Patterns of Hormone Replacement Therapy use in women with hysterectomy and bilateral oophorectomy; a retrospective study of women in Central Scotland.

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Abstract

There have been many published papers exploring women's the use of hormone replacement therapy (HRT), but most of these studies have not examined surgically menopausal women exclusively. This particular group of women may differ in their HRT needs from the general HRT - using population, in that they require an oestrogen-only preparation and often have a premature menopause. For surgically menopausal women, therapy can be considered as a true replacement treatment as it compensates for often abrupt and premature oestrogen loss. The purpose of this study is to describe HRT use in a sample of surgically menopausal women and determine if these women undergoing hysterectomy with bilateral oophorectomy have different patterns of HRT use when compared to HRT users in general.

This study examines HRT use in women who had a hysterectomy with bilateral oophorectomy before the age of 51 years; in the period 1992-2001.All the women were treated in a region of Central Scotland, in one of two district hospitals administered by the same NHS Trust. The clinical indication for their surgery was heavy menstrual bleeding (menorrhagia), a benign and common condition. The study is retrospective, and women were asked to complete a postal questionnaire. The questionnaire was designed to elucidate the prevalence and duration of HRT use in these women, and the reasons they give for stopping treatment. Certain factors associated with adherence to medication in general, and with HRT use in particular, are considered. These variables include the age of the patient and her socio-economic status, the location of her treatment, and the individual consultant gynaecologist in charge of her care. Associations between post-operative HRT use and physician-

gender are explored, together with the reasons these women give for the discontinuance of treatment.

This study found that one hospital performed more operations than the other, which is probably explained by in-patient bed capacity. One of the consultants performed over a quarter of the total number of operations, probably reflecting the differing clinical roles held by different consultants in the department, or perhaps indicating individual practice. Some further evidence of differences in practice between individual consultants is demonstrated by the fact that two consultants jointly operate on significantly younger women when compared to their colleagues.

There is an association found in the target sample (n = 306) between socio-economic group and the age at which women undergo hysterectomy, with women from less deprived backgrounds being significantly older. This difference, however is not significant in the achieved sample (n = 190), and is possibly due to the small sample size. Socio-economic status is not associated with whether or not HRT is prescribed in hospital, but women from less deprived backgrounds take HRT for longer. There are some differences, between women from different socio-economic backgrounds, in how important the possible cardiovascular protection afforded by HRT is rated. The Women's Health Initiative dispelled the claim that HRT was valuable in preventing cardiovascular events in 2002.

When discussions about the *benefits* of taking HRT are considered, it appears that the women treated in one hospital recall such discussions in greater number than those treated in the other hospital do. Discussions about the *risks* of treatment are not

remembered by 65.2% of women, and there is no statistical difference according to where they were treated. The problem associated with the accuracy of data reliant on subject memory is discussed. Most women cite the doctor as the main source of information about HRT, but over a third of those who start HRT say they did not have enough information (the problem associated with the accuracy of data reliant on subject memory is discussed). Whatever the level of information is given, these women start HRT in almost exactly the same high number regardless of where they were treated.

When comparing the findings from these surgically menopausal women with those from previously published studies on HRT users in general, it is apparent that there are some subtle differences in that use. These women are more likely to take HRT, and take it for longer, than the peri-menopausal and naturally menopausal women, who are grouped together as HRT users in general. They stop using HRT for many of the reasons given by the wider HRT-using population, but are more likely to consult their doctor before doing so. These surgically menopausal women, compared to HRT users in general, cite side-effects of treatment less frequently, but the side-effects they do complain of are the same, with the exception of bleeding problems (from which they obviously do not suffer).

The socio-economic difference associated with HRT uptake in the wider population, is *not* seen in these surgically menopausal women, but the duration of HRT use is associated with higher social status, as found in the general population. The women in this study who came from higher socio-economic groups were older than those from more deprived backgrounds at the time of their hysterectomy, which concurs with

previous research. There is acknowledgement, within the text, that since this research was undertaken there have been significant changes in HRT prescribing guidelines and indeed in the treatments available for menorrhagia. These changes have affected the study findings in terms of how relevant they might be today.

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Chapter one

A General introduction

Hormone replacement therapy (HRT) is exactly as the name implies a replacement of hormones that are deficient or absent. The term is specifically associated with the treatment of oestrogen loss in women at the time of menopause or peri-menopause. The main component of the medication is oestrogen. First used in 1941 for the relief of menopausal symptoms, it was promoted and became increasingly popular over the 1970s 1980s and 1990s despite some early concerns that it may increase cancer risk. In 1997, Premarin, one of the earliest preparations, was the first Wyeth product to reach one million dollars in sales, and remained in the top 50 prescribed drugs from 1966 to 2002 (Rothenberg 2005, p31).

In order to understand the principles behind hormone replacement therapy, it is necessary to have some background information about the menopause. It is at this time in a woman's life that she may require hormone replacement therapy to help relieve some of the symptoms associated with oestrogen loss. This chapter will first consider physiological changes of menopause and the effects of oestrogen loss; it will then review the known side effects of HRT. The differences in HRT treatment for women with surgical menopause, compared to women with natural menopause, are examined. There then follows a discussion of how the menopause transition is understood from a sociological or feminist perspective, and how menopause has become "medicalised" as an oestrogen deficient disease, rather than a natural process. Recent changes in prescribing recommendations, together with what is already known about adherence with treatment and reasons for discontinuance, will be introduced subsequently. As there have been significant changes in both the treatment of menorrhagia, and HRT

prescribing, since the inception of this study, an updated review of the literature is appended at 1.9. To conclude the aims of the study are outlined.

1.1 Physiological changes of the menopause

Female reproductive function declines with age over a period of time known as the climacteric, leading eventually to the menopause, which can be defined as the cessation of menstruation due to ovarian follicular failure. The term "menopause" originates from the Greek words "menos" (a month) and "pausos" (an ending), and means the final menstrual bleed (Rees, Purdie and Hope 2003). It is diagnosed retrospectively, and can be said to have occurred once menstrual bleeding has been absent for 12 months. This occurs at a mean age of 51 years, (Glasier and Gebbie 2000). This change of life rarely happens abruptly in nature, and most women experience a transitional period of menstrual irregularity which may last for two or three years (Glasier and Gebbie 2000), or even longer at around four years (Rees 1999).

The natural menopause transition occurs as oestrogen levels gradually decline as the ovaries fail to respond to stimulation by gonadotrophins. These gonadotrophins are hormones, called follicle-stimulating hormone (FSH) and Leutenising hormone (LH), which together control the ovarian cycle and are produced in the pituitary gland. They are in turn controlled by another hormone, GnRH (gonadotrophin releasing hormone), produced by the hypothalamus in the brain. FSH and LH act on the ovaries, which produce the female hormones oestrogen and progesterone, and these hormones are responsible for ovulation. As a woman grows older, her ovaries become less responsive to FSH and LH and produce less oestrogen; they also fail to produce

Inhibin, which controls GnRH production. FSH and LH levels rise, as the normal cut-off mechanism on GnRH is lost, leading to anovular menstrual cycles – that is, menstrual cycles in which no ovum is released. Eventually, consistently low circulating oestrogen levels result in an absence of menstrual bleeding known as 'amenorrhoea'.

For most women, the menopause is a natural and gradual transition, whereby hormone levels fluctuate and decline over a period of years. There are a number of symptoms which women associate with the menopause and these can affect their lives to a greater or lesser extent, depending on their severity. These symptoms are linked to oestrogen loss. Women who experience a natural menopause, or have a hysterectomy before they are naturally menopausal (surgical menopause), are likely to experience some of the effects of oestrogen loss, both short and long term.

1.1.1 Short-term effects of oestrogen loss

The short-term effects are the most familiar to women, and include the vasomotor symptoms, hot flushes and night sweats. These can in turn lead to disturbed sleep patterns and consequent psychosocial effects such as irritability and depression. Some 70% of women are troubled by hot flushes and night sweats (Rees, et al 2003). Urinary and vaginal symptoms result from the loss of oestrogenic influence on the vaginal mucosa, and urethral epithelium can cause urinary frequency, dysuria and vaginal dryness. Losses of sexual desire and/or sexual problems are also reported.

These are the symptoms from which some women seek relief, and may take them to their General Practitioner (GP) for advice on hormone replacement therapy (HRT).

Psychological effects, such as depression, may be coincidental rather than hormone-loss-related, especially as the menopause occurs at the same time as other life changes for many women. Middle age is also associated with children leaving home and increasing responsibility for ageing parents, amongst other social factors that could alone produce irritability and depression.

As the symptoms of the menopause are a result of oestrogen deficiency, hormone replacement therapy is designed to replace that deficiency by restoring circulating oestrogen levels. The most commonly used oral preparations are conjugated equine oestrogens, but there are many differing formulations and methods of delivery.

1.1.2 Long term Effects of oestrogen loss.

In the longer term, the loss of oestrogen has been linked with a number of conditions, all of which women would be keen to avoid if possible. The most widely recognised effect of oestrogen loss is osteoporosis, but oestrogen has also been thought to affect both the nervous and cardio-vascular system.

1.1.2.1 Osteoporosis

The most well known long-term effect of the menopause is osteoporosis. This is a progressive disease in which bone mass is reduced and the structure of bone is weakened, thereby increasing fragility and liability to fracture. Bone mass is said to be greatest at around 30 years of age, and after this there is progressive loss. This loss is accelerated after the menopause, and one woman in every four will develop osteoporosis (Lee 1998). The main determinant of peak bone density is agreed to be genetic (Smith et al 1973 cited in Swiers 1996 p35). According to Abdallah et al in 1984 (cited in Sweirs 1996, p35), the rate of bone loss after the menopause is 5% per

year for 5 to 10 years, with women who have had bilateral oophorectomy experiencing higher rates of loss. When women undergo a bilateral oophorectomy before the time of natural menopause, they are losing their natural oestrogen early and therefore can be said to be at a higher risk of developing osteoporosis in the future.

Osteoporotic fracture occurs in about 40% of postmenopausal women, and one in every six will suffer a hip fracture (Lee 1998). The role of oestrogen in maintaining bone density was recognised as early as 1941 (Albright et al 1941), and there have been many studies since then exploring this effect (Lindsay et al 1976, Bjarnson et al 1996). It is thought that oestrogen may have some effect via Calcitonin and have an anti-resorptive effect on bone by suppressing osteoclast activity and reducing bone turnover (Glasier and Gebbie 2000).

Results from large studies have shown that women taking oestrogen therapy did have a reduced risk of hip and other fractures, (Randell et al 2002, Torgerson and Bell-Syer 2001). The thinking now is that HRT does work as a treatment for osteoporosis but that there a number of non-hormonal treatments that work just as well. The additional risks now identified with HRT have altered the risk/benefit ratio, and it is now recommended that it should not be used as the first line of treatment unless menopausal symptoms are a problem (Lynch 2004).

1.1.2.2 Cognitive function

Oestrogen is possibly implicated also in the functioning of a healthy nervous system by promoting cell differentiation and the formation of synapses. There was, in the 1990s some evidence emerging that Alzheimer's disease, which affects women

usually after the age of 65, may be reduced in women replacing oestrogen loss with HRT (Henderson 1997). This view has now been largely dispelled by the Women's Health Initiative Memory study (WHIMS) 2004, a sub-study of the larger and now famous Women's Health Initiative hormone study (WHI) 2002.The WHI study will be considered in more detail later in this chapter. WHIMS examined the effect that oestrogen has on cognitive function. It concluded that " oestrogen alone does not protect women against the normal declines in cognitive function when compared with placebo", and that using oestrogen may actually increase the risk of developing mild cognitive impairment (WHI 2006 participant website/ findings/cognitive function). These results only apply to women of 65 years or older, and it is not known if the same applies to women of a younger age. Shumaker et al (2004) do not recommend the use of hormone therapy to prevent dementia or cognitive decline in women of 65 years of age or older. There seems to be no advice available to younger women, such as those in this study, as to what effect taking oestrogen will have on their future cognitive function; but the WHI researchers advise that oestrogen should not be used to prevent chronic diseases.

1.1.2.3 Possible Cardiovascular effects

Another long-term effect of oestrogen deficiency was thought to possibly affect the cardiovascular system. Pre-menopausal women are less likely to suffer coronary events than men of similar age; however, coronary heart disease rates increase with age for both men and women. Women after the menopause have an increased risk of atherosclerosis (Schwartz Freeman and Frishman 1995). Oestrogen is thought to alter vascular tone and influence lipid profile, and this protective effect is lost at the menopause (Tunstall-Pedoe 1998). Although more research was required in this area,

there were some indicators in the 1990s that oestrogen replacement may have had the potential to reduce CHD rates in women. The WHI study of women taking oestrogen only HRT after hysterectomy concluded that unopposed oestrogen provided no protection against myocardial infarction or the coronary death of women over 60 years old (WHI Participant website/ findings/heart disease). It did suggest that there might be a lower coronary heart disease risk for the younger women, aged between 50 and 59 years old (Hsia et al 2006), but the evidence is not conclusive statistically. Once again these results are difficult to interpret for women under the age of 50 years who are thinking about taking HRT.

Doctors base their advice to patients on current guidelines and the most recent research. As large-scale studies researching long-term risk benefit ratios of any medication take time to complete, these guidelines are altered in light of the findings of such studies as time progresses. The Steering Committee of the Women's Health Initiative (2004) concluded that oestrogen increases the risk of stroke in post-menopausal women (WHI Participant website/findings/stroke). Therefore, the prevention of cardiovascular disease is now not used as a reason to prescribe HRT.

So the benefits of taking HRT would be to control vasomotor effects, improve general well being and prevent osteoporosis in the future. Given the advice current at the time of this study the participants may also have been expecting cardiovascular protection and preservation of cognitive function. Additionally, however, there are some side-effects associated with HRT, and these need consideration.

1.2 Side–effects of Hormone Replacement Therapy

The opening paragraph of the U.S. Department of Health and Human Services' "Facts about Menopausal Hormone Therapy"(2005) states that HRT "once seemed the answer for many of the conditions women face as they age. It was thought that hormone therapy could ward off heart disease, osteoporosis and cancer, whilst improving women's quality of life." This view has been largely dispelled in the light of continued research over a number of years. The pharmaceutical industry has also been criticised for medicalising the menopause, and for influencing the interpretation of scientific research findings that may damage their own financial interests, (Clark 2003).

