Impact of the Clinical Process on Outcomes of Menstrual Disorders

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by

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Abbreviations

BP	Bridges Project
BSO	Bilateral Salpingo-oophorectomy
COCP	Combined Oral Contraceptive Pill
D&C	Dilatation and Curettage
DCE	Direct Choice Experiment
DUB	Dysfunctional Uterine Bleeding
ET	Endometrial Thickness
FBC	Full Blood Count
GnRHa	Gonadotrophin Releasing Hormone Agonist
GP	General Practitioner
GPwSI	General Practitioner with a Special Interest
H&C	Hysteroscopy and Curettage
HLP	Hysteroscopic Laser Polypectomy
ICR	Integrated Care Record
IUCD	Intra-uterine Contraceptive Device
IUS	Intra-uterine System
LAE	Laser Ablation of Endometrium
LAVH	Laparoscopically Assisted Vaginal Hysterectomy
LH	Luteinising Hormone
LNG-IUS	Levonorgestrel-releasing Intrauterine System
LPD	Luteal Phase Defect
LRI	Leicester Royal Infirmary
MEA	Microwave Endometrial Ablation
MBL	Menstrual Blood Loss
MHz	Mega Hertz
NSAID	Non-Steroidal Anti-Inflammatory Drug
OPD	Outpatients Department
OSC	One-Stop Clinic
OSMC	One-Stop Menstrual Clinic
PBAC	Pictorial Blood Loss Assessment Chart
PCD	Patient Career Diary
PCOS	Polycystic Ovarian Syndrome
PCT	Primary Care Trust
PMS	Pre-Menstrual Syndrome
QALY	Quality Adjusted Life Year
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Controlled Trial
SCC	Squamous Cell Carcinoma
SF-36	Short Form 36
SL-PCT	South Leicestershire Primary Care Trust
TAH	Total Abdominal Hysterectomy
TCRE	Trans-cervical Resection of Endometrium
TVS	Trans-vaginal Ultrasound Scan
UK	United Kingdom
USA	United States of America
USS	Ultrasound Scan
VH	Vaginal Hysterectomy
WTP	Willingness to pay

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Statement

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Abstract

Impact of the Clinical Process on Outcomes of Menstrual Disorders

Introduction: Menstrual disorders have a significant impact on the health and well being of women. There are wide, unexplained variations in treatment and investigation in primary care. Rates of referral to secondary care, where surgery is a more likely outcome, also vary.

Aim: To examine the outcomes of a new model of care for women with menstrual disorders, known as the Bridges Project, involving implementation of an evidence based, GP led pathway of care integrated across primary and secondary sectors.

Study Design: A prospective non-random comparison of two services: women attending the Bridges pathway and those attending a consultant-led one-stop menstrual clinic (OSMC). Outcomes were assessed after eight months and included treatment modalities, health status (SF-36 and menstrual questionnaire), an investigation of patient experience of care using the Patient Career Diary (PCD) and qualitative interviews, resource use and cost, adherence to guidelines and patient preferences for care.

Setting: A large teaching hospital and one Primary Care Trust (PCT).

Results: Between March 2002 to June 2004, 99 women in the Bridges pathway were compared to 94 women attending the OSMC. There were no statistically significant differences in mode of treatment or health status between them at eight months. Interviews demonstrated that women experience significant problems when accessing care for menstrual disorders and perceive their problems to be of low priority within the health service. The PCD demonstrated statistically significant differences for the Bridges group in several aspects of care: information and ease of access ($P<0.001$), choice of doctor ($P = 0.020$), waiting time ($P<0.001$), and sense of co-ordination between sectors ($P< 0.001$). There were significantly fewer outpatient appointments in the Bridges scheme ($P<0.001$) with no increase in primary care workload. The cost per patient for the Bridges project was £751.72 compared to £1022.54 in the OSMC group.

Conclusion: Although there were no differences between groups in the types of treatment (conservative, medical or surgical) women received, the new model of care resulted in significant improvements in patients' experiences of care whilst maintaining clinical quality at reduced cost through more efficient resource use.

Chapter 1: Introduction

1.1 Normal Menstruation

Menstruation has a significant impact on the lifestyle, health and well being of women[1-3]. The reproductive choices of women today compared to fifty years ago involve fewer pregnancies and a reduction in time spent breastfeeding[4]. Women now subsequently experience many more menstrual cycles. The average woman will go through 400 menstrual cycles in her reproductive life, a ten fold increase on 50 years ago[5]. This may in part account for the increasing numbers of women presenting with menstrual disorders[6].

In order to define abnormal menstrual bleeding, it is helpful to first consider what is regarded as normal menstruation. Menstruation has been defined as the "shedding of the superficial layers of the endometrium following the withdrawal of ovarian steroids. The process is associated with a variable degree of blood loss and usually lasts for up to six days"[7]. Two population studies have showed that menstrual blood loss has a skewed distribution with an approximate mean of 30ml and a 90th centile of 80ml (Table 1.1)[8,9]. The normal menstrual cycle is usually described as having a modal length of 28 days, although cycle length may vary from 21-35 days and still be regarded as normal. By convention day 1 is the onset of bleeding. The pre-ovulatory (proliferative) phase lasts for 9-23 days and the post-ovulatory (secretory) phase between 8-17 days[10].

The increase in ovarian progesterone secretion after ovulation and its subsequent fall on regression of the corpus luteum appear to be the main factors controlling menstruation[10]. When circulating levels of progesterone decline, vascular and stromal changes take place in the endometrium which result in tissue shedding followed by regeneration[11-13]. Just prior to menstruation the endometrial arterioles become increasing coiled and constricted and the endometrium regresses. Distal ischaemia is followed by vasodilatation 4-24 hours later. Menstruation itself involves tissue breakdown loss and bleeding from dilated arterioles during which fibrinolysis and clotting are carefully controlled[14]. This is followed by rapid angiogenesis and epithelial regeneration without scar tissue formation. Overall the outer, functional layer of the endometrium is lost leaving a thin basal layer renewed in response to oestrogen[10].

The control of menstrual bleeding appears to involve several systems. Much evidence has accumulated for the role of prostaglandins. Prostaglandin concentrations are low in the proliferative phase and increase during the secretory phase15. After shedding of the functional endometrium, prostaglandin E2 and F2α are thought to control the degree of bleeding from the spiral arteriole fragments by vasodilatation and vasoconstriction respectively. Local production of prostacylin is thought to contribute to impaired platelet plug formation seen during menstruation10. The vasoactive peptides, endothelins, have also been implicated in the control of vasodilatation and vasoconstriction during menstruation. Platelet activating factor is thought to be involved in the paracrine control of prostaglandin E2, and may also make a direct contribution to menstrual haemostasis through its action as a vasoconstrictor and by stimulating platelet aggregation16.

1.2 Abnormal Menstruation

The most commonly encountered presentation in clinical practice is that of regular, heavy periods, menorrhagia. It is estimated that the prevalence of heavy menstrual bleeding in the community may be up to 52%[17]. A survey of women aged 18 to 54 attending the GP with an unrelated problem found that 56% of them reported heavy periods and 27% felt that this interfered with their daily lives. The corresponding figures for women in the community who were not attending the GP surgery was 51% and 23% respectively[18]. Every year in the UK five percent of women between the ages of 30 and 49 consult their General Practitioner for this reason[19]. Other bleeding patterns defined as abnormal are irregular bleeding, including inter-menstrual bleeding, usually referred to as metrorrhagia, and polymenorrhoea referring to either a shortened inter-menstrual interval or prolonged menstrual bleeding[4]. Any of these disorders can be associated with pain (dysmenorrhoea) or the premenstrual syndrome (PMS). Various definitions of PMS exist, but all refer to "the cyclical recurrence in the luteal phase of the menstrual cycle of any combination of distressing physical, psychological and or behavioural changes of sufficient severity to result in deterioration of interpersonal relationships and or interference with normal activities"[20]. These are not the focus of the study described here and so will not be discussed in detail further. Similarly irrelevant for our purposes are the disorders of menstruation more usually encountered in the context of infertility, the absence of menstruation (amenorrhoea) and infrequent menstruation (oligomenorrhoea). Unfortunately, these apparently clear cut definitions and categorisations of menstruation belie a great deal of clinical uncertainty and lack of good quality, up to date evidence about what actually constitutes abnormal menstrual bleeding[20].

Various attempts have been made to objectively define and quantify abnormal menstruation in order to assist clinically in diagnosis and assessment of treatment both in everyday practice and in research contexts. Several methods are available for the objective measurement of menstrual blood loss (MBL), including weight measurements[21], radio-isotopic methods[22,23] and the alkaline haematin method. The alkaline haematin method, first described by Hallberg and Nilssen[24] has become the "gold standard" for the measurement of menstrual blood loss[24,25], having been validated in several studies[26-28]. The patient is required to collect the sanitary protection used

during the course of a menstrual period, which is then soaked in 5% sodium hydroxide. The haemoglobin within is thus converted to alkaline haematin. The total blood loss can be calculated by comparing the optical density measured spectrophotometrically at 540nm of an aliquot of the alkaline haematin solution with the optical density of a known volume of venous blood processed in the same way. This method is sensitive down to 0.1ml of blood and recovers at least 98% of the blood lost[27].

The alkaline haematin method was used to generate what has come to be viewed as the "gold standard" definition of menorrhagia, a blood loss of 80ml or more per cycle, derived from a community-based study of 476 randomly selected women undertaken in by Hallberg et al in Sweden during the 1960s[8]. A significantly greater prevalence of haematological indices indicative of iron deficiency anaemia was found with losses of 60ml or greater and it was calculated that losses of 63ml or greater endangered iron status. After excluding women for whom iron status was abnormal, or who considered they had abnormal menstruation or were unhealthy, 183 "healthy" women remained. The 95th centile of blood loss in this group was 76ml. It was therefore concluded that that the upper limit of normal menstrual blood loss lay between 60 – 80ml per cycle, and the upper limit was adopted as the clinical threshold for menorrhagia.

The results of the Swedish study correlate well with the only other randomly selected population based study of menstrual blood loss, conducted in England in 1971, where 9.5% of the sample were found to have a loss greater than 80ml per cycle (Table 1.1)[9]. Other studies in selected populations around the world, often women attending family planning clinics in developing countries, have demonstrated comparable mean losses of is 24 – 45ml per cycle[29-32] although these estimations may not be directly comparable to European populations due to dietary and other cultural differences.

This definition of menorrhagia has attracted numerous criticisms. Objectively measured MBL does not correlate well with women's subjective assessment of their menstrual loss. In Hallberg's original study all women were asked to describe their blood loss in one of three categories; light, moderate or heavy. Eleven percent considered their periods light, 58% medium and 31% heavy. Twenty-six percent of women with menstrual loss in the normal range (less than 60ml) considered their periods heavy and 40% with objective loss greater than 80ml considered their periods moderate or light. [8]

Since then, studies involving the measurement of MBL in women referred to hospital with menorrhagia have repeatedly demonstrated that fewer than half meet the criteria of loss greater than 80ml per cycle[33-36]. Several explanations for this lack of correlation have been posited. In addition to haemoglobin, menstrual loss also contains fluid. Fraser et al studied total fluid loss in 28 women and found that whilst the mean blood loss was 30.6 ± 6.1ml the total fluid loss was 74.4 ± 10.3ml. It is suggested that the majority of menstrual loss may be derived from endometrial fluid rather then blood, and this might explain the discrepancies between women's subjective assessments of blood loss and objective measures[37]. In addition it has been suggested that different absorbencies of various types of sanitary material and tolerances thereof contribute to inconsistencies in women's reporting of menstrual loss, confounded by the fact that women do not have a standard against which to measure their own experience as normal or abnormal[38]. More recent evidence, mostly from qualitative research suggests that the complaint of menorrhagia hinges on a broader adverse impact of menstruation rather than simply the perception of the volume of blood lost per period, which represents only one concern amongst others including pain, tiredness, mood changes, change in quality of menstruation, interruption to daily life and concern about serious causes of bleeding[3,39-41].

Objective measures of menstrual loss have been further criticised on two counts. Firstly that they require women to collect their soiled sanitary items, which may be unacceptable to some, and secondly that the measurement of blood and fluid loss requires specialist laboratory equipment and staff, and should be undertaken over two cycles (because of cycle to cycle variation)[42] making them impractical for use in routine clinical practice, especially in primary care[25]. Other methods for the objective measurement of menstrual blood loss more applicable to use in day-to-day clinical practice have therefore been investigated including assessments of bleeding duration, use of sanitary protection and haematological indices.

There is conflicting evidence of correlation between the total number of sanitary products used per period and the total blood loss. Chimbria et al found no correlation between MBL, the number of days of bleeding and the total number of sanitary products used[43]. In contrast Warner et al found the features most strongly associated with MBL

were the required rate of change of protection during full flow, the total number of products used and the need to change protection during the night[44].

An attempt has been made to more accurately assess the amount of sanitary protection used through the development of a pictorial blood loss assessment chart (PBAC). This yields a semi-quantitative measure of MBL. The degree to which the items of sanitary protection are soiled during the course of a period are charted by the patient and score is generated from the degree of soiling combined with the number of clots and total number of items used. A score of 100 or more was found to have a sensitivity of 86% and specificity of 89% for a MBL of 80ml or more as measured by the alkaline haematin method[45]. Further work has been undertaken to validate these findings. Reid et al found that PBAC scores did not correlate with objectively measured MBL[46]. Janssen et al found similar correlations to the original study only when a cut of PBAC score of 185 or above was used[47].

Anaemia (defined as haemoglobin concentration of less than 12g/dL) has been shown to have a sensitivity of 43% and a specificity of 94% for objective menorrhagia[47]. So whilst a low haemoglobin makes objective menorrhagia more likely, a normal haemoglobin does not exclude menorrhagia. The serum haemoglobin is therefore not a perfect screening tool for a menorrhagia defined as a MBL of >80ml.

In summary the "gold standard" definition of menorrhagia as 80ml or more per cycle appears to represent a statistical definition of increased menstrual loss rather more than one of clinical relevance in terms of morbidity or disability as a consequence of menstruation, given that iron deficiency is not an inevitable consequence of increased blood loss and is easily treatable with dietary modification or iron supplementation[25,48]. Despite investigation no other alternative quantitative or semi-quantitative definition exists. It has been suggested that the definition of menorrhagia "should reflect the underlying complaint and be prognostic of disease, for compromised iron status or for adverse impact of quality of life, or it should lead to more appropriate and effective treatment"[39] In view of these difficulties it is therefore unsurprising that the simple definition of menorrhagia as "a complaint of heavy cyclical menstrual bleeding over several consecutive cycles" offered by the Royal College of Obstetricians and

Gynaecologists (RCOG) in its guideline for the treatment of menorrhagia[25,49] has been widely adopted[4,20,48].

1.2.1 Causes of Abnormal Menstruation

Despite the fact that menstrual disorders are common, in many cases the cause is never ascertained. Various pathologies have been implicated in abnormal menstrual bleeding however there are few studies directly correlating pathophysiology with objectively confirmed blood loss[48,50]. The causes of abnormal bleeding can be categorised as due to systemic disease, pelvic pathology or iatrogenic causes (Table 1.2). No cause is identified in 50% of cases of objective menorrhagia at hysterectomy[51]. This "unexplained" menorrhagia is usually labelled "dysfunctional uterine bleeding" (DUB) and implies endocrine or paracrine disturbance.

Anovulatory cycles are thought to be the underlying factor in 10% of women complaining of heavy periods and DUB[52]. Steroid hormones regulate many of the factors thought to be involved in menstruation, so it seems plausible that anovulation may cause menstrual disturbance. In ovulatory cycles excessive menstrual bleeding has been linked to abnormal levels of prostaglandins in the uterus[53]. In women complaining of menorrhagia higher levels of prostaglandin E2 and F2α have been found in the menstrual fluid[54], prostaglandin E2, F2α and prostacylin release from the endometrium and myometrium is increased[55,56] and increased concentrations of prostaglandin E receptors are found in the myometrium[57]. Fibrinolytic activity is also significantly elevated in the endometria of women with DUB[58].

Endometrial malignancy and pre-malignant conditions are a cause of concern to both women with menstrual disorders and to their health care providers. Endometrial hyperplasia may progress to malignancy, particularly in the presence of cytological atypia. The progression of hyperplasia without cellular atypia to carcinoma is in the order of 1-3% and 28% when atypia is present[59]. The overall incidence of endometrial cancer in England in 2003 was 19.9 per 100 000, and 93% of these cancers are diagnosed in women over the age of 50[60]. Approximately 50% of all endometrial carcinomas appear to occur in women with particular risk factors[61]. Risk factors for

endometrial carcinoma and hyperplasia include tamoxifen[62,63], unopposed oestrogen administration[64], polycystic ovarian syndrome[65] and obesity[66]. Although it is not clear to what extent women with heavy regular cycles but no risk factors are at risk of endometrial malignancy, it is uncommon in pre-menopausal women and especially in those under the age of 40, in which age group the disease seems to present with irregular bleeding[25]. In pre-menopausal women over 40 the situation with respect to regular or irregular bleeding in the presence of malignancy is less clear cut but still appears to be very low[49].

1.2.2 Management of Menstrual Disorders

In 1994, 822 000 prescriptions were issued from Primary Care for the treatment of abnormal uterine bleeding at a cost of £7 million[19]. The combined cost of managing menstrual disorders in Primary and Secondary care is estimated to be between £250 and £500 million per annum in the UK[67].

1.2.2.1 Clinical Assessment

All women presenting with menorrhagia should be evaluated with a full history and examination[4,49]. A detailed menstrual history should be taken focussing on length, pattern and subjective assessment of blood loss including its impact on quality of life. Any changes from the previous pattern should be noted as should the contraceptive method[48]. It is advised that definitions and labels avoided in clinical practice in favour of an accurate record of the patients' subjective symptoms[4]. Associated symptoms such PMS may be elicited. Dysmenorrhoea in association with dyspareunia and pelvic pain may warrant investigation for endometriosis. An important aim of the menstrual history is to identify women at risk of pathology (i.e. those with risk factors for endometrial hyperplasia and carcinoma) which would require investigation and specific management strategies[49]. Irregular bleeding including inter-menstrual bleeding or a sudden marked increase in blood loss may also indicate sinister pathology warranting further investigation[68]. As systemic disease may affect menstrual loss, a more general medical history is also important to evidence in particular of other endocrine or haematological

conditions[49]. It is also helpful during the initial assessment stage to ascertain the concerns of the patient with regard to her symptoms, and her expectations and desires regarding treatment[4]. General physical examination should be undertaken to identify signs of anaemia or other systemic disease. An abdominal and pelvic examination including speculum (and cervical smear if it is due) and bimanual examination is recommended for all women, except those who have never been sexually active. Structural pathology, such as an ovarian mass or a uterus greater than 10 weeks size or significant pelvic tenderness warrants further investigation[49].

1.2.2.2 Investigation

A full blood count (FBC) is recommended at primary care level by the RCOG[49]. Whilst it has been seen that haemoglobin level is not a good screening test for objective menorrhagia, it can aid in its recognition and allow early detection and treatment of iron deficiency. The primary purpose for the investigation of abnormal menstrual bleeding is to exclude malignancy and pre-malignant conditions in those at increased risk[48,69]. The RCOG advises that the exclusion of endometrial carcinoma is the only indication for evaluation of the uterine cavity and endometrium prior to a trial of drug treatment[49]. The rationale behind investigation in other women is to diagnose treatable causes for menstrual abnormalities such as endometrial polyps and fibroids, and to assess suitability for the various treatments available. A number of techniques are available for this purpose; trans-vaginal ultrasound (TVS) for evaluation of the uterine structure including measurement of endometrial thickness, blind endometrial sampling, hysteroscopy and dilatation and curettage (D&C)[6].

1.2.2.2.1 Trans-vaginal Ultrasound (TVS)

Trans-vaginal ultrasound is a non-invasive, non-painful procedure which is acceptable to patients[70,71] and has become routine in gynaecology practice[48]. It is more sensitive than clinical examination in detecting gynaecological disease[4]. As well as being quicker to perform than a trans-abdominal scan, other advantages of the trans-vaginal route include avoidance of the need for a full bladder and the ability to place the probe nearer

to the structures to be visualised with minimal intervening tissue to attenuate the sound waves, allowing the use of higher frequency sound of 6 – 10 MHz compared to 2.5 – 3.5 MHz for trans-abdominal scans. TVS is thus better at visualising the uterine cavity and endometrium than trans-abdominal scanning[72,73]. Ideally TVS should be performed just after menstruation in the follicular phase of the menstrual cycle. The endometrium appears as a strongly echogenic structure in the central part of the uterus which has different characteristics to the surrounding myometrium, and can be depicted in considerable detail. The ultrasound appearances change throughout the menstrual cycle and in certain pathological states[74].

Endometrial thickness (ET) has been used to determine both physiological changes in the normal menstrual cycle and the presence of endometrial pathology in both pre- and post-menopausal women[25]. It is measured in a longitudinal section of the uterus as the double thickness of the two apposed layers, and correlates to within 1mm with actual endometrial thickness measured on hysterectomy specimens[75]. In normal menstrual cycles, ET varies from 4-8mm in the proliferative phase and 7-15mm in the secretory phase[76]. Abnormalities of endometrial appearance and thickness may be present in a number of pathological conditions; endometrial polyps, submucous or intra-cavity fibroids, septae, haematometra, adenomyosis, endometrial hyperplasia and endometrial carcinoma including measurement of the depth of invasion[74]. Some of these may be further clarified by the instillation of saline into the uterine cavity (known as sonohysterography)[77]. There is evidence that in post-menopausal subjects an endometrial thickness of greater than or equal to 5mm has a sensitivity of 92% for detecting endometrial disease and 96% for detecting endometrial malignancy[78]. Such evidence in pre-menopausal women is lacking. The RCOG Guideline Development Group reviewed the available evidence in 1999 and concluded that 10-12mm represented a reasonable cut-off point for the exclusion of endometrial pathology in pre-menopausal women, although sensitivity and specificity was not quoted[25]. No further work has been identified in the literature since then to clarify matters further.

Other benefits of ultrasound include the ability to diagnose intramural pathology, particularly fibroids and co-existing ovarian pathology, the diagnosis of which may alter the course of treatment[4]. The RCOG suggest that TVS should be the first line investigation for women with menorrhagia in order to select those who do not require

more invasive assessment in the form of hysteroscopy and endometrial sampling. It is however suggested that if hysteroscopy is easily available in the outpatient's department, TVS may be omitted[25]. So, although TVS can be considered a useful screening procedure which may also identify extra-endometrial pathology, it is insufficient on its own to establish a firm diagnosis[48].

1.2.2.2.2 Hysteroscopy and Biopsy

Some from of direct endometrial assessment is advised for all women with abnormal bleeding aged more than 40 years and those with risk factors for endometrial carcinoma. It is also recommended for women under 40 whose abnormal bleeding does not respond to medical treatment[25,49]. Direct endometrial evaluation can be undertaken in several ways; dilatation and curettage, endometrial biopsy and hysteroscopy or by a combination of methods. There is no general consensus as to which method or combination of methods should be used for which group of patients[79].

Dilatation and curettage was once considered the gold standard for the diagnosis of abnormal menstrual bleeding, however it was not originally intended to be used as a diagnostic procedure and its sensitivity and specificity in this context remain unknown[25]. Its use in the investigation of abnormal uterine bleeding is no longer supported by evidence. D&C is essentially a blind procedure which does not sample the whole uterine cavity[80]. Important lesions with implications for choice of treatment such as carcinoma, hyperplasia, submucous fibroids or endometrial polyps can be missed. It has been estimated that D&C will not reveal endometrial pathology in more than 50% of cases[81]. In addition it requires general anaesthetic and is associated with complications such as uterine perforation, haemorrhage, infection and the development of uterine synechiae if curettage is excessive[82]. It has now been replaced by alternative cheaper, safer outpatient procedures.

An endometrial biopsy can be performed as a blind procedure in the out-patient setting and a variety of instruments are available. The RCOG guideline development group evaluated various endometrial sampling devices and concluded that the Pipelle endometrial sampler (Unimar, CT, USA) was preferable in terms of diagnostic

accuracy, patient discomfort, acceptability and cost[25]. It is subsequently the most commonly used device in the UK, and consists of a flexible polypropylene suction catheter 23.5cm long and 3.1mm in diameter with an integral plastic piston within. This is inserted through the cervix to the fundus of the uterus; the plunger once withdrawn generates negative pressure for the aspiration of tissue obtained by moving the catheter up and down whilst rotating it. The pipelle obtains an adequate sample for histological diagnosis in 99% of pre-menopausal women and detects 91% of cases of carcinoma and atypical hyperplasia[83-85]. The fact that pipelle endometrial sampling alone will not detect of 9% of malignancies and pre-malignant conditions, and also that like D&C it is insensitive in the diagnosis of benign conditions such as endometrial polyps or submucous fibroids[86] has led to the introduction of hysteroscopic evaluation of the uterine cavity to complement endometrial biopsy.

Diagnostic hysteroscopy can be performed as an inpatient procedure under general anaesthetic or as an outpatient procedure with or without anaesthetic. Outpatient hysteroscopy appears to be safe, well tolerated, able to detect intrauterine pathology and associated with considerable cost savings[87-89]. When compared to D&C, hysteroscopy detects more benign intrauterine pathology, although it seems to have a low sensitivity for the detection of endometrial carcinoma when employed alone without endometrial biopsy[25]. There is thus no benefit to the majority of women in performing hysteroscopy under general anaesthetic (GA) in the operating theatre[25]. Outpatient hysteroscopy is performed using a 4mm hysteroscope with a 5mm sheath and for many women cervical dilatation is unnecessary[90]. Either saline or carbon dioxide can be used as the distension medium although the RCOG guideline development group found normal saline to be superior in terms of procedure time and patient discomfort, whilst visualisation of the uterine cavity was comparable between methods[25]. Various studies have demonstrated that the routine use of either paracervical local anaesthetic block or local endometrial anaesthesia is not necessary for the majority of women, although it may have a place in women with cervical stenosis requiring dilatation or women reporting severe pain during a previous intrauterine procedure[91-93].

1.2.3 Treatment of Menstrual Disorders

A wide variety of treatments are available for menstrual disorders. The aims of treatment are to regulate and reduce the amount of blood lost, reduce the risk of anaemia and to improve subjective health-related quality of life[48]. In some women, reassurance that her experience is normal and that there is no significant pathology is all that is required[94]. The ROCG guideline recommends that "women should be involved in the decision making process regarding their treatment and be provided with appropriate oral and written information to enable them to do this"[95].

1.2.3.1 Medical Treatments

These are divided into two main groups, hormonal and non-hormonal. They are the only available treatments for women who wish to retain their fertility. Non-hormonal treatments are only taken at the time of menstruation, and as such are the only suitable treatments for women wishing to conceive. Although randomised controlled trials investigating the efficacy of treatments do exist, they utilize a variety of designs, and entry criteria with respect to objectively measured blood loss. This makes comparisons difficult[96].

1.2.3.1.1 Non Steroidal Anti-Inflammatory Drugs (NSAIDs)

Non-steroidal anti-inflammatory drugs reduce endometrial prostaglandin levels by inhibiting cyclooxygenase, responsible for the conversion of arachidonic acid to prostaglandins[97]. Five main groups of NSAID exist: salicylates (eg aspirin), indolacetic acid analogues (eg indometacin), aryl proprionic acid derivatives (eg naproxen), fenamates (eg mefenamic acid) and coxibs (eg celecoxib). A meta-analysis of 16 RCT has shown that no one NSAID is superior to any other[98]. They are effective in women with intrauterine contraceptive devices (IUCDs) and alleviate dysmenorrhoea[99]. The femanates also bind prostaglandin receptors, and of all the NSAIDs have been the most intensively investigated[57]. Reductions in blood loss with mefenamic acid range from 22-46%[33,100]. The dosage normally ranges from 250 – 500mg 2 to 4 times daily[98]. Other

NSAIDs have also been found to reduce menstrual blood loss including naproxen, ibuprofen, diclofenac and fluriprofen. The reductions in blood loss depend on the drug and the dose used, but are in the range of 35-47%[95]. Gastrointestinal side effects are possible with all NSAIDs and are contraindicated in those with peptic ulceration, however there is a low profile of adverse effects in otherwise healthy women[48].

1.2.3.1.2 Anti-fibrinolytics

Tranexamic acid acts through the reversible blockade of plasminogen[101,102]. It reduces menstrual blood loss by up to 50% and has been shown to be superior to NSAIDs in this respect, but has no effect on dysmenorrhoea[33,103,104]. It is also effective in women with copper IUCDs[105]. Side effects, mainly gastrointestinal and dose dependant are reported by approximately one third of patients[106]. There is no evidence of an increased incidence of thrombosis in women treated with tranexamic acid[107].

1.2.3.1.3 Combined Oral Contraceptive Pill (COCP)

The COCP is often used in the treatment of abnormal menstrual bleeding as it induces regular shedding of a thinner endometrium, possibly through induction of endometrial atrophy[108]. It reduces MBL, increases haemoglobin concentrations and reduces iron deficiency anaemia with the additional advantages of producing a regular and predictable menstrual cycle and a reduction in dysmenorrhoea[49]. It is particularly suitable for those who also require contraception. The benefit of the COCP is well known from clinical experience but double-blind placebo randomised controlled trials (RCTs) with adequate patient numbers and duration of use are lacking[109]. The doses of ethinyloestradiol most commonly used in practice are 30-35 mcg, but many of the trials of COCPs have employed higher doses. It therefore remains unclear as to whether these lower doses are as effective as the higher doses, and whether the type of progestogen has an impact on the MBL[48]. The most serious side effect of the COCP is venous thromboembolism. Others include nausea, vomiting, breast tenderness, headaches and mood changes[4].

1.2.3.1.4 Progestogens

There are several methods for the administration of progestogens; oral formulations which can either be taken cyclically in the luteal phase (e.g. from day 19-26) or as long cycle therapy (e.g from day 5-26), depot preparations and via intrauterine systems. Progestogens are generally very safe and have few contraindications. Recognised side effects include bloating, increased appetite and weight gain[4].

The use of oral progestogens is based on the assumption that the majority of women complaining of heavy periods have anovulatory cycles and the administration of luteal phase progestogen induces full secretory changes in the endometrium and consequently normal menstrual loss. The results of a small study conducted in 1960 demonstrated a subjective improvement in MBL in 13 patients appeared to support this[110]. It is now known that 80% of women complaining of heavy periods have ovulatory cycles[111], and a meta analysis of the use of norethisterone to treat heavy periods has suggested that when administered in this way it may in fact increase MBL[112], The use of luteal phase progestogens is therefore no longer a recommended treatment for heavy periods[49]. There is some evidence that long cycle therapy may be effective in reducing MBL[35,113]. The main benefit of oral progestogen treatment lies in the fact that it does provide cycle control and reduces the duration of menstrual bleeding and is particularly useful for this purpose when associated with irregular anovulatory cycles[4].

Depot preparations (e.g. medroxyprogesterone acetate) administered every three months, although primarily a contraceptive, and progestogen administered via an IUCD (e.g. levonorgestrel-releasing intrauterine system, Mirena®, Schering, Germany) both reduce menstrual bleeding through the induction of endometrial atrophy. Depot provera induces amenorrhoea in the half of users within 12 months and is a useful secondary effect for the woman requiring contraception who also experiences heavy periods.[114,115] Irregular bleeding is common in the first three months of use and the duration of action is uncertain, making this an unattractive choice for some[4].

The levonorgestrel-releasing intrauterine system (LNG-IUS) is a plastic IUCD with a reservoir of levonorgestrel in the stem released at a rate of 20mcg per 24 hours, and lasts for 5 years. There is very minimal systemic drug absorption and hence ovulation is

not inhibited. The LNG-IUS is licensed for both reversible contraception and the treatment of menorrhagia[4]. The LNG-IUS is superior to oral progestogens, tranexamic acid and flurbiprofen in reducing MBL[35,116]. It is associated with high rates of reduction in MBL (up to 96%), patient satisfaction and rates of continuation with treatment[35,117-119]. After 12 months continuous use most women bleed lightly for one day a month and 15-20% of women are amenorrhoeic[120,121]. Irregular bleeding is common particularly in the first three months of use[122]. Other side effects usually associated with the use of IUCDs, such as pelvic inflammatory disease and ectopic pregnancy appear to be reduced[120]. The LNG-IUS also appears to offer an alternative to minimally invasive surgery and hysterectomy for some women. When compared to trans-cervical resection of the endometrium (TCRE) it produces smaller reductions in MBL but similar levels of patient satisfaction[118]. When used in women awaiting surgery studies demonstrate that 64-82% of women will decide not to undergo the planned procedure owing to improvement in their symptoms[119,123].

1.2.3.1.5 Danazol

Danazol is an isoxazol derivative of 17α-ethinyl-testosterone which acts on the hypothalamic-pituitary-ovarian axis suppressing the luteinising hormone (LH) surge and therefore ovulation, in addition to having a direct action on the endometrium producing atrophy[4]. Danazol reduces MBL by up to 80% in a dose dependant manner and usually leads to amenorrhoea when taken continuously at doses of 400mg daily[124-127]. Although effective, the use of danazol is limited by its side effects (which are experienced by up to three-quarters of women) and the recommendation of the manufacturer that duration of treatment should not exceed 4 months[4]. The side effects are androgenic and include weight gain, acne, oily skin and deepening of the voice[126]. There is also a potentially virilizing effect on the female fetus and thus effective contraception needs to be used concurrently. Because of this, the use of danazol is usually restricted to women awaiting surgery. It is also employed as endometrial preparation prior to endometrial ablation[48].

1.2.3.1.6 Gonadotrophin-releasing hormone agonists (GnRHa)

GnRHa when administered continuously, reduce MBL by pituitary down-regulation and subsequent inhibition of ovarian activity, creating a reversible hypoestrogenic state, resulting in amenorrhoea in 90% of women[128]. The hypoestrogenic state causes adverse effects on bone mineralization and troublesome side effects such as vaginal dryness and hot flushes and duration of treatment is usually limited to six months[129]. GnRHa are therefore, like danazol most useful for women awaiting surgery, or used pre endometrial thinning prior to surgical ablation[4]. In women in whom surgery is contraindicated, but amenorrhoea desirable, GnRHa can be considered in the medium to long term with add back cyclical oestrogen-progesterone HRT or tibolone[106].

