to the aging process, a reflection of the glorification of youth in British society.

Fertility was discussed by all of the women in this sample and became one of the key themes running through this research. The majority of women in this sample retained to desire to be able to conceive and bear a child / more children. For some this was a theoretical concept; that is they wished to retain their reproductive potential if one day in the future they decided to have another child. For others this was a determined desire to conceive in the present. Several women who considered their family complete and had been sterilized or whose husband of long term partner had undergone

a vasectomy still expressed the desire to retain the uterus in order to have the potential to conceive. They talked of reversal of surgical contraceptive techniques, not in a definite sense but in the abstract, as something that they would not do but could be possible if they wanted it. It is difficult to determine if this was due to their defining themselves as women by their reproductive potential or whether it related to external drives to have another child at some point in the future.

The topic of aging and fertility was individualised and complex. Fertility was a particularly difficult area for these women to discuss as they found that the desire to retain the ability to conceive was extremely difficult to articulate and therefore not clearly understood by health professionals whose range of treatment options was severely limited by the woman's rejection of any treatment that either had a contraceptive effect or involved surgical intervention.

For the older women in this sample the uterus was much more than just a means to bear children. Many of them had a strong desire to retain the uterus and avoid surgical treatment for heavy menstrual bleeding. The women who expressed this desire and considered their family to be complete (that is they did not intend to have any more children), considered their uterus to be an integral part of being a woman. They expressed a similar aversion to hysterectomy as women studied in Hong Kong by Leung *et al.* (2005), who also preferred medical treatment options.

For some women fertility was a significant issue and the major reason for a preference against LNG-IUS. Only in one case was the idea of conception being the beginning of life stated. The other women all wished to conceive in the near future and the contraceptive effect of the LNG-IUS was unacceptable to them.

A few younger women in this study were seeking to postpone or forego pregnancy and motherhood and to seek amenorrhea. This reflects the work of Lin and Barnhart (2007) who advocate menstrual suppression by promoting the use of medication to achieve amenorrhea citing that this would get rid of the hassle of menstruation, perpetuating the myth that normal menstruation is distasteful and unnecessary. It would seem that the essence and true purpose of menstruation has been lost. The renewal of the endometrium so that it may nurture a fertilised ovum and nurture the developing new human life appears to be forgotten in the modern world. Along with this, there is the influence of the possible devaluation of motherhood and the measurement of success in terms of career achievements and material gain alone perceived by the younger women in this sample.

One of the most surprising findings from this research is the strong preference of younger women for surgery and the clearly described perception that hysterectomy was a simple and appropriate treatment option for heavy menstrual bleeding. This viewpoint was expressed almost exclusively by women under the age of thirty five and represented a cultural difference between women of this age range and women over forty. There were two main points discussed by younger women, firstly that hysterectomy would be an instant cure and the surgical procedure and recovery would be relatively simple. Secondly that a child could be acquired through some other means (adoption or surrogacy) rather than conception and pregnancy. The younger women who expressed these views were of a wide range of educational attainment and employment. These findings were in contrast to the older women in this sample and to other groups of women, namely Hong Kong women (Leung *et al.* 2005). Vuorma *et al.* (2003) found that British women who were less well

educated and seen in the secondary care setting were likely to prefer surgical treatment, but these factors did not correlate well with the young women in this sample.

In contrast to the development of treatment preferences where information was primarily sourced from the first hand accounts of family and friends, views relating to surgery were influenced by external sources such as the lay press. It would appear that reports of celebrity surgery and adoptions have led to the belief that surgical intervention is without complication and adoption widely available to anyone. At no time did these women consider costs physical or financial either for themselves as individuals or for society as a whole. They were only focused on the benefits of surgery as they saw them.

6.5 Discussion relating to clinical signs

All women in this sample described excessive menstrual blood loss. O'Flynn and Britten (2004) suggest a proportion of women presenting with heavy menstrual bleeding actually have menstrual blood loss within the medical definition of normal. Based on the narrative accounts of women in this study this does not seem to be the case. Subjective accounts of length of the menstrual cycle and increased sanitary protection have been correlated with higher measured blood loss in the past (Higham and Shaw 1999), so whilst it is not appropriate to think of blood loss in terms of measured volume, it is appropriate to conclude from narrative accounts that these women do have heavy menstrual bleeding in terms of excessive blood volume lost.

A number of women had experienced a change in menstrual pattern and this was a factor in seeking treatment early in the course of their condition.

A change in menstrual pattern was unexpected. Women thought that their menstruation would remain unchanged from puberty to menopause and that menopause was a clearly defined event rather than a progressive change. There was confusion felt, and difficulty managing a change in menstrual pattern and this was the main factor in seeking treatment. Women who had a change in menstrual pattern did not tolerate their heavy menstrual bleeding for very long, the majority seeking treatment within two years of onset. This was in contrast to women who had heavy menstrual bleeding from puberty. The difference was the absence or presence of successful coping behaviours established over time.

For many women menstrual pain was the most significant aspect of their experience of heavy menstrual bleeding. Although noted in earlier research (Santer *et al.* 2007) it would appear that there is still a focus on attempting to ascertain reduction in blood volume as a means of assessing treatment efficacy. Almost all of the women were asked about reduction in blood volume, even though for most explaining blood loss in terms of volume was difficult and inconsistent. Luke *et al.* (2010) tried to quantify the actual amount of reduction in menstrual blood loss that was meaningful to women and suggested that a 22% reduction in menstrual blood loss would be meaningful. The concept of measuring blood loss in this way does not take into account the psychological impact of heavy menstrual bleeding and perpetuates the medical focus on blood loss volume. This idea would not work for the women in this study, as they all had no concept of their menstrual bleeding in terms of millilitres. Many of them described other aspects of their condition such as menstrual pain and psychological distress as having more impact on health, wellbeing and quality of life than blood volume.

Throughout the analysis of women's experiences of heavy menstrual bleeding, the findings of this study would suggest that volume of blood loss was not predominant in their minds. This finding is consistent with O'Flynn and Britten, (2004), and O'Flynn and Britten, (2000). This raises the question of whether health professionals still rely on a reduction in volume of blood loss as a measure of treatment success. The majority of women who presented for their check up six weeks after the fitting of LNG-IUS were asked one question that they specifically remembered. That was 'has your blood loss reduced?' This was usually the first question to be raised and may have indicated an attempt on the part of the health professional to obtain a more objective determinant of treatment success. There is no doubt that for women who were treated with LNG-IUS and no longer had any menstrual bleeding this was a major indicator of success, but for those who still experienced regular menstruation or irregular spotting, measuring treatment efficacy by referring to volume of blood loss was of little use.

The impact of clinical symptoms of heavy menstrual bleeding, such as pain and anaemia had a direct negative impact on quality of life for most women in this sample. When anaemia was treated or there was a significant reduction in blood loss (for example amenorrhea) the women did report improved quality of life in terms of relief from clinical signs such as tiredness and lethargy. This concurs with a study by de Souza *et al.* (2010) who suggested that increased haemoglobin levels following treatment for heavy menstrual bleeding was predicted improved quality of life when measured by SF-36 physical and mental scores. Whilst this is undoubtedly valuable for health professionals who can accurately measure and monitor haemoglobin levels, it is not the whole picture for the women in this sample population. Alongside narrative relating to feeling less tiredness was the equally weighted narrative relating to feeling less

distress, as women were more able to maintain concealment of menstruation. For most women in this study it was impossible to separate the physical from the psychological benefits of successful treatment.

Women did not consider heavy menstrual bleeding to be an illness to be treated but a condition to be borne. There was a clear inference that heavy menstrual bleeding was not pathological, which created a dichotomy in women's minds about seeking treatment and therefore medicalising their condition. Garside *et al.* (2008) proposed a lay model of heavy menstrual bleeding from meta-ethnography of qualitative studies, which countered the patient illness model / medical model. This concept concurs with the findings from this study, although in Garside's model physical characteristics such as type of loss, clinical symptoms and the use of sanitary protection (again a measure of blood volume) remain central, with impact on life including practical issues (labelled physical problems) and psychological impact added on. This is in contrast to the views of the women in this study, who felt that clinical signs and symptoms were often not central to their experience of heavy menstrual bleeding. It is suggested that a more inclusive and holistic concept would be more appropriate and this is where development of the conceptual model **Experiences of Life with heavy Menstrual bleeding – Aid to communication (ELMA)** began.

The concept of heavy menstrual bleeding as a condition rather than an illness fits with the women's perception that their most pressing issues were not necessarily medical. Protheroe and Chew-Graham (2005) suggested that General Practitioners (GPs) fail to communicate a diagnosis of heavy menstrual bleeding and do not provide women with a 'label' when they are referred to secondary care. This finding is replicated in this sample

population although, for the women in this study this was a positive affirmation of their belief that they were not ill.

6.6 Discussion relating to confounding factors impacting on experiences of heavy menstrual bleeding

Communication was one of the key issues relating to the consultation with women find it difficult not only to state their preferences with confidence and also to articulate the rationale for their choices. Protheroe *et al.* (2007) suggest the use of a computerised decision aid to improve decision making about treatment options for heavy menstrual bleeding, yet this approach does not resolve the issues of communication, although it would improve the information women had before making choices. The computerised decision aid also is reliant on access to a computer (in a private setting) and a degree of computer knowledge and skills making it predominantly suitable for educated, reasonably affluent women. Even if this tool was widely used there would still remain the need to communicate the treatment decision and, for the women in this study, this was the most challenging part of the whole process. There remained a lack of freedom from embarrassment even when communicating with health professionals, strongly suggesting that menstruation remains a taboo subject and the women felt pressure to conform to societal norms of concealment of menstrual problems and menstruation in general. There was clear evidence that excellent communication skills were employed by a number of health professionals and in all cases the women's preference was eventually prescribed.

Good open communication was most clearly described in the primary care setting and one of the most important factors influencing this was the pre-

existing relationship between the health professional and the women. General Practitioners and practice nurses knew the women well and therefore women felt more able to discuss their treatment preferences more easily. In the secondary care setting the expertise of the gynaecologists was recognised and valued but women were less confident when discussing their treatment preferences and some women found themselves being either defensive or aggressive when stating their preference. This often created tension during the consultation for both parties. In addition women also described anxiety about the hospital setting, not relating to the prospect of serious pathology, but relating to mundane details such as finding the clinic, parking and also seeing a different doctor to the one who they were expecting. Medical treatment for most women who experience heavy menstrual bleeding may be most appropriately managed within the primary care setting.

Gender was an issue for most women, regardless of consultation setting. The majority of women in this sample would request a female health professional if they could. Many women described feeling unable to communicate about heavy menstrual bleeding, due to embarrassment and a perceived lack of empathy by male health professionals. This finding contrasts with the findings of Babitsch *et al.* (2008) who examined doctors satisfaction with the consultation and provision of medical care within gynaecology and emergency care and found that sex (gender) differences caused minor variation. The difference in findings is not gender but the perspective from which the success of the consultation is being measured.

When women were seen by a male health professional (in the secondary care setting) in some cases they were pleasantly surprised about the level of empathy and ease of communication during the consultation. Some of this can be related to the knowledge and expertise of the gynaecologist but

most of it was directly contributed to good communication and interpersonal skills that projected not only concern, empathy and most importantly, an individualised approach. These were the attributes that accounted for a successful (from the woman's perspective) consultation in the primary care setting too. This finding concurs with Christen *et al.* (2008) who suggest that it is not the gender of the health professional but gender specific (female) communication skills that created patient centred communication and thus positively influenced patient satisfaction.

When it came to rationalising and explaining treatment preferences gender did have an impact. Many women thought that the health professionals had made assumptions about them before the consultations had begun, for example assuming that a woman in her forties would not want to have any more children and from the women's recollection of the consultation process this did appear to be the case.

At the end of the interviews in this study, each interviewee was asked 'what advice would you give to a health professional when a woman with heavy menstrual bleeding arrives for a consultation?' Almost all women said 'listen' in one form or another. The powerful message was that an effective health professional was one who could listen and then treat each woman as an individual. This concurs with earlier findings by Longo *et al.* (2006).

Whilst the expertise of the gynaecologist in the secondary care setting was acknowledged by most of the women who attended there were some women who found communication more difficult in the secondary care setting than in the primary care setting.

Few women in this sample thought that heavy menstrual bleeding signified pathology. This was related in part to their own definition of heavy

menstrual bleeding as a condition rather than illness. A number of women did believe that the onset of heavy menstrual bleeding (a change in menstrual pattern) signalled the onset of menopause. Fear of pathology did not have a negative impact on quality of life for most women. Those women that did consider the possibility of pathology were influenced by a number of factors. First hand knowledge of a family member with a history of gynaecological pathology was most influential, particularly if that person was a close relative or had died as a result of the gynaecological pathology.

Also influential was media reporting of gynaecological pathology, specifically the well-publicised disease progression and subsequent death of a young British television personality from cervical cancer in 2009. Whilst the publicity surrounding this young woman did raise awareness of cervical cancer (resulting in an increase in women attending for cervical smear tests in the UK in following years), it also provided a source of anxiety for a few women in this sample. This had a negative impact on quality of life, whilst awaiting consultation for treatment. Finally a few women who were referred to secondary care for treatment of their heavy menstrual bleeding also questioned the possibility of pathology as an explanation as to why they had been referred. This was a minority view with most women aware that heavy menstrual bleeding was not likely to be related to significant pathology.

There was an expressed fear of consulting a health professional about heavy menstrual bleeding and being prescribed antidepressants as a treatment. This was based on actual individual experience and the perception that health professionals would not believe that heavy menstrual bleeding was a physical condition. There was also the belief that the low mood that the women experienced as a direct result of coping with

their condition and societal expectations would be attributed to depression rather than heavy menstrual bleeding.