The most powerful data on the side-effects of HRT has emerged from the major large scale studies, including the Heart and Estrogen/Progestin Replacement Study (HERS) published in 1998, the Million Women Study of 2003 and, as previously indicated, the Women's Health Initiative in 2002 and 2004.In order to illustrate the timing of these publications in relation to this study a time-line is provided.

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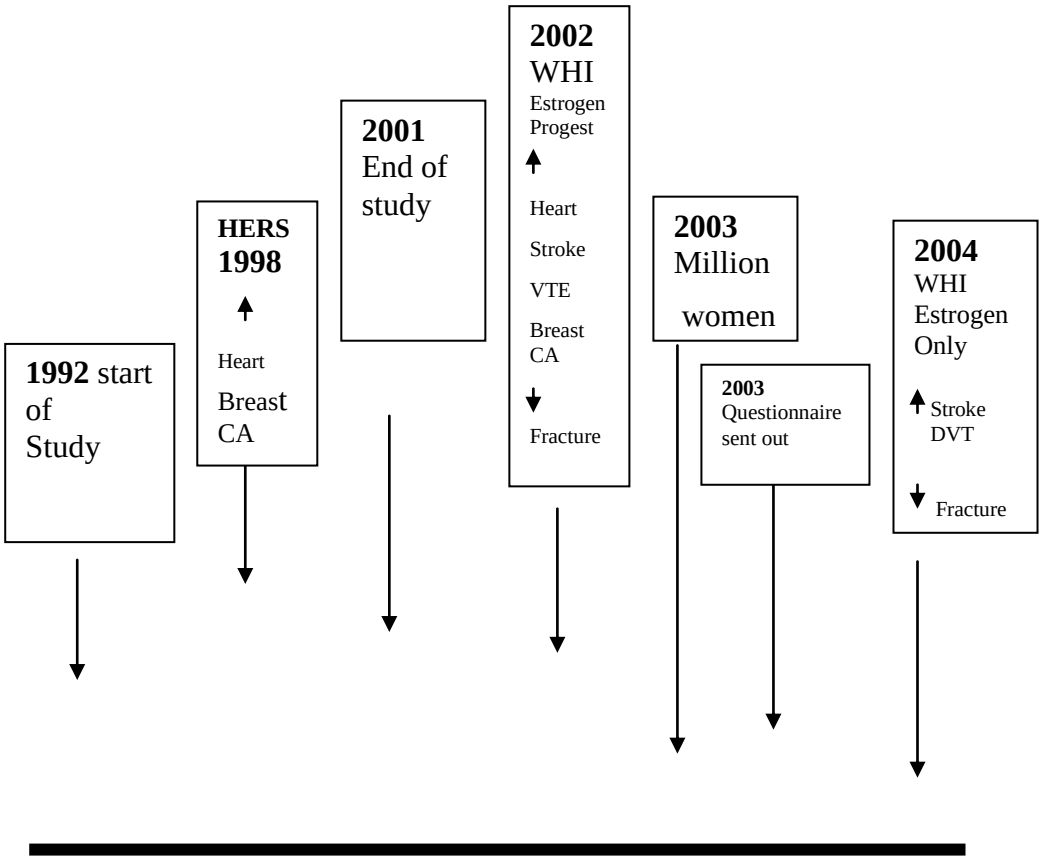


The HERS data showed that daily oestrogens and progestin did not prevent coronary events in women with known heart disease; indeed, it found an increase in coronary heart disease (CHD) rates in the first year of use (Hulley et al 1998). In 1991 the Women's Health Initiative (WHI) was launched as a large US- based study looking at the effects of HRT on heart disease, osteoporotic fracture and breast cancer risk. There were two parts to the study, one involving postmenopausal women with intact uteri who took either a placebo or oestrogen and progesterone, and the other involving women who had undergone hysterectomy and therefore took placebo or oestrogen only. These trials were designed to run until 2005, but were stopped early. The combined therapy trial was stopped in 2002, three years before completion, and the oestrogen only trial ceased in February 2004. The early cessation of these trials was

prompted by safety considerations, as the risks were found to outweigh the benefits. Both arms of the WHI study found a decrease in bone fracture rates in women taking HRT. However, increased coronary events, stokes, breast cancers and DVT's were found in women taking combined HRT, so confirming the findings of the earlier HERS. The oestrogen-only trial also found increased strokes and DVTs but fewer cases of breast cancer and coronary events. The Million Women Study, published in 2003, also found increased incidents of breast cancer associated with combined HRT in British women aged 50-64. Ross et al (2000) conclude that the addition of a progestin increases the risk of breast cancer when compared to oestrogen use alone. According to Hulley and Grady (2004, p.1770) "numerous lines of evidence support an increase in breast cancer with oestrogen use" but they suggests that, for the meantime, given the lack of statistical significance, this finding should be interpreted as having occurred by chance.

So we accept that HRT does increase breast cancer risk, that the Committee on Safety of Medicines (CSM) advises that the risk is related to the duration of HRT use, and that the risk disappears within about 5 years of stopping. The CSM stated in 2006 "that for those using oestrogen only HRT for 5 years breast cancer is diagnosed in about 1.5 extra cases in 1000 "(BNF 2006, p 391). Women in general cite an increased risk of cancer as one of their major worries about taking HRT (Griffiths and Convery 1995, Hope and Rees 1995, Newton et al 1997).

The findings from these American studies were reported in worldwide national newspapers, and presumably produced anxiety in women taking HRT at the time. When considering the findings of any research, it is important to know the

characteristics of the study population. It should be remembered that WHI was an American study, using women over the age of 50 years as their study subjects. 45% of participants were between 60 and 69 years of age, and 45% were classified as obese by body mass index (U.S. Department of Health and Human Services 2005 p7). These facts are likely to have some bearing on the increased rates of CVA and DVT.

Although it is thought that HRT alters the blood clotting processes, and thereby makes the blood more susceptible to clot formation, thromboembolism is multi–factorial in aetiology. Thromboembolism is not related to oestrogen alone and increasing age also plays a significant role, as do obesity, varicose veins and diabetes. These considerations make decisions about HRT prescription difficult for some women.

Jick et al (1996) found a three-fold increase in risk of venous thromboembolism (VTE) in women using oestrogen replacement, after controlling for predisposing conditions, and this increase was seen to be higher in women taking higher doses of oestrogen. Daly et al (1996) confirmed these findings in a British study, and found that the increased risk might be concentrated in new users. Rates of pulmonary embolism in women taking HRT were similarly found to be increased by Grodstein et al in 1996. Both HERS and the two arms of the WHI trials found increased rates of coronary events and venous thromboembolism associated with oestrogen therapy, confirming these results.

According to the Royal College of Obstetricians and Gynaecologist's Clinical Guideline no 19, *Hormone Replacement Therapy and Venous Thromboembolism*

2004, all women commencing or continuing HRT should be counselled about the risk of VTE, be aware of the signs and symptoms, and know to access medical help if they should suspect that they have developed the condition. It does, however, recognise that the risk is small and should be considered in perspective when assessing the overall benefits of therapy. The BNF (2006) states that women who take oestrogen-only HRT are at increased risk of DVT and pulmonary embolism especially in the first year of use.

For women troubled by short-term menopausal symptoms, the benefits of HRT would appear to be convincing. In terms of alleviation of symptoms, such as hot flushes and night sweats, HRT is effective. Rodstrom et al (2002) reported that between 70% and 87% of their Swedish study population considered HRT an effective form of treatment, whereas fewer than 50% of women treated with non-oestrogen therapy reported efficacy. In 2005, an independent panel convened by the US National Institutes of Health still supported the use of HRT for the relief of moderate to severe menopausal symptoms.

1.3 Differences in HRT treatment for women with hysterectomy and bilateral oophorectomy compared to those with natural menopause

There is a group of women who do not experience the menopause as a gradual process. Women undergoing elective hysterectomy with bilateral salpingo-oophorectomy (BSO) – that is, the surgical removal of the uterus, fallopian tubes and both ovaries – do not experience a gradual transition into menopause, and can be described as surgically menopausal. Their ovarian loss produces a post-menopausal hormone profile quickly after surgery. Depending on the age of the woman at the time

of surgery, the hormonal drop after oophorectomy can be abrupt and produce more severe symptoms (Utian 1980, cited in Logothetis 1991, p.461).

There are a number of reasons why a woman would have a hysterectomy; these include excessive menstrual bleeding, endometriosis and malignancy. The ovaries are often removed at the same time as the uterus, as they are often approaching atrophy and can be considered a possible source of future malignancy. For the women selected for inclusion in this study, the reason for their surgery was documented as menorrhagia - that is excessive menstrual bleeding- and all women had been treated surgically with a total hysterectomy with bilateral oophorectomy.

These women lose their natural source of oestrogen suddenly, and often earlier than would be expected in nature, and are therefore different to those women undergoing a gradual natural menopause. Women who have had a hysterectomy need only take the hormone oestrogen as replacement therapy. They do not need a combined oestrogen and progesterone preparation, as women who have not had a hysterectomy do. This is because they no longer have a uterus. Progesterone is necessary to prevent proliferation of endometrial tissue within the uterus, which would occur if oestrogen were taken unopposed by progesterone in women with an intact uterus. Combination HRT- that is with oestrogen and progesterone- has side effects related to progesterone dosage, such as breakthrough uterine bleeding; therefore, women undergoing natural menopause may have additional unacceptable side- effects, and indeed many women taking combined HRT complain of erratic or heavy bleeding, and cite this as a reason to stop therapy (Hope and Rees 1995). These side effects, and the potential for the development of endometrial cancer, are absent in hysterectomised women who take

oestrogen replacement only. So women who have had a hysterectomy and take just one hormone as HRT may therefore have different patterns of use to those women taking combination therapy. Little published research is available which examines hysterectomised women in particular. Most papers discuss findings from women in general, without distinguishing them by hysterectomy status.

The women in this study took oestrogen-only HRT, but the study will not examine which specific preparations were used or how they were administered; it will only determine whether HRT was taken. There are many different HRT preparations, marketed by different pharmaceutical companies, and they differ in dosage and mode of delivery. There are oral tablets, dermal patches and vaginal rings, but the aim is the same: to replace lost hormones. In this study, it was not necessary to investigate which actual preparations the study population used; the focus was instead on the duration of use, and the reasons given to cease treatment.

On balance, it is not difficult to see why, during the decade 1992-2001, oestrogens were used to alleviate short-term menopausal symptoms. They were also thought, at that time, to possibly protect women in their later years against debilitating and expensive disease in terms of health care costs. Nor is it surprising that therapy remains somewhat controversial for many women, given the known side effects, the extent of which has only comparatively recently become evident. Prescribing guidelines have been changed in accordance with recent research findings.

1.4 The medicalisation of the menopause

Before considering the changes in HRT prescribing, it is necessary to consider the way in which the menopause transition is perceived as either a "medical" or "natural" event. The perspective in which menopause is viewed may affect the way it is managed.

So far the description of menopause has been based on a mainly medical perspective because the women in this study have been treated for menorrhagia by surgical intervention, in all cases before the average age of natural menopause. This study would however not be complete without examining the feminist perspective of menopause and the criticism that the "medicalisation" of this time in women's lives is unnecessary and seeks to control women.

Peter Conrad defines "medicalisation" as seeing "a problem in medical terms, using medical language to describe a problem, adopting a medical framework to understand a problem, or using a medical intervention to treat it. This is a sociocultural process that may or may not involve the medical profession, lead to medical social control or medical treatment, or be the result of intentional expansion by the medical profession." (Conrad 1992, p 211). Many conditions, not really "diseases" in a true sense but rather natural human diversity, have been medicalised and treated; for example many types of cosmetic surgery are used to "improve" on nature. Interventions have been made by medicine into "natural" life events such as childbirth and fertility with the use of elective caesarean section and introduction of the contraceptive pill. If, as Grady (1999 p 5) suggests, medicalisation seizes "upon aches and pains that people used to live with and declare them dysfunctions that must be

treated", and where in the past it was "acceptable to leave certain conditions alone, doing so now might be considered cruel neglect", then it is not surprising that medicalisation is usually interpreted as negative. The criticism is that medicalisation transforms social problems into medical ones, and interferes unnecessarily in "natural" processes, and that in both cases it subjects them to the control of the medical profession.

According to some feminist writers, this is what has happened with the menopause: a natural, life-cycle process has been transformed into a medical problem requiring unnecessary intervention. It is this perspective that will now be explored.

If menopause is not regarded as a natural or normal stage of life and one that all women experience, but rather a medical condition caused by oestrogen deficiency, then women are turned into patients. This in turn creates "new markets for special clinics, diagnostic tests, pills and self help books." (Grady 1999 p1). Burrell (2009 p 212) says, "the course of nature in ageing women has been re-categorised as unnatural." As menopause is thought of as a deficiency disease, HRT is marketed as the answer in terms of replacement. She says, "although therapeutic in a few cases, hormone preparations are in fact potentially dangerous lifestyle drugs". There is discussion in her paper about whether or not the findings of the WHI in terms of risk were overstated. She points out that government health advisories have not been altered in the light of criticisms of the methodology used in the WHI studies, and that conservative approaches to treatment are still recommended. The WHI findings will remain as the gold standard of evidence unless future research discredits their conclusions (Cirigliano 2007 cited Burrell 2009 p216).

To understand how the menopause has become a medical problem, Burrell (2009) uses the work of French philosopher Michel Foucault to provide an insight into the effect of power and knowledge on the medical construct of menopause.

Foucault would suggest that the reason that menopause is thought of as a disease is because of the values held within medical science. Medicine likes to classify the "normal" and the "abnormal", it looks to identify disease and categorise symptoms to aid that identification. Deviation from the norm becomes a reason for medical intervention. In *The Birth of the Clinic* (1963/1973), Foucault describes what he calls the medical gaze where "the patient is only relevant in that what they reveal in history, symptoms and measurements permitting identification of disease"(Burrell 2009 p 213). He also suggests that through various power relations "medicine derives social authority, influencing social orthodoxies thus normalising the subject via discursive constructs" (Burrell 2009 p 213). Foucault's theory of genealogy focuses on how one is turned into a subject by this process of normalisation in which the concept of the "normal" is formed, as a product of history, culture and professional discourse all shaping the accepted idea of what for instance is the normal female body.