1.2.3.2 Surgical Treatments

1.2.3.2.1 Endometrial Ablation

Endometrial ablation can be offered to women as an alternative to hysterectomy where medical treatments have failed, or otherwise if considered appropriate by the woman and her doctor[130]. It is generally considered to be most suitable for women with a normal sized uterus (<10cm sound length) in whom menorrhagia is the main complaint, with little or no dysmenorrhoea and for whom amenorrhoea is not essential[4]. The procedure is more likely to be successful in older women[131-133]. A variety of surgical techniques can be used to selectively destroy the endometrium (including the basal layer and up to 3mm of myometrium in order that the endometrium is unable to regenerate). Several different methods are available and these can be categorised as hysteroscopic (involving visualisation of the uterine cavity and directed ablation) and non-hysteroscopic[48].

Hysteroscopic techniques include laser ablation of endometrium (LAE) utilising energy from the neodymium:yttrium aluminium garnet (Nd:YAG) laser directed at the endometrium to destroy it[134], transcervical resection of endometrium (TCRE) involving resection of the endometrium in strips using an electrosurgical loop and rollerball ablation using electrical current delivered by a rollerball device to produce endometrial

coagulation[135]. TCRE and rollerball methods are often combined. All techniques require distension of the uterine cavity with a fluid medium. There is evidence that the use of pre-operative preparation with either GnRH analoges or danazol results in shorter operating times, lower rates of preoperative dysmenorrhoea and increased rates of amenorrhoea[136]. Overall the results obtained with the hysteroscopic methods are broadly similar with around 30% of women becoming amenorrhoeic and the majority of those still menstruating experiencing a satisfactory reduction in their menstrual loss[4]. The main disadvantages of these methods are firstly that they require the acquisition of considerable skill (with the outcome directly linked to the experience of the operator[132]) and the possible complications that can arise from fluid overload as a result of absorption of the distension medium such as hyponatraemia, pulmonary oedema and cerebral oedema[137].

Non-hysteroscopic ("second generation") techniques have been developed to try to overcome these problems. Thermal balloon ablation (e.g. Cavaterm™ Plus, Walleston Medical SA, Morges, Switzerland and Thermachoice™, Gynecare, Ethicon, NJ, USA) involves the placement of a balloon catheter inside the uterine cavity which is then inflated with heated liquid. Published series report amenorrhoea rates of 29 - 68% and high levels of patient satisfaction[138-140]. Other advantages of these systems include no requirement for preoperative pharmacological endometrial preparation as this is replaced by pre-ablation curettage[139], and the ability to perform the procedure in the outpatient setting[141]. Microwave endometrial ablation delivers microwave energy to the uterine cavity via a probe inserted inside the cavity and like thermal balloon ablation results in high levels of patient satisfaction[142]. Other techniques include hydrothermal ablation (involving the instillation of free fluid into the uterine cavity)[143], radiofrequency electrosurgery using alternating current and either monopolar or bipolar electrodes (the NovaSure™System, Novacept, CA, USA)[144] and cryoablation[145]. The likelihood of complications such as perforation and infection arising as a result of endometrial ablation is generally low[146]. Although the chance of conception following ablation is also low, pregnancies have been reported with a variety of adverse outcomes. Women undergoing ablation should therefore be advised to use an effective method of contraception[48].

1.2.3.2.2 Hysterectomy

Hysterectomy, which can be performed via the abdominal or vaginal route with or without laparoscopic assistance, cures menorrhagia and is associated with consistently high levels of patient satisfaction[147,148]. It is especially useful when other pelvic pathology or severe dysmenorrhoea coexist with disorders of bleeding[4]. Various assessments have been made of the numbers of women undergoing hysterectomy for menstrual disorders. The VALUE national hysterectomy study reported 37 298 cases, thought to reflect just below half of all hysterectomies undertaken in England, Wales and Northern Ireland during 1994-5. In 46% of cases, the procedure was performed to treat dysfunctional uterine bleeding[149]. In the UK 20% of women undergo hysterectomy by the age of 60, in half of them menorrhagia is the main presenting problem. Fifty percent of them will have a structurally normal uterus removed[150]. Hysterectomy is accompanied by significant peri-operative morbidity (e.g. haemorrhage, infection, thromboembolism and injury to surrounding structures) and complication rates are to some extent dependant on the approach; for vaginal hysterectomy rates of up to 24% are reported and for the abdominal route up to 43%[151]. The mortality rate for women undergoing the procedure for non-malignant indications is approximately 1:1000[152]. Although concerns exist about the long-term consequences of hysterectomy, problems are not frequently encountered. Sexual function appears to be improved post-hysterectomy, there is little if any effect on urinary or bowel function, and evidence surrounding decline in ovarian function is conflicting[147].

1.2.4 Summary

There are significant uncertainties surrounding the pathophysiology and definition of abnormal menstrual bleeding leading to clinical difficulties with diagnosis, assessment and treatment of women presenting with such problems. There is no straightforward diagnostic test to confirm or refute the complaint and no simple, universally effective treatment. Despite the fact that many treatments are available, none apart from hysterectomy guarantees a "cure", but this carries a significant risk of morbidity (and although very rare, mortality) for otherwise healthy young women presenting with a problem that is distressing but not present on a daily basis, and is almost never life threatening.

1.3 The Health Care Process

In the UK, patients are registered with a general practitioner (GP) who is their primary care provider. With few exceptions, it is the GP who determines patients' access to hospital and specialist care in the secondary sector. Upon request by the GP, patients are seen for a consultation in hospital outpatient clinics before further management is planned. Patient transfer between primary and secondary sectors traditionally involves a "referral", which reassigns some responsibility for care. The referral process is complex and does depend to some extent on the characteristics of both the GP and the patient, although the tendency of a particular GP to refer is does not appear to be influenced by factors such as age, sex or time since qualification, but does seem to relate to proximity to the nearest hospital, country of qualification, attitudes to risk and methods of decision making. Once the referral has been made the hospital doctor decides when the patient is referred back to the GP; the reason behind this decision is often unclear but is influenced by the specialist's perception of the role of the GP and their opinion as to the likelihood of different disease outcomes[153].

1.3.1 The Management of Menstrual Disorders in Primary Care

There are known to be wide variations in the management of menstrual disorders at primary care level in terms of types of treatments prescribed and rates of referral[112,154-158]. One study demonstrated that in terms of medical treatment, the most effective drug (tranexamic acid) was the least frequently prescribed, whilst the least effective drug (norethisterone) was given most often[112]. Data from the Somerset Morbidity Project showed that only 43% of women presenting to primary care had a vaginal examination, and only 39% had their haemoglobin checked. A quarter of women were not prescribed any treatment and 37% were treated with norethisterone, with substantial inter-practice variations in medical management[158]. This suggests that the application of evidence-based medicine with respect to the management of menstrual disorders is sub-optimal in primary care.

These variations in clinical decision-making seem at least in part to be underpinned by difficulties related to related to conceptualisation of what actually constitutes abnormal bleeding and how this is best assessed[159]. The inadequacy of medical understanding of

normal and abnormal menstruation means that almost any menstrual complaint accompanied by apparent distress can be labelled as a menstrual disorder, making the job of judging which patients require investigation and treatment problematic[160,161]. Advice from the RCOG recommends that a diagnosis for menorrhagia should be based on a history of heavy regular periods over several cycles, and practitioners are advised to enquire as to the presence of clots and flooding[49,162]. One qualitative study of GP's assessment of heavy periods found that the majority attempted to assess problems in this way using a standard medical history, but a significant minority regarded attempts to quantify blood loss in this way unhelpful preferring to rely solely on the patient's assessment of her bleeding as heavy[163]. As a result of these uncertainties, practitioners develop their own idiosyncratic working models or "rules of thumb" informed by a variety of professional experiences, and in the case of female doctors, personal experiences of menstruation to enable their daily practice[161]. This may partly account for the variations in primary care management of menorrhagia[158].

Evidence from a variety of qualitative studies suggests that up to half of women with menstrual disorders are dissatisfied with the response from primary care and their GP[41]. Factors other than increased menstrual loss per se, such as tiredness, inconvenience, embarrassment, impact on family, social and working life and mood changes are often just as important as changes in the amount or nature of menstrual bleeding to women when consulting with a menstrual disorder[2,3,41]. Women too, report difficulties in defining what constitutes a "normal" menstrual experience and look to their GP for guidance in this matter[3]. There is a general feeling amongst patients that GPs have a poor understanding of menstrual disorders and fail to acknowledge the impact of the problem, often dismissing women's complaints as psychological[1,2,41,164]. Satisfaction with primary care management is increased by investigation and referral[3]. Referral to secondary care is frequently seen by women as the main route to clarification and resolution of the problem, and there appears to be a significant demand for referral which is goes unrecognised or is ignored[3,41], although there is some evidence that GPs are more likely to refer patients who hold a strong preference for surgical treatment suggesting that they are responsive to the patient's agenda[165]. A further reflection on these difficulties is the labelling of menstrual disorders by GPs. This has been brought into question by investigating concordance between the reasons for referral cited in GP referral letters and patients' account of their symptoms. In one study of women referred

for menstrual problems only 38% of women reported heavy bleeding as their main concern; however this was cited by the GP in the referral letter as the reason for referral in 79% of cases. Under reporting of dysmenorrhoea was also of concern[159].

1.3.2 The Management of Menstrual Disorders Secondary Care

Rates of referral to secondary care for women with menstrual disorders have been shown to vary up to three fold, and women with menstrual disorders make up 12% of those attending hospital gynaecology clinics[154,158]. This is important since referral is known to influence clinical outcome, in terms of increasing the likelihood of elective admission to hospital for surgical treatment[157]. In the case of menstrual disorders, referral is strongly linked with subsequent hysterectomy[158]. Processes of referral from primary to secondary care have been examined across a number of hospital specialties. Whilst all patients thought that the outpatient consultation was "necessary and worthwhile" and GPs felt that they could not have given the patients the care, treatment and investigations they received at hospital, the specialists reported that in one fifth of cases the GP could have done more in terms of examinations and investigations prior to referral[166]. A further problem with 'referral' based patient transition is that it can be inflexible, for apart from assigning different degrees of urgency it may be unable to respond to differing requirements of the referral, for example investigation and diagnosis, advice and reassurance or treatment[155,167].

1.3.3 Improving the Management of Menstrual Disorders

A range of initiatives have been suggested and implemented with varying degrees of success, to improve the management of women with menstrual disorders. These include the introduction of clinical guidelines in various forms and re-structuring care in order to optimise outcomes.

1.3.3.1 Clinical Guidelines

Practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"[168]. A systematic review has shown that in general, explicit clinical guidelines in the context of rigorous evaluations do result in significant improvements in the process of care[169]. In the context of infertility, where there are also wide variations in the management of couples prior to referral, receipt of a local guideline for the management of infertility in primary care resulted in significant more couples having an appropriate history taken, examination performed and investigations requested prior to referral[170]. Guidelines have therefore been suggested as one mechanism to improve the quality of care for women with menstrual disorders and to reduce variations in practice with respect to treatment and referral[154].

The use of guidelines to promote the use of evidence-based care is generally welcomed by physicians[171-173]. It has been suggested that primary care physicians find joint primary-secondary guidelines more acceptable than their counterparts in the secondary sector, but both groups recognise that the use of joint guidelines can lead to harmonisation between specialists and general practitioners[174].

Barriers do exist to the wholesale, widespread adoption of guidelines. In primary care these may exist because of either the characteristics of the GP or the practice setting[175]. For example, lack of time is often quoted by doctors when surveyed as a barrier to the implementation of guidelines[171], and with respect to national guidelines for the management of menorrhagia in New Zealand, difficulties with access to facilities in secondary care such as ultrasound was perceived by GPs to be a barrier to implementation[172].

Systematic reviews of strategies for changing professional behaviour show that relatively passive methods of disseminating and implementing guidelines (such as publication in journals or mailing to the target audience) rarely lead to changes in professional behaviour[176]. Educational approaches such as seminars and workshops can be useful where the main barrier to implementation is lack of knowledge amongst healthcare professionals[177]. The Anglia menorrhagia education study aimed to change

improve prescribing in primary care through a multi-media educational package delivered by independent academics in small practice based interactive groups with a follow-up meeting six months later[178]. The intervention was only partially successful in improving prescribing and given the large amounts of resource required, questions must be raised about its sustainability.

It is suggested that guidelines are likely to be most effective when they operate directly on the consultation between the professional and the patient, including strategies such as restructuring the medical record, patient specific reminders during the consultation and patient mediated interventions (where the aim is to influence professional practice through informing patients) and when they have been agreed by those responsible for implementation[168].

1.3.3.2 Changing the Organisation of Care

A range of innovative approaches have been taken for the reorganisation of care for the improvement of quality and efficiency. One-stop and open access services in secondary care aim to provide a more efficient, patient-focussed service by reducing the number of out-patient and investigation appointments for patients, releasing specialist and clinic time and reducing outpatient waiting times[179].

One-stop clinics (OSC) usually involve the screening of standard general practitioners referral letters by clinic staff and re-organisation of services in secondary care so that consultation, investigation, results and formulation and initiation of management plans are undertaken on the same day. Many examples of one-stop clinics are described across a variety of hospital specialties including gastroenterology (for the management of dysphagia[180], dyspepsia[181,182] and lower gastrointestinal symptoms[183,184]) ENT (neck lumps[185,186]), medicine (chest pain[187], palliative care[188], and neurovascular disease[189]), opthalmology (cataracts[190] and retinal laser[191]), paediatric surgery[192], vascular surgery[193,194], breast surgery[195-200] and obstetrics (first trimester chromosomal abnormality screening[201]). In gynaecology one-stop clinics are reported for the management of postmenopausal bleeding[202-205], infertility[206,207], low-grade cervical

smear abnormalities[208], abnormal uterine bleeding[209,210] and more specifically for menstrual disorders[211,212]

These clinics allow the efficient delivery of appropriate investigations[189,201,204 208] leading to shorter waiting time for investigation[186,193] and consequently reduced time to diagnosis and treatment[180,184,196,198,203,205]. Some clinics report reduced waiting time for appointments, although it is possible that this benefit may reduce with time[202-205]. Patients usually make fewer visits to hospital within the OSC system[180,184,193,197,202-204]. Although the impact on primary care services is not often reported, one clinic reports high levels of satisfaction from referring GPs[189], who may prefer the OSC set-up to open access investigation[181].

OSC are associated with high levels of patient satisfaction[182,184,188,189,195,196,204,211] and seem to be preferred by patients over traditional outpatient clinics[191,193,208], despite increased waiting times whilst at the clinic[186,191,197]. Other advantages for patients may include reductions in patient anxiety levels during the episode of care[193,208], although it is less clear whether this benefit is a sustained over time[197]. OSC are usually reported to be associated with reduced costs to patients[193] or are cost neutral[197]. They can prevent admissions to hospital[189,202-204] and are associated more efficient use of clerical staff time[191].

The main focus of the OSC is secondary care. They do not address difficulties in primary care or at the primary-secondary interface[186,198,199]. Communication across the primary secondary interface between healthcare providers in different sectors is known to be suboptimal and is usually restricted to the exchange of letters, the information contained in which is often not well tailored to the needs of the recipient. There is a need to screen GPs referral letters to assess suitability for a OSC; the information contained in these letters may be of poor quality[190]. Referrals may therefore subsequently be found to be inappropriate, leading to wasted opportunities and reduced availability for those patients who would benefit from such a service[199,204]. After the consultation in secondary care, letters from specialists to referring doctors show that in many cases the replies fail to address the issues that prompted the referral, inadequately describe the reasoning underpinning the specialist's opinions and recommendations, do not contain enough educational content and omit details of follow-up arrangements. The use of structured letter templates has been suggested to improve this communication[213].

There are frequently significant delays in written communication as a consequence of lack of administrative resource[214].

The problems experienced by patients when they move between healthcare sectors have been investigated[215]. Gaining access to appropriate care (as perceived by the patient) can be problematic especially for those with chronic conditions, such as menstrual disorders. Patients are frustrated when care appears to be organised according to the needs to the health service rather than their own[211]. Lack of information and not knowing what to expect, especially in relation to investigation results and diagnosis, and lack of consistent information from, and communication between, staff in different sectors frequently contributes to a sense of being "in limbo" when progress towards resolution of the problem is not being made. The patient has little power to alter this. "Limbo" is most often experienced as patients move from one stage of care to another across interfaces[215].

Very few attempts have been made to specifically address the problems occurring at the primary secondary interface. Reports do exist in the literature of schemes described as "integrated across the primary-secondary interface" or "shared care" although the degree to which the whole process of care is indeed truly integrated in both directions (both to primary and from secondary sectors) is variable[216,217]. There are no reports of the provision of integrated care for women presenting with menstrual disorders.

1.3.2.3 A New Model of Care: The Bridges Project

Opportunities exist to improve the management of menstrual disorders at every stage in the clinical process. Primary care is seen by up to half of women as not being responsive to their particular needs, and strategies to improve the application of evidence-based medicine have not been completely successful. The gap between primary and secondary sectors, the primary-secondary interface causes frustration for healthcare providers and does not benefit patients; in fact it often positively disadvantages them. There is a responsibility to see how it can be reduced[218]. Initiatives to improve processes in secondary care often do not attempt to address these issues; rather they concentrate on optimising management within the outpatient setting, so that the response to referral remains in as inflexible as ever. Optimising care for women with menstrual disorders therefore requires consideration of the whole process from presentation and medical treatment in primary care through investigation and surgical treatment in the secondary sector, and of all the transfers patients make in between.

A guideline-based process of care, completely integrated across primary and secondary sectors was developed and agreed through dialogue between stakeholders in both sectors. This was underpinned by issues such as the application of evidence-based medicine in daily practice, quick and easy access to necessary investigations, continuity of care and improved communication between healthcare providers in both sectors, and patients. It was anticipated that this new type of service provision, known as the Bridges Project would have a significant positive impact on the management and subsequent outcomes of menstrual disorders in terms of patients' experience, clinical outcomes, use of evidence and resource use when compared to the existing route of service delivery.

Study	Hallberg et al 1966[8]	Cole et al 1971[9]
Country	Sweden	England
Measurement method	Alkaline haematin	Atomic absorption
No. of subjects	476	348
Age range	15 – 50	17 – 44
Selection	Random	Random
Mean loss (ml)	43.4 ± 2.3	37.5 ± 3.3
Median loss (ml)	30.0	27.6
10^{th} – 90^{th} Centile	10.4 – 83.9	0.1 – 280
Loss > 80ml	11.0%	9.5%
Loss > 60ml	19.0%	20.7%

Table 1.1: Population studies of objectively measured menstrual blood loss

Systemic Causes	Pelvic Pathology	Iatrogenic Causes
Endocrine	*Infective Causes*	*Hormonal Medications*
Adrenal disease eg Cushing's syndrome Thyroid disturbance PCOS	Cervicitis Endometritis Salpingitis	COCP Progestogens eg POP a Tamoxifen
Haematological	*Benign Neoplasms*	*Other Medications*
Blood dyscrasias Thrombocyopaenia Coagulopathy	Fibroids Adenomyosis Endometrial polyps	Corticosteroids Anticoagulants Antipsychotics SSRIs
Renal disease	*Pre-malignant lesions*	*Intrauterine contraceptive devices*
Hepatic disease	Cervical dysplasia Endometrial hyperplasia	
	Malignancy	
	Cervical SCC Endometrial adenocarcinoma Leiomyosarcoma Hormone secreting ovarian tumours	

Table 1.2: Causes of abnormal menstrual bleeding[219,220]

Chapter 2: Materials and Methods

2.1 Setting

2.1.1 The One-Stop Menstrual Clinic

The One-Stop Menstrual Clinic (OSMC) at Leicester Royal Infirmary was established in 1996 to provide same day consultation, investigation and treatment for women with menstrual disorders[211,221]. The clinic is located within the gynaecology outpatient's department of the Women's Hospital at LRI and offers facilities for same day haematology, trans-abdominal and trans-vaginal ultrasonography (TVS), outpatient hysteroscopy and endometrial biopsy. It is staffed by two consultant gynaecologists, two 'E' Grade staff nurses, two health care support workers, one clinic coordinator, one phlebotomist, one sonographer, and one hysteroscopist (either a clinical assistant or an obstetrics and gynaecology trainee) plus the support of two consultant histopathologists with an interest in gynaecology. It is held in the morning, once per calendar month with provision for twelve 20-30 minute new patient appointments and twelve 10-15 minute follow-up appointments.

The clinic receives traditional written referrals from GPs in all four Primary Care Trusts (PCTs) in Leicestershire. Prior to referral, patients are managed in primary care according to the preferences of their GP who has access to the Leicestershire Health Authority Guidelines for menstrual disorders. Leicester Royal Infirmary operates a "partial booking" system for all outpatient appointments. Once a referral is received a letter is sent to the patient inviting her to telephone for a convenient appointment time. A confirmation letter is sent to the patient along with an information pack about the one-stop menstrual clinic containing a detailed menstrual and medical history questionnaire. Women are asked to fill out the questionnaire and it is used during the consultation as the basis for history taking and discussion.

Initial investigation results are imparted to women, and possible treatments are discussed before women leave the clinic. At 4.30 – 5.00pm the same day, FBC results and endometrial biopsy results are available and women are telephoned to impart results and confirm treatment plans. Routine follow-up appointments are not made unless there is a specific clinical indication. A summary of the patient's attendance is dictated to the

GP and sent by post. Recommended medical treatments are prescribed by GPs and patients are instructed to collect prescriptions from the surgery.

2.1.2 The Bridges Project

The process of development, implementation and evaluation of the new model of care for menstrual disorders was known as the Bridges Project (BP); it was undertaken between March 2002 and March 2004. The Bridges Project involved complete integration across the primary-secondary interface from the time of the patient's initial presentation in primary care through investigation and definite medical or surgical treatment. It allowed GPs to manage women with menstrual disorders according to best evidence with full access to services in secondary care without the need for patients to move across the primary-secondary interface as with traditional referral. The project was accomplished through collaboration between South Leicestershire Primary Care Trust (SL-PCT) and the One-Stop Menstrual Clinic at Leicester Royal Infirmary (OSMC at LRI). A comprehensive evaluation of the impact of the project on outcomes of menstrual disorders was undertaken; including health outcomes, patients' perspectives, use of evidence and resource use.

At the time of the introduction of the Bridges Project, South Leicestershire PCT comprised 21 practices and 89 General Practitioners providing primary care to an urban, semi-rural and rural population of around 150000 people. The PCT was motivated to participate in the project through a desire to improve services for women and to optimise the use of evidence based guidelines. Participation was strongly supported by the PCT Clinical Governance Committee and Chief Executive.

Guidelines are central to the integrated process. The RCOG guidelines for the management of menorrhagia[25,49] and the Leicestershire Health Authority guidelines were modified to form the "Bridges Project Guidance for Menstrual Disorders" a copy of which can be found in Appendix 1. The format of this document was based on two existing guidelines used within SL-PCT for the management of hyperlipidaemia and hypertension. These had been developed by one of the GPs in SL-PCT and their format had proved popular with other GPs. The guideline was agreed and adopted by both

primary and secondary care. Patients' access to secondary care diagnostic facilities and the full range of surgical treatments for abnormal menstrual bleeding was structured by the GP according to guidelines.

To facilitate the adoption of the process into everyday practice, an integrated care record (ICR) was developed. The structure of the ICR was based directly on the guideline, thus embedding the protocol into the clinical process. In addition to outlining the structure of care the ICR also allowed complete recording across healthcare sectors within one document, of the whole episode of care including details of history, examination findings, investigation results and management of the problem. It also served as the principal means of inter-professional communication and transfer of information between health care providers in both sectors. A copy of the ICR can be found in Appendix 2.

The first part of the ICR included a modified, shortened version of the menstrual questionnaire used in the OSMC. The tick box format served as an aid to history taking for GPs with limited consultation time. Women were thus managed by their GP according the guidelines with direct access to outpatient diagnostics including trans-vaginal ultrasound scan, outpatient hysteroscopy and endometrial biopsy. The criteria for investigation were the same as in the OSMC and are detailed in the Bridges Project Guidance (Appendix 1). The GP indicated on the ICR which investigations were required, and it was faxed to the hospital clinic coordinator the same day. The ICR could also be used to request an outpatient consultation for patients with complex problems. The patient was asked to telephone the clinic coordinator the following day to make an appointment for the required investigations. The patient was provided with written information about the proposed investigations by the GP. Investigations were conducted one afternoon per week, in the gynaecology outpatient's department. The Bridges Project clinic ran concurrently with other gynaecology clinics. There was facility for three trans-vaginal ultrasound scans and three hysteroscopies to be performed. Histopathology reports were available by 5.00pm the following day. Results were recorded on the second page of the ICR which was faxed to the GP's surgery. The patients were informed of their results by telephone and asked to make an appointment to see their GP to discuss the investigation results and to obtain medical treatment if necessary.

Medical treatments were prescribed according to the Bridges Project Guidance, and continued for at least three months. Should patients be unsuitable for, or fail three medical treatments GPs had direct access to waiting lists in order to book the following inpatient surgical treatments: Hysteroscopic laser polypectomy (HLP), Laser ablation of Endometrium (LAE), Balloon ablation of Endometrium (Cavaterm *plus*™ system), Total Abdominal Hysterectomy (TAH), Vaginal Hysterectomy (VH) and Laparoscopically Assisted Vaginal Hysterectomy (LAVH).

The second part of the guidance document contained detailed evidence-based information about each of the surgical treatments for menstrual disorders, to support GPs and patients in decision making. Patients with complex needs or atypical problems continued to attend the one-stop clinic for assessment and investigation by consultant gynaecologists.

2.2 Study Design

Ethical approval was secured and a prospective case-control study was conducted to examine the impact of the Bridges Project on outcomes of menstrual disorders compared to patients referred via the traditional route to the OSMC from other Primary Care Trusts. One hundred women from each group were recruited and followed up for eight months.

The sample size calculation was based on previous experiences in secondary care. Following introduction of a protocol for investigation and treatment in the One-stop Menstrual Clinic the use of evidence-based medical treatments for menstrual disorders increased from 32% to 63%[221]. For this study a more conservative shift in prescribing practice of 20% was anticipated. Based on this a sample size of 85 would be sufficient to detect a 20% shift in prescribing at 80% power and $p<0.05$. Additionally, a statistically significant change of Patient Career Diary (PCD) score for the one-stop clinic versus the traditional approach had previously been demonstrated[211]. Assuming a mean score of 80 for the patients treated using the traditional approach, and SD of 18 in each group, it was calculated that 81 patients would be needed per group to detect a

clinically important relative change in score of 10% with 80% power and $P<0.05$. We therefore aimed to recruit 100 patients per group to allow for dropouts.

The follow-up period of eight months was chosen based on the fact that the study was to run for two years and the anticipated rate of recruitment. Experience in the OSMC demonstrated that the majority of women would have undergone investigation and at tried least two medical treatments in this time, and that some would be on the waiting list for, or have had surgery. Given that twelve new patients' appointments were available in both the OSMC and the Bridges project per month, it was estimated that once the Bridges project was fully in place in Primary care approximately ten patients per group would agree to participate per months. Recruitment would be therefore be complete in ten to twelve months, the last patients to be recruited would therefore be followed up eighteen to twenty months into the project, allowing adequate time at the end of the project for postal reminders, final data collection and analysis.

2.2.1 Data Handling

A Microsoft Access Database was created to store all the data collected during the course of the study. Each patient was assigned an identification number for the purposes of the trial to ensure confidentiality and reduce bias. All project documents and database records relating to that patient were marked with the unique identification number only.

2.3.2 Statistical Analysis

Where possible results were summarized as mean values with standard deviation, or as frequencies, as appropriate. For making comparisons between the Bridges group and the OSMC group, continuous data (such as the SF-36 component scores and the menstrual questionnaire score) were analyzed using Student's t-test, categorical data (such as symptoms, diagnoses, histology and type of treatment) were analyzed using the chi-squared test or Fisher's exact test, and the frequency of clinic visits was analyzed using the Mann-Whitney test. Corresponding 95% confidence intervals were then calculated. Statistical significance was defined at the 5% level throughout. All

analyses were carried out using the statistical computer package SPSS version 11 (SPSS Inc, Chicago, USA).

2.3 Recruitment

2.3.1 General Practitioners

Recruitment of GP practices took place between February and June 2002. Practices were originally approached by introductory letter followed up a week later by a telephone call to individual practice managers. The aim was to secure an appointment to meet GPs and introduce the project at the weekly practice meeting. These meetings are usually attended by all GPs and the practice manager, but not by nursing, other paramedical, clerical or administrative staff. This was only possible at eleven practices. Differing ways of working within individual practices required flexibility of approach when introducing the project to GPs. In four practices, all GPs were met on an individual basis. In another four only those who were interested in taking part were met, usually on an individual basis. In one practice, personal contact was only with the practice manager who fed back to the GPs. In one practice, despite strong support from the practice manager, contact of any sort with GPs was unfortunately not possible. The aims of the project were explained in addition to describing the new system. A pack was produced and distributed to every GP containing all necessary paperwork and information needed to work with the new scheme. This contained: the Bridges Project Guidance for Menstrual Disorders, five Integrated Care Records, a letter explaining the scheme to patients including phone number to make appointments for investigation, patient information leaflets on menstrual disorders, investigations and surgical treatments and contact information for members of the project team. Telephone support was available for GPs and practices during office hours from members of the project team.

A combined approach was used to ensure ongoing support for the project and communication between primary and secondary care. A second visit to practices was made three to six months after the initial approach to identify areas requiring improvement and sustain initial momentum. Posters were sent out to GPs at three

monthly intervals to engage and update them with recruitment progress. A presentation was given at the PCT Practice Nurses meeting to introduce the project and spread awareness amongst other members of the primary care team. Informal telephone contact was maintained throughout on an individual basis.

2.3.2 Patients

Patients receiving care through the Bridges Project and those referred to the OSMC in the usual way from other PCTs were recruited to the study and control groups respectively between March 2002 and June 2003. In order to keep the burden on GPs as low as possible and therefore maximize the numbers participating, patient recruitment took place during the first attendance at the outpatient clinic, either the OSMC or in the Bridges investigation-only clinic. This strategy also ensured consistency with recruitment to the control group, where recruitment at the time of referral in Primary care from the other PCTs would have been impossible given time and project staffing constraints. Women were approached whilst waiting for consultation or investigation, and given full verbal and written information about the study by the same researcher. All participants provided written consent.

2.4 Evaluation

It is suggested that the evaluation of integrated care should consider a number of outcomes. These might include some or all of; clinical measures, quality of life, satisfaction measures, non-clinical outcomes such as changes in attitudes, behaviour or knowledge, economic outcomes, process evaluations, communication and access and teamwork[222].

The following outcomes were selected for evaluation of the Bridges Project: Clinical outcome in terms of treatments used during the study and mode of treatment at eight months (Chapter 4), Adherence to guidelines (Chapter 4), Resource use and cost of the two models of care (Chapter 4), Self-assessed health status using generic and disease specific instruments (Chapter 5), Patients' experiences of and attitudes towards care using semi-quantitative (Chapter 6) and qualitative methodologies (Chapters 7 & 8) and Patient's preferences for attributes of healthcare (Chapter 9).

Chapter 3: Study Population

3.1 Participation

All GPs from the 21 Practices in South Leicester PCT were approached to participate in the Bridges scheme. Two (10%) practices formally declined representing 9% of GPs. Overall 28 General Practitioners from 14 practices utilized the Bridges pathway, representing 31% of GPs in the PCT and 67% of practices. The mean number of referrals per GP was 3.5 patients, and the range 1 - 10. Seventeen (61%) of participating GPs were female and 11 (39%) were male. Overall 31 (34%) of GPs in SL-PCT are female. The patients in the OSMC group were referred from all PCTs in Leicestershire, and came via 68 GPs. 24 OSMC group patients were referred by 16 GPs in SLPCT, 8 of whom also referred using the Bridges Project scheme.

One hundred and one women receiving care through the Bridges project and 115 referred to the OSMC were approached at the time of attendance for investigation in outpatients and invited to participate. One woman on the Bridges scheme declined to be involved from the outset and 15 potential controls also declined. It is unknown how many women declined to be involved with the Bridges project at presentation in general practice. One hundred women in each group signed consent forms and took home a pack containing further information and study questionnaires. Of these, one woman in the Bridges group and six in the OSMC group subsequently withdrew consent before participating with any of the postal questionnaires or other patient activities. No reason was given in three cases, one moved to the private sector, two cited lack of time because of work or family, and one was moving home. The characteristics of these women are detailed in Table 3.1.

The Bridges group (study group) therefore consisted of 99 women, and the OSMC group (control group) 94. Seventy-nine women (79.8%) in the Bridges group and 69 (73.4%) in the OSMC completed eight months follow-up.

3.2 Presenting Symptoms

All women presented with one or more of the following symptoms: Heavy menstrual bleeding, irregular bleeding, dysmenorrhoea or pre-menstrual syndrome. The predominant complaints were of heavy and irregular bleeding, 46 (46%) of the Bridges and 44 (47%) of the OSMC attended because of both heavy and irregular bleeding. There was a statistically significant difference between the numbers of women with heavy menstrual bleeding in the two groups (p=0.04), but no statistically significant differences between the two groups with regard to the other three presenting symptoms, or the actual number of presenting symptoms in any combination. The women in the OSMC group had been experiencing their symptoms for a significantly longer period of time before investigation than the Bridges group (p=0.000). Fifty-one women (52%) of the study group had been having problems for 6 months or less, whereas in the OSMC group 63 (67%) had their problems for one year or more (Table 3.3).

3.3 General Characteristics

The mean age of the Bridges and the OSMC groups was 44 and 43 years respectively. The mean height in the two groups was 1.64m and 1.63m and the mean weight 70.4kg and 72.1kg. There were no statistically significant differences between the study and control groups with respect to these physical characteristics. A similar number of women in each group were smokers; 21 (21%) in the Bridges group and 23 (25%) in the OSMC group (Table 3.4).