In the past there have been several research studies suggesting a link between psychological disturbance and the reporting of heavy menstrual bleeding (Gath 1987, Shapley *et al.* 2002) and it would appear that some health professionals believe this to be the case and prescribe accordingly. For the women in this study this was not the case. They clearly differentiated between previous knowledge or experience of clinical depression and the low mood that was related to coping with heavy menstrual bleeding. Shapely *et al.* (2003b) acknowledge the effect of heavy menstrual bleeding on mood and how this may influence women's ability to continue life as normal, but they still suggest a propensity to low mood first. The findings of this study contest this viewpoint as there was clear evidence that once heavy menstrual bleeding symptoms improved so did mood without the use of antidepressants. The women in this study wanted to avoid the use of antidepressants, because they felt they were an inappropriate treatment for heavy menstrual bleeding. They also stated a fear of addiction and a wish to avoid the perceived social stigma relating to mental illness and medications related to mental illness.

6.7 Discussion relating to previous knowledge and experience of treatment

There were high expectations of a positive outcome to treatment, particularly amongst women who had a treatment preference for LNG-IUS. The current study data would suggest that women had high expectations because they felt that they really needed to have a positive outcome. The long term nature of this condition and the physical impact it caused

combined with the difficulties of maintaining the societal norms of silence and concealment made life almost unbearable for these women. This meant they were desperate before they broke the taboos and started to speak to their health professional about treatment. Then, very often the treatments were described in positive terms, particularly LNG-IUS.

In the initial states of treatment with LNG-IUS most women experienced side effects such as irregular bleeding and these were perceived as negative. This was the first study to seek to qualitatively determine patient satisfaction with treatment for heavy menstrual bleeding within the first three months of treatment and at this depth. In addition there is some evidence to suggest that irregular bleeding is a common reason for discontinuing LNG-IUS (Shaw *et al.* 2007, Soysal *et al.* 2002). All of the women had been counselled prior to the fitting of LNG-IUS and were aware of the possibility of progestogenic side effects. From the data there is evidence to suggest that health professionals down played both the likelihood and severity of changes to a woman's menstrual cycle due to progestogenic side effects, such as irregular bleeding, breast changes and weight gain. The women in this study did not anticipate major changes in their menstrual cycle or the length of time that they would experience these changes before they saw an improvement in their condition. Irregular bleeding was more problematic than the volume of blood loss due to its impact on established behavioural coping mechanisms. Most women persevered but this was largely due to perceived barriers to LNG-IUS removal rather than positive expectations relating to the advice given by health professionals. Women in this study may have benefited from and welcomed stronger messages about progestogenic side effects prior to having the LNG-IUS fitted in order to implement changes to their established behavioural coping mechanisms.

More than one year following initial treatment with LNG-IUS most women were satisfied with their treatment and had experienced an improvement in their perceived quality of life. This finding concurs with previous research (Lethaby *et al.* 2005b) Narrative accounts were overwhelmingly positive and a number of women used emotive language to describe the improvement in their health and wellbeing. Some women had experienced amenorrhea, but even the ones who still had a regular menstrual bleed felt better. The change in perceptions of health and wellbeing was always associated with being able to fulfil roles and responsibilities. Some women described an improvement in physical wellbeing but the emphasis for all was on the psychological benefits of being able to maintain the societal norms of concealment of menstruation. This finding adds to the suggestion that assessment of the reduction in volume of blood loss is of limited value when assessing treatment efficacy. When questioned about future treatment options many women stated that they would request another LNG-IUS at the end of their current five year treatment cycle. This concurs with Lete *et al* (2011) who found that 87.9% of premenopausal women in their study would use a second LNG-IUS device.

The fitting of LNG-IUS distressed many women in this study. There were several factors that may have caused this distress including physical aspects of the genital tract, nulliparity, the expertise of the health professional, lack of understanding of the procedure and a lack of psychological preparation. It was not possible to define physical aspects of the genital tract in this research, although a number of women reported comments about their anatomy, which may have added to their feelings of distress by apportioning blame, even if this was not the intention. Nulliparity could have been influential as there are established concerns about the use of LNG-IUS in nulliparous women, however many of the

multiparous women in this sample also found the fitting procedure distressing.

There is little evidence on fitting of LNG-IUS in nulliparous women, but a recent cohort study found that although LNG-IUS was fitted without difficulty in 80% of 636 women, dilator use was three times higher in nulliparous women than in multiparous women (Bahamondes *et al* 2011). The latter concluded that LNG-IUS was suitable for use in nulliparous women but as it was conducted from a medical perspective there is little acknowledgment of the women's perspective. The negative experience of fitting did impact on the perception of the treatment in the short term. Women who recounted distressing fitting experiences were also more likely to express less tolerance of side effects such as irregular spotting, although they did persevere with treatment.

Standard treatment options were considered to be quite different to LNG-IUS by the women in this study. They viewed tablets as a short term measure and one that was within their control. In spite of the fact that these were prescription medicines the women had a very relaxed attitude to starting and stopping standard treatment. For the women prescribed oral contraceptive or injectable contraceptive (depo provera) there was the suggestion that these were not really effective treatments for heavy menstrual bleeding but medications that would help reduce the severity of their condition. This in contrast to the women treated with LNG-IUS who saw it as a 'miracle cure' for their condition, whilst denying it was an illness at all. The relaxed attitude towards contraceptive treatments, particularly the oral contraceptive pill, could have been related to its familiarity and widespread use for contraception, which is a non-medical use in the perceptions of women.

Women who were prescribed tranexamic acid, took the medication as prescribed but did not feel better quickly enough to continue with their treatment. At approximately three months most of them had stopped taking tranexamic acid altogether. At twelve months only two women were still taking it. Both perceived this treatment to be a short term measure whilst they were waiting for something else to happen, namely hysterectomy and menopause. They did both however report improved quality of life when taking tranexamic acid compared to not taking it. This is in contrast to Muse *et al.* (2011) who found that long term use of tranexamic acid was well tolerated.

Previous experience of treatment was influential when developing treatment preferences. For almost all of the women previous treatment had been unsuccessful. This was unsurprising considering that they were again seeking treatment for heavy menstrual bleeding. Treatment preferences were also influenced by previous experiences of contraception or treatment or personal moral or religious beliefs.

The most influential source of information for establishing treatment preferences in this study was not the medical practitioners or the medical press, but first hand accounts from other women (friends and family). This knowledge was highly regarded even if it was contradictory or inaccurate. In common with Leung *et al.* (2005) the majority of women had limited knowledge about the full range of treatment options. Yet they had already formed a treatment preference.

Why didn't women seek information about medical treatments from health professionals at all before forming a treatment preference? The women who formed a preference knew that they have a treatable medical problem yet they did not ask a medical professional for help and information before determining a preferred treatment option. Protheroe and Chew-Graham

(2005) also found that women with heavy menstrual bleeding did not consider GPs to be a source of information about treatment, and it would appear that this had not changed much in the intervening five years. This may be related to the idea that heavy menstrual bleeding is a condition rather than an illness, that is not related to or caused by pathology. Some of these women would seek medical advice if they had a cold yet did not seek advice before requesting an indwelling medical device.

There are several possible reasons identified in this research. Firstly, the women were unsure whether their heavy menstrual bleeding was abnormal or significantly abnormal to require treatment. Secondly, the women were generally unaware that there were possible treatments available for heavy menstrual bleeding until their peers told them about successful treatment. Thirdly, unsuccessful treatment was not discussed amongst peer groups so alternative treatment options were not considered, as they were unknown. Finally for some women the narrative account of successful treatment with LNG-IUS was backed up by unscientific reports in the lay press of its efficacy and suitability as a treatment for heavy menstrual bleeding.

These four factors led to the development of treatment preferences before consulting with a health professional. It is possible that the information from family and peers was valued the most, even when it was known to be inaccurate or contradictory, as it was a reflection of the esteem in which the advisor was held by the woman receiving the advice. The strength and nature of the relationship could also be influential, as a loving relationship is much more likely to result in trust and the advisor's motivation would be perceived to be altruistic.

There was very little accurate medical information about heavy menstrual bleeding available for women in this sample to access. The lack of neutral, easily accessible information from reliable sources (for example an

information leaflet at the pharmacy or supermarket) strengthens the power of first hand accounts. The data analysis showed that these accounts almost always come from trusted close friends or family members lending them even greater veracity.

Women may have found communicating their preferences so difficult, either because of the context (being seen as a potential participant in the ECLIPSE RCT) or because choices were made before the doctor had a chance to have an input either in terms of information or professional opinion. It is possible that both of these factors came into play during some consultations. Whilst the doctors involved in recruitment to the randomised controlled trial did not put pressure on women to be randomised, they had a desire to ensure that women were fully aware of all treatment options and a need to ensure the women had considered participating in the trial fully before prescribing the preferred treatment. Several women who were interviewed had, after seeing their GP, attended gynaecology study clinics that were specifically run to increase recruitment to the randomised controlled trial, so there was an expectation by the medical staff that women would be open to participation when they attended (having had all of the ECLIPSE RCT literature before coming to the consultation). In fact the women just wanted treatment for their heavy menstrual bleeding and had not heard of or considered treatment before being informed about the ECLIPSE Trial by their GP. The different objectives of patient and doctor might have increased the possibility of miscommunication in a few cases.

It is also possible that the women who had a preference were more assertive or aggressive during the consultation. There is evidence of this in one case, where one of the interviewee's previous experiences with gynaecology health professionals had been emotionally difficult for her and this led to an expressed mistrust of all health professionals. It was clear

from her narrative that she had become quite aggressive during the consultation, partly due to her difficulty in explaining her preference and partly due to her previously established mistrust of health professionals.

At the beginning of this research there appeared to be a marketing campaign in the lay press for LNG-IUS (Mirena). This followed on from the publication of the NICE Guideline 44 (2007) suggesting LNG-IUS as a first line treatment for heavy menstrual bleeding. It is probable that the information in the lay press at the time of the first interviews did influence the development of treatment preferences as many women had heard of LNG-IUS but were unsure where from. The lay press did not have a strong influence though, first hand accounts from friends and family were much more powerful influences in the development of treatment preferences.

None of the women changed their expressed treatment preference after talking to their health professional and some found communicating their choice to health professionals difficult. For some this was related to the gender of the health professional but for a number of these women, gender was less of an issue than whether they felt the health professional was actively listening or not. The women in this sample were confident enough to state a preference and had gone to the consultation ready to do so and this may be partly why gender had less of an impact on communication for these women.

Women who expressed a treatment preference (and declined ECLIPSE Trial participation) tended to be better educated, professional / career orientated women. This finding concurs with the published literature on treatment preferences (Cooper et al 1997), including the preference for medical treatment over surgical, however even with this small sample there was an exception to this. They were of mixed age range but shared

characteristics such as personal confidence and personal responsibility for health and wellbeing.

Almost all of the women in this sample were satisfied with their preferred treatment one year on from commencing it. They were happy to continue with their preferred treatment and this finding concurs with Cooper *et al.* (1997). They also reported a higher degree of satisfaction with the consultation process including those women who had experienced difficulty in communicating their preference to the health professional because they achieved their goal of being prescribed their preferred treatment. For the few who were unhappy with their preferred treatment the negative impact was significant, with feelings of guilt and self blame adding to the continuing distress of their on going heavy menstrual bleeding.

6.8 Discussion relating to time

The estimated time to menopause was an interesting aspect of heavy menstrual bleeding not explored in previously published literature to date. This concept was used by many women to rationalise decisions around continuing or discontinuing treatments and was considered to be an important part of the cost / benefit analysis. This is something that is worthy of further research, as the idea that menopause is a transitional stage, like puberty, seemed to be poorly understood.

The interviewees suggested that most health professionals tended to downplay heavy menstrual bleeding and issues with treatments, as they (like the rest of society) have been conditioned to. Heavy menstrual bleeding is not life threatening after all. In addition narrative accounts from friends and family tended to be overwhelmingly positive, as did reporting in the lay press, again particularly in relation to LNG-IUS. The unrealistic

timeframes come from the combination of a desperate need and mainly positive information from external sources. It is clear from the interview data that women were told that treatments would take several months to be effective by their health professionals but they still expected an immediate 'miracle cure'.

Young women who expressed a preference for surgery estimated time to menopause was influential in shaping their views. They determined that having surgery at a young age would be preferable to a further twenty or thirty years of heavy menstrual bleeding. The younger women were also very focused on their working lives, defining themselves by their job title and earnings rather than a broader description of themselves. For some they felt pressure to perform in the same way as their male colleagues and felt that removal of the uterus (and the ceasing of menstruation that would follow) was one way to achieve equality and respect in their male dominated workplace.

When the consultation behaviour of the younger women with a preference for surgery was considered there were a number of differences in their narrative accounts compared to older women. The younger women tended to use more dramatic and emotive language when recounting what they said to the health professional. They also described the thought of managing heavy menstrual bleeding without surgery for a number of years as quite catastrophic. There was also a degree of exaggeration in the number of years they had experienced heavy menstrual bleeding (for two women their suffering started before they were old enough to walk), and the perceived length of time to menopause. These findings correlate with Echlin *et al.* (2002).

6.9 Discussion relating to the conceptual model ELMA

The use of situational analysis to further examine the data led to the development of a conceptual model that differs from previously published models of which Garside *et al.* (2008) is the most comprehensive in the literature to date. In common with Garside *et al.* (2008) ELMA illustrates the aspects of life, both physical and psychological, that are affected by heavy menstrual bleeding. Both models illustrate the complexity of the condition and factors that influence women's experiences. ELMA takes this information a step further by illustrating the range of experience described by this sample population within each parameter of experience illustrated. This was further enhanced when treatment outcomes were overlaid onto the model of women's experiences certain inferences may be drawn about the type of experience that is most likely to be associated with a particular treatment trajectory, for this sample population.