The normal female body is one, which is potentially fertile. Feminists in the 1980s and 1990s criticised the dominant medical construction of menopause on the basis that it represented "women as biologically weak and vulnerable and emphasised popular ideals about beauty and youth." (Murtagh & Hepworth 2003, p 1643). Burrell (2009) concludes that a " Foucauldian lens has revealed importantly that the

construct of post menopause as a defective condition has led to the administration of substances that are unnatural for the time of life concerned, as treatment is based on some standardised ideal of the healthy fecund woman" (Burrell 2009 p 219).

If the popular ideals of beauty and youth are the basis on which women are valued, then the process of ageing becomes less acceptable, and older women are not regarded as highly as their younger sisters are. The promise then of a treatment that preserves youthfulness and attractiveness becomes valuable to women. HRT has been promoted along these lines, with claims of improved skin texture; more lustrous hair and improved libido, all linked to the replacing of lost oestrogen. Frances McCrea, writing in 1983, showed how the two opposing definitions of menopause evolved, and how feminists argued against medicalisation. She uses some rather extreme examples of how menopausal women were described by influential writers in the mid 1960s. There are according to McCrea (1983), four "negative themes common to medical definitions of menopause". She lists them as follows;

1. Women's potential and function are biologically destined.
2. Fecundity and attractiveness determine women's worth.
3. Rejection of the feminine role will bring physical and emotional havoc.
4. Ageing women are useless and repulsive.

She finds evidence for such claims in literature of the time, including the famous book *Feminine Forever* (1966) by eminent gynaecologist Robert Wilson, and in David Reuben's (1969) best seller *Everything you wanted to know about sex but were afraid to ask.* In these publications, the menopausal woman is portrayed, not only as

suffering a deficiency disease, but also causing social chaos. Hormone replacement is strongly advocated as the solution to hot flushes, sagging breasts, irritability, frigidity and depression. Wilson (1966) says, "oestrogen makes women adaptable, even tempered, and generally easy to live with" (Wilson 1966 p 64). Reuben's (1969) book goes even further, saying that "as oestrogen is shut off, a woman comes as close as she can to being a man. Increased facial hair, deepened voice, obesity, and decline of breasts and female genitalia all contribute to a masculine appearance. Not really a man but no longer a functional woman, these individuals live in a world of intersex. Having outlived their ovaries, they have outlived their usefulness as human beings." (Reuben 1969 p287).

It is hardly surprising that these views were challenged by feminist writers at the time, and continue to be of concern today.

There is evidence that similar, but perhaps less extreme, themes exist also in the available published literature on menopause and HRT use. In 2002, Coupland and Williams examined the content of three different sources of information for women, and found this same negative construct of menopause evident in two of them. The three "discourses" examined are based on printed texts on the menopause from the pharmaceutical, the alternative therapy, and the emancipatory feminist perspective. Information leaflets published by or in association with, pharmaceutical companies use "metaphors of deficiency, decline and depletion" and imply that HRT can solve the problem. Such leaflets, because they are provided by the doctor or are available in the surgery, are likely to attract "conferred expertise" status (Fairclough 1989, cited Coupland and Williams 20002, p 422). Although newspaper and magazine articles

proposing “alternative therapies” to HRT reject the need for medical intervention and advocate “natural remedies”, they still view the menopause in a negative way. The same basis of replacing lost hormones applies, but it differs in what is used for such replacement. Manufactured HRT preparations are seen as a cleverly marketed solution, while naturally occurring herbal remedies are preferred. Both the pharmaceutical and the alternative therapy perspective are ageist in their approach, with their focus on the preservation of youthful femininity.

However, books and articles from a feminist stance however reject both the medical and the alternative therapy positions. They argue that menopausal women should not be viewed as patients in need of prescription medicines, or as needing “natural” remedies, on the basis that no remedy is required. They reject the so -called natural alternatives to HRT on the basis that there are no natural substitutes, and advise caution in the use of non-prescription preparations, claiming to act like HRT, which are not endorsed by the Medicine Control Agency (Coupland and Williams 2003, p 436). Feminist writer Germaine Greer, in her book *The Change* (1991), expressed the fear that, by trying to cancel the menopause by the use of HRT, women were being prevented from accepting a rite of passage leading to fresh challenges (Greer 1991, cited Coupland & Williams 2003, p437). She also questioned some of the scientific claims made for HRT, suggesting (for example) that younger looking skin is “magical” and “unsubstantiated”. She also criticises women using HRT as being manipulated by the pharmaceutical industry (Greer 1999, p187, cited Coupland and Williams 2003, p437)

There is little doubt that pharmaceutical companies have profited greatly from the HRT market, a fact often noted by those who believe that women have been, in effect, manipulated by a pharmaceutical conspiracy.

Feminists criticise the medical construct of menopause for assuming that, as all women eventually become menopausal, and because a decrease in circulating hormones is the causal mechanism of menopause, symptoms are the same for all women. Because the menopause is universal, the effects of menopause are also universal. McCrea (1983) illustrates this thinking, and quotes an article in the *New York Times* by Brody in 1975, which included the following statement by an American gynaecologist: "I think of the menopause as a deficiency disease like diabetes. Most women develop some symptoms whether they are aware of them of not, so I prescribe oestrogens for virtually all menopausal women for an indefinite period" (Brody 1975, cited McCrea 1983, p116). So even if women did not suffer from symptoms, HRT was viewed as a necessity by the gynaecologists of the past. Feminist authors have disputed the 'universality of symptoms', finding evidence that there are differences in the experience associated with culture, social class and ethnicity, as shown in work by Lock (1998) and Gifford (1994). There is also a counter-argument from the medical perspective: viewing the menopause as a transition requiring no medical help can lead to severe menopausal symptoms felt by some women being ignored (Murtagh and Hepworth 2003 p 1644).

It can be argued that there remains a medical rational for HRT prescription, even leaving symptom control behind. If menopause is constructed as a long-term health risk, then there is still a medical reason to promote the use of HRT to prevent

osteoporosis in later life. Prior to the findings of the WHI studies, HRT was also thought to prevent heart disease and preserve cognitive function. So even if women reject HRT as a method of preserving their femininity, their doctors may persuade them to take it on a risk management basis to prevent osteoporosis in the future. This may be viewed as an unnecessary control from a feminist perspective, or a health promotion strategy from the perspective of the medical profession and the pharmaceutical industry.

If the "preventative" approach is used, women have a choice whether or not to take HRT as part of their responsibility for their own health. Such decisions are supposed to be made by well-informed, autonomous women. Autonomy is one of the principles of medical ethics, and is the right to freedom of choice and consent; but limitations on autonomy come with the competence of the individual (Murtagh and Hepworth 2003, p1645). Sherwin (1998) states that: 'Autonomy is conventionally understood as a recognition of the authority of the patient to make choices about their health care' (cited Murtagh and Hepworth 2003, p 1646). However the truly autonomous patient is probably a rarity, as social interaction and experience influence autonomy, and it is restricted by the 'role' of the individual in society. Murtagh and Hepworth (2003, p 1643) suggest that the 'ethic of autonomy' and an 'offer of choice' actually are not emancipatory for women making HRT decisions, because they intensify the power relations between women and their physicians. They say that doctors, while claiming to empower women and support their choices, actually do the opposite by limiting their choice through 'constructing menopause solely within biomedicine' (p1646).

Murtagh and Hepworth (2003) use another of Foucault's concepts, namely "governmentality", as a useful way to criticise the biomedical view of menopause. Foucault proposes that all social relationships are essentially relationships of power, and he coined the term " biopower" to refer to the management of people in relation to practices in public health. It is well recognised that the power dynamic between doctor and patient in the consulting room is rarely equal. The doctor is viewed as the expert with the knowledge and authority to advise the patient.

According to Foucault, "The doctor's gaze is not faithful to truth, nor subject to it, without asserting, at the same time, a supreme mastery: the gaze that sees is a gaze that dominates" (Foucault 1963, p39 cited Downing 2008, p 34). Women are thus produced as "the subjects of medical and self scrutiny that act as a mechanism of control". Whether or not they decide to take HRT is required to be a choice, but with "precisely the practice of freedom acting as a mechanism of governmentality" (Murtagh and Hepworth 2003, p1646). Foucault does not accept that authentic freedom is a genuine possibility, due to the many external and internal influences on the individual. He argues that patient-centred practice "does not necessarily lessen the power relation between the doctor's gaze/touch and the medicalised body – indeed it may bring it all the more sharply into focus. Or may create it *ex nihilo*." (Dowling 2008, p37) So real choices for patients are not possible; the individualising of the patient is only the effect of the operation of power, according to Foucault (Downing 2008, p37).

The medicalisation of the menopause, and the criticisms levelled at this, have been explored. We now turn to the feminist view of the menopause as a natural life event perspective, to examine this in more detail.

Instead of the negative construct of menopause leading to medicalisation there is, from a feminist perspective, an acceptance of menopause as part of the natural ageing process for women; but this is regarded as a positive, normal and emancipatory time in women's lives. Gannon (1996) says that at menopause "ovarian serenity is restored", that levels of oestrogen become stable once more as menstruation ceases, and that women are thus released from the reproductive pressures which dominate their younger years (Gannon 1996 p 243, cited Coupland and Williams 2002, pp 439-440). It has to be said that Gannon almost implies, in this particular statement, that it is the reproductive years that are abnormal. Freedom from worries about menstruation and pregnancy, it is claimed, allow women to concentrate more fully on their careers and social activities. Rather than the 'medical' picture of the menopausal woman as 'mad or bad', this construction of menopause sees women re-evaluating their lives, and being able to make choices previously impossible due to family responsibilities.

This rather rosy picture of menopause has been questioned on a number of levels. It has been criticised as ignoring the fact that, for some women, the symptoms of menopause are severe (Daly 1995, cited Murtagh and Hepworth 2003, p 1644) and can be relieved by the use of HRT (Rodstrom et al 2002). McCrea (1983) adds that feminists have overlooked the women who do suffer menopausal symptoms, and that the feminist view is too ideological. She suggests that "in their efforts to fight off the

stigma of menopause, some feminists have inadvertently contributed to ageism", and that they have extrapolated their analysis of the medicalisation of childbirth to that of menopause "without adequate appreciation of the problems of ageing women" (McCrea 1983, p 120).

According to Laura Purdy, "defining states of affairs as "natural" or "normal" implies nothing about how to deal with them". She gives examples of instances where medical intervention in 'normal ' life events like childbirth has been essential to save lives. She also says " 'the natural' still exerts substantial power over us", and that we should resist it, as it makes us accept health trends that could be avoided, such as obesity (Purdy 2001, p254-255). So does the thinking that menopause is universal, "natural" and "normal" to women imply that nature, by design, does not need any outside intervention, that "natural" is best and needs no improvement?

It is interesting to note that menopause is not a normal or natural part of life for the females of any mammalian species, other than humans and toothed whales (Johnstone and Cant 2010). From an evolutionary angle, menopause seems to be an anomaly. Natural selection demands that all species maximise their reproductive potential, thus ensuring the continuation of their genome. The best way for this to occur is to reproduce until death. Most animals die before they lose the capacity for reproduction, and this occurs because they succumb to extrinsic threats. Human beings have, unusually, learned to control extrinsic pressures, and hence have extended their lifespan. It is our extended post-reproductive lifespan that makes us different from other primates, not the fact that we cease to reproduce at an earlier age.

There are two main theories of how menopause emerged: one argues that it is an adaptation, the other argues that it is an epiphenomenon (Peccei 2001). The adaptive theory is that females have better reproductive success by investing in fewer new offspring in favour of extending their protection to existing offspring and their young. That is to say, their genes are better propagated down the bloodline, rather than in the production of multiple children (Johnstone and Cant 2010). The theory of menopause as an epiphenomenon believes that it is a result of some other evolutionary development, in this case extended lifespan. Menopause occurs because the female has lived long enough to exhaust her reproductive capabilities (Wood et al 2001). Evidence from female macaques supports the epiphenomenon theory (Pavelka and Fedigan 1999, cited Citzendium 2011). If this theory is preferred, menopause occurring in human females can be thought of as an evolutionary design fault. Since it can produce unpleasant symptoms for some women it is something which we might wish to correct.

Purdy (2001) argues that, rather than reject medical intervention on the basis that it is against nature and unnecessary, we should use the power of medicine to advance the welfare of women. She clearly does not think that feminism and women's medicine cannot work together. She does, however, argue that the feminist claim that medicalisation is used to control women is too simplistic. Menstruation, fertility, pregnancy, childbirth and menopause are all areas of women's lives subjected to medical scrutiny, yet are all natural processes. She points out that medical advances have indeed liberated women from some reproductive processes, giving them increased control over their own bodies. The most obvious examples of this are the introduction of the contraceptive pill and the legalisation of abortion, where women

have used medicalisation for genuine empowerment. So "the answer is not to 'suffer our fate'" by rejecting treatment which may help us, but rather to "use medical means for our own ends, whether to reduce pain or shape our own lives" (Purdy 2001 p257). The problem, according to Purdy (2001), is therefore not so much medicalisation but rather the culture of medicine itself. The goal of medicine is to treat disease and is government funded accordingly. So conditions that are not really diseases are either medicalised or non-funded. Purdy advocates a need to recognise that it can be appropriate to use medical means to prevent suffering, even if the source of the problem is not a disease. "The biomedical model also focuses on individuals separate from their social context, prefers action rather to watchful waiting, cure rather than prevention, heroic technical fixes and individual solutions to political or social problems" (Purdy 2001, p260).

Women today have a far greater life expectancy than women of the past, and will consequently have many years of life of post-menopause. These years should be supported by health care which understands the needs of such women, and sees them "as persons in their own right, persons whose needs, desires and interests areas intrinsically important as those of men" (Purdy 2001, p259). The recommendations made by Purdy – changes in medical training, so as to include the humanities and social science, longer consultation times, and access to nurse practitioners – would perhaps lead to a greater understanding how women's health is affected by their social role.