There were similar numbers of parous women in each group, 79 (80%) in the Bridges group and 82 (87%) controls. There were no significant differences between the two groups in terms of the number of births, miscarriages or terminations of pregnancy. The majority of women in both groups reported that they considered their families to be complete (84% vs. 90%) and therefore permanent methods of contraception in the form of male or female sterilization were the predominant choice. There were no statistically significant differences between the groups in contraceptive method (Table 3.5).

There were no significant differences between the two groups in terms of all socio-demographic characteristics except ethnicity. The majority of women were in a stable relationship, married or co-habiting; 77 (78%) in the study group and 73 (82%) in the OSMC group. Twelve women in the Bridges group and seven controls did not return their socio-demographic questionnaire, "Your Circumstances" (Appendix 7) despite three postal reminders at two week intervals. There were no significant differences in the numbers of women in full or part time work of any sort or those not in paid work. Levels of educational achievement and household income were also similar, although two additional women in the Bridges group and seven controls did not disclose their income. Most participants described their ethnic origin as white, with two (2%) non-white women in the Bridges group and 12 (13%) in the OSMC group.

3.4 Discussion

Overall, we secured a satisfactory level of participation amongst GPs, enabling recruitment of adequate numbers of patient participants according to our power calculations within the anticipated time-frame. Comparable levels of GP participation and recruitment have been noted in a similar prospective study recruiting women with menstrual disorders in Primary care[223]. Ensuring participation of GPs in research projects is generally accepted to be difficult and our results are similar to those reported in the literature[223-226]. Twenty-four patients in the OSMC group were referred by SL-PCT. A proportion of these were referred to the OSMC prior to the start of the Bridges Project, and some from GPs who did not utilize the Bridges Project at all. It is unclear how, if at all, this would influence health outcomes or patients experience of healthcare.

Few patients declined to be involved in the study, given the time commitment involved over the eight months. Levels of participation were higher in the Bridges group. It seems likely that this was owing to a greater sense of engagement with healthcare, and an improved experience leading to an altruistic desire to be involved with research that may help other women with similar problems.

The two groups were remarkably similar in all but three of the baseline characteristics. Approximately 10% more women in the OSMC group had a complaint of heavy menstrual bleeding, although the numbers of women complaining of both heavy and irregular bleeding were similar in both groups. This discrepancy might be accounted for by doctors' conceptualizations of patients' presenting symptoms. Broad menstrual complaints of cycle related changes, volume of loss and pain are re-framed as "menorrhagia" at referral, a perception which intensifies within the outpatient clinic setting and with subsequent management[159]. The Bridges Project Guidance contained specific advice on investigation management of irregular bleeding which may have reduced the need for both doctors and patients to re-frame irregular bleeding as heavy bleeding in order to access healthcare. Women receiving healthcare through the Bridges Project had had their problem for a significantly shorter time than their counterparts in the OSMC group. There is no reason to suppose that there were differences in the duration of the problem before presentation to the GP in the two groups. It is therefore likely that the Bridges Project provided healthcare that was more responsive to need in terms of prompt initiation of investigation regardless of presentation and shorter waiting time. This is supported by the results of the qualitative interviews (Chapter 7). There were significantly more women from non-Caucasian ethnic groups in the OSMC group although given that the absolute numbers in both groups were small and this is unlikely to affect overall results. High numbers of patients completed follow-up at eight months

ID Number	Reason for Withdrawal	Age	Marital Status	Parity	Symptoms
OSMC group					
18	No reason given	37	Single	2	Dysmenorrhoea
26	Moving to private sector	46	Married	2	Heavy + Dysmenorrhoea
84	No reason given	42	Married	2	Heavy + Irregular
89	No reason given	46	Divorced	4	Irregular
101	Too busy with work	48	Married	2	Heavy
110	Moving to another county	40	Married	3	
Bridges group					
520	Too busy with college course	23	Single	1	Heavy + Dysmenorrhoea

Table 3.1: Characteristics of withdrawn participants

Symptoms	Bridges (n=99)	OSMC (n=94)	P value	Difference in proportion	Lower 95% CI	Upper 95% CI
Heavy Bleeding	75 (76%)	82 (87%)	0.04	-0.11	0.00	0.22
Irregular Bleeding	69 (70%)	55 (56%)	0.58	0.11	-0.02	0.24
Dysmenorrhoea	45 (46%)	39 (41%)	0.11	-0.17	-0.17	0.13
PMS	27 (27%)	20 (21%)	0.33	-0.06	-0.06	0.18
4 Symptoms	**10 (10%)**	**11 (12%)**				
2 Symptoms	**29 (29%)**	**35 (37%)**				
Heavy + Irregular	17	19				
Heavy + Dysmenorrhoea	9	13				
Irregular + PMS	2	1				
Irregular + Dysmenorrhoea	1	1				
Heavy + PMS	0	1				
			0.31			
3 Symptoms	**29 (29%)**	**17 (18%)**				
Heavy + Irregular + Dysmenorrhoea	14	10				
Heavy + Dysmenorrhoea + PMS	10	3				
Heavy + Irregular + PMS	5	4				
1 Symptom	**31 (31%)**	**31 (33%)**				
Heavy	10	21				
Irregular	20	9				
Dysmenorrhoea	1	1				

Table 3.2: Presenting symptoms

Duration	Bridges (n=99)	OSMC (n=94)	P value
≤ 6 months duration	51 (52%)	12 (13%)	0.000
> 6 months ≤ 1 year	15 (15%)	19 (20%)	
>1 year	28 (28%)	63 (67%)	
Unknown	5 (5%)	0 (0%)	

Table 3.3: Duration of symptoms prior to investigation

Physical Characteristic	Bridges (n=99)	OSMC (n=94)	P value	Lower 95% CI	Upper 95% CI
Age at Recruitment					
Mean	44.14	43.39	0.39	-0.95	2.45
SD	6.84	4.92			
Median	45	43			
Range	23-54	29-54			
Height (m)					
Mean	1.64	1.64	0.38	-0.01	0.29
SD	0.068	0.07			
Median	1.65	1.63			
Range	1.47-1.85	1.47-1.80			
Weight (kg)					
Mean	70.48	72.11	0.42	-5.65	2.39
SD	11.94	15.68			
Median	69.5	69.9			
Range	44.5-108.0	47.7-120.7			
Smoking					
Non-smokers	78 (79%)	71 (76%)	0.59	-0.15	0.09
Smokers	21 (21%)	23 (25%)			

Table 3.4 Physical characteristics of participants

Characteristic	Bridges (n=99)	OSMC (n=94)	P value
Parity			
0	20 (20%)	12 (13%)	0.32
1	9 (9%)	8 (9%)	
2	32 (32%)	45 (48%)	
3	30 (30%)	23 (25%)	
4	6 (6%)	6 (6%)	
5	1 (1%)	0 (0%)	
6	1 (1%)	0 (0%)	
Miscarriages			
0	77 (78%)	70 (75%)	0.73
1	14 (14%)	18 (19%)	
2	5 (5%)	5 (5%)	
3	2 (2%)	1 (1%)	
4	0 (0%)	0 (0%)	
5	1 (1%)	0 (0%)	
Terminations			
0	78 (79%)	72 (77%)	0.55
1	20 (20%)	21 (22%)	
2	0 (0%)	1 (1%)	
3	1 (1%)	0 (0%)	
Family Complete			
Yes	83 (84%)	85 (90%)	0.31
No	9 (9%)	4 (4%)	
Unsure	7 (7%)	5 (5%)	
Contraceptive Method			
None / Not required	29 (29%)	32 (34%)	0.55
Female Sterilization	21 (21%)	25 (27%)	
Male Sterilization	23 (23%)	22 (22%)	
Barrier	13 (13%)	9 (10%)	
OCP	6 (6%)	4 (4%)	
IUCD	4 (4%)	0 (0%)	
Mirena IUS	1 (1%)	0 (0%)	
DepoProvera / Implant	1 (1%)	0 (0%)	
Natural Method	1 (1%)	2 (2%)	

Table 3.5: Reproductive history

Characteristic	Bridges n=99	OSMC n= 94	P value
Marital status			
Married	75 (76%)	62 (70%)	0.07
Single	9 (9%)	5 (5%)	
Living with partner	2 (2%)	11 (12%)	
Divorced	7 (7%)	6 (6%)	
Widowed	0 (0%)	1 (1%)	
Separated	6 (6%)	9 (10%)	
Employment			
Full time work	38 (38%)	43 (46%)	0.59
Part time work	34 (34%)	30 (32%)	
Not in paid work	15 (15%)	14 (15%)	
Unknown	12 (12%)	7 (7%)	
Type of employment			
Managerial etc	19 / 72 (26%)	19 / 73 (26%)	0.68
Clerical etc	28 / 72 (39%)	29 / 73 (40%)	
Small Employer etc	3 / 72 (4%)	1 / 73 (1%)	
Lower Supervisory etc	6 / 72 (8%)	4 / 73 (5%)	
Routine	15 / 72(21%)	20 / 73(27%)	
Other	1 / 72 (1%)	0 / 73(0%)	
Household income per annum			
< £5000	2 (2%)	5 (5%)	0.66
£5000 – 11 999	20 (20%)	19 (20%)	
£12 000 – 19 999	17 (17%)	18 (19%)	
£20 000 – 29 999	12 (12%)	15 (16%)	
£30 000 – 44 999	23 (23%)	17 (18%)	
£45 000 – 59 999	8 (8%)	5 (5%)	
£60 000 +	3 (3%)	1 (1%)	
Unknown	14 (14%)	14 (15%)	
Educational Achievement			
Secondary School	38 (38%)	46 (49%)	0.61
A level / AS level	8 (8%)	4 (4%)	
Vocational / Trade / College	26 (26%)	24 (26%)	
Degree level	10 (10%)	10 (11%)	
Post-graduate	5 (5%)	3 (3%)	
Unknown	12 (12%)	7 (7%)	
Ethnic Origin			
White	85 (86%)	75 (80%)	0.02
Black Caribbean	0 (0%)	1 (1%)	
Indian	1 (1%)	7 (7%)	
Asian – Other	0 (0%)	2 (2%)	
Other	1 (1%)	2 (2%)	
Unknown	12 (12%)	7 (7%)	

Table 3.6: Socio-demographic characteristics

Chapter 4: Clinical Outcomes and Resource Use

4.1 Introduction

There are wide variations in clinical outcome in terms of treatment for menstrual disorders and subsequently the cost of providing care. The differences, particularly in terms of rates of hysterectomy between different countries, regions and patient groups are well documented[25,227,228]. The reasons for this variation appear to be multi-factorial, and depend on the patient's decision to consult her GP, the GPs decisions regarding treatment and referral to a gynaecologist and the decision of both the patient and the gynaecologist regarding further treatment which is likely to be influenced by the outcome of investigations and the diagnosis[227]. Historically there has been a widely held view that gynaecologists exploit women by undertaking unnecessary hysterectomies in the absence of identifiable pathology[229,230]. Research suggests however, that physician characteristics play a secondary role to patient and clinical factors in explaining differences in rates of hysterectomy[231] and that patient factors other than diagnosis have a significant impact on treatment outcomes with many patients holding a strong preference for treatment formulated prior to any contact with a gynaecologist[232-234]. Women with a preference for surgery do appear to deploy specific communication strategies during the consultation that influence gynaecologists decision-making[229,235].

Whilst the debate surrounding optimal modes of investigation and treatment for menstrual disorders (particularly the perceived high financial burden of hysterectomy in the absence of structural pathology) will undoubtedly continue, the Bridges Project aimed to apply the same guidelines (based on the best available evidence) in use in the OSMC to the primary care setting. It was hypothesised that the new GP-led pathway of care utilising evidence-based guidelines (provided the two groups were clinically similar and the guidelines were adhered to) would produce similar clinical outcomes at the same or reduced cost to those seen in the consultant-led OSMC.

4.2 Aim

To classify the diagnosis for each patient, to ascertain the degree of adherence to the guideline and resource use in terms of number of contacts with healthcare providers, investigations, treatments and mode of treatment at 8 months, and overall costs..

4.3 Method

Data was collected for all patients in the study at the time of recruitment and eight months later. At exit, hospital case notes and integrated care records were reviewed for the investigations performed, the indication for each, the results and subsequent diagnosis. The investigations undertaken for each patient and the timing of these with respect to commencement of treatment was used to assess adherence to guidelines. The agreed guideline stated that all women should have a full blood count and thyroid function tests performed. Pelvic ultrasound was advised where structural pathology was suspected, or clinical examination was difficult. It was recommended that endometrial assessment be undertaken prior to medical treatment for women 40 years old or over and those complaining of irregular bleeding. Eight months after entry to the study women were contacted by post and asked to provide details of the number of GP consultations they hade made and the types and duration of use of medical treatments they had received during the study period and whether or not treatment was ongoing. A trial of two medical treatments was recommended for women under 40 with regular cycles prior to investigation. Case notes were examined to ascertain if treatment had been prescribed prior to investigation and whether this was appropriate given presenting symptoms. The number of hospital appointments was recorded along with details of surgical interventions undertaken or planned.

Resource use and costs were considered from both an NHS (direct costs) and a societal perspective (indirect costs) as per suggested best practice[236]. Items were identified through discussions within the project steering committee and dialogue with all the staff involved in the delivery of the various services. The direct costs of the two models of care are supplied in Table 4.1 and fall under the following main broad headings:

1. **OSMC resources** included the labour costs for the clinic staff during the clinic; consultants (salary based upon mid point of consultant salary scale with effect from 2003 + 3% for 2004-2005), staff nurse (E grade, scale as above), healthcare assistants (A grade, point 4, as above) and for the clinic administrator (Adminstrative and Clerical grade 4, as abovethe time spent during the clinic and on administrative tasks to prepare for the clinic e.g. locating and collecting case notes. The labour costs of the ultrasonographer, hysteroscopist and histopathologist was deemed to be subsumed in the cost of ultrasound scan, hysteroscopy and endometrial biopsy.

2. **Bridges Project Clinic resources** included the cost of a healthcare assistant and the costs of clinic administration as above. The cost of the doctor performing the hysteroscopy was deemed to be subsumed in the hysteroscopy procedure cost.

3. **GP consultation resources** were based on an hourly rate for GP time and GP appointments were assumed to last for 15 minutes, based on the average figure given for a consultation for a menstrual problem provided by three GPs.

4. **Hospital administration costs** relate to the costs of sending initial appointment letters and maps to patients along with reminder letters and the time spent communicating with patients by phone.

5. **Investigation resources** include the costs of ultrasound, outpatient hysteroscopy and laparoscopy as supplied by the gynaecology services manager in 2002.

6. **Pathology resources** included costs for full blood counts, thyroid function tests and processing and reporting of endometrial pipelle biopsies as supplied by the laboratory manager in 2002.

7. **Medical treatment resources** included the following treatments as per the regime in the agreed guideline: combined oral contraceptives, tranexamic acid (for seven days), mefanamic acid (for seven days), danzol, provera, norethisterone and fluoxetine. Treatments used which were not covered by the guideline included ethamsylate (500mg four times daily), HRT (Prempak-C), metformin (500mg twice daily), and leuprorelin (3.75mg depot injection). Mirena IUS was considered as a one off cost, for which the cost of fitting was added. Costs were supplied by the gynaecology lead pharmacist.

6. **Surgical treatment resources** included the procedure costs of hysteroscopic laser polypectomy, endometrial ablation and hysterectomy, supplied by the gynaecology services manager.

The costs for employer's superannuation and employers national insurance contributions were included in all the labour costs.

The collection of indirect costs was undertaken through patient questionnaires filled in at the time of their first attendance at the hospital outpatients department regarding the costs incurred by them when attending for healthcare. Cost to patients for travel and childcare were considered as were costs incurred by patients and companions through absence from work. Participants were invited to record any other costs incurred as a result of attending for healthcare e.g. parking costs. Copies of these questionnaires can be found in Appendix 7. The indirect costs were not continuously monitored throughout the trial in order to minimise the burden on participants. The initial costs reported by patients for visits to the GP and visits to the hospital were therefore multiplied by the average number of visits patients made, to provide an approximation of overall indirect costs.

4.4 Study Population

A detailed description of the study population can be found in Chapter 3.

4.5 Data Handling and Statistical Analysis

Data was stored on a Microsoft Access database. Results were summarized as mean values with standard deviation, or as frequencies, as appropriate. The chi-squared test or Fisher's exact test were used to compare the two groups. Statistical significance was defined at the 5% level. All analyses were carried out using the statistical computer package SPSS version 11 (SPSS Inc, Chicago, USA).

4.6 Results

There was no statistically significant difference between diagnoses in the two groups. No structural pathology was found in 54 (55%) of the Bridges group and 56 (60%) of the OSMC group. Accordingly, the majority of women in both groups were found to have either normal proliferative or secretory endometrium on pipelle biopsy. There was no statistically significant difference in terms of endometrial histology. Two patients in the Bridges group were found to have endometrial cancer at the time of initial endometrial biopsy, and two women in the OSMC group were found to have endometrial hyperplasia on pipelle biopsy but both proved to have endometrial cancer at hysterectomy (Table 4.2). The mean haemoglobin at presentation in the Bridges group was 12.5 g/dL and 12.7 g/dL in the OSMC group; two women in the Bridges group and one in the OSMC group were found to be hypothyroid. These were not statistically significant differences.

Sixty three (64%) of women in the Bridges group and 93 (99%) in the OSMC had their FBC at least once. This test was duplicated seven times in the Bridges group and 23 times in the OSMC. Seventy-seven (78%) Bridges and 57 (61%) OSMC (4 duplicates) patients had their thyroid function checked. On case note review, a valid indication for a pelvic ultrasound scan was identified in 32 (32%) of the Bridges group; 70 scans were performed, thus 46% of these were clinically indicated. In the OSMC a clear indication was present for 51 (55%) patients and 96 scans were undertaken (9 of which were duplicates), 59% of them appropriately. Therefore in terms of blood tests and ultrasound scans more patients were tested appropriately in the OSMC group, but there was also more duplication of investigation incurring higher costs. Hysteroscopy and biopsy was

indicated in 94 (95%) of Bridges patients and undertaken in all of them. In the control group 85 (91%) had symptoms warranting hysteroscopy and this was done in 82 cases. (Table 4.3) Timing of referral for investigation (in the form of endometrial assessment) with respect to initiation of medical treatment was deemed to be in accordance with the guideline in 82 (83%) women in the Bridges group compared to 63 (64%) in the OSMC.

After eight months 79 (80%) women in the Bridges group and 69 (73%) women in the OSMC group responded with details of the treatments they had used during the study and the number of times they had consulted their GP. There were no statistically significant differences in the number of women not on treatment, those on medical treatment, and those who had undergone or were awaiting surgery between the two groups ($p = 0.789$). Twenty women in the Bridges group and 15 in the OSMC group did not receive any treatment during the study. Four Bridges patients underwent a minor outpatient procedure (avulsion of cervical polyp and cryo-cautery to cervix) and two in the OSMC. (Table 4.4) The costs of medical treatments were therefore similar in the two groups although the costs of surgical treatment in the OSMC group were higher given that four more women had a hysterectomy, the most costly intervention (Table 4.5).

Information relating to *all* direct costs was only available for patients who responded to follow-up questionnaires at eight months. It was possible to obtain missing information from case notes apart from details of follow-up consultations in primary care and any medical treatments issued by primary care.

The total direct cost of the two models of care were £71 362.02 (£ 720.83 per patient) in the Bridges group and £92515.87 (£984.21 per patient) in the OSMC group, a difference of £21 153.85 in total or £263.38 per patient (Table 4.5). This was despite the fact that ten more women in the Bridges group responded to follow-up. The main difference in cost seems to arise mainly from differences in utilisation of services in secondary care. Only 23 Patients managed in the Bridges project were referred for a consultation in the One-Stop menstrual clinic (those deemed to be "complex cases" by their GP), meaning that 76 attended the Bridges clinic at a cost of £28.31 per attendance compared to £77.27 for an appointment at the One-stop clinic. Administration costs in

the Bridges group were lower, as most communication took place by fax and telephone rather than letter, although this was not a major cost driver. The decrease in utilisation of hospital outpatient appointments did not appear to lead to an increase in attendances in primary care (170 visits in the Bridges group and 164 in the OSMC group), and the costs involved in primary care were similar in the two groups. (Table 4.3)

Eighty-nine (90%) of women in the Bridges group and 87 (93%) in the OSMC provided information regarding the costs they incurred when attending the GP surgery, and 86 (87%) and 82 (87%) respectively provided the same information for attendance at the hospital outpatient department (Table 4.6). Overall the costs between the two groups were very similar. The average cost per patient of one attendance at the GP surgery in the Bridges group was £5.04 and £5.68 in the OSMC group. The cost one of attending the hospital outpatient department was £20.29 and £19.75 respectively (Table 4.7) Given that the women in the Bridges group attended the both the GP surgery and the outpatients department slightly less frequently the overall indirect costs per patient were £7.45 lower in the Bridges project than the OSMC (Table 4.5).

The overall costs for the Bridges project were therefore £21 698.84 lower in the Bridges project than the OSMC group, a saving of £270.82 per patient.

4.7 Discussion

The incidence in the general population of the various pathologies underlying menstrual disorders is unknown. Given the conceptual and diagnostic difficulties surrounding the diagnosis of abnormal menstrual bleeding this is not entirely surprising. This does mean however that it is difficult to draw comparisons between the women we studied and other groups of women in the population with menstrual disorders. There are reports of three other UK based one-stop menstrual clinics in the literature, which might be assumed to be serving populations roughly similar to ours, although these are not reported in detail[209,212]. Our rates of women with no structural pathology and proliferate endometrium are broadly similar, although diagnoses of endometrial polyps and fibroids were made less commonly in the women we studied. The rate of endometrial carcinoma in our study was 2% and although similar to that reported by Jones and Bourne[209] is

much higher than the 0.08% incidence for pre-menopausal women estimated by the RCOG Menorrhagia Guideline Development Group[49] (Table 4.3).

More important for the purposes of this study was whether the interpretation and application of the Bridges Project guideline was the same in primary care as in the OSMC. Adherence to all aspects of the guideline was not complete in either group, nor would this be expected given that guidelines are not intended to be rigidly adhered to, but rather "interpreted sensibly and applied with discretion" in any given clinical situation[237] Women receiving GP-led care through the new scheme appeared less likely to have blood tests performed than those attending the OSMC; for both groups the numbers of apparently clinically indicated USS were approximately half of those actually performed. The new scheme did appear to improve the numbers of women undergoing appropriate investigation in the form of hysteroscopy, and more women were investigated appropriately before a commencement of medical treatment, which is of clinical importance given the 2% incidence of endometrial malignancy.

The strikingly similar numbers of women in each group receiving no treatment, medical treatment and surgical treatment (or awaiting the same) provide strong evidence that the guideline was interpreted and implemented similarly in both primary and secondary care. This may also lend weight to the theory that whilst referral to a gynaecologist has been observed to be associated with subsequent hysterectomy, it is possible that it in the case of women who are referred to hospital, the gynaecologist and GP concur as to the severity of the disease being troublesome enough to warrant surgery[227]

The Bridges project resulted in a lower cost to the health service and to patients than the OSMC. Integration of primary and secondary care sectors allowed for a reduction in duplication of workload, both in terms of consultation and investigations. A thorough assessment in primary care at the time of first presentation meant that in 77% of cases an appointment for a consultation in the more costly one-stop menstrual clinic in secondary care was avoided. This was achieved without an increase in workload in primary care.

4.8 Conclusion

Implementation of guidelines in the new scheme was comparable to that in the consultant led OSMC, demonstrated by similar rates of investigation and treatment in the two groups. GP led management of menstrual disorders allowed the initial consultation in primary care to be more effective, improving the timing of appropriate endometrial assessment vital for the early detection of serious pathology. There was a reduction in duplication of investigations across primary and secondary sectors without an increase in primary care workload, resulting in an overall saving of £270.82 per patient.

Resource	Unit cost
Menstrual clinic attendance	£ 77.27
Bridges Project clinic attendance	£ 28.31
GP visit	£ 43.81
Hospital administration costs	
Appointment letter + reminder	£ 0.60
Phone calls	£ 0.20
Investigation	
Ultrasound scan	£ 111.00
Hysteroscopy	£ 149.00
Laparoscopy	£ 710.00
Pathology	
FBC	£ 13.00
TFT	£ 15.00
Endometrial Biopsy	£ 75.00
Medical treatments	One month's supply
COCP	£ 0.94
Tranexamic acid	£ 9.54
Mefenamic acid	£ 0.43
Danazol	£ 53.16
Norethisterone	£ 10.37
Fluoxetine	£ 6.83
Tranexamic acid + Mefenamic acid	£ 9.97
Ethamsylate	£ 21.13
HRT	£ 22.16
Metformin	£ 2.31
Leucoperelin	£ 125.40
Mirena	£ 159.18
Surgical treatments	
HLP	£ 710.00
Endometrial Ablation	£ 710.00
Hysterectomy	£2681.00

Table 4.1: Resources measured and unit costs

	Bridges (n=99)	OSMC (n=94)
Diagnosis		
No Structural Pathology	54 (55%)	56 (60%)
Endometrial Polyps	10 (10%)	6 (6%)
Submucous Fibroids / Fibroid Polyps	14 (14%)	8 (9%)
Intramural Fibroids ≤ 12 weeks size	6 (6%)	10 (11%)
Intramural Fibroids ≥ 12 weeks size	1 (1%)	2 (2%)
Intramural Fibroids and endometrial polyps	1 (1%)	2 (2%)
Cervical Polyp(s)	3 (3%)	3 (3%)
Endometriosis	1 (1%)	2 (2%)
Endometrial Carcinoma	2 (2%)	2 (2%)
Secondary to DepoProvera	1 (1%)	0 (0%)
Secondary to POP	0 (0%)	1 (1%)
Secondary to IUCD	2 (2%)	1 (1%)
Cervical Stenosis	0 (0%)	1 (1%)
Cervical Ectropion	2 (2%)	0 (0%)
Vaginal Stricture	1 (1%)	0 (0%)
Uterus Didelphys	1 (1%)	0 (0%)
Endometrial Histology		
Proliferative	28 (28%)	33 (34%)
Secretory	31 (31%)	25 (27%)
Anovulation	0 (0%)	1 (1%)
LPD	5 (5%)	4 (4%)
Drug Effect	9 (9%)	5 (5%)
Inactive	6 (6%)	3 (3%)
Hyperplasia	0 (0%)	2 (2%)
Carcinoma	2 (2%)	0 (0%)
Not Sufficient	1 (1%)	0 (0%)
Not Done*	2 (2%)	12 (13%)
Dyssynchronous Proliferative	9 (9%)	3 (3%)
Dyssynchronous Secretory	4 (4%)	4 (4%)
Menstrual	2 (2%)	2 (2%)
*Not Done Because:		
For TAH	0	1
Problem resolved	0	2
Not Indicated	1	8
Overlooked	0	1
At patient's request	1	0

Table 4.2: Diagnosis and endometrial histology

Resource	Units consumed	
	Bridges	OSMC
Menstrual clinic		
Initial appointment	23	94
Follow-up appointment	14	36
Bridges Project clinic	76	0
Total number of GP visits	164	170
Hospital administration costs		
Appointment letter + reminder	37	130
Phone calls	99	94
Investigation		
Ultrasound scan	70	96
Hysteroscopy	94	82
Laparoscopy	3	7
Pathology		
FBC	69	116
TFT	77	61
Endometrial Biopsy	93	81
	Total number of cycles of treatment prescribed to all women	
Medical treatments		
COCP (microgynon30)	36	23
Tranexamic acid	116	72
Mefenamic acid	17	49
Danazol	0	3
Norethisterone	42	45
Fluoxetine	5	5
Tranexamic acid + Mefenamic acid	27	25
Ethamsylate	8	0
HRT	16	0
Metformin	0	5
Leuprorelin	0	5
Mirena (number of IUS fitted)	2	3
Surgical treatments		
HLP	3	0
Endometrial Ablation	1	4
Hysterectomy	8	12

Table 4.3: Resources used in the OSMC and the Bridges Project

	All participants		Responders to follow-up	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=79)**	**OSMC (n=69)**
Not using any treatment at 8 months	-	-	**45 (57%)**	**36 (52%)**
Using medical treatment at 8 months	-	-	**18 (23%)**	**16 (23%)**
Tried one medical treatment during study	-	-	54 (68%)	50 (72%)
Tried second line medical treatment during study	-	-	23 (29%)	27 (39%)
Tried third line medical treatment during study	-	-	6 (8%)	7 (10%)
Surgical treatment	**12 (12%)**	**16 (17%)**	**11 (14%)***	**11 (16%)**
Hysteroscopic laser polypectomy	3 (3%)	0 (0%)	3 (4%)	0 (0%)
Endometrial ablation	1 (1%)	4 (4%)	1 (1%)	1 (1%)
Abdominal hysterectomy	8 (8%)	12 (13%)	7 (9%)	10 (14%)
Awaiting surgical treatment	**5 (5%)**	**9 (10%)**	**5 (6%)**	**6 (9%)**
Hysteroscopic laser polypectomy	1 (1%)	1 (1%)	1 (1%)	1 (1%)
Endometrial ablation	0 (0%)	4 (4%)	0 (0%)	1 (1%)
Total abdominal hysterectomy	4 (4%)	3 (3%)	4 (5%)	3 (4%)
Vaginal hysterectomy	0 (0%)	1 (1%)	0 (0%)	1 (1%)

Table 4.4: Treatments used during the study period

* Including one failed Laser ablation of the endometrium awaiting hysterectomy

	Total Actual Cost		Average cost per patient	
	Bridges	OSMC	Bridges (n=99)	OSMC (n=94)
Direct Costs				
Menstrual clinic	£ 2 858.99	£ 10 045.10	£ 28.74	£ 106.86
Bridges Project clinic	£ 2 151.56	£ 0	£ 21.73	£ 0
GP visits	£ 7 184.84	£ 7 447.70	£ 72.57	£ 79.23
Hospital administration	£ 42.00	£ 96.80	£ 0.42	£ 1.03
Investigation	£ 23 906.00	£ 27 844.00	£ 241.47	£ 243.34
Pathology costs	£ 8 202.00	£ 9 698.00	£ 82.85	£ 103.17
Medical treatments	£ 2 728.63	£ 2 372.27	£ 27.56	£ 25.24
Surgical treatments	£ 24 288.00	£ 35 012.00	£ 245.33	£ 372.47
Total direct costs	**£ 71 362.02**	**£ 92 515.87**	**£ 720.83**	**£ 984.21**
Indirect Costs				
For attendances at GP surgery	£ 826.56	£ 965.60	£ 8.34	£ 10.27
For hospital attendances	£ 2231.75	£ 2637.70	£ 22.54	£ 28.06
Total indirect costs	**£ 3058.31**	**£ 3603.30**	**£ 30.88**	**£ 38.33**
Overall Costs	**£ 74 420.33**	**£ 96 119.17**	**£ 751.72**	**£1 022.54**

Table 4.5: Direct, indirect and overall costs of the OSMC and the Bridges Project

Indirect cost	Bridges	OSMC
When attending the GP surgery		
Transport		
Number of women travelling by car	58	52
Total number of miles travelled by car	130	158.75
Number travelling by bus/train	1	3
Patient's absence from work		
Number of patients taking time off work	27	32
Number loosing money as a result	5	4
Companion's absence from work		
Number of companions taking time off work	5	12
Number loosing money as a result	2	2
Number paying for childcare	2	2
Number incurring additional costs	0	0
When attending the hospital outpatient dept.		
Transport		
Number of women travelling by car	60	60
Total number of miles travelled by car	413	413
Number travelling by bus/train	14	10
Number travelling by taxi	1	4
Patient's absence from work		
Number of patients taking time off work	38	49
Number loosing money as a result	12	13
Companion's absence from work		
Number of companions taking time off work	29	33
Number loosing money as a result	12	7
Number paying for childcare	2	3
Number incurring additional costs	49	44

Table 4.6: Numbers of women incurring indirect costs

Indirect costs	**Bridges**	**OSMC**
When attending GP surgery		
Transport	£ 327.05	£ 402.93
Patient's absence from work	£ 75.60	£ 65.52
Companion's absence from work	£ 90.00	£ 40.00
Childcare	£ 6.80	£ 25.00
Total cost of all first attendances at GP surgery	**£ 499.45**	**£ 533.45**
Average cost per attendance at GP surgery	**£ 5.04**	**£ 5.68**
When attending hospital outpatients dept.		
Transport	£ 1100.50	£ 1108.50
Patient's absence from work	£ 259.00	£ 368.00
Companion's absence from work	£ 477.00	£ 293.00
Childcare	£ 10.00	£ 50.00
Additional costs	£ 109.00	£ 88.00
Total cost of all first attendances at hospital	**£ 1955.50**	**£ 1907.50**
Average cost per attendance at hospital	**£ 19.75**	**£ 20.29**

Table: 4.7: Total indirect costs and average costs per patient

	Baskett et al[212]	Jones and Bourne[209]	Dueholm et al[210]
Histology			
Proliferative	29 %	-	16 %
Secretory	21 %	-	6 %
Hyperplasia	0 %	-	11 %
Other			
Diagnosis			
No Structural Pathology	-	55 %	40 %
Endometrial Polyps	12 %	15 %	16 %
Intramural Fibroids / Submucous Fibroids / Fibroid Polyps	71 %	20 %	40 %
Endometriosis	-	1 %	-
Endometrial Carcinoma	-	3 %	-
Treatment plan at first visit			
None	36 %	-	24 %
Medical	31 %	-	25 %
Surgical	29 %	-	41 %

Table 4.8: Comparison with outcomes from other OSMC

Chapter 5: Health Outcomes

5.1 Introduction

Subjective health status is a concept, which although poorly defined aims to incorporate the ideas inherent in the WHO statement "health is state of complete physical, mental and social well being and not merely the absence of disease"[238]. In addition to mortality, morbidity, and patient satisfaction, subjective health status is an outcome of health care as well as a consequence of illness[239].