Exploration of the range of women's experiences is well illustrated by Shaw *et al.* (1998) in the Shaw Menorrhagia Scale. This is an established and respected method of measuring patient experiences of heavy menstrual bleeding and ELMA includes many comparable elements. ELMA differs in that it is a visual model rather than a linear list of questions. A diagrammatic representation may be more accessible to both health professionals and women interested in understanding heavy menstrual bleeding. Shaw *et al.* (1998) questionnaire was familiar to many of the women in this sample population as they were used to completing it as part of the ECLIPSE RCT.

When the model was shown to women as part of the last ten interviews and during the validation process, they suggested that they could use the diagram to explain their experiences to health professionals and to really highlight what mattered to them. It is was women themselves who first

suggested this model could be used to aid open communication with health professionals when considering treatment options and for evaluating treatment efficacy. When the two methods of assessment are compared, Shaw's Menorrhagia Scale gives more detailed information of use to health professionals but may not be as easy to use from the perspective of the patient. Women made an assessment of their condition in just a few minutes when using ELMA, but reported taking much longer to complete the menorrhagia questionnaire. In addition the association between certain experiences and particular treatment trajectories illustrated in ELMA adds a further dimension to assessment and communication. However ELMA requires further testing and refinement before being used as an assessment tool.

This chapter has explored and discussed the findings of this research. Conclusions and recommendations for research will be presented in the final chapter, including implications for clinical practice.

CONCLUSION AND RECOMMENDATIONS**7.0 Conclusion**

Heavy menstrual bleeding is a complex condition that women do not consider to be an illness. Heavy menstrual bleeding has a direct effect on psychological well being with the distress caused by not being able to conceal all evidence of menstruation appearing to be much greater than distress caused by physical symptoms. Women developed numerous coping behaviours and mechanisms to maintain the concealment of menstruation.

The psychological and physical aspects of heavy menstrual bleeding impacted on all areas of a woman's life including her significant relationships and sexuality. In the work place a degree of control over working terms and conditions, for example being self employed, improved women's ability to cope with heavy menstrual bleeding. Family life was often arranged around the menstrual cycle and successful treatment had a beneficial effect on not just the individual woman but on her partner and children as well. Many older women sought to retain their fertility and this made some treatment options unacceptable. Older women also felt retaining the uterus identified them as women, in contrast to younger women in this sample who were more likely to discuss surgery as a treatment option.

Women frequently experienced menstrual pain and ill health caused by the physical aspects of heavy menstrual blood loss. Clinical signs varied between individuals. Confounding factors influenced women's experiences particularly of treatment and these ranged from comorbidities to being unable to communicate with the health professional about heavy menstrual bleeding. Many women had previous experience of treatment for heavy

menstrual bleeding and this influenced treatment expectations. Some women had high expectations and were disappointed. The majority of women treated with LNG-IUS were satisfied with their treatment, although fitting the LNG-IUS was found to be traumatic for some, including multiparous women. The majority of women who were treated with standard treatment were less satisfied and many had discontinued their treatment by the end of the study, preferring to self manage their condition or switch to LNG-IUS. Estimated time to menopause was a significant factor in making decisions relating to treatment options. Women who had a long history of heavy menstrual bleeding had developed successful coping behaviours and mechanisms and treatment sometimes interfered with these. Many women preferred to self manage their condition if coping behaviours were well established.

Women suggested that the conceptual model ELMA helped them to communicate their experiences of heavy menstrual bleeding and also to assess the severity of their condition and treatment efficacy. This model may have a practical application in aiding communication between women and health professionals about heavy menstrual bleeding.

7.1 Psychological aspects of heavy menstrual bleeding and self esteem

The women in this study reflected prevalent societal views about menstruation being a distasteful and problematic part of womanhood. In addition these women had additional negative feelings and attitudes due to the difficulties of managing heavy menstrual bleeding. Negative attitudes were formed at puberty due to a combination of lack of knowledge at first menarche and a perceived lack of support. This was due to the

maintenance of the notion that menstruation is a taboo subject and should not be discussed. This was upheld even between mothers and daughters and between sisters. Conforming to the societal norms of silence about menstruation and heavy menstrual bleeding and concealment of menstruation created a great deal of anxiety for women experiencing heavy menstrual bleeding. The unpredictable nature of heavy menstrual blood flow made concealment impossible for all of these women at some time during their menstrual history. Incidences of menstrual blood leaking onto clothing and becoming visible were associated with strong feelings of embarrassment, shame and failure.

7.2 Relationships and sexuality

Heavy menstrual bleeding had a profound impact on many aspects of a woman's life including her significant relationships and sexuality. Whilst sexuality was rarely discussed during consultation with a health professional most women felt this to be an extremely important part of their significant relationships. Physical problems of excessive blood loss made sexual intercourse impractical, however it was the psychological impact of heavy menstrual bleeding that inhibited women's sexuality the most. Women felt unclean and undesirable during menstruation and this was generated by women's self image rather than by their partner's views. Whilst reported as generally supportive, several partners did express frustration and concern about this issue and this was a trigger for women to seek treatment.

7.3 The impact of heavy menstrual bleeding on life and work

Women in this study defined quality of life as relating to their ability to continue with their roles and responsibilities during their menstrual period. They valued being able to function normally and this mostly related to being physically well and able to conceal their menstrual bleeding adequately. For most the success of treatment was not described as a reduction in blood volume but as a reduction in anxiety related to controlling blood flow.

Many women found their lives dominated by their menstrual cycle as family life was frequently arranged around it. This was problematic with women needing to source regular help with childcare during menstruation, often without wanting to disclose the reason why. Successful treatment had a positive effect not just on women but also on all members of the family. Women reported improved social lives and improved ability to cope with other aspects of their lives.

Most women in this study were employed. Although the impact of heavy menstrual bleeding varied most felt that their condition was detrimental to their working lives. Women who had greater control (through being self employed or in a senior position) over their working lives were able to rearrange their work around their menstrual cycle in the same way that they managed their family or personal lives. This was not possible for most women particularly those in male dominated work environments or professions. Successful treatment changed this completely.

7.4 Fertility and womanliness

It is very important to recognise that many women still retain the desire to conceive a child or to retain the potential to conceive until well into their forties and this may be true whether they could be considered to have completed their families or not. Health professionals should be open to the possibility that women will want to avoid treatments that impact on fertility and communication surrounding future fertility should be handled with caution and respect.

Younger women had a strongly expressed desire for surgery, as a treatment option that they felt should be open to them in the near future. There was a belief that hysterectomy would provide a 'quick fix' and that (further) children could be obtained by adoption, if that is what they wanted in the future. There was no fear of surgery, perhaps a reflection of the influence of media representation of cosmetic surgery.

In direct contrast women over thirty were much more likely to reject surgery as a treatment option and seek to retain the uterus, both for the potential to conceive (another) child or as part of their female identity. Women in this age group also thought that the potential benefits of hysterectomy did not outweigh the risks of complex surgery. This view was often associated with successful coping behaviours and strategies. Women calculated estimated time remaining to menopause and this was also part of their cost benefit analysis when considering surgery.

7.5 Clinical signs

There has been a shift in recent years away from determining the severity of heavy menstrual bleeding in terms of volume of blood loss and the findings of this study would suggest that this is entirely appropriate. Women frequently experienced menstrual pain and ill health caused by the physical aspects of heavy menstrual blood loss. Clinical signs varied between individuals and were wide ranging. For many women their experience was dominated by a combination of clinical signs and women described these as key symptoms to be treated or dealt with. Whilst most women felt themselves to be unwell during menstruation they did not consider heavy menstrual bleeding to be an illness.

7.6 Factors confounding the experience of heavy menstrual bleeding

This study found heavy menstrual bleeding to be a complex condition with multifactorial influences on women's experiences of it. There were a number of confounding factors emerging from the data including physical factors such as a concurrent medical condition or comorbidity and psychological factors such as being unable to communicate with the health professional about heavy menstrual bleeding. Confounding factors influenced women's experiences particularly of treatment, particularly gynaecological comorbidities and difficulties communicating about heavy menstrual bleeding during the consultation with a health professional.

7.7 Previous knowledge and experience of treatment

Treatment expectations were influenced by a number of information sources including first hand accounts from peers, knowledge of family members treatment experiences, information from health professionals and items published in the lay press. Most of these information sources tended to be positive with the exception of information from family members in a minority of cases. This was likely to have created the extremely high expectations of positive outcomes expressed by the women in this sample. A small number of women had unrealistic expectations of huge changes in their quality of life occurring in a very short timeframe. Expectations were highest for women who had a treatment preference for LNG-IUS and those who were randomised to LNG-IUS, a measure perhaps of the confidence in LNG-IUS as a treatment for heavy menstrual bleeding amongst women and health professionals. When considering expected treatment outcomes the women who were younger than thirty had different expectations that those over thirty. Younger women tended to have higher expectations of positive outcomes and were more vocal about expectations and treatment preferences. They were not necessarily more knowledgeable but tended to have more confidence when communicating their expectations.

Women who were treated with standard treatment did not continue with their treatment over the course of the study. Two women did continue but both of them saw their medication as a short term measure, one was menopausal and the other awaiting hysterectomy. Standard treatment was discontinued due to being ineffective. Other reasons for discontinuing treatment related to the number and size of the tablets (tranexamic acid), concerns about long term effects and side effects such as irregular bleeding. As the medication was within their control the women in this

sample discontinued treatment without consulting their health professional and a large proportion opted for no further treatment.

Women who were treated with LNG-IUS found this treatment to be successful in the majority of cases. Fitting of the coil was distressing to most, indicating that more psychological preparation for the procedure would be helpful for the majority of women, as they tended to underestimate the discomfort that they would feel. Most of the women in this sample did experience irregular bleeding at the beginning of their treatment journeys but persevered as they had been forewarned about this potential side effect. Another often cited reason for persevering with LNG-IUS was that removal required medical intervention and this did encourage continuation of the treatment. At the time of the second interviews the majority of the women treated with LNG-IUS were satisfied with their treatment and had seen significant improvements in their condition. Associated with this were improvements in quality of life.

A number of women (about one third of the sample population) had a strong preference for a particular medical treatment for heavy menstrual bleeding before they consult with a health professional. Their preference may be influenced by previous experience of other treatments or by the positive or negative experiences of their mothers or sisters. It is important for health professionals to recognize this influence and to elicit a clear family history when exploring treatment options so that out of date information can be corrected and modern treatment options explained.

When considering the preference for LNG-IUS this was influenced by first hand accounts of the experiences of friends and more distant family members such as cousins. Most of the narrative accounts were positive and this information was valued more highly than written or verbal information from health professionals. None of the women in this study changed their

preference and health professionals need to be aware of the influence of peer and family pressure when discussing treatment options.

Women who felt able to work in partnership with their health professional to determine treatment options or who felt that their preferences were recognised and supported were much more tolerant and therefore compliant with the chosen treatment, leading to better outcomes at twelve months. Crucial to the sense of partnership in decision-making was communication between the health professional and the women. There is no doubt that this was improved when there was an established relationship between the two prior to this difficult consultation and that the most open communication was seen in the primary care setting. It is likely that best practice would be to continue to treat heavy menstrual bleeding in the primary care setting with a health professional who is familiar with and known to the woman.

7.8 Time

Previously unexplored in the literature the women's own estimated time remaining until the menopause was a significant factor in making decisions relating to treatment options. Estimated time to menopause also influenced decisions to discontinue treatment and expressed preferences for no further treatment or surgical intervention. Women who had a long history of heavy menstrual bleeding had developed successful coping behaviours and mechanisms and treatment sometimes interfered with these. For some women this related to irregular bleeding making planning difficult. Many women preferred to self manage their condition if coping behaviours were effective and well established.

7.9 Conceptual model ELMA

The conceptual model provides a visual explanation of the complexity of heavy menstrual bleeding from the perspective of the women who experience it. Overlying the descriptors of aspects of the condition and the range of experience are treatment outcomes for this small sample. The face validity of ELMA was confirmed when presented to women in the study.

The model would be useful as an aid to communication for women and health professionals during the consultation as it illustrates how aspects of life may be affected and how different parameters influence each other. The model also illustrates a range of experience in order to facilitate discussion about treatment options.

7.10 Study strengths and limitations

Qualitative methodology was an appropriate methodology for the exploration of a complex condition with physical, psychological and social impacts on women. However one of its limitations is the position of qualitative methodology in the research hierarchy of knowledge, particularly in medicine, where the gold standard is the randomised controlled trial. A grounded theory approach suited this study and the subject matter as heavy menstrual bleeding is a highly individualised complex condition with physical, psychological and social aspects to explore. In addition there were a range of different treatment options in use. A grounded theory approach generated descriptive themes in eight core categories. Situational analysis was then utilised to pull together the descriptive themes and develop the conceptual model. Situational analysis enabled the researcher to contextualise the descriptive themes and

generate a visual description of women's experiences of heavy menstrual bleeding.

The researcher's background and health care experience strengthen the quality of data collection and analysis. Having a nursing and midwifery background equipped the researcher with good communication skills and knowledge about female anatomy and physiology. This facilitated in depth interviewing particularly within an intimate subject. Professional training in interview techniques also improved the quality of the interview data obtained. Having no personal experience of heavy menstrual bleeding meant the researcher had an open mind and no preconceived ideas about what it would be like to live with heavy menstrual bleeding. This made the researcher particularly suited to the grounded theory approach to data analysis, as every interview revealed something new and interesting and there were no negative personal experiences to put aside. A limitation of having a nursing and midwifery background was that at first, the researcher viewed the interview data from a medical perspective, focusing on treatment efficacy rather than what the interviewees deemed to be most important. This changed quickly as data analysis was conducted alongside further data collection.