To return to the subjects of this study, it is important to recognise that, for all of these women, their menopause was not "natural". Medicine had intervened with their

agreement to rid them of a condition they found debilitating and unacceptable. It was common, at the time of the study, for ovaries to be removed at the time of hysterectomy for menorrhagia, rendering the woman "surgically menopausal". HRT was then prescribed as a true replacement treatment for the *premature* loss of circulating oestrogen. So the feminist argument of "interfering in nature" does not really apply to the HRT prescription for these women, as medicine had already 'interfered' to cure a biological problem. If we were not to interfere with nature, then these same women would have been subject to heavy menstrual bleeding, a common, well recognised complaint, but one, which they themselves found difficult to manage. Left untreated, these women may have suffered a negative impact on their quality of life for a protracted length of time, the relief from such a situation, is the rationale for medical intervention in the first place.

There is perhaps a point of interest, from a feminist perspective, in the removal of the ovaries at the time of hysterectomy for no other reason that these organs may cause problems in the future. From a medical stance, removal was thought to be reasonable on the basis that the risk of future ovarian cancer was negated, and that the ovaries were nearing their functional demise anyway. When women are told that they can avoid a cancer risk in the future by removal of the potential source, at the same time as an operation they are having anyway, most agree to it. Perhaps this is manipulative and controlling of women; yet most would opt to avoid the possibility of malignancy in the future if given that option. It has to be said that since the women in this study were treated, hysterectomy is used far less often as a treatment for menorrhagia. Prophylactic oophorectomy, to prevent ovarian carcinoma, in low risk women is not supported by some studies (Parker et al 2009). Now more conservative alternatives

are preferred, with hysterectomy being the last resort when other methods fail. As discussed in chapter four, there has been a steady reduction in the rate of benign hysterectomy in the United Kingdom since 1995-1996 (Reid and Mukri 2005). Burrell (2009) notes that the medical terminology used to describe exogenous hormones has changed in the course of the last ten years. Authors now use HT rather than HRT, as hormones are now used to treat symptoms rather than simply replace lost hormones. This distinction could be useful when comparing naturally menopausal women and women with surgically induced menopause. For the treatment of symptomatic naturally menopausal women HT is acceptable, as the term does not imply that hormones should be present. For women with premature oestrogen loss due to surgery, HRT is a more useful term as it is a true replacement.

Either way, it is still medicalisation; but the timing is different. Symptomatic naturally menopausal women can use medicine to improve their quality of life. For surgically menopausal women, the medicalisation has already happened by way of surgical intervention in the first place. HRT prescription is a subsequent part of a process already started. Women treated for menorrhagia now will be more likely *not* to have a hysterectomy with bilateral oophorectomy, and will thus avoid the need for further medical intervention in their menopausal years.

Returning now to the current study, an explanation of the time frame over which the data was collected, together with changes in HRT prescribing which have occurred since the study was conducted, follows.

1.5 Changes in prescribing guidelines during the time-scale of the study.

The timing of this study has a major impact on the findings made and their relevance today. So it is important to be clear when the study was conducted, and when the data was analysed, so that the reader may understand how the extended time frame impacts upon the results.

The study was commenced as part of an academic qualification in 2002, and selected patients treated in the preceding 10-year period (1990-2001), to allow a retrospective study of the recent past. There was no other reason to select this particular decade. The questionnaires were sent to participants in 2003, at a time when HRT treatment was beginning to be covered in the national press as the results of WHI 2002 became known. The impact of these studies cannot be ignored as a potential influence on the opinions of the study subjects.

Not only did these studies potentially affect the responses given by women in the study; they have affected the relevance of the study findings to HRT decisions made today. To understand the study, it is necessary to understand the premises at the time. Before the WHI findings were published, HRT was used widely by women and their doctors as a treatment for the relief of menopausal symptoms. It was also promoted as a treatment to prevent osteoporosis, preserve cognitive function and protect against cardiovascular disease. As previously discussed, these benefits have now been somewhat discredited, and side effects such as increased rates of breast cancer and venous thromboembolism become evident.

The questions asked of the study participants were relevant to the area of study *at the time,* and women who had undergone hysterectomy and bilateral oophorectomy had not been considered as a separate group in published papers. The study was therefore, designed on what was known at the time. Due to the extended time taken to present its' findings, and the results of large scale research now apparent, there are fundamental differences today in how HRT treatment is viewed, by the medical profession and women alike.

The current recommendations for the treatment of menorrhagia, the career of HRT to date, and the changes in the attitudes to its' use, will be further reviewed at the end of this chapter.

Women who are pre-menopausal prior to surgery need to be aware that their hormone status will change subsequent to surgery, and that they will have lost their source of natural oestrogen prematurely.

In 2001, according to the British National Formulary (BNF, March 2001), long term HRT was indicated for women with early or surgical menopause (before age 45). These women are at high risk of osteoporosis, and long-term use was considered favourable in risk-benefit terms for menopausal women without a uterus. It was recommended that therapy should continue for 5-10 years, in order to be of benefit in preventing osteoporosis. By 2006 the advice given in the BNF had changed somewhat. It stated that HRT may be used in women with early menopause, either surgical or natural, up to the age of 50, but that alternatives should be considered if osteoporosis is the main concern. It states "that for the treatment of menopausal symptoms, the benefits of short term HRT outweigh the risks for the majority of

women, especially in those aged under 60 years (p 375). These changes to the prescribing guidelines came as a direct result of the research findings of the Women's Health Initiative hormone study.

The women in this Scottish study had their operations between the years 1992 and 2001, and therefore the advice given to them regarding HRT will have been different to that now given to women in terms of length of treatment. As all the study subjects had elective hysterectomy with bilateral oophorectomy before the age of 51 years, the reasons for taking HRT will have been much the same as they are today- that is, the relief of menopausal symptoms. It is likely, however, that these study participants were led to expect more from HRT in terms of osteoporosis prevention and possible cardioprotection, and they may have thought that it should be taken for a longer time. The impact of the publication of the WHI findings in the national press in 2002, which was approximately nine months prior to the women in this study being surveyed, will be discussed later in chapter 5.

The advice given today to women after hysterectomy and bilateral oophorectomy is that they should take HRT until around the time of the average natural menopause at 51 years. They should take it primarily to relieve the short-term menopausal symptoms, such as night sweats, and they are told that it will protect their bones. Once they reach the age of natural menopause, and symptoms are not a problem, there are other effective preparations to use to protect bone density should this be necessary. As indicated earlier, the research on which these recommendations are based is reviewed separately at the end of this chapter.

The information women receive about a medication, and what they might reasonably expect from it in terms of short and long-term risks and benefits, may be considered to affect their decision to commence and/or continue to take it. With this in mind, we now consider the issues around compliance with, or adherence to, HRT prescription.

1.6 General Compliance/ adherence issues

HRT is considered a long- term medication designed to be taken for a number of years to prevent the symptoms of the menopause. In order for it to be effective, it should be taken as prescribed. Before examining what is known about adherence to HRT prescription in particular, some consideration will be made of the subject in general**.**

The term "compliance" is generally accepted to mean adherence, co-operation or acquiescence, the yielding to the wishes or advice of others. In medicine it means that, for example, the patient adheres to the prescribed treatment plan. On the surface, it might be expected that the issue of compliance would be simple in that, once a patient has sought medical advice, they would comply with the prescribed treatment. This, however, does not occur, and it is estimated that between 30-60 % of patients do not fully comply (Richman 2002 p 99). Patients are more likely to comply with treatment if they are suffering physical ill health, but the severity of the illness, its duration and the degree of debilitation have little or no association with compliance (Smith and Birrell 1990). Compliance is now a rather outdated term with its implication of a passive part played by the patient, and health- related literature now uses "adherence" or "concordance" as preferred terms. These terms better reflect a recognition of the patients' own beliefs in the making of their decisions, and, with the advent of nurse prescribing, this different perspective is of importance to nurses.

The term " concordance" was first introduced in 1997 by the Royal Pharmaceutical Society of Great Britain, and is defined as "a new approach to prescribing and taking medicines, based on partnership" (Courtenay and Griffiths 2004 p122). This idea moves away from the traditional dictatorial role of the prescriber, and is designed to produce a more consultative approach, where the patient's wishes are valued and decisions are reached by informed discussion and interaction between patient and prescriber. Bond and Bywaters (1999, p 855) suggest "Compliance is neither an adequate nor appropriate concept to use in relation to women's decision making about HRT". They suggests that it implies a "too narrow a model of consultation" and ignores other sources of information women may access. However, most of the studies conducted so far do use the term "compliance" to describe the continuance of HRT therapy.

Whichever term is used, the reason patients either continue or cease using prescribed medication is a complicated issue. For the purpose of this study the author has chosen to use the term "adherence" as this implies a patient- centred approach, even though the study subjects were treated at a time when "compliance" was the accepted term.

For years researchers have been trying to explain how people make decisions about their health-related behaviours, and adherence to a prescribed treatment is such a decision. Many theoretical models have been developed in an attempt to identify the factors which impact upon such decisions, and which might therefore be useful in predicting behaviour. Three such models -The Health Belief Model, (Becker et al. 1977), Protection Motivation Theory, (Prentice-Dunn and Rodgers 1986) and

Leventhal's Common Sense Model of Self Regulation, (Leventhal, Brissette and Leventhal 2003) - will be discussed here.

It is accepted that a number of factors may influence a person's decision to take medication, and the "Health Belief Model", (HBM) developed in the 1950s, by Becker, and used widely, attempts to explain this. The model illustrates the complicated interaction of many different influences that may determine compliance by modifying the individual perception of personal susceptibility to a disease and the seriousness of that disease (Becker et al. 1977). According to this model, factors such as age, sex, social class and peer pressure determine the likelihood of action based on the balance of "what is to be gained by following a treatment" (perceived benefits) versus "what cost to me, i.e. effort, financial" (perceived barriers), together with the perceived likelihood of suffering from the health threat and the perceived severity of that threat. The validity of The Health Belief Model to predict health related behaviour has been questioned by Harrison et al (1992), and similar but more comprehensive models have now replaced it.

Protection Motivation Theory (Prentice-Dunn and Rodgers 1986) is very similar to the Health Belief Model in that the individual evaluates the health threat in terms of probability of occurrence, severity and the effectiveness of treatment. When considering the costs of behaviour change, however it differs from the Health Belief Model. Where the HBM classes all costs - time, effort, money inconvenience - as one variable, the Protection Motivation Theory separates out the costs. It takes into account the individual's own belief in their ability to adhere to treatment (self-efficacy), and the loss of current internal rewards and extrinsic rewards of change, as

separate variables rather than grouping them together (Weinstein 1993 p 325). Additionally, the model includes an emotional input- that is, how the patient feels about the potential health threat. So it takes into account both the severity of the threat and the susceptibility to the threat, but also how these are dealt with emotionally. Both these theories would predict that a woman who was worried about osteoporosis, and who believed HRT would prevent, it would be more likely to accept and adhere to her prescription, in spite of known risks, than a woman who viewed HRT as ineffective, unnatural or unnecessary.

Leventhal's common-sense Model of self-regulation of health and illness, or CSM, is perhaps the most useful model when considering HRT choices. The very name implies a less medical and more patient- focussed approach. This model is based on problem solving, and acknowledges that fear of a health threat is important; but it recognises that fear alone does not explain patients' decisions. It has a parallel-response framework, representing the ways in which the health threat is represented, coped with and evaluated. Hale et al (2007, p 904) say "the key construct within the CSM is the idea of illness representations or lay beliefs about illness". According to Leventhal et al (2003, p 50) there are five domains of illness representation, which are perceptual in nature and are as follows:

1. Identity or label e.g. symptoms and what they mean.
2. Timeline or duration e.g. perceived time of onset and duration.
3. Consequences or expected outcome e.g. disability or pain.
4. Cause e.g. genetic inheritance, lack of sleep, and contact with sick individual.
5. Control of illness e.g. is treatment effective? Can it be prevented?

All of these domains can be complicated by various social influences, such as the opinions and experiences of other patients, family and friends, and the media. Each patient will have an individual illness representation based on his or her perceptual information. This in turn informs their coping procedures and action plan, and may change over time.

Leventhal et al (1992) suggest that this model is useful when trying to understand adherence, as it combines many of the variables used individually in previous models. To take a simple example, the patient most likely to take the prescribed medication, would believe the following: that he would get bad symptoms; it will happen soon and last; it will be painful or dangerous; medication will take that risk away. The patient for whom any medication is prescribed is likely to question any long-term treatment that has associated side- effects, such as those seen with HRT, and the potential benefit of decreased risk of future illness may be outweighed by shorter-term side-effects. Towey et al (2006), in their review of psychological and social interventions in the menopause, consider Leventhal et al's model a useful tool in consultations about HRT prescription, as it specifically considers the identity, the consequences and the control for the individual. In other words, it allows for the influence of the individual's perception of the meaning of symptoms and their severity, - that is, what will the menopause be like for them. This may well vary greatly between individuals. The possible consequences of not taking the medication in terms of susceptibility to symptoms such as hot flushes and osteoporosis, will vary between different women. Likewise the perception of the risks of treatment will also vary on an individual basis.

Most importantly the individual's belief in the success of treatment, is accounted for in Leventhal's model.

All these models are based on what information the person has to process in order to reach their decisions, so clearly that information is vital. The information about how HRT works, and about the risks and benefits of treatment, are central to the evaluation women make when making their decision, so the source of the information (and how well it is delivered is) important.

The nature of the relationship between patient and prescriber, in terms of communication, will affect adherence, and Latter (2004) suggests that non-adherence may relate to the quality of information given (p125). This has been confirmed by much earlier studies (Svarstad, 1976 cited in Leventhal et al, 1992, p145). Finley et al (2001) cite the influence of the health care provider as a major influence in HRT use.

Consultation styles have been strongly implicated in patient adherence. Consultation styles may vary among different doctors and their patients, and it is recognised that a participatory style (Korsch 1969, cited Richman 2002, p97) produces a higher level of adherence. The participatory style allows the doctor and their patient to become partners in any decision regarding treatment, by open discussion. It is this particular style of consultation that is central to the principle of concordance, since it has room for the patient's views, and values their personal beliefs about medications in general. Communication between medical advisor and patient is important when women are making HRT decisions (Mansfield and Voda 1994).

Martin Robb (2004) states that gender is a factor affecting communication in healthcare services and, if communication between a doctor and their patient is affected, then this may negatively affect the quality of the consultation. This in turn may influence the outcome of such consultations in terms of adherence to therapy. There is some debate here when adherence to HRT is considered. The gender of the doctor is not a significant determinant of adherence with HRT therapy, according to Maclaren and Woods (2001): but Hope et al (1998) found that 52% of their 393 patients, would prefer to see a female doctor, while 65% felt more would be done if men experienced the menopause.