In the context of menstrual disorders, women's perception of their own well-being is important for several reasons. The majority of women complaining of menorrhagia have no identifiable structural pathology and menorrhagia is not usually a serious or life threatening illness[240]. Given the difficulties with definition, diagnosis and thresholds for referral and treatment, and that menstrual disorders can cause considerable discomfort, social embarrassment and disruption to life for many women[241,242], it is therefore appropriate to include some measure of self-assessed health status when considering the outcome of interventions for menstrual disorders[243].

Measures of health status can either be generic, usable across whole populations and a range of conditions affecting health, or disease specific, designed for use in with a specific patient group. Measures should be psychometrically sound, able to detect differences in health in different illnesses and sensitive to changes in health status over time[239]. Widely used generic measures include the Sickness Impact Profile[244] (called in the UK the Functional Limitations Profile)[245], the Nottingham Health Profile[246], Dartmouth COOP charts[247], the EuroQol EQ-5D[248] and the Short Form measures SF-36, SF-20 and SF-12[249,250].

5.1.1 The Short Form 36 (SF-36)

The SF-36 UK version 2 is generic measure of self-assessed health status containing 36 questions. It is the most frequently used generic health status survey in the context of menorrhagia[251]. It was developed in the USA from a questionnaire consisting of 149 questions covering 40 health concepts developed and tested on a population of over 22000 patients as part of the Medical Outcome Study[252]. The study was concerned with investigating how specific components of the United States health care system affected

outcomes of care and one of the main objectives was to produce a practical tool for monitoring patient outcomes in a busy clinical setting. The survey yields eight multi-item dimensions believed to be most affected by illness and conditions affecting health; physical functioning (10 items), role limitations due to physical problems (4 items), bodily pain (2 items), general perception of health (five items), energy and vitality (4 items), social functioning (two items), role limitations due to emotional problems (three items) and mental health (five items). There is an additional un-scaled single item on changes in health over the past year[253].

The measure had been shown to be clinically and psychometrically sound in the US population and has also been extensively evaluated for use within the general UK population including the generation of a set of UK norms[254-258]. It has been demonstrated to be acceptable to patients with response rates to postal surveys usually higher than 75%[254].There appear to be high levels of internal validity[254], good test-re-test properties, high levels of internal consistency[254,256] and sensitivity to change in health status over time[255]. It is also thought to be more responsive to lower levels of sickness and disability than other generic measures of health[239] e.g. Nottingham Health Profile, important in the context of menstrual disorders. Another advantage of the SF-36 for the purposes of our study is its brevity and simplicity. It is far more concise than other surveys e.g. The Functional Limitations Profile, being able to be completed by the average respondent in less than 10 minutes[253]. As participants were also being asked to fill in several other questionnaires, it was important to keep the burden on them as low as possible to ensure high levels on ongoing participation. Relative to the standard SF-36, version 2 of the SF-36 has improvements in layout and wording of some questions, and replaces dichotomous choices for seven items with a five level response set. These improvements have led to increased precision and sensitivity to change, important for studies involving longitudinal group comparisons[258,259].

The psychometrics of the SF-36 have been investigated in the context of menorrhagia. It has been found to be sensitive to changes in health status over time[255]. In the only direct comparison of general health measures undertaken in women with menorrhagia, the SF-36 was found to be superior in this respect to single-item measures of general health such as the EQ-5D[260]. Although the internal reliability of the SF-36 when used in women with menorrhagia is generally high, concerns have been raised that this is lower

than in the general population for the dimensions general health, mental health and social functioning and at a level where caution needs to be exercised when considering its use with single individuals, although it is acceptable for group comparisons[261]. The lower internal reliability appears to be related to issues with the face validity (referring to how the questions are interpreted and understood by those answering them) of some of the questions in the context of menorrhagia. The time frame referred to (four weeks) in some questions can present a problem for women with menorrhagia as their symptoms are not continually present, and may or may not have been present during the previous 4 weeks[261].

It therefore recommended that the SF-36 should not be used alone, but as part of a more comprehensive portfolio of measures to assess many aspects of outcome and should always be used in conjunction with a disease specific measure of health status in order to ensure sensitivity to changes in health[251,253,256,261].

5.1.2 The Multi-Attribute Scale for Menorrhagia

A literature search was therefore conducted to identify a suitable disease-specific measure of health for use in women complaining of menorrhagia. Five questionnaires relating specifically to menstrual health and menorrhagia were discovered. The Menorrhagia Outcomes Questionnaire was designed specifically for use in women who had undergone surgery as a result of their menstrual problems[243]. As not all women in our study would undergo surgery, this measure was unsuitable. The Menstrual Attitude Questionnaire was also unsuitable as it was designed primarily to define attitudes to menstruation rather than in order to measure health as a consequence of menstrual problems[262]. The Menstrual Distress Questionnaire was discounted as it was developed in 1968[263]. Given the socio-political changes that have taken place since then, it would possibly not accurately reflect the attitudes and concerns of women today. The two remaining questionnaires, the first a described as a structured clinical history[242], and the second as a multi-attribute utility assessment[241] were both suitable for our purposes. Both were developed in the UK in the 1990s, have been validated for use in the intended population and generate a numerical score. Both questionnaires showed some overlap with the questions asked in the OSMC forms. In the final analysis a pragmatic decision to use the multi-attribute utility assessment was made as it contains less than

half the number of questions in the alternative, thereby minimising the burden of paperwork on the participants.

5.2 Aim

To assess the impact of the Bridges Project pathway of care on patient's self assessed health status.

5.3 Method

The SF-36v2 ("General Health Questionnaire") and the Multi-attribute scale for menorrhagia ("Menstrual Health Questionnaire") were issued to participants in the form of an A4 booklet at the time of the first attendance to the hospital gynaecology outpatients department. In accordance with the recommendations for the administration of the SF-36v2, women were asked to fill out the general health questionnaire followed by the menstrual health questionnaire whilst waiting in the clinic prior to being seen. Questionnaires were then returned to the clinic reception or in the pre-paid envelope provided. Three postal reminders were sent at two-week intervals to women who did not return their questionnaires. Eight months after recruitment women were asked to complete the general and menstrual health questionnaires again. These were issued by post in the same format, with the rest of the exit material. Three postal reminders were employed at two-week intervals to maximise the response rate. Copies of the questionnaires can be found in Appendix 3.

5.4 Study Population

A detailed description of the study population can be found in Chapter 3.

5.5 Data Handling and Statistical Analysis

The data were entered into a Microsoft Access database.

5.5.1 General Health Questionnaire

Overall response rates at entry and exit to the study were calculated from the number of women returning questionnaire as a percentage of the whole group. The number of usable responses for each dimension of the SF-36v2 was then calculated as a percentage of the total number of returned questionnaires. The change in score for each dimension was calculated for each patient where scores were available at both exit and entry, by subtracting the score at entry from the exit score. The usable response rate for change in score for each dimension was calculated as a percentage of the total number of patients in each group.

SF-36 scale scores were calculated according to the SF-36 v.2 manual in the following stages[259]. Raw scores for each item are first recalibrated for 10 negatively worded items, raw scale scores are then calculated by summing all items for that scale. These are transformed to a 0-100 scale (with a mean of 50 and a standard deviation of 10). The final stage involves transformation of the 0-100 scale to norm based scoring using published population means.

5.5.2 Menstrual Health Questionnaire

The response rate at entry was calculated from the number of patients returning their questionnaire as a percentage of the whole group. At exit, some responders were not menstruating and so were ineligible to complete the menstrual health questionnaire. The usable response rate was calculated from the number of usable questionnaires as a percentage of those still menstruating. The change in menstrual score was calculated for each patient where scores were available at both exit and entry by subtracting the entry from the exit score. The usable response rate for change in score was calculated as a percentage of responders eligible to complete the exit questionnaire.

5.5.3 Statistical Analysis

Statistical analysis was performed using SPSS version 11 (SPSS Inc, Chicago, USA). Results were summarised as mean values and comparisons between the two groups were made using Student's t-test. Corresponding 95% confidence intervals were then calculated. Statistical significance was defined at the 5% level throughout.

5.6 Results

5.6.1 General Health Questionnaire

The response rates to the entry and exit general health questionnaire was over 70% in all cases and were comparable in the Bridges and OSMC group. The vast majority of the returned questionnaires were filled out correctly. It was possible to calculate the change in score for over 68% of participants (Table 5.1).

There were no statistically significant differences in scores between the two groups at entry. When compared to both US and UK population norms the baseline scores were lower than average (but generally within one standard deviation) for all dimensions except physical functioning in the Bridges group, which was 50.43. At the end of follow-up at 8 months, the scores in both groups showed moderate improvements approaching population means for all dimensions except general health in which there was a small decline. The scores for physical functioning reached the population mean in both groups, as did the score for the dimension role-emotional (reflecting ability to carry out work or other daily activities as a result of emotional problems) in the OSMC group. This was the only dimension in which a statistically significant difference in the scores of the two groups was observed, showing an improvement from 40.78 to 49.51 in the OSMC group compared to the Bridges group, which showed a more modest improvement from 43.32 to 45.43 (Table 5.2, Table 5.3 and Table 5.4).

5.6.2 Menstrual Health Questionnaire

There was also a good response rate for the menstrual questionnaire, over 90% of participants returned the questionnaire at entry and it was possible to calculate scores for the majority of returned questionnaires. (Table 5.5) There were no significant differences in the menstrual questionnaire score at entry. At the end of the follow-up period the score had improved in both groups from 49.96 to 60.93 in the OSMC group and from 44.23 to 57.48 in the Bridges group, but there was no statistically significant difference between the two. (Table 5.6)

5.7 Discussion

Health status, as measured by both instruments generally improved over the eight month study period in both groups. The only statistically significance difference between the two groups was the increase in the "role-emotional" (relating to problems with work or other daily activities as a result of emotional problems) dimension in the OSMC group, although paradoxically a decline in the dimension "general health" was observed. It remains unclear as to why a significant increase was observed for the "role emotional" dimension in the OSMC over the Bridges group, and neither can the decline in the "general health" dimension be accounted for, although the same pattern was reported by Cooper et al after 5 years follow up of women randomised to medical treatment or trans-cervical resection of endometrium (TCRE) with no satisfactory explanation[264].

Although the health of the women in our study generally improved after treatment, they still had generally slightly lower general health status than both the UK and US population. Unfortunately, there is no guidance for either the SF-36 or the menstrual questionnaire as to the clinical meaning of the magnitude of changes observed in terms of gains in health status. Comparison with other studies is problematic. There are no other studies which report longitudinal data generated from the menstrual questionnaire, although it has been used to assess the outcome of outpatient thermal balloon ablation in 53 women in the UK. Health status was measured six months after ablation; in the group satisfied with the procedure the mean score was 92, in those dissatisfied the score was 54[265].

Ten other studies identified in the literature, five conducted in the UK have used the SF-36 in the evaluation of menstrual disorders (Table 5.7). All appear to have used the SF-36 v.1, although this is only explicitly stated in the Italian and Dutch studies. It is unknown in the UK studies whether the US, UK, acute or standard form of the SF-36 was employed. The majority of authors have presented transformed data on a 0-100 scale rather than a norm-based transformed score, which would allow meaningful comparison between versions 1 and 2 of the SF-36. With respect to the UK studies, one paper comparing medical and surgical management of menorrhagia over twelve months presents the change in score only, with changes over all dimensions ranging from 0.01 to 0.94[266]. Another examined changes in health status over twelve months with respect to the healthcare process as a whole, aiming to evaluate the effectiveness of implementation of national guidelines for menorrhagia in a hospital setting in the UK[267]. Changes in score for only four domains of the SF36 are reported, and whilst these improved after the introduction of guidelines the difference was not significant. Neither is it clear whether results are presented as 0-100 scale scores or following norm based transformations. It is therefore unfortunately not possible to make any meaningful comparisons between this study and our data.

Two groups in the UK report SF-36 v.1 data on a 0-100 transformed scale from three similar trials. Cooper et al conducted a randomised trial of medical treatments versus TCRE with SF-36 scores reported at baseline, four month, two year and five year intervals[264,268,269]. Baseline scores in both groups were well below the UK population mean scores for women aged 35-54. In both groups scores for all dimensions were significantly improved over baseline at two and five years, however in the medical treatment group they always remained lower than the population mean. Scores for women treated with TCRE were the same or higher than the population mean for six dimensions at four months, all lower at two years and by five years similar scores to the population mean were reported for the dimensions physical functioning, role-physical, mental health and only higher for the dimension role – emotional. The change in scores over five years for all dimensions ranged from -3.88 to +33.81. The only dimension to show a decline in score over the study period was the general health score in the medically treated group which fell by 0.25, 0.67 and 3.88 points each time it was measured.

The same group have undertaken a randomised comparison of MEA vs. TCRE with SF-36 scores reported at baseline, twelve months and five years[142,270]. As before the baseline scores in both groups were well below the UK population means for females in the same age range. Significant improvements in scores were seen at 12 months and five years, and although these approached the population means in many cases they remained lower for all dimensions except for role-emotional which was the same as the population mean in the MEA group. The change in scores observed over the five years was similar to the previous study, -3.3 to +23.9, again with the only overall decline being in the general health dimension. This had dropped by 2.9 points in the TCRE group at two years, and at five years in both groups by 2.4 points in the TCRE group and 3.3 in the MEA group.

Sculpher et al report a randomised trial of hysterectomy versus TCRE with the SF-36 administered once only at two years post-operatively[148]. In the endometrial resection group scores were higher than the UK population mean for mental health and vitality and similar for role-emotional and general health. In the hysterectomy group, scores for all dimensions were markedly higher than population scores except for role-physical which was marginally lower.

Given the heterogeneity of interventions, the lack of clarity as to which SF-36 questionnaire has been employed and the uncertainty as to how scale scores have been calculated it is difficult to draw direct comparisons between the results of these studies and our results. It is reassuring however, that our results are generally very similar in terms of comparison with the population mean and the observed changes in the individual scale scores over time.

5.8 Conclusion

In summary it would appear that patients managed in the Bridges Project had similar improvements in self assessed health status to those referred to the OSMC after eight months.

	Response Rate		Usable Responses	
	Bridges (n=99)	OSMC (n=94)	Bridges (n=99)	OSMC (n=94)
Entry SF-36				
Physical Functioning	95 (96%)	88 (94%)	95 (96%)	87 (93%)
Role-Physical			95 (96%)	87 (93%)
Bodily Pain			95 (96%)	87 (93%)
General Health			95 (96%)	86 (92%)
Vitality			94 (95%)	86 (92%)
Social Functioning			94 (95%)	87 (93%)
Role-Emotional			95 (96%)	87 (93%)
Mental Health			94 (95%)	86 (92%)
Exit SF-36				
Physical Functioning	80 (81%)	69 (73%)	80 (81%)	67 (71%)
Role-Physical			80 (81%)	66 (70%)
Bodily Pain			80 (81%)	66 (70%)
General Health			80 (81%)	67 (71%)
Vitality			79 (80%)	68 (72%)
Social Functioning			80 (81%)	67 (71%)
Role-Emotional			80 (81%)	69 (73%)
Mental Health			79 (80%)	68 (72%)
Change in Score (Entry minus Exit score)	80 (81%)	65 (69%)		
Physical Functioning			80 (81%)	65 (69%)
Role-Physical			80 (81%)	64 (68%)
Bodily Pain			80 (81%)	64 (68%)
General Health			80 (81%)	64 (68%)
Vitality			78 (79%)	65 (69%)
Social Functioning			79 (80%)	65 (69%)
Role-Emotional			80 (81%)	65 (69%)
Mental Health			78 (79%)	65 (69%)
Health transition (health compared to one year ago)	80 (81%)	69 (73%)	80 (81%)	69 (73%)

Table 5.1: General Health Questionnaire (SF-36) Response Rates

	Mean Score		Difference		
	Bridges	OSMC	in score	95% CI	P-value
Entry SF-36					
Physical Functioning	50.43	47.89	2.54	-0.17 to 5.26	0.066
Role-Physical	46.36	45.23	1.13	-1.71 to 3.98	0.432
Bodily Pain	42.70	42.10	0.60	-2.46 to 3.65	0.701
General Health	47.15	44.96	2.19	-0.93 to 5.31	0.167
Vitality	40.90	41.71	-0.81	-3.99 to 2.37	0.616
Social Functioning	40.60	39.48	1.12	-2.26 to 4.50	0.514
Role-Emotional	43.32	40.78	2.54	-1.11 to 6.18	0.172
Mental Health	43.15	40.90	2.24	-1.18 to 5.67	0.198
Exit SF-36					
Physical Functioning	51.51	50.06	1.45	-1.14 to 4.32	0.320
Role-Physical	48.44	48.50	-0.07	-3.48 to 3.34	0.968
Bodily Pain	45.66	45.89	-0.23	-3.78 to 3.32	0.898
General Health	45.19	44.19	1.00	-0.56 to 2.55	0.206
Vitality	45.81	46.90	-1.10	-4.74 to 2.55	0.553
Social Functioning	45.67	45.37	0.30	-3.28 to 3.87	0.870
Role-Emotional	45.43	49.51	-4.08	-7.74 to -0.42	0.029
Mental Health	46.55	46.32	0.23	-3.29 to 3.74	0.898
Change in Score (Exit minus Entry score)					
Physical Functioning	1.03	1.42	-0.40	-3.01 to 2.22	0.764
Role-Physical	2.70	1.45	1.24	-2.44 to 4.92	0.507
Bodily Pain	3.47	2.35	1.12	-2.28 to 4.51	0.516
General Health	-2.60	-2.13	-0.47	-4.05 to 3.11	0.797
Vitality	4.60	5.04	-0.44	-4.01 to 3.13	0.808
Social Functioning	4.97	4.78	0.19	-3.94 to 4.32	0.928
Role-Emotional	1.90	6.70	-5.10	-9.08 to -1.12	0.012
Mental Health	2.53	4.81	-2.28	-5.71 to 1.15	0.190
Health transition (health compared to one year ago)	2.46	2.46	0.00	-0.34 to 0.34	0.994

Table 5.2: General Health Questionnaire (SF-36) Norm-based scoring utilising 1998 SF-36 US population norms

	Mean Score		Difference		
	Bridges	OSMC	in score	95% CI	P-value
Entry SF-36					
Physical Functioning	48.13	45.06	3.07	-0.21 to 6.35	0.066
Role-Physical	43.66	42.35	1.31	-7.98 to 4.61	0.432
Bodily Pain	39.24	38.63	0.61	-2.53 to 3.76	0.701
General Health	46.97	44.72	2.25	-0.95 to 5.45	0.167
Vitality	40.84	41.67	-0.83	-4.08 to 2.42	0.616
Social Functioning	41.39	40.29	1.10	-2.23 to 4.44	0.514
Role-Emotional	44.01	41.45	2.57	-1.13 to 6.26	0.172
Mental Health	44.99	42.79	2.19	-1.15 to 5.54	0.198
Exit SF-36					
Physical Functioning	49.43	47.68	1.75	-1.71 to 5.22	0.320
Role-Physical	46.07	46.15	-0.08	-4.04 to 3.87	0.968
Bodily Pain	42.29	42.53	-0.24	-3.88 to 3.41	0.898
General Health	44.95	43.93	1.02	-0.57 to 2.62	0.206
Vitality	45.86	46.98	-1.12	-4.84 to 2.60	0.553
Social Functioning	46.39	46.09	0.29	-3.23 to 3.82	0.870
Role-Emotional	46.15	50.28	-4.13	-7.84 to –0.42	0.029
Mental Health	48.31	48.09	0.22	-3.21 to 3.66	0.898
Change in Score (Exit minus Entry score)					
Physical Functioning	1.24	1.72	-0.48	-3.64 to 2.68	0.764
Role-Physical	3.12	1.69	1.44	-2.83 to 5.71	0.507
Bodily Pain	3.57	4.24	1.15	-2.35 to 4.65	0.516
General Health	-2.67	-2.19	-0.48	-4.16 to 3.20	0.797
Vitality	4.70	5.15	-0.45	-4.09 to 3.19	0.808
Social Functioning	4.90	4.72	0.19	-3.89 to 4.26	0.928
Role-Emotional	1.92	7.08	-5.16	-9.19 to –1.14	0.012
Mental Health	2.47	4.70	-2.23	-5.58 to 1.12	0.190

Table 5.3: General Health Questionnaire (SF-36) Norm-based scores utilising 1999 SF-36 v.2 UK population norms

	Mean Score		Difference		
	Bridges	OSMC	in score	95% CI	P-value
Entry SF-36					
Physical Functioning	84.32	78.28	6.04	-0.41 to 12.49	0.066
Role-Physical	73.22	70.33	2.89	-4.36 to 10.14	0.432
Bodily Pain	54.04	52.63	1.41	-5.83 to 8.64	0.701
General Health	64.86	60.27	4.60	-1.95 to 11.14	0.167
Vitality	40.09	41.72	-0.62	-8.00 to 4.75	0.616
Social Functioning	62.77	60.20	2.56	-5.18 to 10.31	0.514
Role-Emotional	73.07	67.64	5.43	-2.39 to 13.26	0.172
Mental Health	62.82	58.84	3.98	-2.10 to 10.06	0.198
Exit SF-36					
Physical Functioning	86.88	83.43	3.44	-3.37 to 10.26	0.320
Role-Physical	78.52	87.69	-0.18	-8.88 to 8.53	0.968
Bodily Pain	61.06	61.61	-0.54	-8.93 to 7.85	0.898
General Health	60.75	58.66	2.09	-1.17 to 5.35	0.206
Vitality	49.92	52.11	-2.19	-9.49 to 5.10	0.553
Social Functioning	74.38	73.69	0.68	-7.52 to 8.88	0.870
Role-Emotional	77.60	86.35	-8.75	-16.60 to -0.90	0.029
Mental Health	68.86	68.46	0.40	-5.83 to 6.64	0.898
Change in Score (Exit minus Entry score)					
Physical Functioning	2.44	3.38	-0.95	-7.16 to 5.27	0.764
Role-Physical	6.88	3.71	3.16	-6.23 to 12.56	0.507
Bodily Pain	8.21	5.56	2.65	-5.40 to 10.70	0.516
General Health	-5.45	-4.47	-0.98	-8.49 to 6.53	0.797
Vitality	9.21	10.10	-0.88	-8.02 to 6.26	0.808
Social Functioning	11.39	10.96	0.43	-9.04 to 9.90	0.928
Role-Emotional	4.06	15.00	-10.94	-19.47 to -2.41	0.012
Mental Health	4.49	8.54	-4.05	-10.14 to 2.03	0.190

Table 5.4: General Health Questionnaire (SF-36) 0 - 100 Scale

	Response Rate		Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=99)**	**OSMC (n=94)**
Entry Menstrual Questionnaire	95 (96%)	87 (93%)	93 (94%)	86 (92%)
Exit Menstrual Questionnaire	80 (81%)	69 (73%)		
Number of responders eligible to complete questionnaire	71	57	69 (97%)	55 (97%)
Number of responders not eligible to complete questionnaire	9	12		
Change in Score (MQ2 – MQ1)			67 (94%)	52 (91%)

Table 5.5: Menstrual Questionnaire Response Rates

	Mean				
	Bridges	**OSMC**	**Difference**	**95% CI**	**P-value**
Entry Menstrual Questionnaire	49.96	44.23	5.73	-1.30 to 12.77	0.110
Exit Menstrual Questionnaire	60.93	57.48	3.45	-5.56 to 12.46	0.450
Change in Score	9.22	8.01	1.21	-6.00 to 8.41	0.741

Table 5.6: Menstrual Questionnaire Results Summary

Study	Country	Intervention	Timing of administration	SF-36
Coulter et al[266]	UK	Variety of medical and surgical treatments for menorrhagia	Baseline 9 months 12 months	SF-36 Change in score
Chadha et al[267]	UK	Implementation of guidelines in hospital	Baseline 12 months	Not stated
Sculpher et al[148]	UK	Hysterectomy vs. TCRE	1.8 to 1.8 years post-op	SF-36 v.1 0 – 100 scale
Cooper et al[142.270]	UK	MEA vs. TCRE	Baseline 12 months 5 years	SF-36 v.1 0 – 100 scale
Cooper et al[264.268,269]	UK	Medical management vs. TCRE	Baseline 4 months 2 years 5 years	SF-36 v.1 0 – 100 scale
Bongers et al[271]	Netherlands	Bipolar radiofrequency endometrial ablation vs. Balloon ablation of endometrium	Baseline 2 days 2 weeks 3 months 6 months 12 months post-op	SF-36 v.1 0 – 100 scale
Crosignani et al[272]	Italy	TCRE vs. Vaginal Hysterectomy	2 years post-op	Italian SF-36 v. 1.6 0 – 100 scale
Crosignani et al[118]	Italy	Mirena IUS vs. TCRE	12 months post-op	Italian SF-36 v. 1.6 0 – 100 scale
Hurskainen et al[273]	Finland	Mirena IUS vs. Hysterectomy	Baseline 12 months	Finnish SF-36 0 – 100 scale
Henshaw et al[274]	Australia	MEA vs. Mirena IUS	Mean 14.6 months post-op	SF-36 v.1 0-100 scale

Table 5.7: Use of SF36 in the context of menorrhagia

Chapter 6: Attitudes to and Experiences of Healthcare

6.1 Introduction

When considering the effectiveness of new methods of healthcare delivery it is important that patients' perspectives are ascertained to prevent the adoption of services that patients may regard as worse than the existing arrangements[275]. This has arisen through a general societal trend towards greater consumer influence on services, but is also embedded in health service policy. Working for Patients[276] promoted greater attention to patients' views amongst NHS trusts and was followed by The Patients' Charter[277] which set down standards of primary and secondary care with particular reference to patients' needs. The NHS Executive also promotes the inclusion of patients' views in the assessment of quality and aims for greater patient influence in the development of local and national health policy[278].

Measuring patient satisfaction has frequently been regarded as the method of choice for obtaining patients' views about their care[279,280]. Despite their widespread use, patient satisfaction surveys have been widely criticised[281]. In the past questionnaires often concentrated on asking about that which was easily measurable, e.g. waiting lists and "hotel services" (e.g. food and other amenities) at the expense of probing more qualitative aspects of care which whilst more difficult to measure might be of more importance to patients[282]. At the root of the problem seems to be a the lack of a fully developed theory to explain what is actually meant by patient satisfaction[281,283]. It is thought that asking detailed questions about what actually happened during an episode of care is more useful than attempting to define levels of satisfaction[282].

Whilst various methods and instruments are described in the literature for the elicitation of patients views and experiences of care in primary[284] and secondary[285-288] sectors separately, few tools are available for use across the primary-secondary interface. Two were identified on literature review. The Client Perception of Co-ordination Questionnaire was developed in Australia, and is primarily intended for use with elderly patients who have chronic complex health problems, to investigate co-ordination of health and social care provision[289]. The Patient Career Diary was developed in the UK and is described in detail below[275].

6.1.1 The Patient Career Diary

The PCD was specifically designed for the collection of information regarding patient's experiences of and attitudes to health care across the primary-secondary interface. It is particularly suitable for assessing the impact on patients of new methods of providing care that involve a redistribution of aspects of care between sectors[275]. It has been meticulously developed and evaluated and is psychometrically sound[290]. The various aspects of care examined fall into several broad themes: "Getting In" relating to access to care, "Fitting In" which describes the extent to which care and services are suited to patient's requirements, "Information" relating to the communication of appropriate and timely information, "Continuity" to explain aspects of continuity of care and "Limbo" which describes the extent to which patients feel able to progress through the healthcare system.

The complete diary contains several sections enabling patients to express their views at each different stage of care: Initial visit to the GP, initial visit to hospital outpatients, subsequent visits to the GP, follow-up visits to outpatients, inpatient stay in hospital, the month following discharge and a section relating to overall perceptions of the healthcare process. The diary can either be used in its entirety, or in separate sections. It is recommended that to improve response rate, sections are administered at the time of the relevant attendance rather than issuing the whole diary at the outset[291].

The Likert technique is employed in each section[292]. A set of attitude statements are presented to the participant, who is invited to express agreement or disagreement on a five-point scale from strongly agree to strongly disagree, with a "not applicable" option for use when required. Each degree of agreement is given a numerical value from one to five. Thus a total numerical value can be calculated from all the responses. In the PCD scores for each theme of each section are produced by converting the raw scores of one to five to a scale. Each scale is scored from 0-100, a lower score indicating a poorer experience of care, or negative attitudes towards care[291].

The PCD was employed successfully in the in evaluation of the OSMC. 87% of women attending the new service completed the diary and statistically significant differences were obtained for all components when compared to the traditional approach to service

provision in gynaecology[211]. The PCD has been used in one other study as the basis for the development of a new questionnaire in an evaluation of a shared care programme for newly diagnosed cancer patients[217]. No other studies published in the literature employ the original PCD to evaluate services, but as its suitability for use in the context of menstrual disorders has been demonstrated, and since no other suitable "off shelf" tool exists to measure all relevant stages of care across the primary-secondary interface, it was employed in the evaluation of the Bridges project.

6.2 Aim

To identify differences in patient's attitudes to and experiences of health care across the primary-secondary interface in the Bridges and OSMC groups, and therefore evaluate the degree to which the two models of care meet the needs of patients with menstrual disorders.

6.3 Methods

The PCD was issued to participants in the form of an A5 booklet at the time of the first attendance to hospital outpatients department. A copy is included in Appendix 4. The diary contained the following sections; When the GP told you that you needed to go to the hospital/specialist clinic, Going to your first outpatient or specialist clinic, Other visits to the GP, Other outpatient or specialist clinic visits (two copies were provided), Your health care overall.

Women were asked to complete the sections concerning their initial visit to the GP whilst waiting in the clinic and return it to the clinic reception or in the pre-paid envelopes provided. They were asked to fill in subsequent sections as necessary at home and return them by post. A postal reminder was sent out at exit at eight months requesting that Section five be completed and returned with the rest of the exit material. Three postal reminders, two weeks apart were sent out to participants who did not return sections one, two, three and five. It was not possible to employ postal reminders for

section four, as information about frequency and timing of subsequent visits to the GP was not collected until the time of exit from the study.

6.4 Study Population

A detailed description of the study population can be found in Chapter 3.

6.5 Data Handling and Statistical Analysis

The data were entered into a Microsoft Access database. Response rates were calculated from the number of women returning each section of the PCD as a percentage of the whole group. In order to be able to calculate component scores, a valid response was required for each individual question contributing to that component. The number of usable responses for each component was calculated as a percentage of the total number of returns for that section. Calculation of component scores was undertaken on SPSS version 11 (SPSS Inc, Chicago, USA), as was statistical analysis. Results were summarised as mean values and comparisons between the two groups were made using Student's t-test. Corresponding 95% confidence intervals were then calculated. Statistical significance was defined at the 5% level throughout.

6.6 Results

6.6.1 Section One

This related to the consultation with the GP that took place immediately prior to attendance in the hospital outpatients department. Over 90% of women returned this section, and it was possible to calculate component scores in over 80% of cases (Table 6.1a). There was a significant improvement in the Bridges group for component one (information and fitting in at the point of arrangements made for the patient to attend hospital) 74.40 in the Bridges group compared to 63.31 for the OSMC group, $P<0.00$. There were no significant differences in the scores of the two groups for the other two

components of section one, although the score for component two (getting in, appointments) was 5.81 points higher for the Bridges group than the OSMC group and 2.34 points lower for component three, "Continuity" (Table 6.1b).

6.6.2 Section Two

This related to the patient's visit to the hospital outpatients department. The response rate was very similar in both groups; 89% for Bridges and 87% in the OSMC group and component scores were calculated in over 70% of cases (Table 6.2a). Three components showed a statistically significant improvement in the Bridges group; Component two (Continuity and Choice of Doctor) 56.74 for the Bridges group, 56.37 for the OSMC, P = 0.020, component three (Waiting for appointment) 80.22 for the Bridges group, 58.33 for the OSMC, P<0.001 and component five (Limbo) 67.86 in the Bridges group, 54.96 in the OSMC, P< 0.001. Scores for component one (Information, Fitting in) were markedly similar with a 0.02 point higher score in the OSMC group and for component four (Clinic Organisation) a 1.75 point difference in favour of the Bridges group. These differences were not statistically significant. (Table 6.2b).

6.6.3 Section Three

This concerned with subsequent follow-up visits to the outpatients department. In both groups the structure of the visit was the same, and consisted of a standard outpatient consultation with a consultant gynaecologist to review the outcome of previous treatments and formulate ongoing management plans including booking for surgery. Therefore only patients who attended for follow-up were eligible to complete this section. Sixteen women in the Bridges group and 36 in the OSMC group attended outpatients for follow up. The response rates for section three were 94% and 61% respectively. It was possible to calculate scores for individual components in over 70% of cases (Table 6.3a). There were no statistically significant differences in component scores for section three. Scores for the first three components were markedly similar in both groups, however there was an 8.93-point increase in score for component four in the Bridges group (Table 6.3b).

6.6.4 Section Four

Was completed by women if they consulted with their GP after their initial visit to outpatients and two copies were included in the diary. It is not known how many patients attended their GP subsequently, so it was therefore not possible to calculate response rates for section four. Relatively small numbers of women returned this section, 35 in the Bridges group and 24 in the OSMC group returned one copy of section four, and seven and ten women respectively returned the second copy. Over 70% of returned questionnaires contained sufficient responses to produce component scores, however only 43% of questionnaires were usable for component four of the first copy in the Bridges group (Table 6.4a and Table 6.5a). The scores for all components of the first copy of section four were higher in the Bridges group, although none reached statistical significance. Small numbers of returned copies of the second section four led to a wide range of differences in component scores for the two groups, from –5.16 to 9.72. Again, none of these differences were statistically significant.

6.6.5 Section Five

The final section concerned patient's perceptions of their health care over the eight-month study period. The response rates were 81% (Bridges) and 71% (OSMC) and responses were sufficient to calculate component scores in over 85% of cases (Table 6.6a). The scores for both components were higher in the Bridges group; for component one (Co-ordination, Progress) 2.84 points and for component two (Continuity, Limbo) 2.06 points, although these differences were not statistically significant (Table 6.6b).