This was an extremely large sample population for a qualitative study generating massive amount of data. The sample size had to be large in order to capture the experiences of the range of medical treatments and also a wide range of demographic characteristics. Data was at times unwieldy and was managed through use of NVivo that facilitated data coding and organisation. Through the process of analysis data became removed from the original context and narrative accounts. Following coding and analysis of anonymous data, case study style summaries were written to reset the context and revisit the whole experience and treatment

journey for each woman. In this way it was possible to conduct a through grounded theory and situational analysis and also reflect on each woman's personal experience. This ensured that the women remained the primary focus of the research.

There was restricted access to potential participants as recruitment was set up through ECLIPSE randomised controlled trial. This provided a framework and a potential study population who were known to be experiencing heavy menstrual bleeding of sufficient impact to seek medical treatment. In addition this approach ensured that qualitative findings could be related to randomised controlled trial outcomes in the future. This was a strength in that a wide range of demographic characteristics and a variety of prescribed treatments were sought and obtained in this sample. Nesting within an ongoing RCT also created the opportunity to conduct a longitudinal qualitative study capturing women's experiences over time, through their treatment journeys. One disadvantage of this approach was that there was no opportunity to increase ethnic diversity or the number of women under thirty years of age by recruiting through community groups or by cascading / snowballing recruitment in specific geographical or cultural areas.

It is possible and in some cases likely that participating in this interview study caused women to stop and think about their experiences of heavy menstrual bleeding in more detail than they ever had before. Topics that arose during the interviews included many aspects of life some of which were distressing and some of which were illuminating for the individual woman. Several women, when talking about their heavy menstrual bleeding also thought deeply about their relationships with partners and close family, their working environments, fertility, aging and their own morbidity. This had an impact on their perceptions of their condition and

also their experiences of it. A number of women found the interview process therapeutic. Breaking their silence and describing their experiences to a neutral and impartial observer gave them an opportunity to unburden themselves of some of the confusion, guilt and shame they felt. These women no longer felt so isolated as they realised that there must be other women also taking part in this study and suffering from heavy menstrual bleeding too. In addition the fact that this research was happening gave some comfort and hope that treatment options would continue to improve in the future and that women's voices would be heard. Whilst the impact of this was increased by the longitudinal nature of the research, this was also of benefit as women were able to express themselves more clearly at the second interview after some introspection during or after the first.

7.11 Recommendations for further research

The following recommendations can be made as a result of this research.

This study findings would suggest that there is still a lack of choice of effective medical treatment for heavy menstrual bleeding that suits most women and has a minimum amount of side effects. At present most treatments have been developed primarily as contraception, making them unsuitable for women who still wish to conceive. The non-hormonal treatments such as tranexamic acid were not considered to be effective or tolerable in the long term by this sample population. Future pharmacological research could focus on medical treatments that do not impact on fertility, particularly the ability to be treated for heavy menstrual bleeding without the contraceptive effect.

When considering communication with health care professionals it could be useful to utilise the conceptual model ELMA as an aid to guide conversation

during the consultation process. It is a multifaceted model and thus reflects the complex nature of this condition and may assist with a holistic approach to determining treatment choices. Women were able to identify the factors that impacted most on their lives and the severity of that impact and so the model provided a more individualized aid to communication and assessment of their condition. In addition women in the validation group used ELMA to assess both the severity of their clinical signs and the effectiveness of their treatment. Whilst the findings of this small study demonstrated the usefulness of this model as an assessment tool, it needs to be much more widely tested before it is used as a measure to predict treatment outcomes and determine treatment choices. However the model may be immediately useful as a learning tool for health professionals and as an aid to communication during consultations with women experiencing heavy menstrual bleeding.

Many women who were interviewed wished to discuss surgical treatment options and it would be valuable to follow up on this study with a further study focused on surgical treatment for heavy menstrual bleeding, including a longitudinal component to assess psychological aspects of hysterectomy. In addition the issues of fertility and self-image relating to femininity need further research in the modern context when women are combining traditional female roles with the pursuit of careers.

7.12 Implications for practice

The LNG-IUS proved to be the most successful treatment in this small sample and good results in terms of reduced menstrual bleeding were seen for the majority. In addition this treatment option was the most requested and initial side effects were well tolerated by most of the sample

population. It is probable that the NICE Guideline 44 – Heavy Menstrual Bleeding is correct in proposing LNG-IUS as a first line medical treatment. The results of the randomised control trial, the ECLIPSE Trial should give a clearer answer when they are reported in 2012.

The difficulties of communication about heavy menstrual bleeding, including with health professionals have been highlighted through this research. One recommendation would be to increase the availability of accurate and up to date information for women about heavy menstrual bleeding and treatment options, both medical and surgical, in the lay press. Many women relied upon information from peers and relatives that in some cases was out of date or inaccurate. Part of the problem may be that heavy menstrual bleeding remains a taboo subject in wider society. The evolution of the Internet as a primary source of information would suit this subject as women could seek information discretely. This may also be a good place for support groups or forums as although many women felt isolated and lack of support, few wanted to meet other women face to face.

Women's experience of treatment for heavy menstrual bleeding was enhanced when they were treated in the primary care setting by a health care professional that they knew well. Most women did not associate heavy menstrual bleeding with the possibility of pathology and so were not concerned if they were not referred to secondary care for investigation. The findings of this study would suggest that for the majority the most appropriate place for treatment relating to heavy menstrual bleeding was in the primary care setting at their own GP's surgery. For some women the perceived expertise of the gynaecologist in the secondary care setting was helpful but the study findings suggest that the difficulties communicating with a stranger may have outweighed this benefit. A possible confounding factor in this study may be that the more than half of the gynaecologists

involved were male and most of the GP's were female. This may have influenced the findings relating to communication in the primary care setting as gender issues were less apparent in primary care, although familiarity was also a factor in reducing communication difficulties.

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APPENDIX I Study protocol June 2008

Published as an appendix in ECLIPSE Trial protocol V6.1 dated 21.07.08
(Chief Investigator Prof JK Gupta University of Birmingham)

Medical treatments for heavy menstrual bleeding:

Understanding women's experiences, decisions and their contexts

Aims

To explore, and enhance understanding of the experiences, decision-making and impact on quality of life of women receiving medical treatments for menorrhagia.

This research is nested within the current ECLIPSE trial (www.eclipse.bham.ac.uk), an ongoing randomised controlled trial which aims to investigate the effectiveness and cost-effectiveness of current medical treatments for menorrhagia. This study aims to generate qualitative insights from women's perspectives that contextualise ECLIPSE trial outcome measures, which include measures of quality of life in addition to reduction in blood loss. This should enhance the utility of the quantitative trial findings and their application in practice.

Objectives

1. To explore and develop understanding of women's experiences and expectations of medical treatments for menorrhagia.
2. To explore women's views, beliefs, attitudes and decision making relating to treatments for menorrhagia including treatment preferences, how they may change over time and why.

3. To explore women's perspectives on indicators of quality of life in the context of heavy menstrual bleeding and the effects of treatment on their symptoms and quality of life.

4. To explore potential cultural variations in women's experiences, contexts and decision-making in relation to medical treatments for menorrhagia.

Background

Menorrhagia and other changes in menstrual experience can impact on many aspects of health, well being and social functioning for women (Chapple 1999). Recent publication of NICE Guidelines for Heavy Menstrual Bleeding (HMB) (NICE, 2007) recommends Levonorgestrel releasing intrauterine system (LNG-IUS) be considered as first line treatment for HMB, with other medical treatments as further choices. It is thus timely to explore their effects on quality of life by exploring women's perspectives. This need is underlined by the guidelines, which also highlight need for more understanding of ethnic variation in perceptions of menorrhagia. The ECLIPSE Trial is an ongoing randomized controlled trial comparing the effectiveness and cost-effectiveness of with standard medical treatments for menorrhagia. While LNG-IUS is effective in reducing menstrual blood loss, studies have not shown significant differences in satisfaction with treatment or improvement in perceived quality of life (Lethaby et al. 2005) when compared to surgical treatments, with particular paucity of data comparing LNG-IUS to standard medical treatments.

While there is some evidence comparing effectiveness of various treatments for menorrhagia, there has been less interest in examining women's experiences of menorrhagia and its treatment. Some studies have suggested that society and culture impact on women's perception of severity of menstrual disorders (O'Flynn 2006, O'Flynn and Britten 2004, Chapple 1999). Women have discussed management of menstruation including its concealment to conform to societal norms (O'Flynn 2006). Limited research has explored ethnic variation. One study, that included 13 women of South Asian origin, suggested that cultural perceptions of menorrhagia in South Asian women may lead to reluctance to request treatment and higher levels of iron deficiency anaemia in this population (Chapple 1998, Chapple et al. 1998). Beliefs included positive views of heavy menstrual bleeding as menstrual blood is thought to be impure, and a reluctance to discuss menstruation with a male doctor. Many women studied had experienced a change in their menstruation and required further explanation. Here, it is suggested health professionals can appear preoccupied with volume of blood loss rather than addressing patients' concerns or impact on women's health and well being (O'Flynn and Britten 2004, O'Flynn and Britten 2000).

Earlier work has found many women who require treatment for menorrhagia have predetermined expectations and preferences for a particular treatment (Vuorma et al 2003, Sculpher et al 1998, Coulter et al 1994). Expectations and preferences appear to be influenced by diverse factors such as employment status as well as severity of symptoms (Vuorma et al 2005, Coulter et al 1994). Moreover, they may reflect contraceptive preferences, attitudes to hormonal treatments, 'the pill' or 'coil' and the presence of other symptoms such as painful periods. Individual expectations about treatment prior to consultation have obvious

implications in discussing treatment options, use of NICE guidelines and compliance with treatment.

The picture is further coloured by other factors including the relationship between psychological distress and menorrhagia (Gath 1987). Women with psychological distress appear more likely to report heavy periods (Shapley et al. 2003a), and women presenting with menorrhagia appear more likely to have psychological disturbance than those consulting other illness for example respiratory tract infection. The effect of menstrual bleeding on mood suggested as a strong factor influencing women's inability to continue life as normal (Shapley et al. 2003b). Secondly, the presence of other menstrual symptoms such as pain, mood changes and irregular bleeding as influences on the perception of the severity of menorrhagia (Warner et al, 2004; Santer et al 2007). Thirdly, a relationship between life changes and perception and experience of menstrual disorders has been suggested (Gordley 2000). In particular, the wider context for women - often at a time of life transition and other changes in health - who present to services with change in menstrual experience resulting in treatment for 'menorrhagia' has been little explored.

Given the paucity of relevant research, and in particular a need to understand impact of medical treatments on quality of life (Santer 2008), this study seeks to provide further understanding of women's perspectives to contextualize evidence from ECLIPSE and other trials of treatments in this field. Provision of information and discussion to clarify treatment preferences has been associated with lower rates of subsequent surgery, improved patient satisfaction and, possibly, quality of life (Kennedy et al 2002; Protheroe et al 2007). This study may enhance such information and thus communication about, and negotiation of care between health professionals and women.

Methods

Design: Qualitative study with purposeful sample of women accepting or declining different medical treatments recruited from the ongoing ECLIPSE Trial, generating data by series of semi-structured interviews, with grounded approach to data analysis.

Sampling

A purposeful sample of women willing to participate in this study will be selected from women consulting health professionals about heavy menstrual bleeding who have been identified as eligible and approached for inclusion to the ECLIPSE trial, and who have subsequently agreed to be randomized to treatment arms or have declined to participate in the trial because they had a strong treatment preference for a particular medical treatment, which they have then commenced.

Sampling will include women of varying demographic (age, social and educational background, ethnicity) experiencing different medical treatments for menorrhagia, of differing treatment duration, seeking a purposeful range (Mason, 1996) of respondent characteristics and contexts in relation to the study objectives.

Recruitment & consent

Access to participants will be through GP practices and gynaecology clinics participating in the ECLIPSE trial. Practitioners will identify potential participants at the time that interest in participation in the ECLIPSE trial is discussed, and trial participation accepted or declined. Permission will be sought to pass contact details to the study researchers (part of the trial research team) by means of an additional sentence on the ECLIPSE Trial

consent form or the use of consent to contact form for ECLIPSE Trial decliners. The study researchers will send study information and request for written consent, translated where appropriate, to participate in this qualitative interview-based study.

Data generation and analysis

Semi-structured face-to-face interviews will be conducted at respondents' convenience with respondents given the option of being interviewed in English or their mother tongue as appropriate. These will normally be conducted in the respondent's home unless preferred elsewhere by respondents.

Interviews will be undertaken by study researcher(s) with appropriate interviewing skills and professional backgrounds (e.g. nursing) and, where necessary, by sessional research staff with appropriate bilingual skills working with the research team, or with the support of an appropriate interpreter.

Where possible, two interviews will be conducted with each participant. The first interview will be conducted within 1-3 months of commencing medical treatments. A second interview will be conducted between six months and two years, following commencement of treatment. It is anticipated that varying the interval at which participants are interviewed will allow for the possibility of collecting data on the experience of a change of treatment contemporaneously.

The purpose of a second interview is to explore changes in experience, views and decision-making that have occurred during the treatment process over time. Of particular interest will be those patients who have requested or undergone a change of treatment from their initial allocated

treatment plan. This follow up interview may be conducted by phone rather than face-to-face if preferred and convenient for respondents.

Interviews will be audiotaped and transcribed verbatim. They will follow broad topic areas based upon the study objectives, using a topic prompt modified and refined following early interviews, with participants encouraged to discuss their perceptions and experiences freely. Assessment will be made of the participants willingness to be approached again to participate in a second interview. A sample of respondents will be asked to participate in the validation process. In order to enhance recording of interview context and researcher reflexivity the interviewing researcher will also keep contemporaneous field notes.