We now consider what is known about rates of adherence of HRT treatment in particular.

1.7 Rates of adherence to HRT prescription

It is interesting to note that many studies of the uptake of HRT, and adherence thereafter, have found the rate of long-term compliance to be poor (Hope and Rees 1995, Maclaren and Woods 2001). The literature is extensive on reasons for discontinuance, but most is generalised in terms of sample characteristics.

Many studies group peri-menopausal and menopausal women together, and do not consider those women who have undergone hysterectomy with BSO separately (Maclaren and Woods 2001, Den-Tonkelaar and Oddens 2000, Hope and Rees 1995). This makes the interpretation of data more difficult when considering only those women who have had hysterectomy with bilateral oophorectomy. It could be argued

that women who have had a surgical menopause are different from women experiencing natural menopause, in terms of age and severity of menopausal symptoms, and that they might therefore may have different reasons for continuing or discontinuing HRT. It is also important to recognise that hysterectomies are performed for different reasons, and that post-operative HRT is not appropriate in all cases. The reason for surgery is not documented in most published studies. There are, however, publications which have shown adherence rates with HRT users in general which include women with hysterectomy; some of these studies give separate adherence rates for these surgically menopausal women.

Hope and Rees (1995) investigated 525 HRT users aged between 45 –54 years, divided equally between current and lapsed users. A third (33%) of the sample had undergone hysterectomy, and half of these had also had an oophorectomy. It is not completely clear what criteria were used to classify the lapsed user, but in this group 51% of women had stopped HRT within 1 year and 74% within 3 years. Women with hysterectomy and BSO are not studied separately. There is no presented data on the effect of age on HRT use, so it is not clear if the older women were the ones who stopped early.

A study by Den-Tonkelaar and Oddens in 2000, of 4 general practices in the UK, questioned 615 past or present HRT users. These women were selected on the basis that they had used HRT during the previous three years. They found that women who had had a hysterectomy or oophorectomy were significantly more likely to be long-term users of HRT (over 6 years). Of the 611 women who reported the duration of HRT use, 4.6% had used it for more than 10 years, 19.6% for between 6-10 years, and

28.5% for between 1-2 years. These figures are from a broad population of women, with no figures specific to hysterectomy with BSO, so it is difficult to know how these findings relate directly to this particular group.

Finley et al. (2001) used a mailed survey to assess associations with the prevalence of HRT use in American women. They found that a past history of hysterectomy was associated with a threefold increase in odds ratio of HRT use. Oophorectomy was associated with a twofold higher odds ratio, but there are no details of age as related to type of surgery, or the reasons why it was performed. This study surveyed women of between 50 and 70 years of age primarily to investigate socio-economic trends, and therefore did not explore duration of therapy or reasons for discontinuance.

Maclaren's American study of 884 women, aged between 40 and 65 years (Maclaren and Woods 2001) used an odds ratio to predict HRT use. They showed that hysterectomy is a significant predictor of HRT use, which would be expected, but the oophorectomy status of their subjects was not detailed. The overall duration of use, with no distinction between those who had undergone hysterectomy with BSO and those who had not, was found to be 12% for between 1-18 months, and 86% for one or more years. The wide age range of their study subjects is reflected in these results, as older women would be expected to take HRT for a shorter time. The median duration was 5 years, and 25% of the women in the study took therapy for more than 10 years. The 25% who took HRT for longer than 10 years are not described in terms of natural or surgical menopause, so once again women who have had a hysterectomy with bilateral oophorectomy are not investigated separately.

The Gallup survey sponsored by the North American Menopause Society (NAMS) (Utian and Schiff 1994) showed that 53% of hysterectomised women (oophorectomy status not specified) were current users of HRT, but that 35% had never used it. It has to be said that current user status does not necessarily mean long-term adherence. It is estimated in the U.S.A. that 20%-30% of women who receive prescriptions for HRT do not fill them, and that 70% are non-compliant in the long term (Rowles, 1990 cited Coope and Marsh 1992, p157).

Studies specifically concerned with women who have a hysterectomy and BSO have found higher rates of compliance with HRT. An American study found that 71% of women used HRT after BSO, and that these women were 1.9 times more likely to continue therapy for at least 5 years than were women with a natural menopause (Brett and Maddens 1997).

Likewise, a British study by Griffiths and Convery (1995), using patients from one GP practise in Stockton –on –Tees, Cleveland, UK, found that 71% of women who were under 52 years old when they had a hysterectomy with BSO were taking HRT. 8.4% had taken HRT in the past, but had stopped, and 20.6% had never taken it. Of the women who had started therapy and then stopped, there was no reason for discontinuance recorded for 13 of the 20 women in this group, which also included those women who had had a hysterectomy without removal of ovaries.

Khastgir and Studd (2000) followed 194 patients undergoing hysterectomy +/- BSO for non-malignant reason, and found a therapy continuation rate of 97.4% at 2 years. However, this study used HRT in the form of subcutaneous implants placed in situ at

the time of surgery, and replaced at 6-month intervals with advice to continue the therapy, which may explain their higher rate of compliance.

In one Danish study a calculated compliance rate of 89% at 1-3 years was found in hysterectomised women with BSO (Hee 1999). This study, however, presents its data in ambiguous fashion, and it is not clear when and in what number women discontinue therapy over the 1-3 years.

In contrast to these findings, a Spanish study evaluating the effects of long-term oestrogen on bone density in surgically menopausal women claims only one third of patients were continuing therapy at 5 years (Castelo-Branco et al 1999). There are some problems with the data presentation in this study, as it appears that some of the numbers do not add up, a problem which has been raised by another authors (Ettinger 2000).

It is clear from this (pre- WHI) literature that women undergoing hysterectomy +/- BSO are more likely to take HRT, and to take it for longer, than women experiencing a natural menopause. It is not so clear, however, what the long-term compliance rate is, or, for those who discontinue therapy, exactly when they stop and for what reasons. Cultural influences may also play a part, thus perhaps explaining the differing findings between studies. We now consider the reasons women give for stopping HRT.

1.8 Reasons given for discontinuance and socio-economic considerations

Many authors have studied the reasons behind women's decisions to stop, or indeed never start, HRT. Hope and Rees (1995) found that 38% of lapsed users stopped HRT without medical consultation, and that these women were unaware that there may be other preparations that could have suited them better. In this study, only 33% of the sample had undergone hysterectomy, and half of these had also had an oophorectomy; so once again this data comes from a generalised group of women. Newton et al. (1997) found that 53% of past users stopped therapy on their own, the women in her study being classified by current or past use of HRT rather than by hysterectomy status. Clearly, there must be some powerful reasons behind these actions, and there is consensus in the literature as to what those reasons are.

The main concerns of women would appear to be both current and potential in nature. Side-effects of HRT are a major factor. Oestrogenic effects, such as breast tenderness, headache and sickness, and a dislike of taking hormones, are commonly cited reasons for discontinuation in studies (Draper and Roland 1990, Wren and Brown 1991, Lewis et al 2000, Den-Tonkelaar and Oddens 2000,). Weight gain is also often mentioned as a side-effect important to women and is cited as a reason to ceasing to take HRT (Hope Wager and Rees 1998).

Bond and Bywaters (1999), in a small study of 16 women, make some interesting observations on the lack of information available to women from their doctors, and the somewhat confusing and conflicting opinions they receive- both of which contribute to

discontinuance. Many women view the menopause as a natural event, not requiring medicalisation (Newton et al 1997).

Anxiety about the increased risk of breast cancer is a major concern (Utian and Schiff 1994). Breakthrough bleeding, or the continuation of menses, is only applicable to women with an intact uterus, so will not be discussed here.

The literature cites these aspects of HRT as reasons given for discontinuation, but there does not appear to be a study which examines how long these effects are tolerated before discontinuation occurs, or whether the reasons for stopping therapy change with time. Nor have there been many studies specific to British women having elective hysterectomy with bilateral oophorectomy. If women are discontinuing HRT early after hysterectomy with bilateral oophorectomy, it could be argued that they are putting their future health at risk.

HRT may have long-term benefits for women in their later years in terms of osteoporosis protection, so it is a subject, which can be explored from a health promotion angle. Since the Black Report, published in 1980, it has been recognised that there are inequalities in health status between the social classes, and that behavioural and cultural differences, together with material and life circumstances, combine to affect a person's health. The White paper "*Towards a Healthier Scotland"* (1999) recognised Scotland's poor health record, and health issues for women are part of this. The Scottish Executive Health Departments' (2004) publication, *Health in Scotland*, acknowledges a "Scottish effect" in their opening chapter, stating that for some reason those living in Scotland are still less healthy than in other countries. As in

so many areas of health promotion, those women more likely to use HRT are white, middle class with some higher-level education (Maclaren and Woods 2001, Finley et al 2001, Lewis et al 2000, Brett and Maddens 1997). Younger age is also a correlate of HRT use (Newton et al 1997). Education, life experience, the influence of family and lay beliefs all inform the individual's life expectations and subsequently their health choices. The problem lies in ensuring that that all women regardless of their social background receive appropriate consultation and access to preventative medicine.

1.9 Changes in treatment for menorrhagia, and the career of HRT

Since the original literature review for this study was performed there has been further research published in connection with HRT use, the findings of this research impact heavily upon the relevancy of the study today. In order to avoid confusion as to what was thought at the time and what is known now, the recent literature is discussed separately rather than as part of the main text.

In 2010, women presenting to their doctors complaining of menorrhagia will be offered a number of treatments before hysterectomy is decided upon. These treatments were in their infancy in the 1990's and it was estimated that at least 60% of women with menorrhagia ultimately had a hysterectomy, often without any other treatment being offered (NICE clinical guideline 44 2007 p4). With the efficacy of more conservative treatments, the inherent dangers of major surgery, and the cost implications to the health service, a different approach is now recommended.

The National Institute for Health and Clinical Excellence (NICE) recommend an approach that is individual to the patient and that "Whether menstrual blood loss is a problem should be determined not by measuring blood loss but by the woman herself"(NICE clinical guideline 44 2007 p9). It advocates trying pharmaceutical treatments such as levonorgestrel releasing intrauterine system (LNG-IUS, i.e.Mirena coil), daily norethisterone tablets, or long acting progestogens first. If these fail to control symptoms then non-hysterectomy surgical interventions such as endometrial ablation should be considered. Only when these treatments are contraindicated, fail, or are not wanted by the woman, then hysterectomy is considered. The removal of healthy ovaries at the time of hysterectomy is not recommended and "should only be undertaken with the express wish and consent of the woman" (NICE clinical guideline 44 2007 p20). The resulting impact of oophorectomy must be discussed with the patient. The reasoning behind these recommendations is that these treatments have been shown to be effective in reducing menstrual bleeding. Lethaby, Cooke and Rees (2009), have shown in their systematic review that LNG IUS is more effective than oral norethisterone, and that despite some short term side effects women were willing to continue treatment. LNG IUS is not as effective as endometrial ablation at reducing blood loss but this does not affect patient satisfaction. LNG IUS is however associated with progestogenic side effects not found with endometrial ablation. One trial assessing quality of life in women eligible for hysterectomy found that those women treated with LNG IUS cancelled their surgery in greater numbers than those treated with other medical treatments (Hurskainen et al 2001). This same study reports reduced treatment costs of LNG IUS compared to hysterectomy at one and five years follow up.

Not only the treatment pathway for menorrhagia has changed since the women in this study were surveyed. The expectations of HRT treatment and the recommendations for its use are also altered, and this will now be considered, in historical context.

As long ago as 1981, McKinlay described some types of medical mistakes by outlining the typical career of a medical innovation. By "medical innovation" he means a new drug, a new surgical intervention, the use of new equipment, or a change in clinical management. His paper describes how such medical innovations become part of medical practice, and what types of evidence are employed to support them. A description of an alternative approach, based on randomised controlled trials, then follows. This is a very interesting paper, which notes criticism of obstetrics and gynaecology, as a speciality, for not randomising certain procedures such as induction of labour and foetal monitoring before widespread use (p 376). He describes seven stages of development and this provides a very useful framework to examine the career of HRT, as shown in a paper by Wright in 2005.

The first of McKinlay's stages is that of **promising report**, which he observes, often has no methodological criteria. An exciting therapy is piloted on patients often with no control, and if results are good then a randomised controlled trial (RCT) is recommended but often is delayed for ethical reasons. It may be years later before other clinicians do a controlled trial (McKinlay 1981 p380). During the stage of **professional and organisational adoption,** more widespread and influential support is mobilised and "physicians and their associates believe that they are being more effective, humane scientific, or whatever, and secondarily derive financial

benefit"(McKinlay 1981 p381-382). **Public acceptance and state (third party) endorsement** comes next, "partly because of exposure to promising reports but mainly as a result of professional and organisational adoption, a general approval (acceptance) of the innovation emerges among the public"(McKinlay 1981 p385). This leads to public demand.

Once generally accepted, the innovation becomes established and respected, and this McKinlay calls the **stage of standard procedure and observational reports.** It is at this point that observational studies are initiated, often by those who were involved at the beginning of the innovation, for example, the pharmaceutical industry. McKinlay notes that " for every controlled trial that provides evidence against an innovations' effectiveness, there are sometimes hundreds of observational studies that produce support for it"(McKinlay 1981 p390). Stage five from McKinlay is **the stage of the randomised controlled trial,** and it is this type of research that "remain the most valuable method of evaluating the efficacy of therapies"(p393). It is acknowledged that they are difficult to do due to ethical and legal reasons, and their results can cause difficulties for the medical profession and elicit defensive responses. The results from the large scale RCTs, (the WHI studies) has been discussed earlier, and it is the data from these, and other studies which have led to altered HRT prescription.

Stage six of McKinley's stages is the stage of **professional denunciation**. The medical profession is accused of responding defensively when research findings question what has become a standard procedure. "Much of it is a hostile response from a group self interestingly protecting a domain of activity" according to

McKinlay (1981 p395). In the light of research findings, claims are modified and not as universally applicable as first thought, in the stage of **erosion and discreditation.** This can take a long period of time, often more than a decade, and gradually the support for the innovation is eroded. Sometimes the innovation can be replaced by a new one, but McKinlay says, "discreditation or discard usually occurs only when a replacement becomes available" (p399).