6.7 Discussion

A good response rate to the PCD was achieved for the most pertinent sections (one, two and five). The results demonstrate that women recruited to the Bridges project perceived their care more favourably than those attending the Menstrual Clinic. In general their scores were higher for all components of all sections. Statistically significant improvements were achieved for Bridges Project patients in primary care in terms of the quality of information provided to patients by the GP on referral to outpatients and the degree to which care provided by the GP met patient's requirements. In secondary care

significant improvements were seen as would be expected given the nature of the process redesign, in components addressing wait for appointment, clinic organisation and "Limbo". These findings are supported by the results of the qualitative interviews (Chapter 7). There was an improvement in the component dealing with continuity and choice of doctor. It is more difficult to account for this directly, as what was actually provided in terms of choice and continuity was similar in both groups, so this may be a general reflection on positive experiences of care.

It is not possible to draw firm conclusions from the results for section three, as the numbers of women eligible to complete this section was a relatively small number of the total. It does however seem reasonable to suppose that the experience of patients attending the menstrual clinic for follow-up should be similar in both groups, as the type of attendance (i.e. standard outpatient consultation) was the same. This may provide some reassurance that the PCD is able to detect real differences in attitudes between the two groups. It is possible, even probable that the new model of care produced differences in patient experience of subsequent visits to the GP, however it is even more difficult to draw conclusions for section four, as again the numbers of women returning these sections was small, and the actual response rate is uncertain.

The improvement in patient attitudes to care does not appear to be maintained at eight months. This finding echoes that of the original evaluation of the OSMC where the benefit seen at the original outpatient attendance was not sustained over the subsequent year[211]. In any event women's perceptions of the Bridges Project at exit were no worse than those of the women in the OSMC group. Given that the OSMC has previously been shown to have significant benefits for patients over the traditional model of care, this is in itself reassuring.

6.8 Conclusion

It would appear that data obtained from the PCD is largely robust and that the new model of care meets the needs of women with menstrual disorders more comprehensively that the current system.

Patient Career Diary Section 1: When the GP told you that you needed to go to the OPD

	Response Rate		Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=91)**	**OSMC (n=89)**
Number of diary section 1 returned	91 (92%)	89 (95%)		
Component 1: Information, Fitting in			83 (91%)	84 (94%)
Component 2: Getting in, Appointments			86 (94%)	86 (96%)
Component 3: Continuity			74 (81%)	79 (88%)

Table 6.1a: Response rates for PCD Section 1

	Mean				
	Bridges	**OSMC**	**Difference**	**95% C I**	**P value**
Component 1: Information, Fitting in	74.40	63.31	11.09	5.48 to 16.70	0.000
Component 2: Getting in, Appointments	69.99	64.17	5.81	-0.96 to 12.59	0.092
Component 3: Continuity	63.06	65.40	-2.34	-11.04 to 6.37	0.596

Table 6.1b: Comparison of means for PCD Section 1

Patient Career Diary Section 2: Going to your fist outpatient or specialist clinic visit

	Response Rate		Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=88)**	**OSMC (n=82)**
Number of diary section 2 returned	88 (89%)	82 (87%)		
Component 1: Information, Fitting in			73 (83%)	72 (88%)
Component 2: Continuity, Choice of Doctor			65 (74%)	68 (83%)
Component 3: Wait for Appointment			83 (94%)	75 (91%)
Component 4: Clinic Organisation			84 (95%)	79 (96%)
Component 5: Limbo			84 (95%)	79 (96%)

Table 6.2a: Response rates for PCD Section 2

	Mean				
	Bridges	**OSMC**	**Difference**	**95% C I**	**P value**
Component 1: Information, Fitting in	73.46	73.48	-0.02	-4.89 to 4.84	0.993
Component 2: Continuity, Choice of Dr	59.74	56.37	3.37	0.53 to 6.21	0.020
Component 3: Wait for Appointment	80.22	58.33	21.89	16.70 to 27.07	0.000
Component 4: Clinic Organisation	79.91	78.16	1.75	-2.34 to 5.84	0.400
Component 5: Limbo	67.86	54.96	12.90	7.31 to 18.49	0.000

Table 6.2b: Comparison of means for PCD Section 2

Patient Career Diary Section 3: Other outpatient or specialist clinic visits

	Response Rate		Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=15)**	**OSMC (n=22)**
Number of women attending OPD more than once	16 (16%)	36 (38%)		
Number of diary section 3 returned	15 (94%)	22 (61%)		
Component 1: Information, Fitting in			15 (100%)	18 (81%)
Component 2: Continuity, Choice of Doctor			12 (80%)	16 (73%)
Component 3: Wait for Appointment			14 (93%)	16 (73%)
Component 4: Receptionists			15 (100%)	21 (95%)

Table 6.3a: Response rates for PCD Section 3

	Mean				
	Bridges	**OSMC**	**Difference**	**95% C I**	**P value**
Component 1: Information, Fitting in	72.41	72.99	-0.58	-11.06 to 9.89	0.910
Component 2: Continuity, Choice of Dr	65.00	64.06	0.94	-12.23 to 14.10	0.885
Component 3: Wait for Appointment	65.48	67.19	-1.71	-18.76 to 15.34	0.839
Component 4: Receptionists	83.33	74.40	8.93	-1.52 to 19.38	0.091

Table 6.3b: Comparison of means for PCD Section 3

Patient Career Diary Section 4/1: Other visits to the GP surgery

			Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=35)**	**OSMC (n=24)**
Number of diary section 4/1 returned	35	24		
Component 1: Information, Fitting in			34 (97%)	19 (79%)
Component 2: Getting in, Appointments			34 (97%)	23 (96%)
Component 3: Communication, Information			31 (89%)	21 (88%)
Component 4: Continuity, Choice of doctor			32 (91%)	20 (83%)

Table 6.4a: Response rates for Section PCD 4/1

	Mean				
	Bridges	**OSMC**	**Difference**	**95% C I**	**P value**
Component 1: Information, Fitting in	72.24	63.49	8.75	-1.47 to 18.98	0.092
Component 2: Getting in, Appointments	66.00	65.22	0.78	-12.84 to 14.39	0.910
Component 3: Communication, Information	76.01	66.67	9.34	1.85 to 16.83	0.016
Component 4: Continuity, Choice of doctor	70.57	67.92	2.66	-12.20 to 17.51	0.721

Table 6.4b: Comparison of means for PCD Section 4/1

Patient Career Diary Section 4/2: Other visits to the GP surgery

	Bridges (n=99)	OSMC (n=94)	Usable Responses Bridges (n=7)	OSMC (n=10)
Number of diary section 4/2 returned	7	10		
Component 1: Information, Fitting in			5 (71%)	8 (80%)
Component 2: Getting in, Appointments			6 (86%)	9 (90%)
Component 3: Communication, Information			3 (43%)	9 (90%)
Component 4: Continuity, Choice of doctor			6 (86%)	9 (90%)

Table 6.5a: Response rates for PCD Section 4/2

	Mean Bridges	OSMC	Difference	95% C I	P value
Component 1: Information, Fitting in	73.75	78.91	-5.16	-28.16 to17.85	0.632
Component 2: Getting in, Appointments	69.79	69.44	0.35	-29.44 to 30.39	0.980
Component 3: Communication, Information	81.25	76.39	4.86	-12.15 to 21.87	0.539
Component 4: Continuity, Choice of doctor	84.72	75.00	9.72	-13.04 to 32.49	0.373

Table 6.5b: Comparison of means for PCD Section 4/2

Patient Career Diary Section 5: Your health care overall

	Response Rate		Usable Responses	
	Bridges (n=99)	**OSMC (n=94)**	**Bridges (n=80)**	**OSMC (n=67)**
Number of diary section 5 returned	80 (81%)	67 (71%)		
Component 1: Co-ordination, Progress			72 (90%)	64 (95%)
Component 2: Continuity, Limbo			70 (86%)	62 (92%)

Table 6.6a: Response rates for PCD Section 5

	Mean				
	Bridges	**OSMC**	**Difference**	**95% C I**	**P value**
Component 1: Co-ordination, Progress	70.23	67.38	2.84	-4.49 to 10.17	0.444
Component 2: Continuity, Limbo	52.14	50.08	2.06	-2.55 to 6.68	0.378

Table 6.6b: Comparison of means for PCD Section 5

	Mean Score	
	MDC (Abu et al)[211]	PCD (Baker et al)[275]
When the GP told you that you needed to go to the OPD		
Component 1: Information, Fitting in	-	65.97
Component 2: Getting in, Appointments	-	71.73
Component 3: Continuity	-	67.90
Going to your first outpatient or specialist clinic visit		
Component 1: Information, Fitting in	84.38	63.74
Component 2: Continuity, Choice of Doctor	91.67	58.69
Component 3: Wait for Appointment	75.00	57.39
Component 4: Clinic Organisation	87.50	69.39
Component 5: Limbo	58.33	54.20
Other outpatient or specialist clinic visits		
Component 1: Information, Fitting in	-	68.24
Component 2: Continuity, Choice of Doctor	-	54.62
Component 3: Wait for Appointment	-	65.85
Component 4: Receptionists	-	74.34
Other visits to the GP surgery		
Component 1: Information, Fitting in	-	67.43
Component 2: Getting in, Appointments	-	72.17
Component 3: Communication, Information	-	73.29
Component 4: Continuity, Choice of doctor	-	73.36
Your health care overall		
Component 1: Co-ordination, Progress	75.00	67.13
Component 2: Continuity, Limbo	70.00	55.61

Table 6.7 Mean PCD scores obtained in other studies

Chapter 7: Access to Healthcare

7.1 Introduction

The Bridges project pathway was developed in response to the recognised problems existing at the interface between primary and secondary sectors for both patients and health care providers[211,215]. It was specifically designed to facilitate the patient's journey and provide seamless transition between sectors, whilst allowing more effective utilisation of resource. In the Bridges project patients utilised services in a very different way to those referred to the one-stop menstrual clinic. We were keen to examine women's experiences of accessing and receiving healthcare in order to understand the processes, strengths and weaknesses of the two models of care from the patient's perspective.

7.2 Aim

To investigate women's experiences of care within the existing system and the Bridges project, and to explore women's views towards the relationship between primary and secondary care sectors with particular reference to integrated care.

7.3 Method

As this study was intended to be exploratory, qualitative methodology using semi-structured interviews was employed. This methodology is especially suitable for investigating the point of view and experience of patients, and is also valuable for explaining and validating findings from quantitative research[293]. A prompt guide was used was used to facilitate the interviews. A copy can be found in Appendix 6. This was developed through discussion within the research team and literature review; it was continually modified to explore issues raised by participants. Specific prompts aided discussions surrounding the relationship between healthcare sectors and integrated care. Twenty-three women chose to be interviewed in their homes, and one in a quiet room in the OSMC. The interviews lasted between 20 and 60 minutes.

7.4 Study Population

Participants were drawn from the study population described in Chapter 3. Twenty-five women were approached to participate and one declined. Equal numbers of women were chosen from each group. A maximum variation sampling approach was used to capture a range of views. Selections were made based on age, socio-economic group, ethnicity, presenting symptoms and mode of treatment. The mean age of interviewees was 43, range 22-54 years, standard deviation 8 years; other characteristics are presented in Table 7.1.

7.5 Sample Size, Data Handling and Analysis

Interviews were audio-taped and transcribed verbatim. Data analysis was based on the constant comparative method[294], assisted by QSR N4 software (QSR International Pty Ltd)[295]. Open codes were assigned to each event in the data in the first six interviews, and these were organised into a provisional analytic thematic framework[296]. Interviews were conducted in batches of six concurrently with analysis of earlier transcripts, allowing emergent themes to be explored in subsequent interviews. The analytic framework was modified to accommodate new data and changes were documented. The final version can be found in Appendix 6. After 18 interviews that the point of 'theoretical saturation' (when new additional data does not further modify the analytic framework) had been reached[294]. Six more interviews were undertaken to confirm and challenge the framework, making 24 interviews in total.

7.6 Results

7.6.1 Accounts of Menstrual Disorders

Menstrual disorders had a significant impact on the health and lifestyle of the majority of the women interviewed. Symptoms such as heavy menstrual loss, irregular or unpredictable bleeding and dysmenorrhoea had an impact on the physical well being of fourteen women. Eight reported that their periods were having an adverse impact on their family life, social life and work. Ten women reported adverse effects on their mental health, giving accounts of low mood, feelings of isolation and excessive worry as a result

of their symptoms. Ten women had been experiencing problems with their periods for a number of years and had been attempting to access help for some considerable time, nine of these women gave accounts of prolonged suffering as a result.

Then when it started to be every two weeks for two weeks, I knew that in another two weeks that I was going to have a period and I can't go swimming, sometimes I couldn't socialise, sometimes I felt too tired...
Participant 45

It's disrupting my life because we've been invited out and I've said, "Well, I should be all right", and I've had to wave the kids off, my husband off and friends off when they went to Water World and I couldn't go and I wasn't due on for ten days after that and so I said, "Yes", and then everything has to cancel ... leading up to it and I resent it because I miss out on things happening because I've had to have carrier bags in friends cars to sit on ... I've had my friend follow me to the toilets, pass wet toilet paper underneath the door and when we were in somebody else's car with beige seats and I had to go and borrow a carrier bag and this is what happens ... then the next two months I'll go to the doctors and say, "Oh, it's been terrible, I'm flooding and everything". "Well, we'll see how you get on for the next couple of months". And then sod's law the next months it isn't so bad but not brilliant and then you think, "Oh well p'raps it's ok, and I'll leave it another couple of months and then all of a sudden I'll have another bad patch...
Participant 81

The majority of participants had a formulated some idea as to the underlying cause of their problem. Four women constructed their problem as "hormonal" and as an expected consequence of aging and the approach of the menopause. Three younger women were particularly concerned about the possibility of premature menopause as they associated problems with heavy or unpredictable bleeding as belonging to an older age group than their own. They experienced particular distress due to an inability to voice these concerns for fear of medical ridicule. All were concerned for their future fertility.

It'd been going on for that long and what worried me was that ... looking round in the waiting room and there was nobody my age there... and I honestly thought that I was probably going through that time of life at my age.
Participant 16

Seven women attributed their problems to structural causes such as fibroids. Ten interviewees disclosed underlying concerns about gynaecological malignancy as a cause for their symptoms. Two women with a family history had specific concerns about endometrial carcinoma; other women cited cervical and ovarian malignancy as particular concerns. Only two woman interviewed divulged their concerns to the GP at the time of presentation, in both cases this was in order to secure referral to secondary care and subsequent investigation.

Yeah, well I had a distant cousin who had a baby and she died six months later with womb cancer and me grandma died with womb cancer and my mum, when she was about forty five, forty two, something round about that age had it D&C and they found cancer cells inside her womb. And they caught it in time fortunately. But she had to go through all the checks what you have to have afterwards. So I was really worried, 'cos it was there in the family. On me dad's side and me mum's side.
Participant 646

7.6.2 Patients' Requirements of Healthcare

Given the impact on well-being and their concerns about malignancy all women wanted their complaints to be taken seriously at the time of first presentation to the GP. Every woman interviewed felt that investigation was appropriate if the GP was unable to reassure her as to the normality of the symptoms or undertaken in a timely manner if initial treatments produced no response. All interviewees saw a definite diagnosis as the starting point to successful treatment and therefore resolution of the problem.

To be able to give me some advice, I suppose to tell me whether the symptoms were normal or not, and if not, to be able to refer me to have it checked out further.
Participant 2

At the end of the day you just want to be seen so you know what's wrong.
Participant 60

All participants felt that attendance at the hospital clinic was important. Referral was seen as desirable and it provided women with access to specialist knowledge, information and access to investigations and therefore diagnosis. For nine women (six of whom had undergone, or were awaiting surgery), access to effective treatments was cited as one of the reasons why they wanted referral.

Because I looked forward to the out patient clinic days because, (laughs) because I was going to find out if, well the first one I went to, if there was something wrong with me, and the second one that I went to I was going to find out what they were going to do and probably the third time I went I was looking forward to it because I was going to find out when something was going to help me.
Participant 1

Eleven women reported that they did not feel as if they were "in the system" and making progress towards resolving their problems reported that until they were seen in secondary care.

Feeling that you're going to get somewhere with the problem. I feel then I'm going to people who've got more knowledge of what the particular problem is as opposed to going to the GP. I would expect those people to actually, you know, be specialists in that field. So although I might not get a result there and then, I like the idea that you are then in the system and are going to be hopefully sorted out by the end of it.
Participant 30

7.6.3 Obstacles to Access

Eleven women had experienced difficulties when attempting to get for their problems, either in the past or during the current episode of care. The first obstacle to access was connected to the inherent nature of menstrual disorders. Six women felt that their difficulties were exacerbated by the chronic and cyclical nature of their condition; leading to problems firstly with identifying whether their problem was genuine and therefore worthy of presentation to a doctor and secondly with medical legitimization of the problem once presented. Three of these felt they were more likely to secure their doctor's agreement as to the necessity for healthcare if they presented during menstruation. At this time their complaints seemed more immediate and real and could be presented more legitimately.

I mean it's very difficult, it's a bit like childbirth, you know, it's pretty intense and dramatic at the time and then after a while you've just really forgotten all about it and it's a bit like that with a period. I think it's hard to just explain exactly how it's affected you afterwards, you know, it sounds like, you know, to me it sounds like you are trying to be dramatic and over, over-egging it a little bit but at the time it is very real, you know, in the cold light of day perhaps a week or ten days after the event, you know, it sounds, it even sounds a bit ridiculous to me.
Participant 754

Ten participants reported that menstrual problems were not accepted as legitimate medical conditions worthy of medical attention by some GPs. They felt that the medical profession viewed menstrual disorders as a natural part of the female condition and an accepted consequence of aging with the approach of the menopause. They often felt they were expected to endure their symptoms as part of "a woman's lot in life". Seven participants felt that difficulties with legitimization were particularly likely to occur when consulting a male GP, because of their inherent inability to sympathise with a woman's experience of menstruation and the suffering that may result. Four of them had subsequently changed to a female GP and been referred immediately, two were referred by male GPs after changing GP practice several times and one woman was eventual referred by her single-handed male GP. It is of note that seven of the women reporting no difficulties with getting help in primary care attended male GPs and six consulted female doctors.

Well, women have the same problems don't they? Men ain't got a clue have they? That's it basically. You know, male doctors think, "Oh women's problems. They're just moaning because, you know, they're having one irregular bleed or something". I don't know. They don't just don't appreciate it do they? They don't understand what we have to go through. A woman appreciates it more.
Participant 16

Eight women felt that an inevitable lack of specialised knowledge and experience in dealing with menstrual disorders on the part of the GP (whose role was recognised to be that of a generalist) contributed to problems in accessing appropriate help. Five women alluded to possible difficulties with keeping up to date with new developments in all specialties, particularly on a background of severe time constraints.

I think it's probably the case that the doctors, the GPs don't know the type of treatments that're available and they're not kept up to date on the treatments... but then you look at the percentage of women within the communities that suffer with periods, then I would say it's quite important for them to have that type of information.
Participant 57

Twenty women perceived there to be a lack of resource within the NHS. They reasoned that this would inevitably lead to some system of prioritisation or rationing to determine which patients received healthcare and in what form. Menstrual disorders were not felt to be a high priority.

I think it's to do with the funding and also priorities you know. There must be a list of priorities where somebody is really on that so they come up the top of the list, you know. Whether it's a smoker with lung cancer or whether it's an elderly patient who will die or whatever, I don't know. So they must be having to pick and choose on how bad it is.
Participant 32

...it would start all over again, so I've been in and I said, "Oh, and I've looked on the internet and there's this Mirena coil and it's supposed to be fantastic for people with heavy painful periods and, you know, some people say it's probably good for PMT too," and I said, "this, you know, I think this could be the way to go, what do you think?". And he was like, "Oh dear, well I don't think, I don't think so", you know. And this is when he put me on the hormones and gave me the cyclokapron. He said, "Oh this works very well for women...". And I think it was a money thing, I think it was purely a financial thing.
Participant 57

Women also recognised that there are limitations to what can be achieved given current healthcare structures. It was accepted that facilities for investigation and some treatments are not available to GPs without referral to secondary care. Given this and the problems outlined above, primary care itself was often presented as an obstacle to be overcome before progression to investigation and effective treatment in secondary care. Once a referral to secondary care had been made, difficulties at the interface between primary and secondary care contributed to the perceived lack of progress. Nine women gave accounts of poor communication between healthcare providers adversely influencing their healthcare by causing delay and fragmentation of the whole process. All participants gave some account of waiting for appointments and treatment, accepted as a natural consequence of the existing system. The women felt they had very little direct power to influence the course of their healthcare. The few strategies available to them to positively influence progression from primary to secondary care were indirect, and usually only exercised as a last resort, out of a sense of desperation. Strategies such as changing doctor (mentioned by 12 women), repeated re-attendance with the same problem (18 women) or compelling the doctor to refer (10 women) were seen as potentially compromising the much valued doctor-patient relationship

With the doctor you basically just sit there, don't you? And you talk to him and he gives you the treatment, and all right, he can give you an internal, but that is as much as they can do... but without a referral from your doctor you're not going anywhere. So you can pressurise him but maybe there is no point in doing that because you have to be able to communicate with your doctor, don't you? But, oh yes, without your doctor referring you, you're not going anywhere because it has to come from your doctor.
Participant 45

I'd been back with it quite a few times it was, it was like a constant thing and obviously staying in touch it ... I think it was obviously ... obviously she gave me several lots of antibiotics and 'cos they weren't working and I was going back straight away, I think she sort of thought it was obviously getting at me and therefore something needed sorting out. I think if I'd have left it, you know, a couple of weeks in between here, and a couple of weeks there, she'd have thought, "Oh you know, we'll leave it a bit longer and see, you know, how things progress". But she sorted everything out. I was a bit annoying, as well. I kept phoning her, trying to get it sorted out.
Participant 570

In addition, current healthcare structures appear to leave patients unclear as to who is controlling and co-ordinating their healthcare. Nine women felt that the GP was their chief healthcare provider, eight felt that their gynaecologist was in charge. One woman felt she was solely responsible for her own healthcare and another three felt that they shared this responsibility with their GP. Three felt that there was nobody was overseeing the process. Despite this the majority of participants (twelve), when asked, indicated that they would contact their GP in the event of a query about their care. This was related to the familiarity of the GP and the perceived inaccessibility of services in secondary care, which three patients felt they would contact in the first instance. Four women were uncertain as to the most appropriate point of contact in the event of a query or related medical problem.

7.6.4 Facilitators of Access to Healthcare

Thirteen women reported that the current episode of care had resulted from their first presentation to their GP and had not experienced difficulties in accessing appropriate care. Nine of them received care through the Bridges project. Accounts of physical or mental suffering as a result of symptoms were absent from the accounts of eight of these women who felt they had received an appropriate, timely response to their complaints from the GP. They were more likely to report having been listened to by the GP and most reported a small number of visits to primary care prior to attendance at hospital. Five were surprised to progress through the system so easily.

Well I was very pleased. I was surprised that everything happened so quick. I thought it'd be the usual six month wait and the usual make an appointment and, so when he said that everything happens in the same day and just ring up to make an appointment I couldn't believe it really. I thought, "Well goodness."
Participant 735

All interviewees valued the input their GP to some extent. The central co-ordinating role of primary care, particularly with respect to record keeping and knowledge of the patient was felt to be especially valuable by 16 women. The ongoing relationship with the GP was felt to facilitate continuity of care and was important for 14 women. Women who disliked recounting problems of a "personal" nature especially valued a personal relationship. Seven women also appreciated the convenient location of their local GP surgery and felt this was important when accessing care.

They're local and, and usually if you go to the same one more or less, I mean they know you ... and, and they've got your records there and they can go through and look back on your records and see if there's anything that that illness is related to or anything like that...
Participant 508

The GP sort of knows you a little bit more, doesn't he? The specialist is only seeing you perhaps once or twice, so maybe that's one of the differences ... I mean obviously depends on how often you see your GP. But, I would think it is better, you know them better, don't you and they know you a little bit more. I mean the surgery I go to there's four or five doctors but I usually try and see the same doctor, especially if it is a gynae problem. So, yes, I think that is important. You don't know the doctor or the specialist at hospital do you? I think you would be more comfortable with your own GP.
Participant 507

The ability to see a doctor of their choice was therefore felt to be important by seventeen women when consulting for a menstrual disorder. Only two patients explicitly stated that having a choice of doctor was not important. Women recognised that whilst choice of GP was generally possible, this was usually not the case in secondary care. Seventeen women expressed a preference for a female doctor when consulting for a menstrual disorder five stated that this was because of embarrassment when undergoing pelvic examination.

Others felt that female GPs were more likely to have a better understanding of menstrual disorders (both through personal experience and better medical knowledge) and would be more sympathetic to women's complaints and more able to manage menstrual disorders effectively. Knowledge of menstrual disorders on the part of the GP was felt to facilitate access to hospital. Eleven women, ten receiving care within the Bridges project, felt that communication between primary and sectors had been satisfactory. These women were more likely to perceive primary and secondary care to be working together for the patient's benefit.

7.7 Discussion

This study has helped us to better understand women's experiences and knowledge of menstrual disorders, their consequent healthcare needs and their expectations of the healthcare system when seeking help. Well over half the women interviewed were experiencing troublesome physical symptoms which were having a considerable influence on various aspects of their lives, consistent with the findings from other studies[2,3,18,40,41]. A significant proportion of women in our sample had concerns that their menstrual problems were due to underlying malignancy. Women therefore require their problem to be taken seriously at first presentation, to undergo investigation to make a diagnosis and rule out pathology and to have rapid access to best available treatments to ameliorate morbidity as soon as possible. The response of primary care was key. As long as these steps were undertaken women did not necessarily seem to require or expect consultation with a gynaecologist in secondary care.

Given the fact that menstrual disorders have such an impact on women's well being it is important that they should have access to appropriate help and treatment. Despite this approximately half of the women interviewed had experienced difficulties, consistent with the findings of other studies[41]. The inherent chronic and cyclical nature of menstruation and menstrual disorders caused some difficulty for women when attempting to assert their need for healthcare. Lack of understanding among women regarding what is normal and acceptable menstruation lead to problems for women in identifying what is abnormal. Women looked to their GP for guidance in this matter, but there is evidence that GPs find this distinction just as problematic[161]. There appears to be a perception amongst patients

that menstrual disorders are likely to be dismissed by general practitioners as not worthy of investigation or treatment[1,3]. This problem was especially thought to apply when consulting a male GP. Although female GPs are felt to be more sympathetic to such complaints, there is no convincing evidence of difference in practice between the sexes[156]. The response of the GP led some women to believe that their problems occupied a low priority within the healthcare system. They became frustrated by their lack of progress and felt there were few opportunities to influence this.

Primary care was highly valued by women who appreciated the ongoing relationship with their GP who was usually seen as a familiar and trusted professional with a responsibility for co-ordinating of healthcare overall. Women also recognised the scope for choice when consulting a doctor in primary care, especially the ability to select a female doctor. This has previously been found to be important not only in the context of gynaecological conditions, but also when women consult for more general problems[297-299]. The Bridges Project retained these valued characteristics of primary care whilst addressing the deficiencies in the current system. The guideline-based system legitimises the complaint of abnormal menstrual bleeding in primary care and reduces uncertainty on the part of the GP. The system also provides a structure for more meaningful consultations in primary care. Allowing access to rapid investigation in secondary care with same day communication of results across sectors removes barriers to progress at the Primary-Secondary interface and better meets women's needs with respect ruling out serious pathology and making a diagnosis. The guideline promotes the use of evidence-based medical and surgical treatments and provides a possible framework for redesign of services between primary and secondary care.

7.8 Conclusion

It would appear that the Bridges Project model of care efficiently meets the needs of women presenting with menstrual disorders who require investigation to rule out serious or structural pathology. The provision of primary care led, highly structured management appears to reduce the numbers of women who perceive a struggle to proceed through the system and prompt investigation in secondary care without a traditional gynaecology outpatient consultation was acceptable to women.

	Number of women
Ethnicity	
White	21
Non-White	3
Socio-economic group	
Managerial / Professional	3
Clerical / Intermediate	6
Small employer / Own account worker	4
Lower supervisory / Technical	3
Routine / Semi-routine	4
Not working	4
Diagnosis	
No structural pathology	14
Polyps / Fibroids	7
Endometrial carcinoma	2
Endometriosis	1
Treatment	
None	4
Medical treatment	9
Surgical treatment	11

Table 7.1 Interviewees characteristics

Chapter 8: Attitudes toward Clinical Decision Making and Clinical Guidelines

8.1 Introduction

The Institute of Medicine defines guidelines as:

"Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[300]

There is an abundance of literature concerning guidelines, including development[301], implementation[302], their effect on practice[169], legal aspects[237] and clinicians' attitudes towards their use[173]. However, whilst work is being done to ensure the patients' perspective is considered during the development of national guidelines[303], little is known about patients' perceptions of doctors' decision making and how this might be affected by guidelines. In the Bridges Project, evidence-based guidelines formed the basis for the interaction between primary and secondary care and had a central role in defining the overall health care process. Given this, it was important to explore patients' understanding of the use of clinical guidelines in order to understand how they might perceive the new pathway of care.

8.2 Aim

To determine the attitudes of women with menstrual disorders towards guideline-based care.

8.3 Method

See Section 7.3, page 115.

8.4 Study Population

See Section 7.4, page 116.

8.5 Data Handling and Analysis

See section 7.5, page 116.

8.6 Results

8.6.1 Accounts of decision making

For most participants, decision making was seen as the outcome of a quasi-mysterious process, in which doctors' intuition, insight, experiential and medical knowledge is combined with their intimate knowledge of the patient gained through history and examination. Women found it difficult to define the precise characteristics of doctors' knowledge, though elements of doctors' status and training were involved.

Although women were unclear as to the exact mechanisms of doctor's decision making, two specific elements were thought to be important, knowledge of the individual patient and knowledge of the disease process. In the case of female doctors, these aspects were felt to be supplemented by the doctor's personal experience of menstruation and possibly also of menstrual disorders. Participants tended to emphasise one or the other element as being the most important influence on decision making, however some participants included components of both in their narratives. The relative importance of each aspect varied according to whether the participant was discussing decision making by a GP or a Gynaecologist or a male or female doctor.

Half of the participants constructed decision making in general as a highly individual process in which menstrual problems were seen as unique to the individual. The most important factors informing the decision making process were the specific information elicited from the woman during the index consultation and the doctor's insight into the patient and her individual circumstances gained during previous consultations.

Each case is different isn't it? They have to look at the evidence they've got and ... you know, what the person's been suffering and different ways of how to go about it.
Participant 508

Knowledge of the disease process was thus secondary to knowledge of the patient. Treatments were felt to be tailored according to individual need. For women who perceived decision making in this way, the quality of the doctor-patient interaction was paramount in their satisfaction with the decision making process. If the woman felt her voice had not been sufficiently heard during the consultation, she was likely to be dissatisfied with the decision making process and consequently disinclined to accept the doctor's decision in terms of management or treatment.

This construction of decision making was only applied in the context of the GP consultation. In discussions surrounding the decision making processes used by gynaecologists a "disease-centred" construction was employed. This is not unexpected since hospital specialists are unlikely to have prior knowledge of individual patients and may only see them once. This account was also given by approximately half the participants to describe the way in which they believed their GP made decisions. Women had more confidence in the decisions made by gynaecologists, as in addition to a supposed higher status in the medical hierarchy, they were perceived to have greater experiential knowledge from previous patients and a deeper "medical knowledge" of menstrual problems. These factors are central in the "disease-centred" account of decision making, in which all women with menstrual disorders are seen as having the same condition, will present in the same way and will be responsive to the same treatments.

I s'pose he can just go on his other patients and if any of them have had the same problem and ... you know, it's all in the sort of the same routine really isn't it?
Participant 16

Despite the recognition that similarity can often be drawn between cases participants did not volunteer guidelines as the basis of decision making in everyday practice. Accordingly in both types of account decision making was presented as unstructured process, often in terms of "trial and error".

I'm on HRT now and the first thing she said, she asked me about whether there was anything else, anybody else in the family suffered blood clots or anything else. So it's all done on what information you give them and trial and error, cos she said, "Well if this, if you have this one for three months, you come back in three months and if you tell me that you've suffered headaches, dietary problems, going to the toilet, we'll have to change it" so you are a guinea pig aren't you?
Participant 1

This contributed to the perceived lack of transparency surrounding decision making, seen as an inevitable consequence of the application of medical knowledge to individuals. Despite this, participants generally reported a desire to be more involved in decision making.

It's you that's being involved in this and I, I think it's important that you, you're treated like a ... an equal really and not sort of left in the dark about things.
Participant 59

8.6.2 Accounts of guidelines

Participants experienced a number of difficulties when accessing health care for their menstrual problems. These were either as a consequence of the structure and nature of the health care system or as a result of unsatisfactory encounters with doctors, or both. Many women struggled to prove the legitimacy of their compliant of a menstrual disorder to their GP. Often this was felt to be as a result of lack of knowledge or interest in menstrual disorders on the part of the GP combined with the "hidden" nature of the condition. Some women felt that their care had been disjointed (exacerbated by the chronic, cyclical nature of the condition) and lacking in overall structure and progression towards resolution. There were also doubts about the efficacy of the treatments offered, particularly when the decision making process was perceived as unsatisfactory.

We were interested to discover women's views on the possible impacts of a guideline-based system for delivering health care. Although guidelines were not mentioned

spontaneously when prompted nineteen women demonstrated some understanding of the nature and use of clinical guidelines, although five did not. The use of guidelines in general was familiar to only three women, at work and at school. Overall the participants' attitudes to guidelines were positive; they felt guidelines did have a role to play in resolving some of the difficulties they had experienced, although some problems with their use were identified.

Guidelines were most commonly constructed as a set of rigid rules that doctors must adhere to (ten women). They were concerned about the position of patients or doctors who disagreed with the guidelines or deviated from them.