Data will be analyzed using constant comparison (Strauss & Corbin, 1990) by the study researcher(s), with research colleagues of different disciplinary and professional backgrounds contributing to development of the analysis and conceptual framework to maximize theoretical sensitivity. Analysis will acknowledge the impact where appropriate of use of interpreters during data generation. Coding will be aided by application of NVivo software in identifying emerging categories and concepts from the data. Data generation and analysis will be iterative, each informing the other, with the seeking of deviant cases (Mason, 1996) and further theoretical sampling and data collection to extend and challenge earlier data and interpretation. This will test the integrity and credibility of the analysis, until no new categories or concepts emerge suggesting theoretical saturation. It is estimated up to 40 initial and up to 30 follow-up interviews may be necessary.

Validation

Findings will be fed back and reviewed with a sample of up to a third of interview study participants (i.e. up to 20), who are willing to be approached again. This will be by audiotaped telephone interview following distribution of written summaries, translated where appropriate. Respondents will be asked to consider and comment on the results, enabling the research team to confirm or further refine data interpretation and analysis if appropriate.

References provided in main reference section on page 228.

APPENDIX II Sample Matrix

Table A and Table B were the original sample matrices that proved to be too complex to use in practice. The matrix was simplified as seen in Table C and this was used to aid sampling. The rationale for the original sample matrices is given below. The rationale for the sample matrix used to aid sampling is within the main body of the work in Chapter 3 on page 40.

Initial sample matrices

A purposeful sample of women willing to participate in this study will be selected from women consulting health professionals about heavy menstrual bleeding who have been identified as eligible and approached for inclusion to the ECLIPSE trial, and who have subsequently agreed to be randomized to treatment arms or have declined due to an expressed treatment preference.

Sampling will include women of varying demographic (age, social and educational background, ethnicity) experiencing different medical treatments for menorrhagia, of differing treatment duration, seeking a purposeful range of respondent characteristics and contexts in relation to the study objectives.

From the ECLIPSE Trial population the qualitative study will sample some women who are randomized to each of the treatment arms and those who decline randomization due to a preference for or against a particular treatment.

Purposeful selection criteria

Primary criteria

Age

Ethnicity

Treatment prescribed

Treatment preference

Parity

Secondary criteria

Employment status / education

Treatment duration / change

Life events / transitional stage

Relationship status

From the literature published to date and the pilot interviews conducted, it was suggested that age, ethnicity and parity have a strong influence on women's experience of menorrhagia and expectations for treatment. The experience of treatment will also be strongly influenced by the treatment itself and whether that was the choice of the patient, of both the patient and clinician together or a random choice as in the case of women participating in the randomised controlled trial. As many of the recommended treatment options for menorrhagia have a contraceptive effect then parity is likely to be influential particularly amongst those women who decline randomisation.

Other variables that may be influential include education and employment. However life events such as completing a family, children starting school or leaving home, a change within a significant relationship may be more influential on attitudes and decision making than has been previously thought. For this reason it would be important to conduct second interviews with women who may discuss transitional events during the first interview to consider how the perception of treatment efficacy changes over time. In terms of relationships, it is not just the relationship with a husband or partner but also the relationship with female family members,

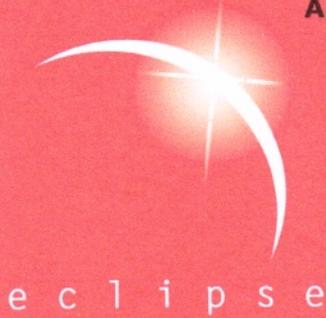
such as mothers, sisters and daughters, who may also have experienced menorrhagia or the treatments offered, such as the LNG-IUS. Their experiences may well have an impact on the views of the sample selected. This kind of information is not available prior to obtaining consent to interview so has not been included in the sample matrix.

		Randomised to Mirena Coil		Randomised to Standard Treatment	
		Nulliparous	Multiparous	Nulliparous	Multiparous
Age <40	Caucasian	1	1-2	1	1-2
	Asian	1	1-2	1	1-2
	Other	1	1-2	1	1-2
Age >40	Caucasian	1	1-2	1	1-2
	Asian	1	1-2	1	1-2
	Other	1	1-2	1	1-2
Employment activity across allocated treatment					
Professional		2-4		2-4	
Vocational		2-4		2-4	
Housewife		2-4		2-4	
Unemployed		2-4		2-4	

TABLE A Sample matrix ECLIPSE participants

		Preference for Mirena		Preference for Standard	
		Coil		Treatment	
		Nulliparous	Multiparous	Nulliparous	Multiparous
Age <40	Caucasian	1	1-2	1	1-2
	Asian	1	1-2	1	1-2
	Other	1	1-2	1	1-2
Age >40	Caucasian	1	1-2	1	1-2
	Asian	1	1-2	1	1-2
	Other	1	1-2	1	1-2
Employment activity across preferred treatment					
Professional		2-4		2-4	
Vocational		2-4		2-4	
Housewife		2-4		2-4	
Unemployed		2-4		2-4	

TABLE B Sample matrix Women with treatment preference



The Eclipse Trial

Effectiveness and Cost-Effectiveness of Levonorgestrel containing Intrauterine system in Primary care against Standard treatment for Menorrhagia

Medical Treatment for Heavy Menstrual Bleeding:
Understanding women's experiences



Division of Primary Care



Division of Obstetrics and Gynaecology

Aim

To explore the experience of medical treatment for heavy menstrual bleeding from the woman's perspective.

Design

Qualitative component of randomized controlled trial. Longitudinal interview study with purposeful sampling of ECLIPSE trial participants and those who decline due to treatment preferences. Women who consent will be interviewed in the initial treatment phase and again following a period of between one and two years of treatment. Interviews will be audio taped. Grounded approach to data analysis.

Setting

General practices and gynaecology clinics mainly in the East and West Midlands.

Participants

Women aged 25 to 50 with menorrhagia who are able to give informed consent to audio taped interview.

Recruitment

Aim to collect data until theoretical saturation is reached.

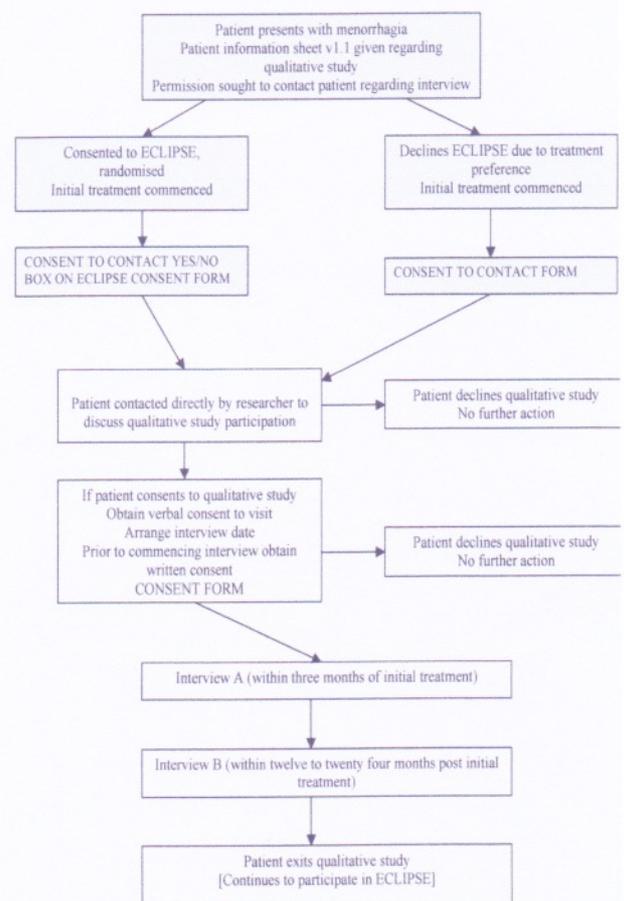
Outcome

The qualitative component should help to improve understanding of this condition and the experience of medical treatments. It aims to contextualize the outcomes from the ECLIPSE Trial. It also aims to promote discussion related to treatment preferences.

NHS R&D partner: Derby City PCT

www.eclipse.bham.ac.uk

Qualitative study schema



Coordinated by Birmingham Clinical Trials Unit

email: eclipse-trial@bham.ac.uk

University of Nottingham

Principal Investigator: Professor Joe Kai
Research Associate: Gail Prileszky

CONTACT gail.prileszky@nottingham.ac.uk 01332 724722 07964 631193
Joe.kai@nottingham.ac.uk 01332 724606

University of Birmingham

Principal Investigator: Professor Janesh Gupta
Trial Management: Laura Gennard
Trial Management: Lisa Leighton

Medical Treatment for heavy menstrual bleeding: Understanding experiences, decision-making and their contexts.

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take the time to read this information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of the study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study

Please contact us if anything is not clear or you need to ask for more information, or if you would like this information in another language. Contact details are given below.

Part 1

Purpose of the study

Heavy menstrual bleeding (sometimes called by the medical term 'menorrhagia') is a very common condition affecting large numbers of women, most of who are treated in the community by their GP at least initially. There are several medical treatment options available including hormonal medications such as the contraceptive pill, non-hormonal medications such as tranexamic acid and mefenamic acid, or treatment

using a hormone releasing coil (a Mirena coil) fitted inside the womb. All of these treatments are known to reduce heavy menstrual bleeding.

The purpose of the study is explore the experience of heavy menstrual bleeding and its treatment from the perspective of women themselves. We hope to better understand this condition and the effects of the differing treatments by collecting detailed information from individuals who are undergoing medical treatment.

1.2 Why have I been invited?

You have been invited to take part because you are currently receiving medical treatment for menorrhagia from your GP or gynaecologist.

1.3 Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet with you. If you decide to participate we will ask you to sign a consent form. You will be given copies of this information sheet and your consent form. You are free to withdraw at any time without giving a reason. Deciding not to participate or withdrawing from the study will not affect your care in any way.

1.4 What will happen to me if I do take part?

A researcher will visit you at home to interview you at a date and time best suited to you. The interview will last about one hour. You will be asked to talk about your experience of menorrhagia and its effect on your life and also the treatment that you have received. We would like to do one further interview with you between six months and up to two years after your initial interview in order to talk to you about any changes in your experiences and views about treatment over time and to assess the impact of your treatment over time.

In order to make sure that we remember the information that we collect from all the different interviews, the interviews will be taped with your consent. Before the interview begins we will check again that you consent to the interview being taped. If it is more convenient for you the second interview may be conducted over the telephone.

Participating in this study will not change your treatment in any way.

1.5 What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks of taking part in this study and participation will not change your treatment in any way. For some people talking about their personal experiences can be upsetting. Please consider this before making your decision.

1.6 What are the possible benefits of taking part?

We cannot promise this study will help you but with the information that we get from this study we hope to improve the treatment of women with menorrhagia. We hope that the information you give us might help us to understand the impact of menorrhagia and its treatment on the lives of women. Some women may find it useful to talk about their experiences.

1.7 What happens when the research study stops?

We can send you a summary of the research findings once the study is completed. Your medical treatment will continue without interruption.

1.8 What if there is a problem?

Any complaint about the way that you have been dealt with during the study will be addressed. More information is given in Part 2.

1.9 Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be kept confidential.

This completes Part 1, if you are interested in taking part in the study please read the additional information in Part 2 before making your decision.

Part 2

2.1 What will happen if I decide not to continue with the study?

You are free to withdraw from the study at any time without giving a reason. Your treatment for menorrhagia will not be affected. If you decide to withdraw from the study we will destroy both your contact details and any taped or paper record of your interview.

2.2 What if there is a problem?

If you have concerns about the study or about how you have been treated by the researcher please contact the research team. If you are still unhappy you can make a formal complaint through the NHS Complaints Procedure. Details can be obtained from your GP surgery or local hospital.

2.3 Will my taking part in the study be kept confidential?

Yes. We will keep information in accordance with the 1998 Data Protection Act. Contact details will be kept in a locked filing cabinet at the University of Nottingham. Interview tapes and printed copies of interview transcripts will not have your name on.

Only members of the research team will see the information given by you and all have a duty of confidentiality to you as a research participant. We will do our best to meet this duty.

2.4 What will happen to the results of the research study?

We will send a summary of the main findings to all of the women who were interviewed. A full report will be sent to Health Technologies Assessment as they are sponsoring this research. We anticipate that the results of this study will be published in the medical and nursing press. You will not be identified in any of the reports or publications.

2.5 Who has organized and funding the study?

The study is being organized by the University of Nottingham, University of Birmingham and Birmingham Clinical Trials Unit. It is being funded by Health Technologies Assessment program, which is part of the National Health Service.

2.6 Who has reviewed the study?

All research in the NHS has been looked at by independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by South West Multi-Centre Research Ethics Committee.

Contact details: Gail Prileszky Research Associate
01332 724722 07964 631193
University of Nottingham
Graduate Medical School, Derby City General
Hospital
DE22 3DT
[**gail.prileszky@nottingham.ac.uk**](mailto:gail.prileszky@nottingham.ac.uk)

APPENDIX V

Consent to contact form

Medical treatment for heavy menstrual bleeding: Understanding women's experiences, decision-making and their contexts.

Researcher: Gail Prileszky

Please tick box

I agree to the above named researcher from the University of Nottingham and the University of Birmingham contacting me to explain more about this study

These are my preferred contact details;

telephone.....

email.....

I will need an interpreter who speaks

.....(name of language)

Name of Patient

Date

Signature

Name of person
taking consent

Date

Signature

When completed 1 copy to patient, 1 copy to researcher site file, 1 original to be kept in medical notes.

APPENDIX VI

Consent Form

Medical treatment for heavy menstrual bleeding: Understanding women's experiences, decision-making and their contexts.

I confirm that I have read and understood the information sheet (version 1.0 dated 01/06/08) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I give permission for the interviews to be tape-recorded.

I give permission for the study researchers to contact me by telephone or email to arrange interviews.