McKinlay (1981) suggests that potential harm could be avoided if medical innovations were evaluated earlier. He advocates that there must be demonstrated benefit over and above any placebo effect, and that side effects and added risk must be part of the outcome measures. He maintains that "with few exceptions, acceptable evidence of effectiveness can be established only through comparative experiments, that are as free as possible from sources of bias"(p 405).

These seven stages, can well describe the career of HRT as an innovation, as shown by Wright in 2005, and will now be examined. The early claims made for HRT, have been discussed in the preceding text, and include the idea that all menopausal women could benefit from treatment, and remain forever feminine (Wilson 1966). By the 1990's, HRT was also recommended as a preventative medicine, against osteoporosis and heart disease. Based on observational studies, it was recommended for five years after menopause to prevent osteoporosis (Barzel 1988, Lindsay 1987 and Stott 1991 cited Wright 2005 p1091). It was reported in the press that it may reduce coronary related death in women by up to 50% (Clark 1994, cited Wright 2005 p1091). These

are powerful claims, but as McKinlay points out they were not based on sound methodological criteria.

Due to the increasing claims of HRT and its endorsement by Menopause societies, celebrities and eminent doctors, the rate of prescriptions for HRT more than doubled to 32 million in 1989, and by 1990 doctors were finding it difficult "to maintain a conservative approach to prescribing HRT" (Wright 2005 p1091-1092). As the public believed that HRT was an effective and desirable treatment, so the demand for prescriptions grew. McKinlay believes that this demand is created by a combination of powerful marketing by the pharmaceutical industry, together with doctors endorsing an innovative treatment for a new condition, and in this case, a population who wants a panacea for the menopause.

There is certainly a vast literature on the risks and benefits of HRT, generated throughout the 1990's, but still no completed RCT. Prescription became a "standard procedure", despite evidence that the claim of reduced heart disease in HRT users was flawed (Vandenbroucke 1991). McKinney et al (1998) maintained that continued use of long-term HRT was necessary to reap the benefits of treatment. So the women in this study were treated at a time when although the risks were known; the benefits of treatment were thought to outweigh the risks. Then came the results of the randomised controlled trials, some thirty years after the introduction of HRT as a treatment for the menopause and associated symptoms.

The efficacy of hormone therapy for the relief of menopausal hot flushes has been well documented in a number of RCTs, which were reviewed by MacLennan, Lester and Moore in 2004. It is thought that a better than 75% reduction in hot flushes can be attributed to treatment (Currie and Cochrane 2010, MacLennan, Lester and Moore 2004). Oral oestrogens relieve vaginal atrophy in menopausal women but local preparations in the form of pessaries, creams or vaginal rings are also effective (Suckling, Lethaby and Kennedy 2006).

The Cochrane review of long term hormone therapy for perimenopausal and postmenopausal women was updated in 2009, in an attempt to provide an overview of all relevant clinical outcomes, to aid clinicians and patients in their HRT decisions (Farquhar et al 2009). This review selected a total of nineteen randomised double-blind trials of treatment versus placebo, including HERS and WHI 1998. Classifying surgically menopausal women together with naturally menopausal women, as the postmenopause group, the review focuses on both combined and oestrogen only therapy. The WISDOM 2007 trial (Vickers et al 2007) and some smaller trials (Haines 2003, Munard 2000), included in the review examined oestrogen-only treatment, in hysterectomised women, and these, together with the oestrogen-only arm of the WHI trial, provide the basis of current recommendations for oestrogen only therapy. The conclusion of this Cochrane review is that HRT should not be used for chronic disease management. Long term oestrogen-only treatment increases the risk of VTE, stroke and gallbladder disease. Breast cancer rates with oestrogen only treatment were seen to decrease (although not to a statistically significant degree) in the WHI study. A recent review of breast biopsies taken from the participants, shows an increase of benign breast disease, which requires longer follow up, to clarify if

indeed this translates into an increase in malignancies (Rohan 2008 cited Farquhar 2009 p23). The authors acknowledge that more research is needed to provide evidence on the safety of HRT in younger women, especially as their review is dominated by the WHI findings, which did not include women under the age of 50 years. For women in their fifties " the absolute risk of a life-threatening event is low"(Farquhar et al 2009 p25). However, in a review of therapies in 2009, MacLennan concludes that breast cancer risk increases after several years of combined HRT, but there is no such increase associated with oestrogen only HRT. A review of hormone therapy for endometriosis and surgical menopause was also published in 2009 by Al Kadri et al, but is not relevant to this study, as it examines women taking HRT who were treated surgically for endometriosis, and measures pain and recurrent disease outcomes.

There has been previous comment about the relevance of the findings made in the large American trials to the women in this study, earlier in this chapter. It is interesting to see that certainly HRT use was defended from some powerful quarters, such as the menopause society and articles in the medical press in 2004 (Wright 2005 p1095).

It can be argued that the benefits attributed to HRT treatment may have been eroded, but it has not been completely discredited. It has been shown to be effective at relieving menopausal symptoms, but many so–called benefits have been disproved, and the risks of treatment now have some quantification.

There are a number of alternative therapies of a herbal nature, that have claimed success in treating menopausal symptoms, together with lifestyle changes in diet and exercise, but as discussed earlier these often have no support from The Medicines and Healthcare products Regulatory Agency (MHRA). The efficacy of such herbal, or homeopathic remedies have been refuted by MacLennan (2009), who concludes that phytoestrogens, black cohosh, and other complementary therapies have no greater effect than placebo in quality RCT's, and that their long term safety has not been evidenced. The claims made by bisphosphonates to treat osteoporosis made it popular for a while, but long term safety is now questioned (Watson, Wise and Green 2007).

The prescribing of HRT to women, in the UK, aged 40 years and older has fallen by about 50% since 2002 (Watson Wise and Green 2007). Menon et al (2007), in their study of post menopausal women aged 50- 70 years, attribute the decline in its use to the early closure and subsequent publicity of the WHI trials. Attitudes to menopause and HRT have been studied in the light of these major studies. Lindh-Astrand et al (2007) concluded that Swedish woman, had a mainly biological view of menopause, a perspective unchanged between 1999 and 2003. However in 2003, fewer women thought that HRT should be used for menopausal symptom relief, a change they attribute to women's and their health care provider's appraisal of the risk/benefit ratio. In a study of Icelandic women aged 47-53 years old by Sveinsdottir and Olafsson in 2006, more positive attitudes to HRT treatment were associated with higher age, current HRT use, and discussing treatment with their physicians. This same paper recommends the strengthening of the advisory nature of the nurse's role. There is still little published on adherence rates for women taking oestrogen only HRT. The WHI oestrogen only arm found 53.8% of women were non-adherent with treatment at 6.8

years (Farquhar et al 2009). A study of British women conducted between 1992 and 1998, found that 53.8% of women, aged 45-64 years, with hysterectomy (oophorectomy status not known), used HRT for at least 3 years (Bromley, de Vries and Farmer 2004). The reasons given for discontinuance are still the fears of side effects, especially breast cancer as shown in a study of Spanish women aged between 40 and 65 years (Castelo-Branco et al 2007). This same study found that few (9.4%) current users were worried about treatment and that their main reason for continuance was the efficacy of treatment for menopausal symptoms. There still seems to be no data on the reasons for discontinuance given by surgically menopausal as a separate group.

Wright (2005) concludes her paper by saying that the historical pathway of HRT is an example of how the Medical and Nursing professions continue to accept innovation uncritically. In the interests of patient safety she urges doctors and nurses to attain best practice by adopting evidence based care. For the women in the present study, treated in the time frame 1992-2001, before they had reached the average age of natural menopause, it is difficult to determine, (in view of the extended duration of treatment as recommended at the time), whether or not their treatment was, to their overall benefit. However, if we consider what the recommendations for HRT use are for women in 2010, and apply them to the study participants, treated in the past, then it is possible to defend the use of HRT in these women.

Oophorectomy before natural menopause, results in a sudden drop in circulating oestrogen, which in turn may produce severe menopausal symptoms. HRT is still

recommended as the most effective therapy to relieve hot flushes, night sweats vaginal dryness and dyspareunia (McLennan 2009,Pinkerton and Dale 2010, Currie 2010). It is also improves joint pains and protects against fractures (McLennan 2009, Currie 2010, Pinkerton and Dale 2010). For women, without thrombotic risk factors, HRT taken around the age of menopause is associated with only a small increase in VTE (McLennan 2009, Currie 2010). The Nurses' Health study observed long-term health outcomes in women who had hysterectomy at age 30-55 years, for benign disease. It commenced in 1976 and follow up finished in 2004. The results of this observational study found, that bilateral oophorectomy at the time of hysterectomy, was associated with an increased risk of coronary heart disease, and the authors suggest that oestrogen only therapy may reduce this increased risk (Parker et al 2009). Women in the oestrogen only arm of the WHI trial showed no increased risk of coronary heart disease (Currie 2010), suggesting that, if oophorectomy does indeed increase CHD risk, then HRT be of benefit. The increased risk of breast cancer is only apparent after 5 years of oestrogen-only HRT use, and is only small (Currie 2010), or is not apparent at all (McLennan 2009). There is still debate about the effect of oestrogen on cognitive function. Evidence from short term RCT's in women with surgical menopause suggested that HRT might be of benefit, and there is some thought that there might be a "critical window" when treatment is of benefit. It is proposed, but not proven, that HRT commenced around the time of menopause be of benefit, while starting later may be detrimental (Pinkerton and Dale 2010, Henderson and Sherwin 2007).

So, for the women in this current study, after their hysterectomy with bilateral oophorectomy for benign disease, HRT prescription can be justified. The treatment

would primarily relieve menopausal symptoms, and it would also protect their bone density. There may even be some positive effects on cognitive function and reduced CHD after all, however these effects are not proven. There is a slight increase in the risk of VTE in the first year, and a small risk of breast cancer after five years of use. A much shorter duration of treatment is now recommended, with regular review to assess the risk/ benefit ratio.

1.9.1 Conclusion

In conclusion, it would appear that compliance with HRT had been well covered in the literature available at the time the study subjects were surveyed. However, there had been few studies concerned only with women who had undergone hysterectomy with BSO, a group of women most at risk from the effects of early oestrogen loss. Since the WHI findings were published, there has been much more data available on women taking oestrogen-only HRT, but studies specific to younger, surgically menopausal women are still lacking.

Compliance rates are uncertain, the reasons for discontinuance, although well specified, have not been examined in relation to the age of the patient. The timing of discontinuance has not been linked to the reasons given for stopping. It may be expected that the reasons for discontinuance differ between those women who stop HRT early and women who take it for a longer time.

Socio-economic parameters are influential on patterns of healthcare access in general, and will therefore affect HRT use. Most of the current literature is based on either American women or those in the south of England (Draper and Roland 1990,Hope and

Rees 1995, Rees 1997, Tanna and Pitkin 1997, Hope et al 1998, Khastgir and Studd 2000). The social backgrounds and cultural beliefs of these study subjects may be different to women in central Scotland. As lay beliefs are now more widely recognised as of importance in health decisions, Leventhal's model may be useful in understanding the adherence to or discontinuation of HRT.

There have been "rapid changes in the attitudes of HRT use in the past 20 years" (Newton et al 1997), and indeed attitudes to preventative medicine in general. The general public now demands a more consultative approach from their health care providers, rather than the dictatorial one of the past.

Most of the published data appeared in the 1990s and there was a 10% rise in the number of female GPs, and a 6% increase in female consultants, in the 10 year period in which this study was carried out (Statistics for General Medical Practitioners 1990-2000). This may well affect prescribing patterns for HRT. Although not statistically significant, Maclaren and Woods (2001) found that women consulting male gynaecologists were more likely to use HRT.

The publication of the Women's Health Initiative, occurring towards the very end of this study's time-scale, has altered somewhat the advice that women now receive about HRT. For women experiencing surgical menopause, HRT is prescribed post-operatively with the advice to continue therapy until the timing of natural menopause, when re-evaluation can occur.

Women having hysterectomy and bilateral oophorectomy before the age of natural menopause are at increased risk of suffering menopausal symptoms and developing osteoporosis. Given that most published data does not study these women as a separate entity within the general population of HRT users, it is appropriate to revisit this field.

In every gynaecology unit, women are admitted for elective hysterectomy, and many are advised to take hormone replacement therapy after surgery. There has been a vast amount of literature published, both in medical journals and in the general press, concerned with the risks and benefits of such therapy. This in turn has led to somewhat confusing advice for women trying to decide whether or not to take such therapy after surgery, and how long to take it for. This study will examine the patterns of HRT use specifically in women undergoing elective hysterectomy with BSO for menorrhagia within a region of Scotland, between the years 1992- 2001.

1.9.2 The aim of this study was to answer the following questions

- How many women in the study area, who have undergone elective hysterectomy with bilateral oophorectomy for menorrhagia, take hormone replacement?
- When do they commence therapy?
- When do they stop therapy?
- Why do they stop?
- Are the reasons for early discontinuance different from those for late discontinuance?
- What factors affect HRT use?

With respect to all these questions, the aim is to be able to see if the patterns of HRT use in these hysterectomised women differ to those of HRT users in general.

The next chapter will examine the variables thought to exert an effect on women's HRT decisions, variables which therefore need to be taken into account when considering these questions.

Chapter Two

Variables that may influence the use of HRT

The purpose of this chapter is to review the variables that might effect HRT decisions. Much of the information on rates of adherence and the factors believed to contribute to the decisions women make has been gleaned from women experiencing a natural menopause – that is one that has not been surgically induced. As previously indicated, the HRT decisions of women following hysterectomy with bilateral oophorectomy, as a sub-section of the general HRT - using population, are not well documented. There are reasons to suppose that, following hysterectomy with bilateral oophorectomy before the age of 51 years for benign reasons, the risk/ benefit balance is weighted in favour of treatment. These women have lost their oestrogen abruptly, and because they have no remaining uterus, do not suffer the problems with erratic uterine bleeding that some women with intact uteri might experience. So do these women differ in any way from those whose menopause was a natural event?

In this chapter, the variables which might influence HRT decisions (for any woman) will be examined. Each variable will first be discussed in terms of its known general influence on health care, and subsequently in terms of its effect, if known, on HRT use in particular. In the conclusion, reasons why these particular variables may affect HRT use in hysterectomised women will be suggested.