Well guidelines is rules in't it? You know, guidelines are rules, they're given obviously a set of rules, this is what you need to follow ... no I mean it's like if it's a rule then they've got to follow that haven't they?
Participant 3055

Guidelines were perceived by ten participants (eight of whom gave accounts of decision making as a patient-centred process) through their inflexibility, as interfering with decision making and clinical freedom, restricting decisions that need to be made on an individual basis. There was concern that the use of guidelines might lead to care becoming more "procedural" and less "personal".

I think you could perhaps end up being merely that, a number, and not an individual with problems that are related to whatever you've come about.
Participant 8

Women who felt that their health care had previously lacked direction and structure were less likely to see this as a problem. Seven women saw guidelines as having a positive impact on progression by providing a "useful framework" (Participant 754) in which care could proceed, and within this more potential for continuity of care.

I think it would be good because presumably you'd have one person controlling your care and following it through and saying, "Right, OK we've tried this, now we need to do this and ...". Erm ... that, that might be easier from that point of view. And in theory you would know that person.
Participant 30

One of the most important perceived functions of a clinical guideline was for the categorisation of patients into groups, although reasons behind this were varied. Three women were suspicious that this use of guidelines could be an underhand method to justify rationing of access to secondary care. Eight women felt that categorisation would help to standardise care for specific conditions, ensuring quality and equality of health care, delivered through continuing medical education.

Like following certain guidelines for certain things. Because, at the end of the day, most illnesses follow a certain pattern. There's only the odd few that, you know, don't show certain symptoms, well then the odd few you're gonna expect, but if you follow certain guidelines for the, for the multitude, as a whole, you're gonna get more people having proper care.
Participant 60

Thirteen participants struggled to prove the legitimacy of their problem. Seven women felt that guidelines for menstrual disorders would provide them external validation for their complaints, reducing the need to "prove their case", and provide evidence that the doctor is taking them seriously.

I think in a way you start to understand that ... it's not just you ... and that they're taking you seriously because they are following a pattern, so there is not this, you know, this thing about it's just a period, it's not a problem. Erm ... and that ... I don't know I think it's more reassuring, when you don't think that they're like ... spitting in the dark.
Participant 60

On a practical note, four women were concerned that a guideline-based system in primary care would be unworkable at present for a number of reasons; lack of resources,

doctors' time, or the support networks necessary for implementation. Specialist GPs, who would have more knowledge of the condition in question and thus be in a better position to interpret guidelines, were seen as being best placed to deliver guideline-based care.

I can't see it would work because you would need guidelines on every subject under the sun for the GP wouldn't you? And they'd just be sitting there looking through ... I don't know if that would actually give you the confidence unless there was a specialist doctor within the practice.
Participant 754

8.6.3 Information

In order to make sense of their medical problems and health care, women require more information. Thirteen participants explicitly reported an unmet need for information, both clinical and procedural. Some raised the issue of access to guidelines for patients, so in subsequent interviews we explored the extent to which women felt patients should have access, and the likely consequences.

Twelve participants believed that access to guidelines would be beneficial. It was felt that access to guidelines would equalise the balance of power within the doctor-patient relationship, through transparency of decision making. There would be more scope for patients to question and monitor the care they receive and participate more fully in decision making if desired, thus increasing the sense ownership of the health care.

You'd be more reassured that you are actually following a path towards your goal of, of being better, because you would know that you'd jumped in at step one and this would help. You know, and a little arrow taking you back to stage two and if it fails something else that you can try again. At least you feel like you're in the system if you like and somebody actually has an interest in you and where you are within the system and where you're going, and everybody's pushing towards an outcome.
Participant 754

Three women commented that it was important to ensure that the guideline was presented to patients appropriately. There were concerns from six participants about the consequences of patients' access to guidelines. Firstly that access might lead some patients to feel overly responsible for their health care, causing them unnecessary anxiety through a lack of understanding and secondly that the knowledge gained from guidelines might allow some patients to unfairly manipulate the system. Six women thought that patients should not see the guidelines at all. Offering patients guidelines was felt to be irrelevant, particularly by women who reported a trusting doctor-patient relationship and previous satisfactory experiences with accessing health care.

8.7 Discussion

Patients seem to be unclear about the exact basis for the decisions that determine their medical care and perceive it to be unsystematic and based on "trial and error". This lack of transparency is disempowering for women and seems partly responsible for the frustration experienced by some women when attempting to access health care for menstrual disorders.

The two aspects of clinical decision making identified by participants as important; knowledge of the individual patient and knowledge of the disease process concur with what is known about the decision making process, in that experience and context are influential factors[161,304]. Knowledge of the patient was seen as being most important by half of the participants. This may in part be a consequence of the nature of menstrual disorders; very "personal" conditions frequently having a significant impact on lifestyle. It is therefore possible that patients suffering from other medical conditions might view decision making differently. Knowledge of the disease was felt to be more important in gynaecologists decision making, in whom women reported more confidence. This contrast reflects probably the ways that GPs and specialists work and is likely to be influenced by factors other than perceived quality of decision making, such as the perceived status of the consultant over the GP.

Most participants identified how guidelines would be utilised in the context of clinical decision making, although actual experience of their use was unfamiliar. The use of

guidelines sits more readily with the "disease-centred" construction of decision making than the "patient-centred" view with which there is potential for conflict. Overall women were positive about the use of guidelines as long as they were not interpreted too rigidly and the needs and wishes of the individual woman were considered. They were felt to be a useful mechanism to ensure progression towards resolution firstly by providing external validation for menstrual disorders and raising awareness of the condition in primary care and also by providing pre-defined pathway of care on which to move forward. These views of guidelines; ensuring the equality and quality of health care but in a potentially inflexible way are the same as the published views of physicians[173,305].

Over half of our sample expressed a desire for more information about the nature of their problems and their management. It is widely recognised that patients with many different conditions in a variety of circumstances require information from their healthcare providers, and there is a significant proportion of patients whose needs in this respect are not currently being met[306-311]. Patient's desire for information is linked to their desire to be more actively involved in decisions about their management. Individuals are more likely to wish to be actively involved in decisions about medical conditions which are chronic, not life threatening and which have a significant impact on quality of life[312]. In general, studies have shown that better informed patients are more likely to comply with treatment, to be more satisfied, less anxious and to have improved outcomes[311,312]. One investigation into the needs of women with abnormal uterine bleeding found that 98% wanted to be informed about their condition and the majority wanted to be involved in decision making. Increased patient participation led to enhanced satisfaction with treatments[313]. Similar results were obtained from a qualitative study which found that women felt they were given inadequate explanations for their problems and felt that more information would enable them participate more fully in their care[2].

Healthcare professionals in the NHS have thus been encouraged to involve patients in decisions about their care[277,314,315]. This can be achieved in a variety of ways including conversation during the consultation, pamphlets, books, videotapes and educational interventions[306,310]. although concerns have been raised about the extra time this may require during a consultation and the inherent difficulties in eliciting patient's

preferences for decision making[311,316]. It has been suggested that patients should have free access to guideline-based integrated care pathways if they wish[317]. Half of the women we interviewed supported this idea. Using guidelines in this way has the potential to enhance patients' experiences of accessing health care and improve clinical outcomes by promoting the partnership fundamental to patient centred care. This is especially relevant in the case of menstrual disorders where decisions are made on the basis of subjective symptoms. Exactly how this would be best achieved requires further investigation.

8.8 Conclusion

Overall, patients' views of the use of a guideline-based pathway of care were positive, but with some reservations.

Chapter 9: Patient's Preferences for Healthcare

9.1 Introduction

Limited healthcare resources and seemingly unlimited demand for healthcare means that decisions must be made surrounding the allocation of resource[318]. Recent NHS reforms have advocated increased patient and community involvement in these decision making processes[277,319] and a variety of approaches have been used to elicit their views. Relatively simple methods such as opinion polls and patient satisfaction surveys have been criticized on the basis that they ignore intensity of preferences for, and benefits of various aspects of healthcare, they provide little help in addressing policy questions as they do not address the real decision making issues faced by policy makers and they do not incorporate any concept of scarcity of resource or the need to make sacrifices when planning healthcare, the "opportunity cost" [318].

Within the discipline of health economics efforts have been made to address these criticisms and elicit patients' preferences through the use of visual analogue scales, standard gamble, time trade off and willingness to pay methods[318]. The first of these three have been used within the context of the Quality Adjusted Life Year (QALY) paradigm[320]. Comparisons can be made between the numbers of QALYs gained between different healthcare interventions. However, whilst the use of the QALY gives an indication of strength of preference for various clinical states and outcomes as a result of healthcare interventions it ignores attributes of the provision of healthcare (for example waiting times, provision of information to patients and location of healthcare provision) that are also known to be important to patients. Willingness to pay can be used to estimate the value of interventions and attributes of healthcare services in monetary terms and is based on the argument that the maximum amount of money a consumer is willing to pay for a commodity is a measure of consumer satisfaction with or benefit derived from that commodity. Like other methods, it does not incorporate the notion of opportunity cost[318].

Conjoint analysis is a rigorous economic method which allows the estimation of strength of preference for various attributes of a service which can be designed to address a specific question incorporating the notion of sacrifice[318]. The technique was originally developed in the context of market research and has been widely used in transport and environmental economics and in the valuation of provision of public

services.[321] During the 1990's it was investigated and developed as a tool to elicit the views and preferences of patients and communities with respect to various aspects of healthcare. In a conjoint analysis questionnaire, respondents are presented with a series of hypothetical scenarios comprising different levels of key attributes of a good or service and are asked to choose between them. This allows the estimation of the relative importance to consumers of different aspects of a good or service by examining the trade offs made between aspects when choosing between options[322].

There are five key stages in the development of a conjoint analysis questionnaire[321,322]. The first is to identify the attributes to be included. When considering optimal ways to provide a service the attributes are often predefined by proposals for that service such as location, waiting time, staffing and degree of choice involved for patients. If attributes are not predefined, the possibilities can be explored through literature review, group discussion and qualitative interviews. Levels must then be applied to the attributes that are plausible and actionable in reality, thus encouraging respondents to trade between them. Scenarios are then drawn up which describe all configurations given the attributes and levels chosen, the number of possible scenarios will thus increase with the number of attributes and levels. It is rarely practical to present all possible scenarios to respondents in one questionnaire, and these are reduced to a manageable level using experimental designs. Preferences are elicited using one of three methods; Ranking (in which respondents are asked to list the scenarios in order of preference), rating (respondents assign a score to scenarios to indicate their preference) and discrete choices (DCE) in which respondents are presented with a series of choices and asked to select their preferred option. Since ranking and rating exercises are rarely used by individuals when making decisions in the real world and discrete choices are felt to more closely resemble decision making on a day to day basis this is the preferred method for undertaking conjoint analysis in the healthcare setting[321,322].

The final stage involves the use of regression techniques to analyse responses. The importance of the attributes to respondents is indicated by the statistical coefficient for that attribute. Coefficients with a p value of less than 0.05 are assumed to be statistically significant and therefore important to respondents. The relative importance of the attributes is indicated by the relative size of the coefficients for each attribute. Willingness to trade between attributes can be useful when deciding the best way to

provide a service within a framework of limited resources. The ratio of any two coefficients shows the marginal rate of substitution between these attributes (the rate at which individuals trade between these attributes). If cost is included as an attribute in the study, WTP for an individual attribute can be estimated indirectly by the ratio of any attribute coefficient to the cost coefficient. Finally benefit or utility scores can be generated for alternative ways of providing services allowing the ranking of one against another when setting priorities[321,322].

The technique has previously been used successfully to elicit patient's preferences for the delivery of healthcare in the UK in both primary and secondary care sectors. Attributes of care and clinical outcome with respect to out of hours GP services[323], orthodontic services[322], liver transplantation services[324], vascular surgery[325], and outpatient gastroenterology services[326] are all reported. Trade offs between location of care (local vs. central) and waiting times (for initial consultation, investigations and results) are common themes running through all these studies[327]. In the context of women's health services, conjoint analyses have been used to investigate women's preferences for the clinical management of miscarriage[328], preferences for home versus hospital intra-partum care for low risk women[329] and costs, process and clinical aspects of IVF treatment[330]. One study has been undertaken in women with menorrhagia, primarily to demonstrate the application of the technique to valuation of healthcare interventions, in which preferences for hysterectomy were compared to minimally invasive surgery although processes of care were not considered[331] .

Although conjoint analysis has been widely described and reported, there several methodological issues which have yet to be fully resolved, requiring consideration in the final design of the questionnaire and caution in analysis of results. It is important that the attributes and levels included are indeed important to respondents. Exclusion of important attributes or unrealistic levels will result in inaccurate estimates of benefit[321]. Further work is required to investigate attribute levels and their effects on estimated benefits. There is limited evidence that order of presentation of the scenarios themselves has no effect on results, which requires further reinforcement[332]. Fundamental to the concept of a discrete choice experiment is that respondents engage in the task and trade rationally between all levels of attributes whilst completing the questionnaire. There is some evidence that this is not the case. It is suggested that participants respond through

a "veil of experience" when considering new types of service provision, and will demonstrate statistically significant preferences for the service provision they are most familiar with[333]. Additionally it has been suggested that a significant amount of non-random error may be generated by participants engaging poorly with the task through lack of incentive. Some may ignore much of the information they are presented with, misunderstand information or simplify the task by only considering their favourite attributes when answering (known as holding a dominant preference) although it is unclear to what extent these might pose a threat to the data generated from DCE[334]. Further concerns exist with respect to the validity and reliability of the technique, especially the use of conjoint analysis to elicit WTP values in the context of healthcare services. It is possible that in a publicly funded healthcare system such as the NHS, participants may misinterpret this attribute as the cost incurred by the healthcare service, or simply ignore the cost attribute altogether since they have never borne the cost of healthcare directly[335]. Further work is needed to elucidate what respondents actually understand by the WTP attribute. There is also evidence that the levels of the WTP attribute may impact on the final benefit estimates[336].

In summary, conjoint analysis is a potentially useful technique for assessment of patients' preferences for healthcare and in establishing the importance of various aspects of care to users. Further methodological work is needed before the technique can be considered established.

9.2 Aim

We set out to establish patients' preferences for healthcare provision when accessing services for menstrual disorders by using conjoint analysis in the form of a discrete choice experiment.

9.3 Methods

A list of possible characteristics for inclusion in the final questionnaire was generated through discussion amongst the project steering committee and conversations with patients and staff. The preliminary results coming from the qualitative interviews were also considered. Ten characteristics thought to delineate the two models of service provision were short-listed: Consultation with GP or consultant, sex of doctor (relating to degree of choice available to women), continuity of care, clinical information about diagnosis and treatment, procedural information about what will happen and when, number of consultations, waiting time in primary care, waiting time in secondary care, distance travelled to get healthcare and waiting time for test results. A ranking exercise was undertaken with patients waiting in general gynaecology clinics where women were asked to rank the ten characteristics in order of importance. The final selection of 6 attributes was made by the steering committee after reflecting on these responses. (Table 10.1) In order to ensure the attributes selected were important to patients, a small pilot conjoint analysis was undertaken on 37 women waiting in the general gynaecology clinic, all the coefficient were significant and the attributes were not changed as a result.

The levels for the attributes were selected to relate to prevailing waiting times for results, and waiting for a doctors appointment; the attribute relating to how often you get to see the doctors was included to establish how much patients value continuity of provision, and had 3 descriptive levels. The type of doctor patients consulted (either a Consultant or GP) delineates the two models of care. A cost attribute was also included in order to normalise the value of differences in other attributes in monetary terms. We attempted to establish a descriptor for this that the majority of participants would understand and engage with. We asked women waiting in the general gynaecology clinics to rank descriptors for describing this attribute (including willingness to pay, cost to you, and amount to you). Most women appeared to identify with the descriptor 'cost to you' this was therefore used in the questionnaire.

Scenarios were drawn up from the attributes and levels chosen to describe all possible service configurations. The scenarios were organised into pairs, if all possible combinations of levels were used it would result in 768 possible scenaorios. This was

reduced to a more manageable level using the fractional factorial experimental design software package SPEED[337]. Checks were made to ensure attributes were not correlated using SPSS version 11 (SPSS Inc, Chicago, USA). A constant comparator with attributes set to correspond with the OSMC was used for choice scenarios to make the choices easier to understand and to help maintain the statistical properties of the design. In order to minimise the burden on participants half of the sample of questionnaires incorporated the first half of the choice scenarios generated by SPEED, whilst the other half contained the remainder. The design was also ordered in such a way as to help prevent respondents being influenced by 'ordering effects'[332]. Consistency type rationality checks were also included. Postal questionnaires were sent out to women with a pre-paid return envelope. One reminder was sent after two weeks. A copy of the final questionnaire can be found in Appendix 8.

The econometric analysis was been undertaken using random effects Probit using STATA (StataCorp LP, Texas, USA). Figures in brackets underneath the coefficients and willingness to pay figures relate to 95% confidence intervals which allow for uncertainty. Willingness to pay confidence intervals allow for uncertainty both in relation to the value of the coefficient and also in relation to 'cost to you' which is used as the denominator to derive willingness to pay figures.

9.4 Study Population

The study population is described in Chapter 3.

9.5 Results

One hundred and twenty-four questionnaires were returned, a response rate of 64%. 117 of these were consistent responders.

All the coefficients except those related to continuity of care, appear to be highly significant and consistent with our prior expectations about the signs of the coefficients. They suggest that the average respondent is willing to pay £63.94 (CI: £8.65/£253.03)

in order to have a Consultant rather than a GP, and would be WTP £64.48 (CI: £10.45/£249.25) to have a female rather than a male doctor. Avoiding an extra day waiting to see the doctor is worth £3.60 per day (CI: -£1.79/-£9.78) to the average respondent, whilst avoiding an extra day waiting for test results is worth £4.74 (CI: -£1.79 / -£14.86). Patients also seem to place a value upon continuity of care, with a difference between getting to see the same doctor all of the time rather than half of the time being valued at £44.76 (although not significant at the 5% level using a 2 tailed test), whilst a difference between getting to see the same doctor half of the time rather than none of the time is valued at £61.77 (CI: -£1.64/£278.57) (Table 10.2).

9.6 Discussion

It is reassuring that the actual coefficients for the baseline model seem to have signs that make intuitive sense, fit with some prior expectations about what we would expect about patients' preferences and also the results we have obtained from the qualitative interviews in the current study. All coefficients except those related to continuity of care were statisitically significant, indicating that they were important to women when receiving health care for a menstrual disorder. The continuity of care attribute may well have proved significant if the comparison was made between seeing the same doctor "all of the time" and "none of the time".

The results indicate that the Bridges project model of care fits well with patients' preferences. Although the preferred model would be one where a patient was able to consult a same female gynaecologist all of the time with minimal waiting for an appointment and test results, this is simply not available within current structures. It would appear that the ability to see a female doctor (a choice usually available in primary care, but not in the OSMC) is worth as much as seeing a consultant. In The NHS Plan, the target waiting time to consult a GP is 48 hours, and the maximum waiting time for a hospital outpatient appointment is 12 weeks[338]. The impact of one day's wait in our study was -£3.60, which amounts to -£7.20 for the Bridges project and -£302.04 for the OSMC, a very favourable comparison.

Attributes	Levels
How long you have to wait for test results	1 day 2 days 2 weeks 4 weeks
The type of doctor you see	GP Consultant
The sex of the doctor you see	Male Female
Time spent waiting for an appointment to see the doctor (either the GP or the consultant)	1 day 4 days 6 weeks 12 weeks
How often you get to see the same doctor	None of the time Half of the time All of the time
Cost to you (i.e. perhaps because of absence from work or travel costs – Please assume you would loose this amount of money even if you would not).	£0 £25 £75 £125

Table 9.1: Attributes ands levels chosen for the conjoint analysis questionnaire

Attribute.	Coefficient.	P > [322]	Willingness to Pay (WTP)
Difference in type of Doctor (Value Consultant vs. GP)	0.356972 (.0746903 / .6392536)	0.013	£63.94 (£8.65 /£253.03)
Difference in type of Doctor (Value Male vs. Female).	-0.3599656 (-.6296926 / -.0902386)	0.009	-£64.48 (-£10.45/ -£249.25)
Difference in time spent waiting to see doctor (impact of a day)	-0.0200937 (-.0246967 / -.0154906)	0.000	-£3.60 (-£1.79/ -£9.78)
How often you get to see the same doctor (all of the time - half of the time).	0.2498718 -.0405287 / .5402724)	0.092	£44.76 (-£4.69/ £213.85)
How often you get to see the same doctor (half of the time – none of the time).	0.3448268 (-.0141253 / .7037788)	0.060	£61.77 (-£1.64/ £278.57)
How long you have to wait for test results (impact of a day)	-0.0264861 (-.0375339 / -.0154383)	0.000	-£4.74 (-£1.79/ -£14.86)
Cost to you.	-0.0055826 (-.0086389 / -.0025264)	0.000	
Constant	0.4077861 (.0571077 / .7584645)	0.023	£73.05 (£6.61/ £300.21)

Table 9.2: Results of conjoint analysis questionnaire

Chapter 10: Discussion

10.1 Achievements

This study entailed the implementation and evaluation of a novel approach to the delivery of health care for women with menstrual disorders, involving a significant role change for both primary and secondary care and a change in the way in which patients interact with the healthcare system. We demonstrated that GPs do seem motivated to engage with this type of integrated service provision. The timing of investigation with respect to treatment was improved (very important given the 2% of women with endometrial malignancy), and that the clinical outcomes of guideline-based GP-led management of menstrual disorders are comparable with the highly organised, consultant-led care provided by the OSMC over the study period in terms of investigations requested, numbers of medical and surgical interventions and patient self-assessed health status. These improvements were not associated with an increase in resource use in either primary or secondary care.

Modern health care provision should take into account patients' expectations and needs. Despite the fact that the Bridges model of care was compared with a one-stop clinic that had previously been shown to be associated with considerable benefits in terms of patient experience over traditional outpatients clinics[211] further improvement was demonstrated in the Bridges Project group. Several aspects of the Bridges pathway scored better in the PCD evaluation; the accounts women provided of accessing care during the in depth interviews helped us to explore the themes addressed semi-quantitatively by the PCD in more detail. Preston et al[215] argue that progress both within the health care system and also towards resolution is central to patients' perception of health care quality. Progress, as measured by the PCD, encompasses accessing appropriate care or "getting in", how the service provides for patients' requirements or "fitting in", provision of information, continuity of care including good communication, and the overarching theme that negates a sense of being left in "limbo".

Women's needs ranged from reassurance in the face of concerns over serious pathology (especially gynaecological malignancy) to definitive treatment. Existing health care structures often did not cater for these needs and many women were left with the impression that their problem was not listened to or was dismissed with male doctors being perceived as particularly reluctant to respond to complaints of abnormal

menstruation and the associated distress. These difficulties encountered in "getting in" were at least partly related to the nature of the problem, but perhaps exacerbated by competing pressures and hindered by procedures designed to address other health needs or performance targets. Thus it is arguable that procedures adopted to achieve a maximum of 48h waiting time to see a GP, whilst suited some patient groups has disadvantaged others. This is perhaps not surprising as different groups of patients have different criteria for 'fitting in'. The guideline-based system appeared to facilitate women's access to investigation and this rapid access was highly appreciated; more so by women who were primarily seeking reassurance. For those who saw it as a step towards cure, it often raised further questions and in some instances left them uncertain about the next step, as access to effective treatment particularly in terms of surgery is perceived to lie within in secondary care. That patients preferred the Bridges model even though they did not consult with a gynaecologist (highly valued in the conjoint analysis) in the majority of cases, might be a reflection on the observation that patients attending primary care with menstrual problems often exercise some choice of the doctor they see, especially the ability to select a female doctor (valued equally in the conjoint analysis with seeing a consultant) who may be perceived to be more understanding of the problem and therefore more likely to offer real help. It should however be noted that the decision to select a female doctor was often made after initial contacts with a woman's usual GP were non-productive, and in that sense the decision to select an alternative female doctor was not a positive one, rather a means to an end in which overall continuity of care with a single GP was sacrificed. Most participants did express a preference for continuity of care (supported by the findings of the conjoint analysis) and it is clear from their accounts that this was often not achieved in primary care; many patients were resigned to lack of continuity, or were willing to sacrifice continuity in favour of progress.

Overall, the Bridges pathway appears to allow patients better control over their journey through the healthcare system and more purposeful visits to healthcare providers both in primary and secondary care especially at the outset. The final section of the PCD ("Your healthcare overall") suggests that the impact of the new pathway may blunt over time, consistent with previous observations when comparing the OSMC to the traditional gynaecology clinic[211]. This may reflect the fact that once initial investigation is complete and patients are commenced on medical treatments in primary care the

overall direction of care becomes less well defined and formal arrangements for follow-up with the GP less prescribed. This matter requires further investigation and expected later steps in the process may require clearer delineation or modification.

In terms of resource use and overall costs, one of the most important findings was that the initial fears that the Bridges pathway may result in increased workload in primary care did not materialise, in fact women referred to the OSMC continued to utilise GP services at the same rate as those who were not referred to the clinic, which suggests that multiplicity of providers may increase resource use with no clear benefit. This requires further evaluation. Overall the integrated approach resulted in reduction of workload both in primary and secondary care and therefore reduced cost to the NHS. Given that health outcomes were comparable we assume that such saving largely resulted from reduced duplication and non-value adding work.

10.2 Obstacles

In order to successfully undertake the study with limited time and resources, a pragmatic approach to study design, particularly recruitment was required. It is possible that a randomised controlled trial would have yielded more robust conclusions, however this would not have been feasible in the current structures in primary care without a considerable risk of contamination. We attempted to keep the burden on GPs in terms of patient recruitment as low as possible in order to maximize the numbers of GPs participating. The project was therefore formally explained to women and consent secured for participation in secondary care. Few patients declined to be involved in the study in either group, given the amount of time and commitment involved in terms of initial paper exercises, ongoing diary commitment, possible interview and paper exercises at eight months on exit. Levels of participation were higher in the Bridges group; a likely consequence of a greater sense of engagement with healthcare, and an improved experience. This strategy also ensured consistency with recruitment to the control group, where recruitment at the time of referral in Primary care from the remaining PCTs would have been impossible given time and project staffing constraints. It is unknown whether GPs utilizing the Bridges Project explained the nature of the scheme to women at the time of referral for investigation and how many patients may have subsequently requested a traditional outpatient's referral. Twenty-

four patients in the control group were from SL-PCT. A proportion of these were referred to the Menstrual Clinic prior to the start of the Bridges Project, and some from GPs who did not utilize the Bridges Project at all. It is unclear how, if at all, this would influence health outcomes or patients experience of healthcare. It is possible (although unlikely given the traditionally low uptake of guidelines in Primary care) that GP referral and prescribing may have been positively influenced by the distribution of the project pack containing guidelines to each GP in SL-PCT.

Levels of GP participation may seem unsatisfactory on first inspection, but similar levels of participation have been noted in other studies involving general practice[223-226]. Given that the study was undertaken during a period of re-negotiation of the GP contract, a time of great change and low morale within general practice as a whole, the level of GP participation was realistic. Menstrual problems generally tend to be dealt with by female GPs within practices and this may also have been a factor in the total number of GPs who participated in the project.

It was necessary to be flexible when making the approach to general practice. In all cases the initial approach was made through the practice manager and only through individual GPs when this failed. This strategy may not be ideal in that it is generally part of the as the practice manager's responsibility to protect GPs from unsolicited approaches from external bodies; refusing access to the doctors is therefore a legitimate course of action. The power which practice managers hold is negative rather than positive in that it is far easier for them to obstruct meetings with GPs than to grant them[225]. An alternative strategy is to ensure that individuals are provided with written information about the proposed research prior to being approached in person about participation, in order that agreement is not obstructed by suspicion, incorrect assumptions or lack of adequate information. It is suggested that following this GPs and practice managers are contacted simultaneously and asked for their reactions to the information so that practice managers are not left to negotiate with GPs on behalf of researchers[225]. Whilst being initially more time consuming this approach may have saved resources in the long term and minimised irrational refusals to participate.

During the course of engagement with SL-PCT, GPs and other members of the Primary care team expressed a variety of views and opinions about the Bridges Project and the

concept of integrated care. Attitudes were mixed from the outset and changed as the GPs experience with the new scheme grew, and was often influenced by positive feedback from patients. Given that the Bridges project was an entirely new way of working for most of those concerned, a formal exploration of experiences of GPs would have enabled us to learn more about how the Bridges Project pathway functioned in primary care; the factors motivating participation, barriers to change and how the scheme has impacted on practice. A series of focus groups, the aim of which "is not to infer, but to understand, not to generalise but to determine the range and not to make statements about the population but to provide insights about how people perceive a situation"[339] may have been a feasible methodology given the available project resources, but ensuring adequate participation would probably have proved challenging. It may have been easier to secure participation for in depth qualitative interviews with individuals, but given the labour intensive nature of this methodology it would simply have not have been feasible.

10.3 The Bridges Project within the wider healthcare context

Previous attempts have been made to influence the pattern of referral between primary and secondary care with variable results. In East Anglia, an educational package on the management of menorrhagia delivered to general practitioners was shown to positively influence their referral rate and prescribing patterns[178,340]. Re-organisation in secondary care, coupled with evidence-based guidelines adopted in primary care was shown to result in more rapid management decisions in patients presenting with acute renal colic[179]. On the other hand, dissemination of infertility guidelines to practices in Glasgow coupled with educational meetings resulted in only a modest change in the rate of investigations carried out before referral, with no detectable differences in outcomes or costs[341]. Published research accepts referral as a means of communication between healthcare sectors. It attempts to improve care by improving adherence to guidelines and subsequently influencing referral. In the case of menstrual problems, this system is supported by the two-phase RCOG guidelines for use in primary and secondary care[25,49]. Referral however is influenced by a range of complex factors beyond the dissemination of knowledge, guidelines and education. Our approach was different in that we aimed to promote patient progress whilst removing the traditional boundaries between the care sectors.

It is important that services evolve to embrace changing patient expectations and to respond to the national agenda. Patients are increasingly better informed of treatment options, which in theory should facilitate better engagement with services and greater control over their healthcare. In practice women with menstrual disorders frequently feel that their problems are not a high priority within the overall strategy of the NHS and some do struggle to assert their needs, especially at primary care level. Difficulties were still reported by women registered with general practices in whom one or more GPs were actively engaged with the project. Full empowerment for these women thus remains elusive even within the new scheme.

Centralisation allows hospitals to concentrate resources towards more complex interventions, and there is increasingly a need for services to be provided in community settings[342]. Practice based commissioning and payment by results will change the dynamics between primary and secondary care and changes in referral patterns consequent to these initiatives should be evidence based and able to demonstrate advantage[342,343]. An important feature of the Bridges pathway is its ability to deliver clinical care that is booked, communicated and delivered in such a manner as to minimise disruption to patients. The project aimed to achieve improvement through an integrated network of provision, and by tackling the rigid barriers between the main sectors[342]. Within UK health policy the Bridges pathways embraces the evolving and widening role of the GP[344].

10.4 The Future

Having had the experience of implementing the new scheme, on reflection there are a number of areas in which improvements could be suggested. One issue is that of communication of clinical information between healthcare sectors. The scheme in its present form relies on the transfer of information stored on paper by fax, which in some cases generates large numbers of pages of the integrated care record containing the same information. This system is relatively labour intensive, and involves some duplication which appears to be a disincentive for some "paperless" GP practices and could potentially cause problems in knowing whether the copy of the ICR to hand is the most recent. Electronic transfer of information between primary and secondary care

would seem the best solution to the problem, but until the NHS has the necessary infrastructure in place in terms of computer systems, the ability for those in primary care to access the results of investigations undertaken in secondary care electronically and the necessary booking systems this cannot become a reality. A more realistic alternative at the present time might be to ask women to carry the ICR in booklet form to each of their attendances in a similar fashion to the system of "hand held" notes which operate maternity units in the UK, returning the notes to the GP at the end of the episode of care.

The concept of a patient held record in addition to providing a more efficient means of inter-professional communication might also be used to address women's continued needs for information both on menstrual disorders and their management in terms of investigation and treatment. A modified ICR containing information for patients at each stage could be issued to patients at presentation. There is evidence that the provision of information can alter patients' treatment preferences and improve outcomes of care. The introduction of a structured package of information, including formal interview to elicit and explore treatment preferences in the context of menorrhagia did alter clinical outcomes and resulted in fewer women undergoing hysterectomy[345]. In addition, it is possible that this might have a positive effect on patient's sense of ownership of the healthcare process and redress the balance of power within the doctor-patient relationship, going some way to further empowering women.

This model of care would appear to have the potential to be applied to areas other than menstrual problems. Any condition in which patients' presentations and needs in terms of investigation and treatment (medical and surgical) are fairly predictable could be considered suitable. Within gynaecology this might include urinary incontinence, infertility and fertility control (termination of pregnancy and sterilisation). It is also easy to imagine how the model might be applied in other surgical specialties where the workload is largely elective such as urology and opthalmology. It is not however possible to directly extrapolate from our findings to other areas, and there is a need for further research using different patient groups and disease conditions.

The Bridges project has been a success and continues to provide a popular service for women with menstrual disorders in SL-PCT; we plan to extend it to the other PCTs in

the area. This would be an ideal opportunity to implement and evaluate some of the suggestions for improvements including a more formal qualitative exploration of the attitudes and experiences of those working in general practice towards integrated care, in order to inform future developments.

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Appendix 1: Bridges Project Guidance for Menstrual Disorders

BRIDGES PROJECT GUIDANCE FOR MENSTRUAL DISORDERS

This guidance applies to **premenopausal women of any age with abnormal menstrual bleeding** with or without dysmenorrhoea. Abnormal bleeding is defined as that which is:

- **Heavy** causing anaemia, excessive, flooding, clots, deviating from previous pattern, or which interferes with normal activities
- **Prolonged** more than 7 days
- **Irregular** beyond a 21-35 day cycle, or deviating from previous pattern, or unpredictable
- **Intermenstrual bleeding** is any bleeding outside the normal days of flow

See Appendix 1 for the rationale for investigation and treatment, and routes of investigation.