I understand that relevant sections of my medical notes and the data collected may be looked at by responsible individuals from the University of Nottingham, University of Birmingham or from regulatory authorities. I give permission for these individuals to have access to my records.

I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and the reporting of results.

I agree to take part in this study.

Name of Patient

Date

Signature

Name of person
taking consent

Date

Signature

When completed 1 copy to patient, 1 copy to researcher site file, 1 original to be kept in medical notes.

APPENDIX VII Demographic proforma

STUDY NUMBER

Name Telephone number
Mobile number
Address Email
Address
Address
Postcode

Consent to contact: Signed dated Consented by

Consent form: Signed dated Consented by

ECLIPSE: Yes / No Trial no: Treatment: Allocated / Preferred

Date commenced: Hospital / Surgery:

DoB: Age:

Parity:

Duration of menorrhagia: Presentation:

Interview date: A

B

Outcome:

Occupation:

Educational level attained:

O levels / CSEs / GCSEs	<input type="checkbox"/>	NVQ level 1	<input type="checkbox"/>
A levels / AS levels	<input type="checkbox"/>	NVQ level 2	<input type="checkbox"/>
First Degree (BA BSc)	<input type="checkbox"/>	NVQ level 3	<input type="checkbox"/>
Higher Degree	<input type="checkbox"/>	NVQ level 4	<input type="checkbox"/>
Other qualifications	<input type="checkbox"/>	No qualifications	<input type="checkbox"/>

Ethnic group:

White	White British	<input type="checkbox"/>
	White Irish	<input type="checkbox"/>
	White (any other)	<input type="checkbox"/>
Mixed	White and black Caribbean	<input type="checkbox"/>
	White and Black African	<input type="checkbox"/>
	White and Asian	<input type="checkbox"/>
	Any other mixed background	<input type="checkbox"/>
Asian	Indian	<input type="checkbox"/>
	Pakistani	<input type="checkbox"/>
	Bangladeshi	<input type="checkbox"/>
	Any other Asian background	<input type="checkbox"/>
Black	Caribbean	<input type="checkbox"/>
	African	<input type="checkbox"/>
Chinese	Chinese	<input type="checkbox"/>
	Any other	<input type="checkbox"/>

APPENDIX VIII Topic Guide

Introduction

Aim: To introduce the research and set the context for the discussion

- Introduce self and ECLIPSE (qualitative component)
- Talk through purpose of interview, approximate length, consent and voluntary nature of interview, right to withdraw from the study
- Talk through recording, confidentiality and the reporting of findings
- Questions from interviewee

Consent form signed at this point.

Background and personal details

Aim: To record the interviewees details and social circumstances, to start a more open conversation

- Date of birth, age, parity, family circumstances
- Education – highest level attained
- Occupation
- Self-defined ethnicity (2001 census categories)
- Duration of heavy menstrual bleeding, presentation, surgery or clinic involved with treatment
- If ECLIPSE participant, treatment allocation and date commenced
- If declined randomisation, treatment preference, date commenced

All of the above would be recorded in interviewers notes not digitally recorded.

Digital recording commenced at this point.

Menstrual history

Aim: To explore early attitudes to menstruation, to ascertain sources of information and principal support networks at that time, to examine family history, to increase the depth of the conversation

- Looking back could you tell me about your periods through your life?
- What were your first experiences like? Who was there to support you, and how was that?
- What about other women in your family, did they share their experience, knowledge?
- How has your cycle changed over time?

Clinical signs

Aim: To determine the most distressing aspects of heavy menstrual bleeding to the interviewee, to make an assessment of relevance of blood volume lost, to make an assessment of the relevance of pain, to determine impact on daily physical activity

- Could you describe what your periods were like when you sought treatment?
- What led you to seek treatment at this time?
- What aspect of heavy periods troubled you the most? Can you explain why?
- Have you independently tried anything to help? How did that affect the pain / bleeding / tiredness?
- Had you had treatment for heavy periods before? How was that?

Treatment

Aim: To explore attitude towards treatment offered, to ascertain expectations of treatment, to examine the decision-making process with

regard to the treatment commenced, to explore the development of a treatment preference

- What effect did you think this treatment would have?
- Could you describe what having this treatment has been like? How do you feel about it?
- How has this changed your condition? Effect on bleeding, pain, other symptoms.
- What did you know about this treatment before you sought treatment?
- How have the doctors and nurses responded to this problem?
- Could you describe how you made the decision about which treatment option was best for you?

Social factors

Aim: To explore impact of heavy menstrual bleeding on social and work activity, to examine perceptions of society's expectation in relation to heavy menstrual bleeding, to identify differences due to culture, ethnicity or socio-economic group

- How did heavy periods affect your social life?
- Were you able to continue with your normal activities? What was its impact on your working life?
- How do you think your colleagues and friends viewed this problem?
- How do you think people perceive problems with periods in general?
- Have you felt the need to conceal your problems with periods and if so why?

Relationships and family life

Aim: To determine impact of heavy menstrual bleeding on significant relationships, childbearing and sexuality, to ascertain attitudes to contraception and fertility both of interviewee and partner if applicable.

- Some people who have heavy periods say that it affects their relationships / sex life, may I ask what your experience has been. How does your partner feel about this?
- How has it altered your sexual relationship?
- How have heavy periods influenced your contraceptive choices?
- Do you think your choices about having children have been influenced by heavy periods? In what way?
- How does it impact on your family life / children?
- Are your children aware of your condition? How do you explain / handle their questions?

Emotional well-being

Aim: To explore the impact of heavy menstrual bleeding on emotional and psychological health, to discuss the effect of treatment on emotional and psychological wellbeing, to explore if the women is experiencing a transitional stage of life.

- How do heavy periods make you feel?
- Did this affect your confidence / self-image?
- How does heavy periods affect your quality of life?
- Now that you have experienced treatment, how have your feelings changed?
- Has this condition affected your ability to cope with other things in your life? Could you tell me more about that?

Future options

Aim: To briefly discuss expected outcomes, to determine interviewees knowledge of further menstrual changes and treatment options, to close interview on more general conversational level

- What do you hope this treatment will achieve?
- If this treatment does not meet with your expectations what other treatments would you consider?
- What would be your best outcome following treatment? (Normal period / no periods)
- Would advice would you give to other women?
- What advice would you give to health professionals? What should they know in order to understand this condition better?
- Is there anything else you would like to say?

Closure (Recording stopped)

Aim: To return the interviewee to a plane of normal conversation, to address concerns and express thanks and to ascertain if contact to discuss second interview would be permitted.

- Is there anything that you would like to comment on or ask now that the recording has stopped?
- Thank you for sharing your story, you have made a valuable contribution to the study.
- We would like to follow this with a second interview in about twelve to eighteen months time to see how your experience has changed following treatment, would you mind if I contacted you again?

APPENDIX IX Detail of sample demographic characteristics and factual information relating to treatment

General demographic data

Table D on page 283 at the end of this Appendix details the general demographic characteristics for the twenty seven women selected to participate in the interview study.

Age of study participants

The study criteria sought participants between the ages of twenty five and fifty years old, in line with the recruitment criteria of the ECLIPSE randomised controlled trial. This complete range was represented in the current study. As expected for this condition many women who consented to be contacted were in their forties and effort was made to select younger women, particularly as their differing views and experiences emerged from the early data collection and analysis. However this was difficult as many women did not present for treatment for heavy menstrual bleeding at an early age either because they did not develop heavy menstrual bleeding until they were older, or more often because they did not recognise that treatment might be an option for them. This is evidenced by the number of women who had had heavy menstrual bleeding for more than ten years before seeking treatment; duration of heavy menstrual bleeding being a demographic characteristic that was not part of the sample selection matrix. In all six women who were thirty five years old or younger were selected and included in the sample.

The average (mean) age of participants was 40.5 years of age, similar to that in the randomised controlled trial sample (forty one years). Although a number of women initially queried whether they were menopausal,

particularly if they had experienced a recent change in menstrual blood flow, only one interview participant was diagnosed as menopausal during the two years of the data collection phase. She was also the oldest participant being fifty at recruitment (consent to contact) and turning fifty one just before the first interview was conducted. Figure 10 on page 273 shows the distribution curve for age.

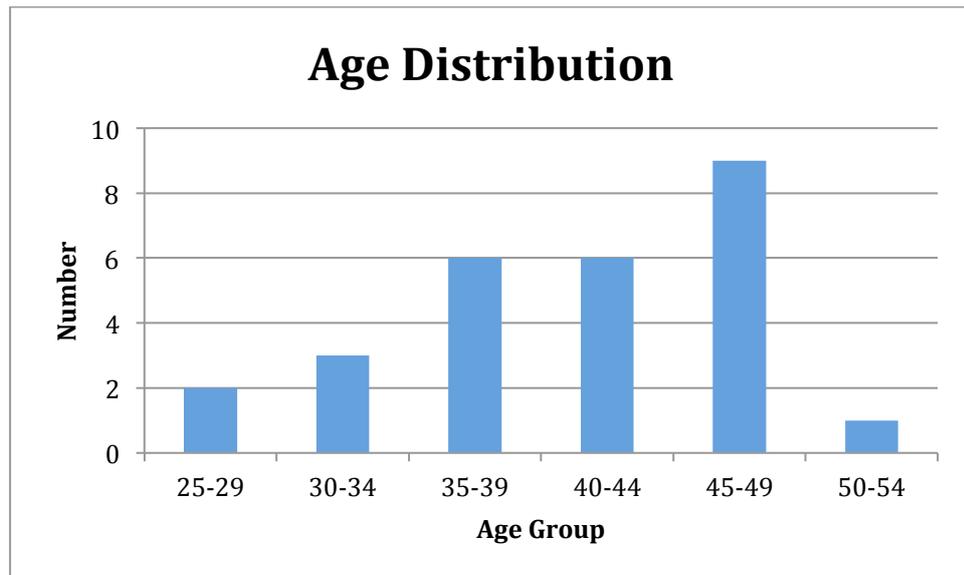


Figure 10 Study participants age distribution curve

Parity

The decision to collect data on parity was influenced by the evidence in the literature of its relevance to treatment preferences. A good range of parity with a bell shaped distribution curve was achieved between one live born child and four live born children, broadly reflecting societal norms (see Figure 11 on page 274). It was recognised from early interviews that the views of nulliparous women were different from multiparous women with regard to being prescribed treatments that had a contraceptive effect. Fertility was an issue for nulliparous and multiparous women and contrasted sharply with established general and medical views on parameters such as childbearing age. For this reason, driven by themes

emerging from early data analysis, nulliparous women were specifically selected. A total of four nulliparous women were recruited of a wide age range between 25 and 47 years of age.

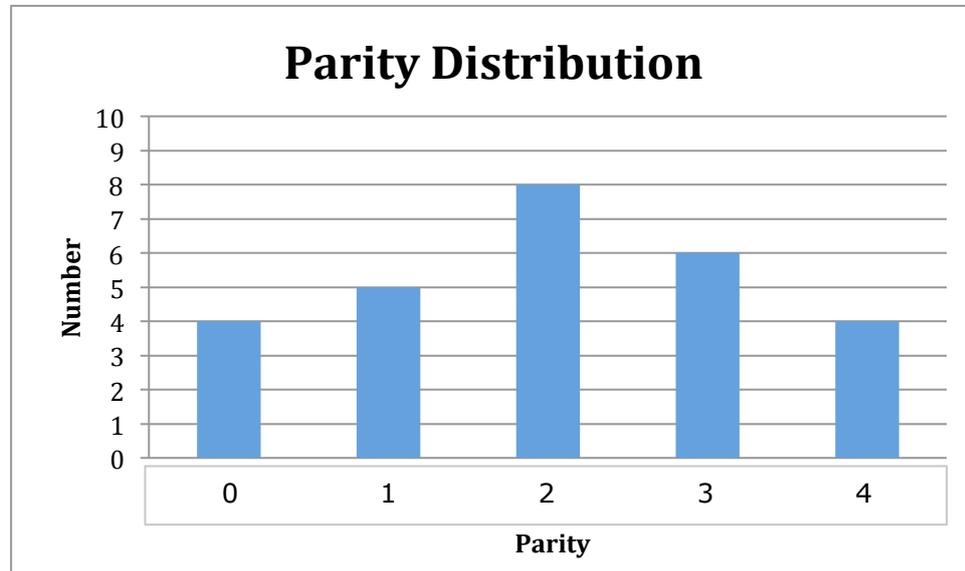


Figure 11 Study sample parity distribution

Occupation

The majority of women who completed the consent to contact form were in some form of paid employment and from early data collection and analysis the type of employment appeared to be influential to the women's experience of heavy menstrual bleeding. For this reason occupation became important in selecting women in the later stages of sampling. Occupations ranged from cleaning staff through healthcare workers and administrators to senior managers, professionals and one self employed entrepreneur.

In addition women were selected who were not working outside the home; both to capture their experiences and as a means of testing the data gathered from employed women. With on going analysis the data from women who were not working outside the home again highlighted two sub

samples within this group, namely those who had not had the opportunity or had chosen not to work, and those who considered themselves to be on a career break to raise children. In both subsamples the majority had children and the most apparent difference between these two sub-samples was the level of education they had achieved. The spread of occupations can be seen in the main sample characteristics results in Table D on page 283.

Level of educational attainment

Previous studies have indicated a correlation between the level of education achieved, employment status and treatment preferences (Vuroma, *et al.* 2005, Coulter, *et al.* 1994) It is also possible that the level of education of the patient may impact on communication with health professionals and, particularly relating to decision making. In this study women defined their own level of education for the proforma used. This was a parameter that warranted further investigation so the study sample was selected to include the widest possible range of educational achievement from leaving school at sixteen with no formal qualifications to those with formal postgraduate qualifications. Table D on page 283 demonstrates the range of level of education achieved.