2. 1 Factors that may affect HRT use

What affects women's decisions to take HRT in general? Probably the same influences that shape decisions about health care and medication in other situations. It

is known that a number of variables, such as socio-economic group, media-influences and health promotion strategies, can influence these health decisions. What is not so clear is whether or not women undergoing surgical menopause follow the same patterns of HRT use as their natural menopause counterparts, and whether they are influenced by the same variables. All the women in this study had their hysterectomies performed for the same clinical indication, but they are not in any other sense identical, given that they were treated by different consultant gynaecologists, in two different hospitals and cared for by two different nursing teams. The women themselves differ in their age at the time of operation, and in their social background.

There are therefore a number of independent variables that may directly affect the individual woman's decisions to take HRT, and how long she takes it for. The variables listed below, which may determine patterns of HRT use, will be considered.

- The socio-economic group to which the study participants belong, as defined by Scottish Index of Multiple Deprivation (SIMD).

- The ability of the patient to pay prescription charges.

- The geographic location of the hospital in which the women were treated

- The individual consultant in charge of care.

- The gender of the consultant in charge of care.

- The information given by health professionals to their patients about the risks and benefits of taking HRT.

- The age of the woman at the time of surgery.

- Media effects on HRT taking.

The rationales for the examination of these variables are as follows.

2.1.1 Socio-economic group to which the patient belongs

It has long been recognised that social class influences health. The poorer an individual, in terms of income, environment and education the poorer their health is likely to be. Sir Douglas Black's landmark report, *Inequalities in Health* 1980 found that, in Britain, there were "large differentials in mortality and morbidity that favoured the higher social classes," (Smith et al 1990, p 373). The Black Report concentrates on mortality and morbidity, and found that it tends to rise inversely with falling occupational rank or status for both sexes and at all ages. Social class is used as the principle indicator of social inequality, since it is correlated closely with various other measures of inequality such as morbidity and sickness absence rates.

This report used the Registrar General's classification of social class, in which individuals are classed by occupation. Professional people are classed as group 1, intermediate (for example managers or teachers) as group 2, skilled workers non-

manual and manual, as group 3, partly skilled manual workers as group 4, and unskilled manual workers as group 5. The report found that even with the National Health Service available to all, the rates of chronic illness rose with falling socio-economic status, and tended to be twice as high in unskilled manual males as in the professional classes.

In trying to explain these differences the report looked at health service usage and geographic differences in service availability. In 1968, Titmus had argued that, although the NHS was designed to give free access to all regardless of their status or means, higher income groups knew how to make better use of the service. When Black examined GP consultations and preventative services, it was found that the middle class patient generally had longer consultations with their GP, and made better use of health promotion services than those in lower classes. Class gradients were found in antenatal attendance and cervical screening.

It had also been argued, by Tudor Hart (1971) that the "Inverse Care Law" could explain differences in the availability of health care found between "wealthy" and "poor" geographical areas. The suggestion is that the health services in the areas of most sickness, are overworked in terms if case load, lack of equipment and recruitment problems; consequently, good medical care varies inversely with the needs of the population it serves. The Black report confirmed differences in health service usage by social class and differences in health care provision by geographic location.

The Black report proposed four explanations for the continuing influence of social class on health.

1. The first is an artefact, due to a reduction in the number of the lowest classes as a percentage of the whole population. The oldest, less healthy people are left in the bottom group, and the younger, fitter people get better jobs and have better health compared to those left behind.

2. The second is a natural and social selection explanation, where health actually dictates social resources, and therefore class, where young fit people climb the social ladder. The fittest people moving to those areas in which opportunities for employment are better, leaving the sick behind in the poorer areas, could explain geographic differences.

3. The third explanation is based on social structural considerations, and suggests that impoverished early years in childhood affect cognitive ability, education and therefore opportunity. Middle class children were believed to be more likely to leave school with a greater ability to control their social and economic environment.

4. The final explanation is culturally and behaviour – related, given that higher income families tend to have a healthier diet and lifestyle. Some would attribute this to better education and more financial resource, while others would say that a "culture of poverty" exists and that deprivation is transmitted. Lack of education

may be responsible for unhealthy practices, or people may feel unable to alter their life course via health promotion exercises.

The conclusions of the Black report were that further research was necessary, but that the focus should be on reducing inequalities in childhood. Apart from recommending greater surveillance of child health, it also suggested a preventive and educational approach to improving the health of a larger proportion of the population as a whole.

Since the publication of the Black Report there has been a vast literature published on socio-economic inequality in relation to health. Smith, et al (1990) find that even ten years after the Black Report, the social class differences in mortality are actually widening, and that alternative measures of socio-economic position have exhibited greater inequalities. Wilkinson (1997) agrees that the divide is widening, and that health remains very sensitive to socio-economic status. He stresses that the differences in mortality are linked more closely to relative income and social inclusion, rather than just income alone. The Independent Inquiry into Inequalities in Health, chaired by Sir Donald Acheson was published in 1998. It found an overall downward trend in mortality between 1970 and 1990, but confirmed persistent differentials between the social classes. In particular, differences in income and in mortality rates per social class had increased, so providing evidence of a continued and increasing divide. Further evidence of the importance of both individual income and income inequality is provided by Kahn (2000). His study of American women found that poorer women suffered self- reported poor health and depressive symptoms in greater numbers than richer women. In those states where there was greater income inequality, greater numbers of low-income women suffered poor health when

compared to low-income women living in states with less income inequality. So health is affected both by personal income, and by how that income compares with that of others living in the community you live in. Evidence that richer people are getting healthier more quickly and that they continue to live longer in the UK is found in The House of Commons Health Committee's Health Inequalities 2009. This report demonstrates the divide vividly when it says that, "in 2006 a girl born in Kensington and Chelsea has a life expectancy of more than ten years higher than Glasgow City, the area in the UK with the lowest figure" (p9). This same report found that the health inequalities between social classes have widened more for women, than they have for men. The gap has increased by 11% for women and 4% for men, so demonstrating clear gender differences in health inequalities (p 15). The report concludes that inequalities are not only apparent between socio-economic groups and by gender, but they also exist between different ethnic groups and that the elderly and those suffering mental health problems have worse health than the rest of the population (p 26).

Deprivation indices, including housing, education, car ownership and unemployment levels are now thought to be more accurate classifications of socio-economic status than the old professional classification of the Registrar General's, (which was replaced by NS-SEC in 2001). Using such indices, Smith, Bartley and Blane (1990) suggest that Black's artefact and social selection explanations for inequalities in health do not account for differences in mortality, but that his materialistic and behavioural explanations are more useful. Likewise Pincus et al (1998, p 407), in summarising the literature on the importance of access to medical care suggest: "poor health in socio-economically disadvantaged populations results more from unfavourable social conditions and ineffective self management than from limitations

in access to care". Access to healthcare is also acknowledged as having a less significant role than other determinants in the House of Commons Health Committee's Health Inequalities report 2009.

It remains difficult to ascertain which parameters that make up socio-economic categories are most influential on health. Education, income, occupation, environmental and behavioural factors all contribute and together affect health outcomes (Link and Phelan 2005, p 72, Health Inequalities 2009).

HRT use has been shown to be associated with women of higher socio-economic status, with poorer women less likely to use it (Finley et al 2001). In order to classify the study participants in this research project in terms of socio-economic background, the Scottish Index of Multiple Deprivation (SIMD) was used. This index is a tool used by local authorities, the Scottish Government and the NHS for effective targeting of resources. First published in 2004, this index divides Scotland into 6505 data zones, and uses seven domains of social indicators - namely income, employment, crime, education, health, housing and access to services - to " score" and rank each data zone. These ranks are then used to calculate a SIMD rank for each data zone. The *lower* the score, the more deprived the area is classified to be. It is possible to obtain a SIMD for each postcode, so that a given study population can be classified according to the area in which they live. This index however cannot be used to determine the individual characteristics of people. It is not possible to say that an individual living in a SIMD1 area is economically or educationally disadvantaged when compared with someone from a SIMD 9 area, only that they live in very different areas, as classified

by deprivation measures. On the basis that health decisions are determined by many different factors, it is an appropriate tool to use in order to classify the participants. Like other census information the SIMD is updated and SIMD 2006 has been used, as this was the index in use at the time the data was analysed.

2.1.2 The ability of the patient to pay prescription charges

Income, although closely linked to socio-economic group, has been shown by Ettner (1996) to positively affect health when other factors are controlled for. She suggests that reductions in disposable income could potentially affect morbidity.

"In 1979 a prescription cost 20 pence"(Moore 2005), but now the charges have risen considerably. There is evidence that many people "do not get the medicines they require because they cannot afford them" (Moore 2005). There is pressure to abolish prescription charges across the UK and, in early 2007, this was achieved in Wales. However, in Scotland and in England charges still apply and produce considerable revenue to the sum of about £300 million annually (Campbell 2002).

It may be supposed that, if a woman was under financial pressure and having to pay for her HRT, then she may not fill her prescription. This decision may be influenced by her perception of the benefits of taking the medication against the financial cost of continued adherence.

For the time that the participants of this study were taking HRT they would have been charged the appropriate fee, unless they were exempt due to chronic disease or in receipt of income benefits.

2.1.3 The unit in which treatment took place

"The random countrywide variations in the provision and quality of public services have been referred to as ' the postcode lottery of care', that is where you live dictates where you are treated, which in turn dictates how you are treated, and this affects whether you survive"(Munro 2001, cited Bungay 2005, p37). It has been argued by central government that these regional differences are due to a lack of national standards, and decisions being made at a local level as to what services to provide, (Bungay 2005 p37). GP fund holding allowed faster access to treatment for the patients of budget- holding GP practices, resulting in a two-tier postcode lottery (Butler 2000).

Sarah Bosely and Sarah Hall, writing in The Guardian in 2006, say that provision of treatment differs widely between primary care trusts, and that not all the differences can be attributed to the age and needs of individual patient populations. Although the focus of such reports are the management and treatment of serious illness such as cancer and coronary heart disease, geographic differences are recognised in the access to all types of service in practice (Bungay, 2005, p 37). Waiting times, availability of certain drugs and access to cancer screening services are all affected.

If we accept that there may be differences between treatments in one unit when compared to another, then the possible reasons for this need to be explored. Eddy

(1984, p 86) suggests that regional differences in medical practice are seen because individual doctors tend to "follow the pack" and concur with the practice of their peers in their locality. This, he suggests, provides "safety in numbers", with the practice "defended by the concurrence of colleagues".

It may be supposed that, if differences occur in all aspects of service provision, as is suggested by Bungay (2005), then there may be geographic differences in the use of hysterectomy for the treatment of menorrhagia and subsequent HRT prescription. There are, according to Gupta and Manyonda (2006), wide variations in the rates of hysterectomy, not only between developed countries but also between regions of the same country and between consultants at the same hospitals. If rates differ depending on which consultant is seen, then it is conceivable that, overall, one unit differs from the other in terms of treatment option. Allowing for the "concurrence of colleagues" theory, consultants in one unit may collectively differ from those in the other unit.

2.1.4 The individual consultant in charge of care

Individual doctors may have different ideas about best therapy for their patients. They may also have different consultation styles, and reach clinical decisions in different ways. David Eddy (1984) states: "nothing more underscores the reality that medical care represents a melding of art and science than the wide variation in the use and cost of that care" (p 74). He believes that variations in practice occur partly owing to the "uncertainty in the minds of doctors about how to approach a particular medical problem" (p 74). As a doctor and also a mathematician, he describes the role of uncertainty in clinical decision-making. He gives many examples of situations where physicians have come to very different conclusions when faced with the same clinical

details. He recognises that “uncertainty, biases, errors, and differences of opinions, motives, and values”(p 75) can affect treatment selection. He describes how complex clinical decision-making is, and how poorly it is understood. He focuses on the uncertainty which surrounding the outcome of any procedure, and how this will affect the advice given by the physician. It may be this uncertainty in the outcomes of treatment that makes doctors concur with their colleagues when making clinical decisions.

Strategies to reduce the uncertainty in clinical decision making in general have included policy development and the construction of clinical guidelines. The Royal College of Obstetrics and Gynaecology (RCOG) have published many such guidelines, and one exists for the management of menorrhagia, specific to secondary care in hospital (RCOG 1999 Guideline no 5). Developed using clinical research findings, the aim is to produce standardised, cost-effective practice known as evidence- based practice (EBP). Much has been written about evidence-based practice or evidence- based medicine. Sackett (1996, p 71) says that “evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”. He argues that “good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough.” He suggests that “external clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.”

EPB has been criticised by some for putting constraints on clinical freedom, and being designed to cut costs. One general practitioner said that the environment of medicine was becoming "like that of a Stalinist state" and that, if he chose through experience to deviate from a protocol when treating his patients, then he "must expect to be brought to task"(Sherifi 2004, p 4). Sackett (1996, p 72) counters this opinion by saying that evidence based medicine is not " cookbook" medicine and that, because it combines best clinical evidence and the expertise of the doctor, together with patient choice, it cannot result in dictated outcomes; instead, it will provide better but perhaps more expensive care.

So, even allowing for guidelines and protocols, it is still possible that there might be some differences in the way different doctors assess and manage their patients, and likewise the way that those individual patients then choose to be treated. This may explain the differences in hysterectomy rates between consultants seen by Gupta and Manyonda (2006). Individual clinicians may vary in the way they assess symptoms and some may favour trying less invasive treatments more exhaustively than others before recommending hysterectomy. If we consider the consultation a woman has with her hospital doctor regarding treatment for menorrhagia then the doctor, as in consultations for many other conditions, bases his opinion on the symptoms told to him by the patient, and relies on the patient's description of the extent of her bleeding, and resultant debilitation.

Menorrhagia is defined as excessive menstrual bleeding but, in practice, it is difficult to specify what counts as "excessive bleeding" because what is acceptable to one woman may be unacceptable to another. It is difficult, as Eddy (1984, p 75) says, to

determine the dividing line between normal and abnormal. Part of the RCOG 1999 guideline for the management of menorrhagia is that an objective or semi-objective assessment of menstrual blood loss should be carried out before surgical treatment. Ali et al (2007) found that this particular assessment was not performed for women being treated in (for example) Blackpool.