TREATMENT OF MENSTRUAL DISORDERS

Women should keep a menstrual diary to record cycle regularity and response to treatment
Continue treatments for 4 months to assess response unless side effects are unacceptable

WOMEN AGED < 40 WITH REGULAR HEAVY PERIODS

1st & 2nd line choose one:

Continue indefinitely if effective

- **Combined Oral Contraceptive Pill**
  If no contraindication
- **Tranexamic acid 1g qds** when heavy
- **Mefenamic Acid 500mg stat then 250 mg tds**
  Use preferentially if pain
- **If has IUCD**
  Remove it or change to Mirena
  or add 1st then 2nd line treatment

If treatments 1 and 2 fail then ENDOMETRIAL ASSESSMENT is needed

3rd & 4th line choose one:

Continue indefinitely if effective

- **Mirena**
- **Tranexamic Acid & Mefenamic Acid** at dose above
- **Danazol 200mg od continuously** for 4 cycles only

If three or more treatments fail and patient suitable for surgery book directly

WOMEN AGED ≥40 WITH REGULAR HEAVY PERIODS

ENDOMETRIAL ASSESSMENT FIRST

1st & 2nd line choose one:

Continue indefinitely if effective

- **Tranexamic acid 1g qds** when heavy
- **Mefenamic Acid 500mg stat then 250 mg tds**
  Use preferentially if pain
- **If has IUCD**
  Remove it or change to Mirena
  or add 1st then 2nd line treatment

3rd & 4th line choose one:

Continue indefinitely if effective

- **Mirena**
- **Tranexamic Acid & Mefenamic Acid** at dose above
- **Danazol 200mg od continuously** 4 cycles only

If three or more treatments fail and patient suitable for surgery book directly

WOMEN OF ANY AGE WITH IRREGULAR PERIODS OR INTERMENSTRUAL BLEEDING

ENDOMETRIAL ASSESSMENT FIRST

1st line	• **Combined Oral Contraceptive Pill** if no contraindication
2nd line	• **Provera 10mg bd** for 21 days out of every 28 day cycle Start day 5 for 3 - 4 cycles, then stop
3rd line	• **Norethisterone 5mg tds** for 21 days out of every 28 day cycle Start day 5 for 3 - 4 cycles, then stop

If three or more treatments fail and patient suitable for surgery book directly

MENSTRUAL DISORDER WITH PRE-MENSTRUAL SYNDROME

If any woman has significant PMS symptoms, see age group guidance, but also consider as first line (after investigation if indicated) one of the following:

COCP	If no contraindication
Fluoxetine	20mg / day for 3 – 6 months in combination with other treatment
Danazol	200mg od continuously for 4 cycles only

WHEN TO BOOK FOR SURGERY

- Failure to respond to or unacceptable side effects of at least 3 types of medical therapy
- Due consideration for surgical and anaesthetic risk
- Risk-benefit considerations
- Consider Laser or Balloon Endometrial Ablation as a less invasive alternative
- Family complete (contraception is required after Endometrial Ablation)

You may directly book the patient for surgical treatment as follows:

- Hysteroscopic Polypectomy
- Laser Ablation of the Endometrium
- Endometrial Balloon Ablation
- Total Abdominal Hysterectomy, ovaries conserved (TAH)
- Total Abdominal Hysterectomy and Bilateral Salpingoophorectomy (TAH & BSO)
- Laparoscopic Assisted Vaginal Hysterectomy (LAVH)

See Appendix 2 for further information about each of the options
Patients will be reviewed by their consultant at pre-assesment clinic 1 week prior to surgery

Book through Menstrual Disorders Clinic (MDC) co-ordinator, Debbie Rawlinson

Phone (0116) 258 5072 Fax (0116) 258 7560

APPENDIX 1: RATIONALE FOR INVESTIGATION AND TREATMENT

All women should undergo the following:

- **Abdominal examination:** Note the presence of masses or tenderness.
- **Speculum examination:** Confirm the health of the vulva, vagina and cervix, cervical smear if aged 20-64 and not had a test in the last 5 years.
- **Vaginal Examination:** Assess the size, shape and mobility of the uterus (eg may be enlarged and nodular in the presence of fibroids) elicit any tenderness (eg adenomyosis). Assess the adnexae for masses (eg ovarian cysts), tenderness or cervical excitation (eg endometriosis). Assess of the pouch of Douglas and uterosacral ligaments if the woman has significant dysmenorrhoea or dyspareunia, for thickening, tenderness or nodularity that may indicate endometriosis in the presence of these symptoms.
- **FBC:** Detect iron deficiency anaemia. May give an indication of degree of menstrual blood loss. Dietary advice/iron supplement should be commenced if appropriate.
- **TFT:** Exclude thyroid disease, hypothyroidism may be associated with menstrual disturbance.

Investigations should be initiated depending on history and clinical findings:

PELVIC ULTRASOUND SCAN

Indicated for:

- Suspected structural lesions eg. fibroids or ovarian cyst
- Difficult clinical examination eg. overweight, virgin, vaginismus

Request through your preferred Radiology Department as usual
If Gynaecology opinion required on the result, fax with integrated care record to MDC co-ordinator

GYNAECOLOGY OPD HYSTEROSCOPY & BIOPSY (ENDOMETRIAL ASSESSMENT) ± GYNAECOLOGY OPD ULTRASOUND SCAN

Indicated to exclude malignancy/hyperplasia/submucous fibroids/polyps in:

- Irregular / intermenstrual bleeding
- Women aged ≥ 40 before starting treatment
- Women aged < 40 if 1st and 2nd line treatments fail
- Women with other risk factors: eg. PCOS, tamoxifen, obesity, unopposed oestrogen

Book via MDC co-ordinator, Debbie Rawlinson: Phone (0116) 258 5072 Fax (0116) 258 7560

DIAGNOSTIC LAPAROSCOPY

Indicated to diagnose endometriosis in women with:

- Tenderness / thickening / nodules in / on uterosacral ligaments or pouch of Douglas
- Significant dysmenorrhoea or dyspareunia

Book via MDC co-ordinator, Debbie Rawlinson: Phone (0116) 258 5072 Fax (0116) 258 7560

Evidence-based medical treatment for menstrual disorders

- Results from meta-analysis and RCT show the following percentage reductions in menstrual blood loss:

COCP	52% [1]	
Danazol	49% [2]	
Tranexamic acid	46% [2]	
Mefanamic acid	29% [2]	
Mirena	58% [2]	recently reductions of 74 - 97% have been reported [3]

- Low dose cyclical progestagens alone either have no effect on, or may increase menstrual blood loss, but are useful for cycle regulation[2].

- Danazol at the quoted dose is effective in achieving light, regular cycles, but is not recommended for more than 4-6 cycles owing to its side effect profile [2].
  Side effects are reported in up to 75% of patients and are unacceptable in 40% [4].
  In addition careful use of barrier contraception is required (possible virilising effect on the female fetus)[5, 6].

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APPENDIX 2: SURGICAL TREATMENT

LASER ABLATION OF ENDOMETRIUM (LAE)

Suitable for

- Women with a normal uterus
- No significant PMS or pain
- Family complete

Endometrial preparation

- 3.6mg Zoladex every 28 days for 2 months[1]

Procedure

- Day case
- General Anaesthesia
- Takes 45 – 60 minutes
- Hysteroscopic procedure
- Endometrium is systematically ablated to a depth of 5mm
- The procedure results in the formation of synechiae and in some cases obliteration of the uterine cavity [2]

Complications

These LRI figures are comparable to those in the literature [2]

• Fluid overload	1 / 215
• Uterine perforation	1 / 215
• Endo / Myometritis	1 / 215
• Haemorrhage	0 / 215

Outcomes

Of 215 LAE performed 1992 – 1998 at LRI (unpublished data)

• Amenorrhoea	36%
• Spotting/Light Periods	44%
• Periods same or worse	20%
• Satisfied with outcome	77%
• Repeat (all successful)	7%
• Elective hysterectomy	14%

These figures are comparable to those reported in the literature [3,4]

Postoperative course

- 'Period pains' - treat with simple analgesia
- Serosanguinous vaginal discharge for around 4 weeks - avoid tampons and sexual intercourse to reduce risk of infection

Contraception

- Still required afterwards
- Small numbers of pregnancies (unintentional and planned) are reported following the procedure with high rates of pregnancy complications and loss [5,6]

ENDOMETRIAL BALLOON ABLATION

Suitable for
- Women with a normal uterus
- No significant PMS or pain
- Family complete
- An alternative to laser ablation

Endometrial Preparation
- Not required

Procedure
- Day case
- General Anaesthesia
- Takes 20 minutes
- 'Cavaterm plus' system in use in Europe since 1993[7]
- The uterine cavity and endocervical length are measured
- A balloon catheter is passed through the cervix
- The balloon is inflated with 5% dextrose
- The liquid is heated and circulated automatically causing thermal injury to the endometrium

Complications
- In theory fewer than with laser ablation
- Reduced risk of perforation and fluid overload
- Endo/myometritis incidence 2%[8]

Outcomes

The procedure is new to the LRI
No local figures are available.

Figures in the literature[8] are comparable to those for LAE:

• Amenorrhoea	30%
• Spotting / Light periods	65%
• Periods same or worse	5%
• Satisfied with outcome	90%
• Elective hysterectomy	8%

Postoperative course
- 'Period pains' - treat with simple analgesia
- Serosanguinous vaginal discharge for around 4 weeks - avoid tampons and sexual intercourse to reduce risk of infection

Contraception
- Still required afterwards
- Very small numbers of pregnancies are reported following the procedure with high rates of pregnancy complications and loss [9]

DIAGNOSTIC LAPAROSCOPY

Suitable for

- Women with a suspected diagnosis of endometriosis
- Dysmenorrhoea / Dyspareunia
- Abnormal findings on examination

Procedure

- Day case
- General Anaesthesia
- Takes 30 minutes
- 2 – 3L of CO_2 is insufflated to create a pneumoperitoneum
- Laparoscope is inserted into the abdominal cavity via a 10mm port placed just below the umbilicus
- Usually a 5mm port is placed suprapubically
- The uterus is instrumented from below to facilitate movement and visualisation of the pelvic organs
- Abdominal wounds are closed with absorbable sutures

Complications

Generally rare

Figures from three large observational studies[10, 11, 12]

• Mortality	1/30 000
• Haemorrhage	1/ 1 000
• Bladder/bowel/ureter injury	1/ 1 000
• Laparotomy	1/ 1 000

Postoperative course

- Most well enough to go home the same day
- Discharged once mobile, passed urine and eaten a light meal
- May have some shoulder tip pain secondary to diaphragmatic irritation by residual CO_2
- Pain usually controlled with simple analgesia

TOTAL ABDOMINAL HYSTERECTOMY

Suitable for

- Women with enlarged uterus due to fibroids
- Family complete
- Ovarian conservation if aged <40
- Consider ovarian conservation vs. oophorectomy with HRT in women aged 40 – 45
- Women nearer the menopause stand to gain fewer years of benefit for the same operative risk than younger women

Outcomes

- Relief from symptoms and quality of life after hysterectomy is consistently good[17]
- In addition to the cessation of bleeding other symptoms are reduced, such as pain dyspareunia and PMS[17]
- Satisfaction with outcome is generally high, up to 95% of patients are satisfied in some studies[18]

Procedure

- General Anaesthesia
- Takes 45 – 60 minutes
- Usually Pfannenstiel incision (low transverse / bikini line)
- Midline incision may be necessary for very large fibroids
- All internal sutures including those to the vaginal vault are absorbable
- Skin closure with either subcuticular absorbable suture, prolene and beads or staples
- Some may require a drain and or a
- urinary catheter
- All receive one dose of prophylactic antibiotics and thromboembolic prophylaxis

Postoperative course

- By 24 – 48 hours most are mobile, taking fluid and light diet and are using oral analgesia
- Drips, drains and catheters are usually removed at 24 hours
- Discharge on day 3 – 5 postop
- Return to work, resume driving and sexual intercourse at 6 – 8 weeks

Complications[13, 14, 15, 16]

• Mortality	1/1000
• Infection	30%
• Haemorrhage	3%
• Unintended surgery and returns to theatre	3%
• Bladder/urinary injury	1%
• Thromboembolism	0.2%

Long-term[17]

- No increase in psychosexual morbidity
- Little if any effect on lower urinary tract
- May be a small increase in the incidence of constipation
- Hysterectomy may cause a decline in ovarian function
- Risks of endometrial and cervical carcinoma are eliminated
- Suggestion of reduced incidence of ovarian carcinoma
- No consistently demonstrated effects on CVS or bone density

TOTAL ABDOMINAL HYSTERECTOMY AND BILATERAL SALPINGOOPHORECTOMY (TAH & BSO)

Suitable for

- Women with enlarged uterus due to fibroids
- Women with significant pain or PMS
- Family complete
- BSO is appropriate for those over 45 who wish to undergo the procedure
- Consideration should be given to commencing HRT postoperatively

Procedure

- General Anaesthesia
- Takes 45 – 60 minutes
- Usually Pfannenstiel incision (low transverse / bikini line)
- Midline incision may be necessary for very large fibroids
- All internal sutures including those to the vaginal vault are absorbable
- Skin closure with either subcuticular absorbable suture, prolene and beads or staples
- Some may require a drain and or a
- urinary catheter
- All receive one dose of prophylactic antibiotics and thromboembolic prophylaxis

Complications[13, 14, 15, 16]

Risk of surgical complications increases with difficulty of surgical procedure. This may be relevant in discussions with women who have endometriosis adhesions or large fibroids

• Mortality	1/2000
• Infection	30%
• Haemorrhage	3%
• Unintended surgery	3%
• Bowel/urinary injury	1%
• Thromboembolism	0.2%

Outcomes

- Relief from symptoms and quality of life after hysterectomy is consistently good[17]
- In addition to the cessation of bleeding other symptoms are reduced, such as pain dyspareunia and PMS[17]
- Satisfaction with outcome is generally high, up to 95% of patients are satisfied in some studies[18]

Postoperative course

- By 24 – 48 hours most are mobile, taking fluid and light diet and are using oral analgesia
- Drips, drains and catheters are usually removed at 24 hours
- Discharge on day 3 – 5 postop
- Return to work, resume driving and sexual intercourse at 6 – 8 weeks

Long-term[17]

- No increase in psychosexual morbidity
- Little if any effect on lower urinary tract
- May be a small increase in the incidence of constipation
- Risks of endometrial, cervical and ovarian carcinoma are eliminated
- Risks of osteoposis and cardiovascular disease increased in oophorectomised women not taking HRT

LAPAROSCOPIC ASSISSTED VAGINAL HYSTERECTOMY (LAVH)

Suitable for

- Non-overweight women
- Previous vaginal deliveries
- No previous pelvic surgery or caesarean section
- Uterus lees than 10 weeks size
- Family complete

Procedure

- General Anaesthesia
- Takes 90 minutes
- Abdomen is distended with CO2 as for laparoscopy
- Laparoscope is inserted into the abdominal cavity through a 10mm port just below the umbilicus
- Two further ports are placed laterally in the right and left lower quadrants
- The upper portion of the hysterectomy is performed laparoscopically
- Lower portion is done vaginally the uterus and cervix are Extracted through the vagina
- Absorbable sutures used to close the port sites in the abdomen and the vaginal vault
- All patients receive prophylactic antibiotics and thromboembolic prophylaxis

Complications[1, 14, 15, 16]

• Haemorrhage	2%
• Infection	9%
• Unintended major surgery	3%
• Bowel/urinary injury	3%
• Thromboembolism	0.3%

Outcomes

- Relief from symptoms and quality of life after hysterectomy is consistently good[17]
- In addition to the cessation of bleeding other symptoms are reduced, such as pain dyspareunia and PMS[17]
- Satisfaction with outcome is generally high, up to 95% of patients are satisfied in some studies[18]

Postoperative course

- Recovery form LAVH is quicker than from abdominal hysterectomy[19]
- Drains and catheters are not used
- Discharged on the second day
- Return to work at around three weeks

Long-term[17]

- No increase in psychosexual morbidity
- Little if any effect on lower urinary tract
- May be a small increase in the incidence of constipation
- Hysterectomy may cause a decline in ovarian function
- Risks of endometrial and cervical carcinoma are eliminated
- Suggestion of reduced incidence of ovarian carcinoma
- No consistently demonstrated effects on CVS or bone density

HYSTEROSCOPIC LASER POLYPECTOMY

Suitable for
- Endometrial polyps that protrude into the uterine cavity

Endometrial Preparation
- Not required

Procedure
- Day case
- General anaesthesia
- Takes 20 minutes
- Hysteroscopic removal of polyp with laser

Complications
Occur rarely, but include[20]:
- Endometritis
- Haemorrhage
- Uterine perforation
- Fluid overload

Outcomes
A series of 195 women is reported.[21]
After 5 years:
- 80% had normal periods
- 5 went on to have a hysterectomy
- 5 minor complications occurred

Postoperative course
- "Period pains" – treat with simple analgesia
- May have serosanguinous vaginal discharge – avoid tampons and intercourse to reduce infection risk

Contraception
- Still required as fertility unaffected

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Appendix 2: Bridges Project Integrated Care Record

 THE LEICESTER ROYAL INFIRMARY NHS TRUST **The Menstrual Clinic**	**South Leicestershire** **Primary Care Trust**

BRIDGES PROJECT
INTEGRATED CARE RECORD

To request investigations or to book surgery, fax this document to:

Debbie Rawlinson, clinic co-ordinator

Fax (0116) 258 7560

Patient to telephone for an appointment date on:

Phone (0116) 258 5072

NAME	REGISTERED GP
ADDRESS	NHS NUMBER
DOB	HOSPITAL NUMBER

DATE

GP

PRESENTING PROBLEM

Heavy periods ☐
Flooding ☐
Clots ☐
Irregular/Unpredictable bleeding ☐
Bleeding between periods ☐
Post Coital Bleeding ☐
Painful Periods ☐
Deep Dyspareunia ☐
PMS Symptoms ☐

Bleeding interfering with:

☐Work ☐Family ☐Leisure
☐Sleep ☐Sex ☐Holidays

Pain interfering with:

Risk factors for hyperplasia/malignancy

☐Obesity ☐Family History
☐PCOS ☐Irregular Bleeding

Duration of symptoms

CYCLE

K = Number of days of bleeding eg 7-9
Cycle length in days 21-35

K =

OBSTETRIC / GYNAE HISTORY

No of pregnancies .....
No of births .....
Contraceptive method .....

PREVIOUS TREATMENTS

EXAMINATION FINDINGS

General

Cervix
Uterus

Adnexae

INVESTIGATIONS PERFORMED

☐ FBC ☐TFT ☐ Cervical Smear (if indicated)

CONSULTATION / TREATMENT 1 **DATE:**
If appropriate before investigation

CONSULTATION / TREATMENT 1 **DATE:**
Outcome of previous treatment

INVESTIGATION REQUEST

☐ Pelvic Ultrasound Scan ☐Hysteroscopy and Biopsy
☐ Outpatient Consultation ☐Diagnostic Laparoscopy

Book through Menstrual Clinic Co-ordinator, Debbie Rawlinson:
Phone (0116) 258 5072 Fax (0116) 258 7560

NAME	DOB	ADDRESS

RESULTS OF INVESTIGATIONS

BLOOD TESTS

Haemoglobin	FT4
WCC	TSH
Platelets	

PELVIC ULTRASOUND SCAN Date: Sonographer:
Findings:

HYSTEROSCPY Date: Hysteroscopist:
Findings:

BIOPSY Date: Pathologist:
Findings:

COMMENT

Authorised by ..... Mr M.A. Habiba / Mr N. J. Naftalin

CONSULTATION / TREATMENT 3 **Date:**
Outcome of previous treatment

CONSULTATION / TREATMENT 4 **Date:**
Outcome of previous treatment

CONSULTATION / TREATMENT 5 **Date:**
Outcome of previous treatment

REQUEST FOR SURGICAL TREATMENT

☐ Laser Ablation of Endometrium	☐Balloon Ablation of Endometrium
☐Hysteroscopic Polypectomy	☐ LAVH
☐Total Abdominal Hysterectomy (TAH)	☐TAH & BSO

Book through Menstrual Clinic Co-ordinator, Debbie Rawlinson:
Phone (0116) 258 5072
Fax (0116) 258 7560

Appendix 3: Health Status Questionnaires

General Health Questionnaire

This survey asks for your views about your health.

Date of completion of survey _____

Answer every question by selecting the answer that best applies to you and placing a tick in the box provided. Please tick only one box for each statement. If you are unsure about how to answer a question, please give the *best answer you can.*

---

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

---

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

---

3. The following questions are about activities you might do during a typical day. *Does your health now* limit you in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a. Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries or heavy bags	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several hundred yards	☐	☐	☐
i. Walking one hundred yards	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

---

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health?*

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the *amount of time* you spent on work or other activities	☐	☐	☐	☐	☐
b. *Accomplished* less than you would like	☐	☐	☐	☐	☐
c. Were limited in the *kind* of work or other activities	☐	☐	☐	☐	☐
d. Had *difficulty* performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

---

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a *result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the *amount of time* you spent on work or other activities	☐	☐	☐	☐	☐
b. *Accomplished* less than you would like	☐	☐	☐	☐	☐
c. Did work or activities *less carefully than usual*	☐	☐	☐	☐	☐

---

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

---

7. How much *bodily* pain have you had during the past 4 weeks?

None	Very Mild	Mild	Moderate	Severe	Very Severe
☐	☐	☐	☐	☐	☐

---

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

---

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	☐	☐	☐	☐	☐
b. Have you been very nervous?	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e. Did you have a lot of energy	☐	☐	☐	☐	☐
f. Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐
h. Have you been happy?	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐

---

10. During the past 4 weeks, how much of the time has your *physical health or emotional problems* interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

---

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a. I seem to get ill a little easier than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Menstrual Health Questionnaire

This survey asks for your views about your health relating to your menstrual cycle (periods).
In each of the following areas of health, select the statement that *best applies to you* and place a tick in the left hand side box provided. Please tick only one statement in each area, for example:

3. During my cycle:
- ☐ I have no worries I can cope normally.
- ☐ I experience some anxiety and worry.
- ☐ I often feel down and worry about how I'll cope.
- ☐ I often feel depressed and cannot cope.

---

1. During my cycle I have:
- ☐ No practical difficulties, bleed no more than I expect and take no extra precautions.
- ☐ To carry extra sanitary protection with me but take no other precautions.
- ☐ To carry extra sanitary protection and clothes because of the risk of flooding.
- ☐ Severe problems with flooding, soil the bedding and need to be close to a toilet.

2. My Social life is:
- ☐ Unaffected during my cycle I can enjoy life as much as usual.
- ☐ Slightly affected during my cycle. I may have to cancel or modify my plans.
- ☐ Limited during my cycle. I rarely make any plans.
- ☐ Devastated during my cycle. I am unable to make any plans.

3. During my cycle:
- ☐ I have no worries I can cope normally.
- ☐ I experience some anxiety and worry.
- ☐ I often feel down and worry about how I'll cope.
- ☐ I often feel depressed and cannot cope.

4. During my cycle:
- ☐ I feel well and relaxed. I am not concerned about my health.
- ☐ I feel well most of the time. I am a little concerned about my health.
- ☐ I often feel tired and do not feel especially well. I am concerned about my health.
- ☐ I feel very tired and do not feel well at all. I am seriously concerned about my health.

5. There are:
- ☐ No interruptions to my work /daily routine during my cycle.
- ☐ Occasional disruptions to my work /daily routine during my cycle.
- ☐ Frequent disruptions to my work/daily routine during my cycle.
- ☐ Severe disruptions to my work/daily routine during my cycle.

6. My Family Life / Relationships:
- ☐ Are unaffected during my cycle.
- ☐ Suffer some strain during my cycle.
- ☐ Suffers quite a lot during my cycle.
- ☐ Are severely disrupted as a result of my cycle.

Appendix 4: Patient Career Diary

PATIENT DIARY

Bridges Project
Department of Obstetrics and Gynaecology
Robert Kilpatrick Clinical Sciences Building
Leicester University
Leicester Royal Infirmary
Infirmary Square
Leicester

PATIENT DIARY

This questionnaire asks for your views on your health care. Your replies are **TOTALLY CONFIDENTIAL**. All information given will be treated in the strictest confidence. No-one treating you will be informed about your personal views. Any information that you give will not affect the care that you receive.

FILLING IN THE QUESTIONS:

All the questions are set out in the same way. For each question, you should tick the answer that is closest to what you think, for example:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
The GP surgery is too big	☐	☐	☐	☐	☐	☐

Neutral means that you have no feelings either way. You should tick **N/A** only if the statement does not apply to you.

YOUR HEALTH CARE RECORD

There is a section at the beginning of the diary and at the end of each set of questions that you can use to record the details of your health care, and to make comments about your health care, if you wish to.

REMEMBER, YOU ONLY NEED TO FILL IN THE SECTIONS THAT APPLY TO YOU.

THANK YOU FOR YOUR HELP

YOUR HEALTH CARE RECORD

Use this section to write about the things that happen in your health care, and how you feel. You should start by writing what happened when you found out that you needed to go to the hospital, outpatient or specialist clinic, and the things that have happened since then, and continue to write about the things that happen during the time that you have this diary.

Things that you can write about include: visits to the GP or outpatient clinic, a stay in the hospital, letters that you receive about your health care, cancelled or missed appointments. You can also write about how you feel when nothing is happening in your health care. Please remember to put the date each time you write in this section.

You can write as little or as much as you want in this section.

Date	What happened?	Comments

YOUR HEALTH CARE RECORD continued...

Date	What happened?	Comments

SECTION 1 WHEN THE GP TOLD YOU THAT YOU NEEDED TO GO TO THE HOSPITAL/SPECIALIST CLINIC

The following questions are about your visit(s) to the GP that led up to you being told that you would have to go to the hospital/ specialist clinic.

Date the GP told you that you needed to go to the clinic: .....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. It was easy to get an appointment quickly with a GP	☐	☐	☐	☐	☐	☐
2. My appointments with the GP were arranged with no problems	☐	☐	☐	☐	☐	☐
3. It was difficult to get to see the same GP at each consultation	☐	☐	☐	☐	☐	☐
4. It was difficult to get to see the GP of my choice	☐	☐	☐	☐	☐	☐
5. The receptionists sometimes made me feel that I was not important	☐	☐	☐	☐	☐	☐
6. The receptionists never made it difficult for me to see a GP	☐	☐	☐	☐	☐	☐
7. The GP was very good at listening to me	☐	☐	☐	☐	☐	☐
8. Sometimes I felt that the GP did see my condition as being very important	☐	☐	☐	☐	☐	☐
9. I always saw the GP that I needed to see	☐	☐	☐	☐	☐	☐
10. I sometimes felt that the GP did not quite understand how ill I was	☐	☐	☐	☐	☐	☐
11. I felt that the GP always told me everything that I wanted to know	☐	☐	☐	☐	☐	☐
12. The GP told me how long I would have to wait before I went to the hospital, outpatient or specialist clinic	☐	☐	☐	☐	☐	☐
13. The GP gave me enough information about what to expect at the hospital, outpatient or specialist clinic	☐	☐	☐	☐	☐	☐
14. I came away from the GP visits with some of my questions unanswered	☐	☐	☐	☐	☐	☐

SECTION 2 GOING TO YOUR FIRST OUTPATIENT OR SPECIALIST CLINIC VISIT.

The following questions are about your first outpatient or specialist clinic visit.

Date of visit: .....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. I felt I was left "in limbo" after I was told that I would need to go to the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
2. Once I was told that I would need to go to the outpatient/specialist clinic, I felt that I was "out of the hands" of the GP	☐	☐	☐	☐	☐	☐
3. It was easy to get an appointment quickly at the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
4. I was kept informed of what was happening in between being told that I would need to go to the outpatient/specialist clinic, and going to my first appointment	☐	☐	☐	☐	☐	☐
5. I didn't know how long I would have to wait for my first appointment at the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
6. I didn't have to wait too long before I went to my first appointment at the outpatient/ specialist clinic	☐	☐	☐	☐	☐	☐
7. I always felt that the receptionists were very helpful	☐	☐	☐	☐	☐	☐
8. The receptionists sometimes could make me feel that I was not important	☐	☐	☐	☐	☐	☐
9. I did not have to wait too long in the outpatient/ specialist clinic	☐	☐	☐	☐	☐	☐
10. I saw the doctor that I needed to see	☐	☐	☐	☐	☐	☐

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
11. It was difficult to get to see the doctor of my choice	☐	☐	☐	☐	☐	☐
12. I had to see junior doctors when I wanted to see the consultant doctor	☐	☐	☐	☐	☐	☐
13. I would have preferred a little more privacy in the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
14. I sometimes felt that the doctor was not very good at listening to me	☐	☐	☐	☐	☐	☐
15. The doctors did not fully involve me in decisions about my care	☐	☐	☐	☐	☐	☐
16. Sometimes I could not completely understand what the doctor told me	☐	☐	☐	☐	☐	☐
17. Sometimes I felt that the doctor did not see my condition as being very important	☐	☐	☐	☐	☐	☐
18. I felt I had enough time to discuss my condition during my consultation	☐	☐	☐	☐	☐	☐
19. The doctor always gave me a lot of support	☐	☐	☐	☐	☐	☐
20. I got enough advice on how to look after myself	☐	☐	☐	☐	☐	☐
21. I came away from outpatient/specialist clinic appointments with some of my questions unanswered	☐	☐	☐	☐	☐	☐
22. I think it was unnecessary for them to repeat some of the tests	☐	☐	☐	☐	☐	☐
23. They did not fully explain why they were doing some of the tests	☐	☐	☐	☐	☐	☐
24. I was told exactly what to expect when having tests	☐	☐	☐	☐	☐	☐
25. I have always been quickly notified of the results of tests	☐	☐	☐	☐	☐	☐

SECTION 3 OTHER OUTPATIENT OR SPECIALIST CLINIC VISITS

Complete this section if you have made more than one visit to the outpatient or specialist clinic. If you have not made any more visits to the outpatient or specialist clinic leave it blank.

The following questions are about outpatient or specialist clinic visits.

Date of visit:.....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. I felt I was left "in limbo" after I was told that I would need to go to the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
2. Once I was told that I would need to go to the outpatient/specialist clinic, I felt that I was "out of the hands" of the GP	☐	☐	☐	☐	☐	☐
3. It was easy to get an appointment quickly at the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
4. I was kept informed of what was happening in between being told that I would need to go to the outpatient/specialist clinic, and going to my first appointment	☐	☐	☐	☐	☐	☐
5. I didn't know how long I would have to wait for my first appointment at the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
6. I didn't have to wait too long before I went to my first appointment at the outpatient/ specialist clinic	☐	☐	☐	☐	☐	☐
7. I always felt that the receptionists were very helpful	☐	☐	☐	☐	☐	☐
8. The receptionists sometimes could make me feel that I was not important	☐	☐	☐	☐	☐	☐
9. I did not have to wait too long in the outpatient/ specialist clinic	☐	☐	☐	☐	☐	☐
10. I saw the doctor that I needed to see	☐	☐	☐	☐	☐	☐

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
11. It was difficult to get to see the doctor of my choice	☐	☐	☐	☐	☐	☐
12. I had to see junior doctors when I wanted to see the consultant doctor	☐	☐	☐	☐	☐	☐
13. I would have preferred a little more privacy in the outpatient/specialist clinic	☐	☐	☐	☐	☐	☐
14. I sometimes felt that the doctor was not very good at listening to me	☐	☐	☐	☐	☐	☐
15. The doctors did not fully involve me in decisions about my care	☐	☐	☐	☐	☐	☐
16. Sometimes I could not completely understand what the doctor told me	☐	☐	☐	☐	☐	☐
17. Sometimes I felt that the doctor did not see my condition as being very important	☐	☐	☐	☐	☐	☐
18. I felt I had enough time to discuss my condition during my consultation	☐	☐	☐	☐	☐	☐
19. The doctor always gave me a lot of support	☐	☐	☐	☐	☐	☐
20. I got enough advice on how to look after myself	☐	☐	☐	☐	☐	☐
21. I came away from outpatient/specialist clinic appointments with some of my questions unanswered	☐	☐	☐	☐	☐	☐
22. I think it was unnecessary for them to repeat some of the tests	☐	☐	☐	☐	☐	☐
23. They did not fully explain why they were doing some of the tests	☐	☐	☐	☐	☐	☐
24. I was told exactly what to expect when having tests	☐	☐	☐	☐	☐	☐
25. I have always been quickly notified of the results of tests	☐	☐	☐	☐	☐	☐

SECTION 4.1 OTHER VISITS TO THE GP SURGERY
(in connection with your hospital/clinic visits)

Complete this section if you have seen your GP since you were referred to, or attended, the hospital/clinic. If you have not made any more visits to the GP surgery since the GP told you that you would have to go to the hospital/specialist clinic, leave it blank.

Date of visit: .....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. My appointment with the GP was arranged with no problems	☐	☐	☐	☐	☐	☐
2. It was difficult to get to see the GP of my choice	☐	☐	☐	☐	☐	☐
3. I felt that the GP told me everything that I wanted to know	☐	☐	☐	☐	☐	☐
4. It was easy to get an appointment quickly with a GP	☐	☐	☐	☐	☐	☐
5. It was difficult to get to see the same GP at each consultation	☐	☐	☐	☐	☐	☐
6. The receptionists sometimes could make me feel that I was not important	☐	☐	☐	☐	☐	☐
7. The receptionists never made it difficult for me to see a GP	☐	☐	☐	☐	☐	☐
8. The GP was very good at listening to me	☐	☐	☐	☐	☐	☐
9. Sometimes I felt that the GP did not see my condition as being very important	☐	☐	☐	☐	☐	☐
10. I saw the GP that I needed to see	☐	☐	☐	☐	☐	☐
11. I came away from the GP visits with some of my questions unanswered	☐	☐	☐	☐	☐	☐
12. The GP seemed to be in contact with other people involved in my care about my progress	☐	☐	☐	☐	☐	☐
13. I did not get enough advice on my condition	☐	☐	☐	☐	☐	☐
14. Some of the GP's advice has been different from the advice that I got from the hospital/clinic	☐	☐	☐	☐	☐	☐
15. The hospital/clinic doctor has kept the GP informed of my progress	☐	☐	☐	☐	☐	☐

SECTION 4.2 OTHER VISITS TO THE GP SURGERY
(in connection with your hospital/clinic visits)

Complete this section if you have seen your GP since you were referred to, or attended, the hospital/clinic. If you have not made any more visits to the GP surgery since the GP told you that you would have to go to the hospital/specialist clinic, leave it blank.