Some surprising findings emerged when occupation and education were considered together in relation to treatment preferences and these were tested through ongoing data collection and analysis and the development of descriptive themes.

Ethnicity

The sample was recruited from across eight counties of the UK including areas of different ethnic populations. Effort was made to ensure that language was not a barrier to participation and this included offers of

interpreters and of translation of written information into other languages. There were six consent to contact forms received from potential interviewees for whom English was not their first language and two of those women consented to take part in the study. These two women were offered the use of an interpreter but they preferred to conduct the interviews in English as they were fluent and comfortable communicating in English. In addition there were two other women who identified themselves as belonging to a different ethnic background than white British, and they both spoke English as their mother tongue.

For many South Asian cultures heavy menstrual bleeding is not recognised as a problem (Chapple 1998) and this may have been one of the reasons why less Asian women seek treatment. Cultural and religious beliefs also play a part when considering that women should not be seen by men other than their husband and the concern about being examined by a male doctor may also be a barrier. Recruitment was restricted by the sample being selected from women who were eligible for the ECLIPSE Trial and presenting to primary care practitioners seeking treatment. It is probable that a greater range of ethnicity would have been achieved if the sample population had been selected from the wider community of women who had heavy menstrual bleeding but who had not sought treatment for it.

The study included twenty three women who identified themselves as White British, two women who identified themselves as South Asian, one woman who identified herself as black Caribbean and one woman who identified herself as white European. All of these women had had a traditional upbringing typical of their ethnic background in that they conformed to specific religious teachings or cultural norms relating to concealment of menstruation. However they had all adapted to modern British culture as adults and this was reflected in their dress, use of

language and in the behaviours and aspirations they described. There were a number of feelings and attitudes about menstruation that still reflected their traditional beliefs.

Treatment for heavy menstrual bleeding

At the time of the first interview thirteen women were prescribed standard treatments and fourteen women were prescribed LNG-IUS. By the time of the second interview twelve to eighteen months later fourteen women were being treated with LNG-IUS, three women were being treated with standard treatments, one woman had undergone a hysterectomy and six women had opted for no further treatment. Three women were lost to follow up. Table C on page 64 gives a detailed breakdown of the treatment outcomes for the women in this sample.

It is clear from the treatment outcome data that LNG-IUS was more consistently used by the women in this sample, with high numbers of women continuing with LNG-IUS over twelve months and longer. Standard treatment was not as consistently used with the majority discontinuing their prescribed medication within the first few months.

Standard treatment

Thirteen women in this sample were treated with standard treatment and this included the range of treatment recommended by NICE (2007). Of the thirteen, nine were ECLIPSE Trial participants who were randomised and four had a treatment preference against LNG-IUS. The women who were randomised to standard treatment then had a choice of treatment options. Some women working in partnership with their health professional to

choose a treatment option and some were simply prescribed a treatment by their doctor.

Tranexamic acid was the most often prescribed treatment with nine women beginning their treatment journey with this drug, including all four of the women who had a treatment preference against LNG-IUS. Seven women had opted to change this treatment at the time of the second interview (twelve months following commencing treatment), with one woman remaining on tranexamic acid and one woman lost to follow up (treatment outcome unknown). Four women who discontinued tranexamic acid opted for no further treatment. Two women opted for LNG-IUS, one woman proceeded to hysterectomy (following failure to fit LNG-IUS due to uterine prolapse), and one woman returned to tranexamic acid following a period of no treatment, as a short term measure whilst awaiting hysterectomy.

Two women were treated with depo provera (both randomised). They both discontinued this treatment citing progestogenic side effects, such as breast tenderness and weight gain and irregular bleeding as the reason. One woman opted for no further treatment and the other opted for LNG-IUS.

One woman was treated with the oral contraceptive pill and she also discontinued her treatment within the first six months. At twelve months she had returned to the oral contraceptive pill; a decision that was influenced not only by increased heavy menstrual bleeding but also by the beginning of a new relationship and the need for contraception.

Only one woman was prescribed norethisterone and she was very quick to discontinue her treatment after one cycle citing headaches as her reason. She also opted for no further treatment.

LNG-IUS

Fourteen women in this sample were treated with LNG-IUS, of those eight were ECLIPSE Trial participants and were randomised to this treatment and six had a treatment preference for LNG-IUS. After twelve months eleven women were still being treated with LNG-IUS, one had a change of treatment, opting for no further treatment, and two women were lost to follow up so their treatment outcome data was not known.

The treatment outcome for one woman was unknown but she was dissatisfied with the LNG-IUS at the time of the first interview, two months after commencing treatment. Of the eight women who were randomised to LNG-IUS, six of them were satisfied with the treatment after twelve months. One woman opted for a change of treatment at the time of LNG-IUS fitting citing not wanting to have an indwelling device as the reason.

Treatment preference

Ten women in this sample population had a strongly expressed treatment preference at the time of the initial consultation and were selected partly for this reason. The most often requested treatment was LNG-IUS with six women requesting this. The development of treatment preferences for LNG-IUS will be discussed in detail in the following chapter.

The other women who expressed a treatment preference did so, not because they specifically wanted one of the other medical treatments but because they did not want LNG-IUS.

Geographical area and place of treatment

Sample selection was aided by a sample matrix as seen in Chapter Three on page 40. Capturing a wide range of demographic characteristics,

treatment options and also a number of different primary and secondary care settings were facilitated by sampling from a wide geographical area across England. Sampling in this way reduced the potential for the practice of one health professional to influence the experience of a significant number of women in the sample population.

Geographical area

Interviewees were selected from across eight counties in England UK ranging from Derbyshire in the north to Cambridgeshire in the south, although fifteen women came from the West Midlands. This enabled a range of women of different socio-economic backgrounds and ethnicity, consulting differing health professionals. Knowledge of different areas also enabled the researcher to select women from both rural and urban settings.

Primary or secondary care

Women in this sample either had their consultations and treatments administered with their general practitioner (GP) in one of four different primary care settings (nine women), or with a gynaecologist in one of three different outpatient secondary care settings having initially presented to their GPs (eighteen women). Fifteen women were seen in one specific outpatient clinic and it could be argued that this may have impacted on the findings, but were seen by two different health professionals.

Discussion relating to demographic, treatment and geographical findings

The age of the study participants is similar to both the ECLIPSE RCT and the published literature. Most women who present requesting treatment for

heavy menstrual bleeding are in their late thirties or early forties. This sample was purposefully selected, with more young women being sought when differences in qualitative findings began to emerge. It was difficult to recruit young women as they did not tend to present seeking treatment and this is probably why the average of women in this sample is not dramatically reduced by the need to recruit young women.

A broad range of parity was achieved. Again the findings from nulliparous women were different and interesting and so purposeful selection sought to recruit a number of nulliparous women both young and older. Whilst parity did not seem to have an impact on the experience of treatment it definitely impacted on treatment preferences and decision making about continuing or discontinuing treatment. The other area where parity had an impact was around discussion of surgical treatments, with future fertility being a consideration for most women, including nulliparous and parous women.

Previous research identified level of educational achievement as influential in determining treatment preferences. The women who expressed a treatment preference were more likely to be highly educated, which concurs with Cooper *et al* (1997) but this was not always the case. Occupation and job status was also a significantly influential factor in the development of treatment preferences for this sample population. Whilst education and occupation were often linked there were a few women who had high status occupations but did not have a high level of educational achievement, and there were also a few women who had a high level of educational achievement who were not working, usually due to childcare commitments. Occupation and education combined often gave women in this sample a greater sense of control and responsibility for their own health and well being. Those women who were neither educated nor employed had a reduced sense of personal responsibility for their own

health and wellbeing and also tended to express a fatalistic view of health and wellbeing.

Ethnic diversity proved to be difficult to obtain in this sample population, although four (15%) women did not describe their ethnic background as white British, which is broadly similar to the ethnic diversity captured in the ECLIPSE RCT (Gennard, personal communication, 2010). Several strategies were employed to increase participation, including focusing recruitment in areas of high ethnic minority populations and offering translation services for women whose first language was not English. These strategies were partly successful in that four women were recruited but limited all four of these women reflected western cultural norms rather than the traditions of their ethnic background. The findings for this subset is in contrast to the work of Chapple (1999), who achieved insight into South Asian cultural beliefs by interviewing several South Asian women who lived in much more traditional households. It is likely that extending recruitment outside of the ECLIPSE RCT framework would have addressed this issue.

Study number	Age	Parity	ECLIPSE	Duration	Treatment	Preference	Occupation	Education	Ethnicity	Primary Care	Area	Marital status
2	42	3	yes	1 Year	depo provera	none	housewife	A levels	white british	secondary care	west midlands	married
5	47	0	yes	1 year	LNG-IUS	none	bus driver	CSE	white british	secondary care	west midlands	married
7	43	4	yes	1 year	tranexamic acid	none	shop assistant	none	white british	secondary care	nottinghamshire	married
9	34	3	no	1 year	tranexamic acid	against LNG-IUS	advertising director	first degree	white british	primary care	lincolnshire	married
10	39	2	no	1.5 years	LNG-IUS	for LNG-IUS	office manager	NVQ level 3	white british	secondary care	west midlands	single
11	45	3	no	20 years	LNG-IUS	for LNG-IUS	teacher	first degree	white british	secondary care	derbyshire	married
12	42	3	no	1 year	LNG-IUS	for LNG-IUS	care assistant	O levels	white british	secondary care	west midlands	married
15	32	2	no	10 years	LNG-IUS	for LNG-IUS	cleaner	none	white british	primary care	derbyshire	married
16	46	1	yes	2 years	LNG-IUS	none	probation officer	first degree	white british	secondary care	west midlands	single
18	34	1	yes	1 year	tranexamic acid	none	student	GCSE	white british	secondary care	west midlands	single
19	48	1	no	10 years	tranexamic acid	against LNG-IUS	university tutor	first degree	white british	secondary care	west midlands	partner
22	39	0	no	20 years	tranexamic acid	against LNG-IUS	administrator	diploma	asian indian	secondary care	west midlands	married
25	39	2	yes	1 year	depo provera	none	housewife	NVQ level 1	white british	secondary care	west midlands	married
30	35	2	yes	15 years	tranexamic acid	none	housewife	GCE NVQ level 1	white british	primary care	derbyshire	married
23	25	0	no	10 years	LNG-IUS	for LNG-IUS	police officer	diploma	white british	secondary care	west midlands	single
31	46	4	yes	1 Year	northisterone	none	cleaner	none	white british	secondary care	west midlands	married
27	37	4	no	20 years	tranexamic acid	against LNG-IUS	service co-ordinator	NVQ level 4	white mixed	secondary care	derbyshire	married
28	42	2	yes	2 years	LNG-IUS	none	property manager	postgrad diploma	asian indian	primary care	northamptonshire	married
29	45	2	yes	20 years	LNG-IUS	none	administrator	O levels	white british	primary care	northamptonshire	married
26	45	2	yes	1.5 years	LNG-IUS	none	support co-ordinator	none	white british	secondary care	west midlands	married
8	35	4	yes	20 years	tranexamic acid	none	housewife	none	white british	primary care	northamptonshire	married
37	47	2	yes	20 years	LNG-IUS	none	teaching assistant	NVQ level 3	white british	secondary care	west midlands	married
43	44	1	yes	5 years	microgynon 30	none	sales person	O levels	white british	primary care	derbyshire	single
39	45	0	yes	1 Year	LNG-IUS	none	administrator	NVQ level 3	black caribbean	secondary care	west midlands	married
42	40	3	yes	5 years	LNG-IUS	none	senior clerk	none	white british	secondary care	west midlands	married
51	29	1	no	18 years	LNG-IUS	for LNG-IUS	waitress	GCSE	white british	primary care	derbyshire	partner
32	51	3	yes	8 years	tranexamic acid	none	scheduler	O levels	white british	primary care	cambridgeshire	married

Groups

- Preference for / against LNG-IUS
- Nulliparous
- >10 Year duration
- Professional / career orientated
- Primary Care
- <= 35yrs old
- Initial Treatment - Standard Treatment
- Initial Treatment - LNG-IUS

Table D

Annotated demographic characteristics

APPENDIX X Coding examples

Open codes

This is an example of open coding for the first interview conducted with participant 28. The initial open coding was done directly from the original verbatim transcript as soon as possible after each interview (usually within five days), using field notes and memory of body language to aid coding. Nvivo software was used to help organise the amount of coded data.

"With the tablets I feel, I feel that it is something I can stop. And its instant I will stop it if it doesn't agree so that I think is probably a benefit. But as you know I don't take tablets but then you know I used to take the pill you know I took that so I think well, well possibly consider taking the tablets but I would need to know more about that side of it and it would be useful to, I think with this project was that I never got to speak to somebody who has had one, I didn't know anyone so I couldn't speak to them and it wasn't, you know I didn't have a friend who had had it.

- Gail Prileszky 20/6/12 11:50 AM
Comment [1]: Control over medication
- Gail Prileszky 20/6/12 11:50 AM
Comment [2]: Natural approach
- Gail Prileszky 20/6/12 11:52 AM
Comment [3]: Previous treatment experience
- Gail Prileszky 20/6/12 11:52 AM
Comment [4]: Needing more knowledge

Most of the women that I see maybe at school or friends or my sisters they don't have it and sometimes it's a personal thing so you can't really ask everyone you know but the people that are relatively close that I can speak to friends they didn't have it so I had no knowledge of it, first hand knowledge of it from somebody. I couldn't see that person and think you know they look fine it's perfect if you could see that then that might make a huge difference I don't know.