Date of visit: .....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. My appointment with the GP was arranged with no problems	☐	☐	☐	☐	☐	☐
2. It was difficult to get to see the GP of my choice	☐	☐	☐	☐	☐	☐
3. I felt that the GP told me everything that I wanted to know	☐	☐	☐	☐	☐	☐
4. It was easy to get an appointment quickly with a GP	☐	☐	☐	☐	☐	☐
5. It was difficult to get to see the same GP at each consultation	☐	☐	☐	☐	☐	☐
6. The receptionists sometimes could make me feel that I was not important	☐	☐	☐	☐	☐	☐
7. The receptionists never made it difficult for me to see a GP	☐	☐	☐	☐	☐	☐
8. The GP was very good at listening to me	☐	☐	☐	☐	☐	☐
9. Sometimes I felt that the GP did not see my condition as being very important	☐	☐	☐	☐	☐	☐
10. I saw the GP that I needed to see	☐	☐	☐	☐	☐	☐
11. I came away from the GP visits with some of my questions unanswered	☐	☐	☐	☐	☐	☐
12. The GP seemed to be in contact with other people involved in my care about my progress	☐	☐	☐	☐	☐	☐
13. I did not get enough advice on my condition	☐	☐	☐	☐	☐	☐
14. Some of the GP's advice has been different from the advice that I got from the hospital/clinic	☐	☐	☐	☐	☐	☐
15. The hospital/clinic doctor has kept the GP informed of my progress	☐	☐	☐	☐	☐	☐

SECTION 5 YOUR HEALTH CARE OVERALL

The following questions are about your recent experiences of health care.

Date: .....

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1. Sometimes I could not completely understand what the doctors told me	☐	☐	☐	☐	☐	☐
2. I have had to go through the same information several times with different staff	☐	☐	☐	☐	☐	☐
3. Sometimes it was difficult to get to see the medical staff that I needed to see	☐	☐	☐	☐	☐	☐
4. Sometimes I felt a little as though I was left "in limbo"	☐	☐	☐	☐	☐	☐
5. The staff involved in my care always seemed to work together very efficiently	☐	☐	☐	☐	☐	☐
6. I have always felt as though I was being treated as an individual	☐	☐	☐	☐	☐	☐
7. Sometimes it could be confusing to see different doctors	☐	☐	☐	☐	☐	☐
8. Overall I made very smooth progress through the health service	☐	☐	☐	☐	☐	☐
9. My care was perfectly coordinated from start to finish	☐	☐	☐	☐	☐	☐

Appendix 5: Interview Prompt Guide

TOPICS TO BE COVERED	PATIENT'S CONCERNS	QUESTIONS TO ASK
Primary Care		**Primary Care**
1. Attitudes towards the service received before attending hospital	Male/Female Doctors and choice	1. What sort of service did you receive from your doctor?
Perceived interest of GP in problem		Did your doctor know much about it?
Problem taken seriously	Examination	Was your doctor interested in your problem?
Appropriate timely action (neuroticism)		Was your problem taken seriously?
Hopes/expectations for outcome	Information provision	What did you want /expect your doctor to do?
Degree to which "own" Dr is valued		Is it important to see a doctor you know?
	Education	
2. Resources GPs draw upon in order to make decisions	When is it OK to use tablets	2. How do you think your GP decides on the best way to help you?
CME, Books, Peers, Experience, RCGP		How do they decide / keep up to date?
Is this the way it should be?	How your Dr makes you feel	What do you think about that?
Is there any perceived inequality?		Is it fair? Good and bad points?
Evidence Based Pathways		**Evidence Based Pathways**
3. Patient's understanding of evidence-based pathways		3. How do you feel about doctors using guidelines to decide your treatment?
Are there any perceived benefits?	Flexibility	Good and bed things about this system
Transparency		Is it fairer?
Progression to resolution	Clinical Freedom	Would it speed up treatment?
Validation for menstrual disorders		Would it give more importance to period problems?
Reducing inequalities and wait	Patient centered	Should patients have access to guidelines?
Getting the best available treatment		
Treatments proven to be of benefit	Continuity of care	
The Interface 1		**The Interface 1**
4. Attitudes to the GP's role as gatekeeper		4. Does your doctor control your access to hospital?
Is this a function patients are aware of?	Bothering the doctor	Why is this?
What purpose does this serve?		What do you think about that?
Helps the NHS / Society in general?	Anxiety	
Impact on care they received?		5. How do you feel during the time you are waiting?
5. Waiting for an appointment at hospital and waiting for results	A long wait =	For an appointment?
What effect does this have?	A short wait =	Any difference of you made your own?
Does organizing own appointment lead to more Feelings of control / reduced anxiety?	Liason	To go to the hospital
		For test results? For treatment?
Secondary Care		**Secondary Care**
6. The importance of a hospital visit	How did you feel	6. Is going to the OPD important? Why?
Is contact with the specialist in itself important?		What about seeing the specialist?
Is the specialist a gatekeeper to investigation and surgical treatment	Embarrassment	What did you expect the specialist to do?
Facilitation of pregression	Relationship	What did you want the specialist to do?
7. What resources to specialists draw upon in order to make decisions?	Knowledge	7. How does the specialist decide on the best way to treat you?
CME, Books, Peers, Experience, RCOG		How do they decide / keep up to date?
		What do you think about that?
8. Perceived differences between GP and hospital services	Value	Is it different from the GP?
Time, knowledge, access to tests, provide prescription, access to surgery		8. What is the difference between seeing the Specialist and your GP
The Interface 2		**The Interface 2**
9. Relationship between 1 and 2 care		9. How much do you think the GP and the Specialist are working together to help you?
Perception of degree of communication		How do they do this?
Co-operation		Who is in charge of your care overall?
Impact on care	Practice Nurses	Who do you see if there is a problem? Why?
10. Changes to the present system	Referral between GPs	10. In what way could the system be improved
Should the interface exist at all?		Should you be able to see a specialist
		Without seeing your GP first? Why?

Appendix 6: Interview Coding Frame

Theme 1: Narrative and Impression Management
Stories of being a patient

Level 1	Definition	Level 2	Definition	Level 3	Definition
1.1 Construction of narrative	How narrative is constructed				
		1.1.1 Enplotment	Indications of the enplotment of the narrative around going through the healthcare process		
				1.1.1.1 The Ideal Plot	Experience of being in the system leads to a view of an ideal scenario
				1.1.1.2 Atrocity Stories	Accounts including some element of bad practice
				1.1.1.3 Construction of the Bridges Project	How the project is constructed narratively
				1.1.1.4 Threat to self	Dramatic construction of threat to self from menstrual problem

		1.1.2 Characterisation	Characters that feature in the plot		
				1.1.2.1 Hero	Character constructed very positively
				1.1.2.2 Villain	Character constructed very negatively
1.2 Construction of participant	Participant constructs a particular view of herself				
		1.2.1 A good patient	Participant constructed as compliant, non-demanding patient		
		1.2.2 As Genuine	Participant constructed herself as genuine patient		
		1.2.3 As Knowledgeable / Intelligent	Participant narratively constructs herself as informed etc.		
		1.2.4 As Assertive	Participant narratively constructs herself as assertive, robust etc.		

Theme 2: Candidacy
Being deserving of progression through the healthcare system

Level 1	Definition	Level 2	Definition	Level 3	Definition
2.1 Diagnosis	Any indication of the participant's diagnosis				
2.2 Necessity for healthcare	References to how necessary it was to access healthcare				
		2.2.1 Construction of menstrual problem by participant	How the participant presents the menstrual problem e.g. as physical, impact on quality of life, degree of severity, longstanding etc.		
		2.2.2 Construction of menstrual problem by doctors	Descriptions of how the menstrual problem is constructed by the doctor e.g. significant or not, purely physical etc.		

		2.2.3 Basis for participants' judgements about necessity	Why the participant believes she is deserving of receiving healthcare		
				2.2.3.1 Pain if no healthcare	Patient will continue to suffer pain if she does not get healthcare
				2.2.3.2 Impaired quality of life	Patient will be compromised in her functioning if she does not get healthcare
				2.2.3.3 Uncover pathology	Progression through the healthcare system is necessary to rule out pathology
				2.2.3.4 Not serious enough	Menstrual problems are not serious enough to be deserving of healthcare

		2.2.4 Formulation of problem as identical between doctor and patient	Extent to which doctor and patient agree on the necessity for healthcare		
		2.3.5 Struggle to define healthcare as necessary	Disagreement between patient and doctor as to whether it is necessary to proceed through the system		

Theme 3: Healthcare
Patient's pre-conceptions about healthcare

Level 1	Definition	Level 2	Definition	Level 3	Definition
3.1 Patients experience of healthcare	Accounts of previous experience of the healthcare system / lack of experience				
		3.1.1 Little previous experience	Participant lacks experience of accessing healthcare		
		3.1.2 Previous experience	Participant has experience of accessing healthcare in the past either satisfactory or unsatisfactory		
		3.1.3 Satisfaction with healthcare	Accounts surrounding satisfaction with healthcare received including any factors which may influence satisfaction		

		3.1.4 Dissatisfaction with healthcare	Accounts surrounding dissatisfaction with healthcare received including any factors which may produce dissatisfaction		
3.2 Patients' beliefs	Participants beliefs about illness, health and treatment				
		3.2.1 Illness beliefs	Participants beliefs surrounding illness		
		3.2.2 Treatment beliefs	Participants beliefs surrounding treatments		
		3.2.3 Beliefs surrounding menstruation	Beliefs about what constitutes normal menstruation		
		3.2.4 Health beliefs	Beliefs about health on general		
3.3 Limitations of the system	Descriptions of the shortcomings of the system				

		3.3.1 Doctor's Competence	Accounts of how the perceived competence of the doctor may influence healthcare		
		3.3.2 Resources / Staff	Accounts of lack of capacity / resources / staff within the system and the implications for patients and their progression through the system		
		3.3.3 Compartmentalisation	Accounts of compartmentalisation within the system		
		3.3.4 Inequality	Accounts suggesting that the system operates in an unjust fashion, reasons why this might be the case and any factors which contribute to unfairness or inequality		

		3.3.5 Priorities	Any accounts referring to the existence of set priorities within the healthcare system, why this might be the case and what determines priority		
3.4 Expectations of the healthcare system	Accounts of participants expectations of the healthcare system				
		3.4.1 Influences on expectations	How patients' expectations are formulated e.g. the media, talking to other people		
		3.4.2 Waiting	Indications of the degree to which patients expect to wait to receive healthcare		
		3.4.3 Expectations of the consultation	Accounts of how patients expected the consultation might go or what consultations might consist of		

Theme 4: Progression
Factors which affect progression through the healthcare system

Level 1	Definition	Level 2	Definition	Level 3	Definition
4.1 Access	Any references to accessing care				
		4.1.1 Ease of Access	References to how easy / difficult it is to get access to healthcare, including any factors facilitating or preventing		
		4.1.2 Access Controlled	Degree to which access to healthcare is perceived to be controlled and by whom		
				4.1.2.1 By GP	References to the degree to which the GP controls patients' access to healthcare, reasons why this is perceived to be the case, and why the system operated in this way

				4.1.2.2 By Patient	References to the degree to which the patient has control over access to healthcare, reasons why this is the case, and situations in which the patient has control
		4.1.3 Who *should* access	Ideas surrounding who should be able to access healthcare		
				4.1.3.1 GP	Extent to which GP should be solely responsible for accessing healthcare on patients' behalf
				4.1.3.2 Patient	Extent to which patients should have direct access to healthcare system, under what circumstances and the possible consequences

		4.1.4 Getting access	The factors involved in getting access to healthcare eg the seriousness of the condition, the length of time the condition has been present and the type of condition		
				4.1.4.1 Who gets access	The type of patients who get access to services
				4.1.4.2 Who does not get access	The type of patients who do not get access to services
4.2 Waiting	Any accounts of waiting				
		4.2.1 Waiting for Appointments	Accounts of waiting for appointments at the GP or OPD, how this is perceived by patients in the system and any effects that waiting has on patients		

		4.2.2 Waiting for tests / results	Any accounts of waiting for tests or results how waiting for tests or the results of tests is perceived by patients in the system and the effect of waiting for results on patients		
		4.2.3 Waiting for Treatment	Any accounts of waiting for treatment and how this is perceived by patients including the effect that is has on them		
4.3 The Hospital OPD	Any references to the hospital outpatients department				
		4.3.1 What OPD does for patients	Accounts of what the hospital provides for patients e.g. reassurance, diagnosis, information and the value of the visit		

		4.3.2 Disadvantages of hospital OPD	Accounts of any limitations of the hospital OPD or drawbacks of attending the hospital		
4.4 Ease of progression	Accounts describing the ease with which participants progressed through the healthcare system				
		4.4.1 Struggle to progress	Any accounts of a struggle to progress through the system and the consequences of the struggle		
				4.4.1.1 Self blame as a consequence	Accounts suggesting the participant blames herself for the lack of progress
		4.4.1.2 Smooth progress	Accounts of smooth progress through the system and the consequences		

4.5 Who influences progression	Accounts of what patients and doctors do that affects progress				
		4.5.1 Doctors' influence on progression	Accounts of what the GP or specialist did (or could have done) that influenced progression		
				4.5.1.1 Interest in the problem	The doctors level of interest in the problem as perceived by the patient
				4.5.1.2 Physical examination	Whether examination was performed or not and the degree to which this is seen to be important in progression and why
				4.5.1.3 Investigation	Mention of requesting tests or not and the degree to which investigation is perceived to be important for progression

				4.5.1.4 Medical treatment	Prescribing of medical treatments and the place of medical treatment in progression / resolution
				4.5.1.5 Referral	Mention of referral by doctor and how referral influences perceptions of progression
				4.5.1.6 Knowledge of doctor	Any references to how level of knowledge of the doctor influences progression
				4.5.1.7 Act as patient advocate	Any mention of doctors ability to act on behalf of patient to influence progression
				4.5.1.8 Make a diagnosis	Any mention of attempt to make a diagnosis, or reach a diagnosis and how this affects patients perceptions of progression

				4.5.1.9 Surgical treatment	Surgical treatments and how these relate to progression / resolution
		4.5.2 Patients' power to influence progression	The strategies that patients use, or that are available to them to influence progression and when these are used		
				4.5.2.1 Take custom elsewhere	Patients have the ability to seek healthcare from other providers e.g. seek an opinion from another GP or clinic, and the consequences of this strategy for patients or the system
				4.5.2.2 Re-attendance	Re-attendance as a strategy for achieving progression including references to the consequences

				4.5.2.3 Emotional blackmail	Getting upset or using other emotional blackmail as a strategy to achieve progression
				4.5.2.5 Assertiveness	Use of assertive behaviour as a strategy to achieve progression
				4.5.2.6. When patients' power is exercised	Circumstances under which patients exercise their power
				4.5.2.7 Choose timing	Patients choosing to attend when they feel most likely to achieve progression e.g. when they look ill
		4.5.3 The patient's agenda	What patients want when accessing healthcare, what they want doctors to do e.g. Reassure, Investigate, Refer, Treat		

Theme 5: Doctors and Patients
What GPs, hospital doctors and patients do – and how they work together

Level 1	Definition	Level 2	Definition	Level 3	Definition
5.1 Role of the doctors	Any account of the expected role of the doctor				
		5.1.1 Role of the GP	What can be reasonably expected of a GP, the roles undertaken by the GP		
				5.1.1.2 Record keeper	The role of the GP is to keep a complete record of the patient
				5.1.1.3 Personal characteristics	GPs should have certain personal characteristics in order to be able to fulfil their role
				5.1.1.4 Knowledge / Competency	Degree of knowledge / competency expected, the degree to which GPs have special interests and the desirability of this

				5.1.1.5 Aware of own limitations	Accounts suggesting that GP should be / is aware of limitations of own knowledge / role and is responsible for referring patient when limitations are exceeded
				5.1.1.6 Provider of information	Degree to which role of GP is perceived to involve provision of information to patients
				5.1.1.7 The value of the role of the GP	Accounts indicating the value of the role of the GP to patients
		5.1.2 The Role of the Specialist	Any account of the expected role of the specialist and the function that the specialist fulfils within the system		

				5.1.2.1 When specialists should be involved in patients care	Accounts of when specialist involvement in a patient's care is appropriate
				5.1.2.2 Level of knowledge / competency	The level of knowledge or expertise expected for a specialist
				5.1.2.3 What specialists do	Accounts of the work of the specialist
				5.1.2.4 Personal characteristics	Personal characteristics expected of specialists
				5.1.2.5 Value of the role of the specialist	Degree to which contact with the specialist is of value in the healthcare process
		5.1.3 Difference between the GP and the Specialist	Accounts of the degree to which the GP and Specialist are different / similar and reasons why		
		5.1.4	References to		

		Doctors as individuals	differences between individual doctors		
				5.1.4.1 Not all doctors are the same	Indications that the patient distinguishes between doctors on the basis of their personal characteristics or other attributes
				5.1.4.2 Getting what you want depends on finding the right doctor	Indications that getting what you want depends on finding the right doctor
5.2 The Relationship between Primary and Secondary care	Any accounts of the way that the two health sectors work together (or not) or the way they relate to each other				
		5.2.1 Who is 'in charge' of the patients' healthcare	Participants view on the extent to which different people are in charge of her healthcare		

				5.2.1.1 GP in charge	Degree to which it is perceived that the GP is in charge, and examples of the circumstances under which the GP is in charge and reasons why this is the case
				5.2.1.2 Specialist in charge	Degree to which it is perceived that the Specialist is in charge, circumstances under which the specialist would be in charge and reasons why this is the case
				5.2.1.3 Patient in charge	Degree to which it is perceived that the patient is in charge, and examples of the circumstances under which the patient is in charge and reasons why this is the case

				5.2.1.4 Bridges Project in charge	Degree to which it is perceived that the Bridges Project is in charge and reasons why this is the case
				5.2.1.5 Unsure / Nobody in charge	Perception that nobody is responsible for patients healthcare and progression and reasons why this is the case
		5.2.2 Contact Person	Who patients contact if they have a problem, and why. Who would they prefer to contact?		
				5.2.2.1 GP	Participant would contact GP if in need
				5.2.2.2 Hospital	Participant would contact Hospital if in need
				5.2.2.3 Bridges Project	Participant would contact Bridges Project if in need

		5.2.3 Communication between Primary and Secondary care	Any references to communication between the two healthcare sectors including extent of communication, mode, content and consequences for patients		
5.3 Continuity of care	Any accounts of how continuity of care is achieved, the degree of importance that the participant attaches to continuity of care, factors which affect its importance and reasons why it is important				
5.4 Clinical method	Accounts of the clinical processes used by doctors				

		5.4.1 Patient involvement	Patient involvement in the clinical process including accounts of patients being involved in or excluded from decisions about their healthcare, and how much they wish to be involved		
		5.4.2 Doctors' knowledge	Accounts of the knowledge doctors use when making clinical decisions and where it comes from including past experience		
		5.4.3 Decision making	Accounts of decision making by doctors and way in which doctors make decisions		
5.5 Guidelines in clinical practice	Any accounts of the use of guidelines in clinical practice				

		5.5.1 Construction of guidelines	How guidelines are thought of by patients e.g. as protection for doctors or patients		
		5.5.2 Positive aspects of guidelines	Accounts of any advantages that guidelines may have		
		5.5.3 Negative aspects of guidelines	Accounts of any disadvantages that guidelines may have		
		5.5.4 Accessing guidelines	Who should have access to guidelines		
				5.5.4.1 Doctors only	Accounts suggesting that only doctors should be privy to guidelines
				5.5.4.2 Patients should have access	Accounts suggesting that patients should have access to guideline in addition to doctor including when and what the consequences of this might be

5.6 Doctor-Patient relationship	Any references to the relationship between doctors and patients				
		5.6.1 Communication	Any references to communication between doctors and patients including mode of communication, influences on communication and satisfaction with the communication that has taken place		
		5.6.2 Power	Any references to the power held by either party		
				5.6.2.1 Patients' resources are less legitimate	Patients' knowledge e.g. lay knowledge, knowledge of own body is less valued in the consultation
		5.6.3 Trust	Any references to trust		
				5.6.3.1 Trust in doctors	Any references to trust in doctors

				5.6.3.2 Trust in the system	The degree of trust the participant has in the system as a whole
		5.6.4 Structural issues in the doctor-patient relationship	Accounts of the influence of social structure in the doctor patient relationship		
				5.6.4.1 Gender as an issue in the doctor-patient relationship	Accounts of gender as an issue in the doctor-patient relationship
				5.6.4.2 Age as an issue	Age as an issue in the doctor-patient relationship
		5.6.5 Choice of doctor	Degree to which this is desirable, a "right" and the reasons why		
				5.6.5.1 No choice of doctor	Accounts of there being no choice of doctor, when this is most likely to occur, the reasons why and the consequences

5.7 Information	Any references to information given to patients or required by patients				
		5.7.1 Information patients need and degree to which need is met	References to the type / amount etc. of information that patients require and whether or not the information was available		
				5.7.1.1 Information about what will happen	References to the need for information about what will take place in healthcare and accounts of getting such information
				5.7.1.2 Clinical Information	References to the need for information about diagnoses / tests / treatments/ side effects etc. and accounts of getting such information

				5.7.1.3 Written information	References to the degree to which written information is required and accounts of getting such information
				5.7.1.4 Personalised information	The degree to which information should be appropriate for / personal to patients and accounts of getting such information
		5.7.2 Sources of Information	Any references to where patients get their information from, where they like to get information from		
				5.7.2.1 Hospital	References to information obtained as a result of a hospital visit

				5.7.2.2 General Practice	References to information gained as a result of a visit to the GP surgery
				5.7.2.3 The media	References to information gained form a media source
				5.7.2.4 Lay networks	References to information gained from lay networks
				5.7.2.5 Books / Internet etc.	References to information gained from books, internet etc
		5.7.3 Ability to acquire information	Accounts of patient's ability to acquire the information they need and factors affecting this e.g.: access to healthcare professionals, ability to understand medical terms etc		

Appendix 7: Cost Questionnaires

About your circumstances

The following questions are about you and your circumstances. This information is required to ensure that the information gathered from the study comes from people of different backgrounds.

Please tick only one box for each question.

Work

1. Are you currently in paid employment?

Yes full time	☐
Yes part time	☐
No	☐

2. Which of the following describes your job category?

Managerial / Professional	☐
Clerical / intermediate occupations	☐
Small employer /own account worker	☐
Lower supervisory / technical	☐
Routine / semi-routine occupation	☐
Other (*Please describe*)	☐
.....	
.....	

Income

3. Which of the following represents the gross annual income f your household, before deducting tax and national insurance?

Less than £5,000	☐
£ 5,000 - £11,999	☐
£12,000 - £19,999	☐
£20,000 - £29,999	☐
£30,000 - £44,999	☐
£45,000 - £59,999	☐
£60,000+	☐

Please turn over...

Qualifications

4. What is the highest level of education you have completed?

Secondary School	☐
A level / AS levels	☐
Vocational / Trade / College Qualification	☐
Degree level qualification(s)	☐
Post-graduate qualification(s)	☐
Other (please describe below)	☐

.....
.....
.....

Ethnic Origin

5. Which of the following ethnic groups do you consider you belong to?

White	☐
Black – Caribbean	☐
Black – African	☐
Black – Other	☐
Indian	☐
Bangladeshi	☐
Asian – Other	☐
Chinese	☐
Other (please describe below)	☐

.....
.....
.....

Cost to you when visiting the GP surgery

The following questions are about how much it cost you to attend your GP's surgery. Please tick all the boxes that apply to you.

Access to care

1. For your last visit to the GP surgery in relation to your menstrual problem how did you travel?

Car	☐	Walked	☐
Taxi	☐	Other, please describe	☐
Bus / train	☐	.....	

2. How long did it take you to travel to the GP surgery?
.....hours .....minutes

3. If you travelled by bus, taxi, or train, what was the total fare both ways for you? (Don't include anyone else's fare) £.....

4. Approximately how many miles from your home is the GP surgery? .....miles

5. Did anyone accompany you to the GP surgery?

Yes, an adult	☐
Yes, a child (less than 15 years old)	☐
No	☐

Dependants

6. Do you have any children for whom you had to make child care arrangements in order to be able to attend the GP surgery?
Yes ☐ No ☐

7. If 'Yes' approximately how much did it cost you? £.....

8. Do you have any other dependants for whom you had to make alternative arrangements in order to be able to attend the GP surgery?
Yes ☐ No ☐

9. If 'Yes' approximately how much did it cost you? £.....

Please turn over...

Time spent by you

10. How long were you at the GP surgery (please include waiting time, time with the GP etc.)? .....hours .....minutes

11. Did you take time off paid work to attend the GP surgery?
Yes ☐ No ☐

12. If 'Yes', how much time did you take off paid work?
.....hours .....minutes

13. If you answered 'Yes' did it result in loss of wages for you?
Yes ☐ No ☐

14. If 'Yes', how much was your wage loss for this visit? £.....

15. If you did not take time off paid work, what would you otherwise have been doing if you had not gone to the appointment?

Housework / caring	☐	Other (please describe)	☐
On sick leave	☐	.....	
Leisure activities	☐	.....	

Companion's time

16. If someone accompanied you to the GP surgery, did they take time off paid work?
Yes ☐ No ☐

17. If 'Yes', how much time did they take off paid work?
.....hours .....minutes

18. Did your companion loose wages for taking time off work to accompany you?
Yes ☐ No ☐

19. If 'Yes', how much was their wage loss? £.....

Other costs

20. Did you incur any other costs because of your visit to the GP?
Yes ☐ No ☐

21. If 'Yes', how much were these costs in total? £.....

Cost to you when visiting the hospital outpatients department

The following questions are about how much it cost you to attend the hospital outpatients department.
Please tick all the boxes that apply to you.

Access to care

1. For your last visit to the hospital in relation to your menstrual problem how did you travel?

Car	☐	Walked	☐
Taxi	☐	Other, please describe	☐
Bus / train	☐	.....	

2. How long did it take you to travel to the GP surgery?
   .....hours .....minutes

3. If you travelled by bus, taxi, or train, what was the total fare both ways for you? (Don't include anyone else's fare) £.....

4. Approximately how many miles from your home is the hospital?
   .....miles

5. Did anyone accompany you to the hospital?

Yes, an adult	☐
Yes, a child (less than 15 years old)	☐
No	☐

Dependants

6. Do you have any children for whom you had to make child care arrangements in order to be able to go to the hospital?
   Yes ☐ No ☐

7. If 'Yes' approximately how much did it cost you? £.....

8. Do you have any other dependants for whom you had to make alternative arrangements in order to be able to go to the hospital?
   Yes ☐ No ☐

9. If 'Yes' approximately how much did it cost you? £.....

Please turn over...

Time spent by you

10. How long were you at the hospital (please include waiting time, time with the doctor etc.)? .....hours .....minutes

11. Did you take time off paid work to attend the hospital?
Yes ☐ No ☐

12. If 'Yes', how much time did you take off paid work?
.....hours .....minutes

13. If you answered 'Yes' did it result in loss of wages for you?
Yes ☐ No ☐

14. If 'Yes', how much was your wage loss for this visit? £.....

15. If you did not take time off paid work, what would you otherwise have been doing if you had not gone to the hospital?

Housework / caring ☐ Other (please describe) ☐
On sick leave ☐ .....
Leisure activities ☐ .....

Companion's time

16. If someone accompanied you to the hospital, did they take time off paid work?
Yes ☐ No ☐

17. If 'Yes', how much time did they take off paid work?
.....hours .....minutes

18. Did your companion loose wages for taking time off work to accompany you?
Yes ☐ No ☐

19. If 'Yes', how much was their wage loss? £.....

Other costs

20. Did you incur any other costs because of your visit to hospital?
Yes ☐ No ☐

21. If 'Yes', how much were these costs in total? £.....

Appendix 8: Conjoint Analysis Questionnaire

REF:

HEALTH CARE FOR WOMEN WITH PERIOD PROBLEMS

A SURVEY OF WHAT YOU PREFER

By:

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This is a questionnaire to find out what women would like when they get help for their period problems.

We hope you will help us with this important research by filling in this survey and returning it in the FREEPOST envelope provided.

Instructions:

- We want you to choose between different types of health care. The questions are made up examples of different types of health care we could offer to women. This means that we will be asking you to think about things that might not have happened to you.
- We are asking you how you would have like to get health care for a period problem not what health care you have had in the past.
- There are no right or wrong answers, we just want to know what you prefer.
- Your choices are important to us. We can only make things better if we find out what people want. Filling in this survey will not affect your health care, but you will be helping us to help other women in the future.
- This survey is confidential. None of the doctors or nurses who have treated you will find out your answers.

What you need to do:

In section A there are 12 parts. Each part has two different examples of the kind of option which women with period problems could be offered.

- For each part we want you to tell us the option you would prefer. Put a tick underneath the list for the option you would prefer i.e. put a tick either under option A or B.
- In section B there are questions about you and your health care.
- The questionnaire usually takes about 20 minutes to fill in.
- Many people find filling in forms difficult. If you would like some help filling in this survey please phone me. I will be very happy to phone you back and go through it with you, or answer any questions you might have.
- Thank you in advance for your help.

Dr. Sophia Julian

Tel (0116) 252 5883
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Section A

In Section A these are the things we want you to think about:

The thing that may vary	**Could be**
How often you get ti see the same doctor	None of the time Half of the time All of the time
How long you have to wait for test results	1 day 2 days 2 weeks 4 weeks
Cost to you (i.e. perhaps because of Absence from work or travel costs - Please assume you would loose this amount of money even if you would not)	None (no money lost) £25 £75 £125
The type of doctor you see	GP Consultant
The sex of the doctor you see	Male Female
Time waiting for an appointment to see the Doctor (either the GP or the consultant)	1 day 4 days 6 weeks 12 weeks

- Note there is no question of you being charged for health care, but we want you to pretend that you would lose the amount of money shown even if you would not.
- Just a few of the possible combinations are included, these are chosen by a computer programme.
- Remember, everything else apart from the things on the list, like the receptionists, nurses and waiting area etc, is the same for option A and B.
- Remember there are no right or wrong answers.

Please read the whole descriptions of option A and B below and for each of the parts choose A or B.

Part 1	Option A	Option B
How often you get to see the same doctor	Half of the time	All of the time
How long you have to wait for test results	1 day	2 weeks
Cost to you	None	None
The type of doctor you see	Consultant	GP
The sex of the doctor you see	Male	Male
Time waiting for an appointment to see the doctor	12 weeks	6 weeks

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 2	Option A	Option B
How often you get to see the same doctor	Half of the time	All of the time
How long you have to wait for test results	1 day	1 day
Cost to you	None	£25
The type of doctor you see	Consultant	GP
The sex of the doctor you see	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	1 day

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 3	Option A	Option B
How often you get to see the same doctor	Half of the time	All of the time
How long you have to wait for test results	1 day	4 weeks
Cost to you	None	£125
The type of doctor you see	Consultant	Consultant
The sex of the doctor you see	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	12 weeks

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 4	Option A	Option B
How often you get to see the same doctor	Half of the time	Half of the time
How long you have to wait for test results	1 day	1 day
Cost to you	None	None
The type of doctor you see	Consultant	Consultant
The sex of the doctor you see	Male	Male
Time waiting for an appointment to see the doctor	12 weeks	6 weeks

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 5	Option A	Option B
How often you get to see the same doctor	Half of the time	Half of the time
How long you have to wait for test results	1 day	2 weeks
Cost to you	None	£25
The type of doctor you see	Consultant	Consultant
The sex of the doctor you see	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	4 days

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 6	Option A	Option B
How often you get to see the same doctor	Half of the time	None of the time
How long you have to wait for test results	1 day	4 weeks
Cost to you	None	£25
The type of doctor you see	Consultant	Consultant
The sex of the doctor you see	Male	Male
Time waiting for an appointment to see the doctor	12 weeks	6 weeks

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 7	Option A	Option B
How often you get to see the same doctor	Half of the time	Half of the time
How long you have to wait for test results	1 day	4 weeks
Cost to you	None	None
The type of doctor you see	Consultant	GP
The sex of the doctor you see	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	4 days

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 8	Option A	Option B
How often you get to see the same doctor	Half of the time	None of the time
How long you have to wait for test results	1 day	2 days
Cost to you	None	None
The type of doctor you see	Consultant	Consultant
The sex of the doctor you see	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	1 day

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 9	Option A	Option B
Cost to you	4 weeks	1 day
The type of doctor you see	£125	None
The sex of the doctor you see	Consultant	Consultant
Time waiting for an appointment to see the doctor	Female	Male
How often you get to see the same doctor	12 weeks	6 weeks
How long you have to wait for test results	All of the time	Half of the time

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 10	Option A	Option B
Cost to you	4 weeks	2 days
The type of doctor you see	None	£75
The sex of the doctor you see	GP	Consultant
Time waiting for an appointment to see the doctor	Female	Male
How often you get to see the same doctor	4 days	4 days
How long you have to wait for test results	Half of the time	All of the time

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

Part 11	Option A	Option B
Cost to you	4 weeks	4 weeks
The type of doctor you see	£125	None
The sex of the doctor you see	Consultant	GP
Time waiting for an appointment to see the doctor	Female	Female
How often you get to see the same doctor	12 weeks	4 days
How long you have to wait for test results	All of the time	Half of the time

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑

The last of this type of question but this time choose the best option out of 3

Part 12	Option A	Option B	Option C
Cost to you	None	£25	£125
The type of doctor you see	Consultant	GP	Consultant
The sex of the doctor you see	Male	Male	Female
Time waiting for an appointment to see the doctor	12 weeks	12 weeks	12 weeks
How often you get to see the same doctor	Half of the time	Half of the time	All of the time
How long you have to wait for test results	1 day	2 days	4 weeks

Which option would you choose? (tick 1 box only) Choose A ❑ Choose B ❑ Choose C ❑