- Gail Prileszky 20/6/12 11:51 AM
Comment [5]: First hand account valued
- Gail Prileszky 20/6/12 11:53 AM
Comment [6]: Seeking first hand knowledge from peers
- Gail Prileszky 20/6/12 11:53 AM
Comment [7]: Taboo subject
- Gail Prileszky 20/6/12 11:54 AM
Comment [8]: Seeking first hand knowledge
- Gail Prileszky 20/6/12 11:54 AM
Comment [9]: Not able to ask about taboo subject

My sister-in-law did say that she knew of some women but what put me off there was that I said to her oh would you have it then and she goes "I don't know" so kind of but she said they seem to be fine with it. It wasn't like I could ask her have they had any problems with their weight or you know did they have any pains or anything like that or their periods. I couldn't ask her because obviously she hadn't asked the women but she just knew that they one of them had had that fitted so.

- Gail Prileszky 20/6/12 11:57 AM
Comment [10]: Second hand knowledge valued from trusted family source
- Gail Prileszky 20/6/12 11:55 AM
Comment [11]: Taboo subject

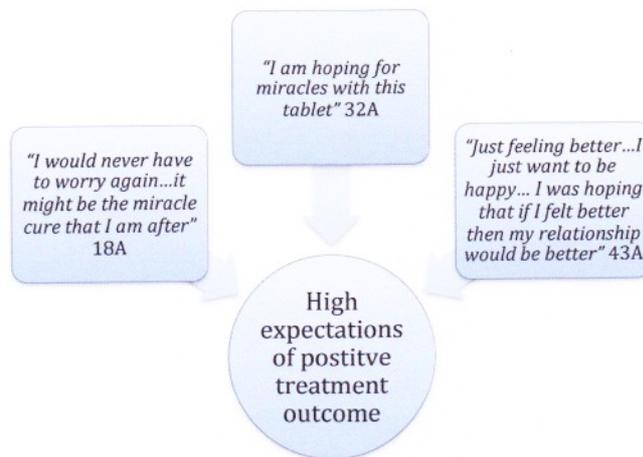
With, with the tablet again it would be nice to maybe see or speak to somebody just to show that you know this person is on that treatment and they are quite happy. I think that would give you a lot of confidence I am not saying that everybody is the same because everybody reacts to things differently. You can't take it for granted just because that person is fine it's going to be fine for you but you know if you could see that it might be a lot easier to accept and follow and do.

Gail Prileszky 20/6/12 11:55 AM
Comment [12]: Seeking first hand account of treatment

Gail Prileszky 20/6/12 11:56 AM
Comment [13]: High value attached to first hand knowledge from peers

Axial coded data

The following is an example of axial coded data relating to women's experiences and feeling relating to high expectations of a positive treatment outcome.

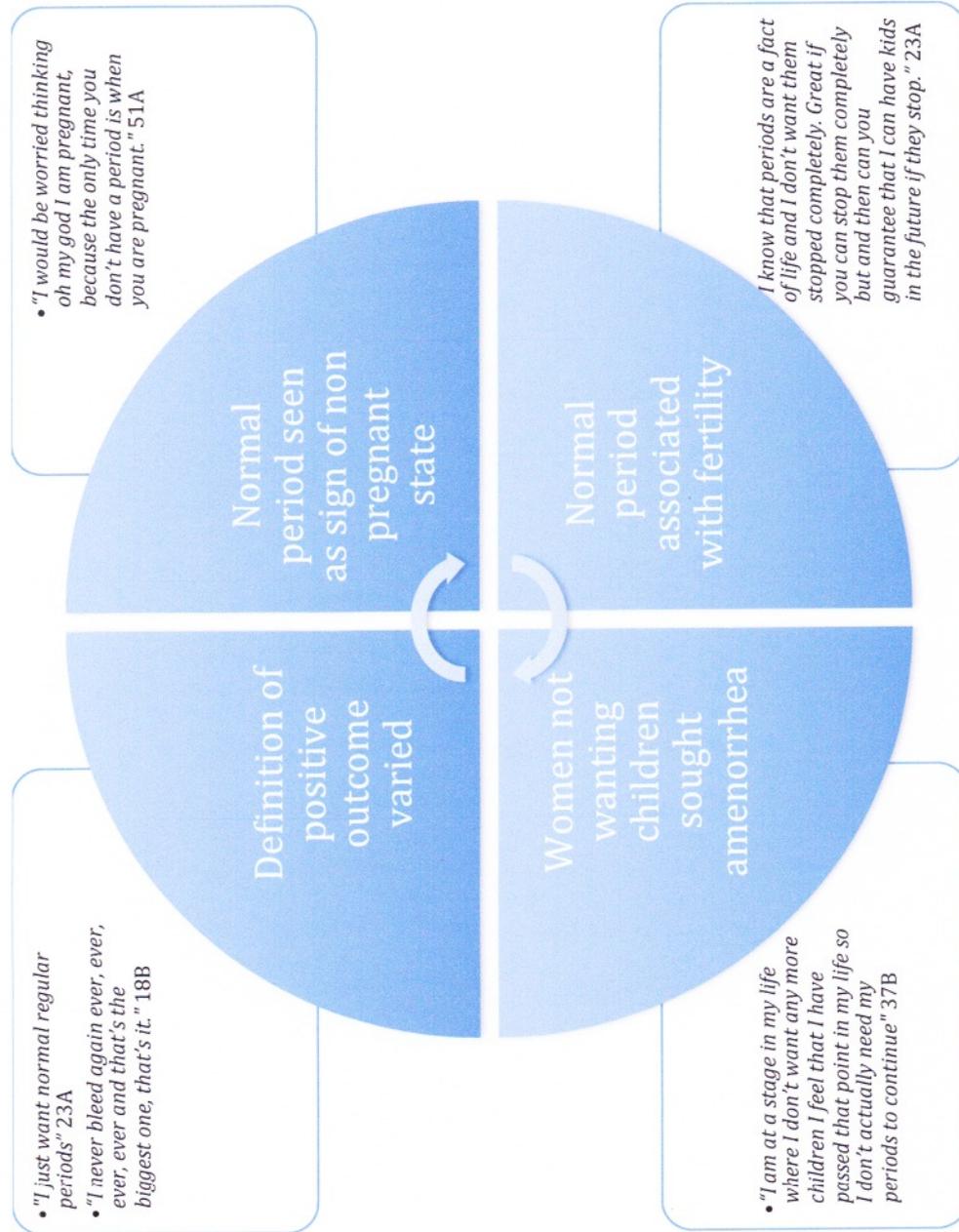


Selective coded data

Through further analysis of axial codes and their relationship to each other, selective codes emerged. It was possible to group the selective codes with four core categories aligned with the objectives of the study. The addition of information from the published literature and interview field notes enhanced interpretation and understanding. This then formed the basis of descriptive themes with further analysis through constant comparison leading to the final descriptive themes discussed in the finding chapters.

SELECTIVE CODING

Normal period or amenorrhea?





30 June 2010

Dear

Medical Treatments for Heavy Menstrual Bleeding: Understanding women's experiences

I am writing to you to thank you for your participation in the interview study and to share some of the findings from the stories that the interviewees have told. In addition I would like to ask for your feedback so that I can verify or alter my interpretation of the data before the final reports are written.

The first part of the study results outline the results arising from directly from the interviews themselves considered collectively. They may not specifically reflect your personal experience but reflect the general feelings and experiences of the group. Please feel free to comment, either from a general or more personal perspective.

The second part of the study results is derived from my interpretation of the interview data and is a diagram (ELMA) representing the experiences described. Each segment of the diagram represents an aspect of women's experiences. Within each segment is a representation of the range of experiences described in the interviews. I would be grateful if you could comment on the diagram and also what you think it might be useful for in practical terms.

I would like to telephone you to find out your views as discussed at your last interview and will be contacting you in the evenings (between 6pm – 8pm) during the week commencing Monday 12th July 2010. If you would prefer to write your comments please leave a message on 07964 631193 before that date, then fill in the enclosed form and post it back to me.

Thank you again for your help. I look forward to hearing from you.

Yours sincerely,

Gail Prileszky

Interview Study Findings Part 1

A total of fifty-two consent to contact forms were received. From those twenty-seven women were selected for inclusion in the interview study. These women were selected to include a wide range of demographic characteristics and treatment options and experiences.

Twenty-seven initial interviews were conducted within three months of commencing treatment for heavy menstrual bleeding. Twenty-four second interviews were conducted more than twelve months after commencing treatment, giving a total of fifty-one recorded interviews ranging in length from 27 minutes to 1 hour and 25 minutes. Data was coded and analysed using a grounded theory approach.

Findings

There were five core categories that emerged from the data, namely:

- Attitudes towards heavy menstrual bleeding

Most of the women in this study had negative attitudes towards heavy menstrual bleeding and these views were related to the negative impact of the condition on their lives. Interestingly many had negative views on menstruation that seemed to be present from menarche. First experiences of menstruation were described in detail by a number of women, including evidence of distress and the use of emotive language. Most of these women also described a lack of knowledge about menstruation either before or around the time of menarche and feelings of isolation due to the perceived reluctance of their mothers to discuss what was happening to them.

Associated with the inference that talking about menstruation is still taboo, many women had difficulty recognising that their heavy menstrual bleeding was abnormal, particularly if other female relatives were also affected by the condition. There was also not only a lack of knowledge about treatment for heavy menstrual bleeding but a strong sense that women should 'put up' with heavy menstrual bleeding and not complain about it.

- Treatment expectations and experiences

Many women interviewed had unrealistically high expectations of a positive outcome from their treatment, particularly those who had a treatment preference or who were initially treated with LNG-IUS (Mirena coil). The majority of women who were treated with Mirena found the coil fitting to be more distressing than anticipated and a number felt unprepared psychologically for the procedure. This was the case for women who were treated in hospital and at their GPs and for women who had previously had children as well as those who hadn't.

Generally the Mirena coil was found to be problematic within the first three months of treatment with irregular bleeding being the most common side effect. However at twelve months most women were satisfied with this treatment and had experienced a significant improvement in their condition.

Most women with a Mirena coil were happy to continue with this treatment long term.

Generally women who were treated with standard medical treatment (tranexamic acid, depo provera, oral contraceptive pill) were less satisfied with their treatment and most had stopped taking the prescribed medication at twelve months. The majority who were treated with tranexamic acid were compliant with the prescription but did not see significant improvements and so stopped taking their medication with two to three months. This was related to the size and amount of tablets prescribed daily. Many of these women did not discuss changing treatment with their doctor and elected not to try any other treatment, preferring to manage their condition themselves by changing coping behaviours and strategies. This was particularly true of the women who had a long history of heavy menstrual bleeding and those who anticipated the onset of menopause within the next few years.

- Treatment preferences

Information about treatment options was primarily gathered from first hand accounts from family and peers and this source of information seemed to be valued above all other sources for the majority of women in this sample, even if it was unclear or out of date. Many women who were aware of a family history of treatment for heavy menstrual bleeding (particularly maternal history) assumed that they would have the same experience of treatment. None of the women changed their expressed treatment preference after talking to their health professional and some found communicating their choice to health professionals difficult.

The most requested treatment was the Mirena coil. The women often cited stories of positive outcomes with Mirena from their peers or families. However women felt that if treatment was unsuccessful, the subject of heavy menstrual bleeding would remain taboo, so the negative experiences of treatment were not being told. Women who expressed a preference for standard treatment did so because they specifically did not want Mirena, due to its effect on fertility and also the invasive nature of the coil.

- Quality of life

Most women felt that heavy menstrual bleeding had a significant impact on all areas of life. In clinical terms many women found pain and other clinical signs such as tiredness and the presence of blood clots to be more distressing than the volume of blood. Anaemia was also important. The women were unclear about whether heavy menstrual bleeding was an illness as they were very unwell in some cases but felt pressure to continue as normal as their physical symptoms were related to menstruation.

Quality of life for the women in this study was most often related to their ability to function effectively in their daily roles; to be able to cope well with their responsibilities at home, at work and within their relationship with their partner, during menstruation. The negative impact on roles and responsibilities was influential in the decision to seek treatment.

When considering the experience of treatment women who had a positive experience of treatment with Mirena described overall improvement in their quality of life and these women were the majority. Conversely women who were treated with standard treatment did not have such improvement in their quality of life and this was influential in their decisions to discontinue treatment.

- Cultural factors

One of the most often described aspects affecting women was the need to conceal menstruation and the difficulties that heavy menstrual bleeding caused with this. Most women described complex behaviours and coping mechanisms to enable them to conceal their condition, not only from work colleagues and friends but also from family members. They clearly described feelings of embarrassment, guilt and failure if their condition became evident.

The majority of women who had experienced a change in menstruation associated the onset of heavy menstrual bleeding with the normal aging process and not with pathology such as cancer. Some women believed that heavy menstrual bleeding might signify approaching menopause and this belief added to the perception that there was no point in seeking treatment. Women expressed strong feelings of revulsion in relation to their periods stating that they felt 'unclean' during menstruation and this view was prevalent throughout regardless of ethnicity and age.

Communication with health professionals, work colleagues and family and friends was influenced by gender, with most women feeling uncomfortable discussing heavy menstrual bleeding with men. When communicating with health professionals the perceived level of expertise and understanding of the health professional was also influential.

Fertility was an important issue for many women regardless of their age or the number of children that they had and most wanted to preserve the uterus. This view was also related to being female and the individuals' sense of identity as a woman. However there were a number of younger women who felt that surgery (hysterectomy) would be their best option and this was related to their perception of the costs of surgery versus the length of time until menopause. There was also less fear of surgical complications amongst younger women perhaps associated with less knowledge.



Medical Treatment for Heavy Menstrual Bleeding: Understanding womens experiences

Interviewee Feedback Form

Please comment on the findings report you have read, continue overleaf if necessary. Then post in return envelope.

Part 1 Attitudes towards heavy menstrual bleeding

Treatment expectations and experiences

Treatment preferences

Quality of life

Cultural factors

Part 2 ELMA Experiences of Life with Menorrhagia - Assessment

Qualitative study schema