Anecdotally, it is of interest that only a few women admitted to the units in this Scottish study, for hysterectomy for menorrhagia, had at any time pre-operatively, an abnormally low haemoglobin level. This would indicate that the blood loss is not seriously excessive, but may of course still be debilitating to the patient. Exact figures were unfortunately not collected as part of the study. In order to diagnose menorrhagia, the doctor necessarily relies on the patient's description of blood loss and associated symptoms such as fatigue. According to Eddy (1984, p 77), doctors vary in their ability to ask about symptoms, observe signs; interpret test results and record answers; and women may perceive their menstrual loss as heavier than it actually is (Ali et al 2007 p172).

Hysterectomy is the most effective, but also the most invasive, treatment option for menorrhagia and carries the risks associated with major surgery. Consent advice for doctors provided by The Royal College of Obstetricians and Gynaecologists (Consent Advice 4 2004) states clearly that alternative, less invasive treatments - including no treatment at all - must be discussed with the patient prior to deciding on hysterectomy. Many women when offered more conservative treatments refuse them in favour of hysterectomy (Ali et al 2007).

So the symptoms of menorrhagia are difficult to assess objectively, and there are treatment options other than hysterectomy; which means that the result of each individual consultation may be different. The timing of hysterectomy may be delayed in favour of initial conservative management, which in turn would make the patient older at the time of surgery. The age of the patient at the time of hysterectomy affects the duration of recommended HRT use, with older women needing it for a shorter time.

During the consultation, when hysterectomy with bilateral oophorectomy is decided upon, the resulting early menopause and the possibility of subsequent use of HRT should be discussed (Royal College of Obstetricians and Gynaecologists, Consent Advice 4 2004). This, however may be a secondary issue with the bulk of consultation time being devoted to focusing on the operative procedure itself, the recovery, time spent in hospital, and the need for convalescence and time off work.

Subsequent post-operative discussion regarding HRT choices are conducted on the ward, when consultants are busy and patients are perhaps reluctant to ask too many questions. The patient may therefore base her choice on the recommendation given to her at the longer, more private, pre-operative consultation. Conversely some patients may insist on an in-depth discussion with the consultant, prior to making a decision, before they leave hospital; or they may wait to discuss issues with their GP once at home. Whatever the timing of these discussions, the quality of the communication between doctor and patient is important.

In general, after hysterectomy with bilateral oophorectomy, most women commence therapy soon after surgery. It would not be surprising if some women were better informed than others were, as a result of more detailed discussions with their individual consultants. These more detailed discussions may result in earlier commencement of therapy and better adherence rates for HRT use. The age of the patient at the time of surgery does affect the advised duration of that use (a topic which will be discussed later).

2.1.5 Gender of consultant in charge of care

Because menopause, whether natural or surgical, is a time of change in both physical functioning and psychological adjustment, consultations regarding these changes are important in terms of the patient's perception of sensitivity and understanding by the doctor. The perceived quality of these consultations may well affect the patient's adherence to medication prescribed. There have been studies conducted in the past to explore whether or not the gender of the physician affects the physician-patient relationship and patient satisfaction.

"Gender" refers to the meanings, associations and identities associated with basic sexual differences. The term denotes more than just the biological and physiological differences between men and women (Robb 2004). Differences in communication with patients have been demonstrated between physicians of different genders, with female doctors taking a more "emotionally focussed" approach than their male colleagues. The patients of female doctors, whether they are male or female, tend to express more "biomedical and psychosocial information" during consultations than do

patients of male doctors. Female doctors also build partnerships with their patients to a greater degree than do male doctors (Hall et al 1994, Roter et al 1991, cited Roter et al 1999, p 635).

Roter, et al (1999) acknowledge previous research concluding that patients prefer same-gender physicians when seeking help for intimate health problems including gynaecologic and obstetric care. The extent of this preference is not perhaps as great as one might expect, and Schmittdiel et al (1999) in their large mailed survey found that only just over half (52%) of women prefer a female provider for basic gynaecological care.

Roter et al, (1999) studied women making their first antenatal visit and attempted to describe the communication between doctor and patient. The findings in this study were that, although male doctors engaged in longer consultations and made more checks to determine whether the patient had understood them properly than did their female counterparts, women were still more satisfied with a female physician. Roter et al (1999) also cite Hall, Roter and Katz (1988), who found that patient satisfaction, recall of information, and adherence to medical recommendations was associated with female physicians (p 636). Lurie and Slater et al (1993) found that patients of female primary care doctors are more likely to undergo cervical screening and mammography. It would appear then that most women prefer to see women when faced with gynaecological or intimate problems, but it is not clear that female gynaecologists provide better information and advice than their male colleagues do.

2.1.6 The information given by health professionals to their patients about the risks and benefits of taking HRT

The information about a medicine that a patient receives is central to their understanding of its method of action, its expected benefits, and possible side-effects. Information allows patients to make informed choices. Rosalyn Anderson, a pharmacist, writes about the responsibilities of prescribing, and the provision of adequate patient information. She specifies that the patient should be told the reason for, and the purpose of, the prescription, the duration of treatment to be expected, and possible side effects (Anderson 2002, p 78). Verbal information is important but often difficult to remember in its entirety, whereas it is believed that written information may be referred to repeatedly to clarify understanding. Leaflets, both generic and product-specific are available and used by some health care professionals to reinforce or expand the discussions they have had with their patients.

Waller et al (2005, p 123) points out: " most people know that medicines may have side effects but, unless clearly told otherwise, they expect these to be minor and reversible or to be so rare that it won't happen to them". It is important, then, that women are advised, on an individual basis, as to what they may expect in terms of personal risk and benefit.

Apart from discussions with the doctor about the risks and benefits of HRT, there are other information sources. Nurses are a source of such information, and should be able to give relevant information to patients. Do nurses give adequate information to women about HRT? Women making HRT decisions are known to use written information (Newton et al 1998), but general educational materials are "limited in

helping women judge personal benefits and risks of HRT" according to O'Connor et al (1998, p 268). O'Connor et al (1998) found that using a decision aid was of value in women deciding about HRT. Working in Canada, they devised an audiotape and illustrated booklet for women to use at home before returning for a follow-up visit with the doctor for further discussion. The booklet contained general HRT information and a personal worksheet which identified the patient's individual risks and benefits of taking HRT, together with her own assessment of the importance of the risk/benefit ratio. Any questions the patient might have were also listed. The completed worksheet then provided the basis for the next consultation. The use of this tool did not radically alter the women's decision, but they felt more confident about those decisions. In Forth Valley, such a tool is not used, and women rely on information given verbally or in written form. We do not know who or what they consider to be their primary source of information, or how good is that information deemed to be.

2.1.7 The age of the patient at the time of surgery

The Health Survey for England (1998) found that, for both men and women, the use of all types of health services increases with age, with those considering themselves to be in poor health using GP consultations and hospital outpatient departments more frequently. Likewise, the use of prescribed medication rises steeply from the age of 45 years, with considerably more women than men under the age of 65 years taking prescribed medication (Bajekal 1998 p10). Most users of HRT (62%) in the Health survey sample had commenced therapy between the ages of 45-54 (Bajekal 1998 p13).

Twenty percent of women in the United Kingdom will have had a hysterectomy by the time they reach the age of 60 years (Gupta and Manyonda 2006). These operations will be performed for a number of reasons, of which menorrhagia is only one. The timing of hysterectomy, in terms of the age of the patient, for non-malignant reasons is left up to the individual gynaecologist and their patient.

In a descriptive study of hysterectomy patients with benign disease in England, Wales and Northern Ireland in 1994 and 1995, the median age at operation was 45 years, and 43% of women had no ovaries conserved (Maresh et al 2002). This is similar to American findings of Jacobson et al (2006), who found that the hysterectomy rate over a 10-year period ending in 2003 was highest in women aged between 40 and 49 years. The women in the Jacobson study were analysed by 5- year age groups, with the youngest being 20-24 years old and the eldest 55 years or over. Although the study was to ascertain hysterectomy rates for benign disease, it did not look specifically at menhorragia as a clinical indication; nor did it specify whether oophorectomy was also performed.

The age of a woman at time of hysterectomy with bilateral oophorectomy will affect what is the recommended duration of treatment with HRT. A woman having a hysterectomy with bilateral oophorectomy in her early 40s will need HRT for a longer time than a woman of 48 years at the time of operation. This is because the younger woman will have "lost" more years of natural oestrogen. Reference to the changes in prescribing guidelines during the data collection timing of the study has been made in chapter one, however the broad principles regarding the duration of HRT treatment with regard to age still apply. Younger women, who may experience more severe

menopausal symptoms, would be required to take medication for a longer time. Older, peri-menopausal women approaching the time of average natural menopause, who may have already suffered some menopausal symptoms, and who may even commenced HRT prior to their operation, may need a shorter duration of therapy post- operatively.

The advice given to patients will take into account their specific requirements, and because of this it is expected that the duration of use will vary across the age range.

2.1.8 Media influences on HRT taking

The Media has a powerful effect on thinking and behaviour in general. Most people can be influenced by what they read in newspapers or watch on television, and the quality of these reports can vary. Margot James, chief executive of a public relations company employed by several pharmaceutical companies, acknowledges that the quality press gives the best information when it comes to public health. She also states that "people from lower socio-economic groups get their information from television and the tabloids" and are more likely to read sensationalist material than to receive useful information (Ferriman 1999, p 1208). Walley and Williams (2004, p 71) point out that " the media portrays sensation and tends to see medicines either as 'wonder drugs' or 'killer drugs': the notion that what is a wonder drug in one situation can also be a killer in another is a subtlety that banner headlines cannot deal with".

Scare stories sell newspapers and in general cause public concern. This is especially true of stories about prescription drugs. Waller et al (2006) is an interesting paper on drug safety, and the media, pointing out that journalists and television presenters have total control over how they present medical material and may tend to use the more

controversial aspects, rather than the more mundane but fairer representative angles, and that this can lead to a too simplistic interpretation of data. They further question the lay public's ability to interpret data in terms of risks and benefits, without a proper understanding of how the data was acquired. They state that "media coverage of drug safety issues rarely reflects uncertainty"(p 124), and highlight how the media has in the past possibly damaged patients by "scares" surrounding drug safety. One obvious example of this is the MMR story, where the press made uncritical use of unsubstantiated research reports concerning the possible side-effects of the vaccine, leading to a fall in immunisation rates (Anderson 1999). However, Waller et al, (2006) also point out that the media represent a useful communication tool if used responsibly.

A report in The Scotsman newspaper on Tuesday 4th March 2003 (p 7) was headed "Late HRT treatment for women may do more harm than good." This article was concerned with the findings of the American Women's' Health Initiative, and the early cessation of the trial when increased risks of breast cancer, stroke and heart attack became apparent in older post menopausal women taking combined oestrogen and progesterone HRT. An earlier article in The Herald, July 17th 2002 (p 3), concerned with oestrogen-only HRT, was entitled: "HRT linked to cancer twice in one week". Even the front page of The Times announced on 10th July 2002: "HRT is linked to breast cancer", and "Patients suffer 41% increase in stroke risk".

Articles such as these, and other more sensational reports in the tabloid press, could certainly alarm women taking HRT, despite government ministers advising calm, and confirming that there was no need for women to rush to their GP and stop treatment.

The reported findings from the American study were difficult enough for medics to interpret. The women participating in the trial were aged between 50 and 79 years old, and they used slightly different HRT formulas than are prescribed in the UK. In terms of the relevance to British women who were taking HRT after hysterectomy, being younger and taking oestrogen-only preparations, the risks might be less applicable. For the lay public, however, it would have been more difficult to interpret the findings, and women may have been worried by the reported facts, which were not necessarily completely applicable to their individual case.

Joe Collier, Editor of the *Drug and Therapeutics* Bulletin thinks, "more information for patients is good", but that "in many ways biased information is worse than no information at all because it thoroughly confuses people" (Ferriman 1999 p1208).
Certainly, the complex nature of the data emerging from the Women's Health Initiative made it difficult for women to interpret what was relevant to them personally, without the benefit of specialist knowledge. Some of these women may have sought advice from their GP, but others may have been frightened enough to have discontinued therapy without the benefit of such a consultation.

(In the present study there are no questions in the questionnaire exploring, specifically, the possible affect of the media on HRT decisions. In hindsight this is a pity because such questions may have yielded some interesting data. The reason for this omission is the timing of the press releases in relation to the formulation of the questionnaire. The questionnaire was compiled, and ethical approval gained, before the press carried the big headline reports from the WHI trials. To change, or add a question would have necessitated a further review from the ethics committee, a time

consuming process and one, which would have further delayed the mailing of the questionnaire. It was hoped that media influence would be revealed by the responses to the question about the reasons for discontinuing therapy.)

2.2 How this study attempts to examine the factors affecting HRT use

Having explored the reasons why certain variables might be thought to influence HRT use, we now describe how the study of women in Scotland might attempt to ascertain whether or not these variables do, in fact, affect the patterns of HRT use in this particular group of women. (The design of the study is described in more detail in the next chapter.)

Previous studies have found differences in HRT use linked to social class. The women in this study were selected for participation based on the criteria for the study, which did not include any assessment of their socio-economic status or income, *per se*. However, these women obviously come from different backgrounds in terms of income, and social status. It is therefore supposed that some differences in their use of HRT, associated with these differences, may be apparent.

Using the Scottish Index of Multiple Deprivation (SIMD), women were ranked according to their postcode to be given a score representing their deprivation decile. As noted earlier, this system is an alternative to the NS-SEC classification for the purposes of determining socio-economic group. The higher the score on a scale of 1-10, the less deprived in terms of current income, employment, health, education, geographic access to services, housing and crime the respondent is deemed to be. The

Index of multiple deprivation has been shown to be an effective tool when trying to explain differences in health inequalities (Jordan et al 2004).

Not only did the women included in this study differ in terms of social background, they also were of different ages at the time of their operation. A woman having a hysterectomy with bilateral oophorectomy at the age of 50 years will have different HRT needs from a patient aged 30 years. The effect of patient age at time of operation on subsequent use of HRT was examined over the age range of study participants. All the women in this study were up to 51 years of age at the time of their operation, but their ages range from 28 years old to this upper age limit. HRT will have been offered to all these women, but the advice on duration of therapy will have differed according to their age, as previously discussed.

In order to determine if there were differences in terms of geographical location or postcode variations in HRT use, patients were recruited from two hospitals.

Study participants were treated in two different general hospitals in a region of Scotland. These two hospitals, although administered by the same NHS trust, operated as two distinct units during the time of this study. Each had its own gynaecology outpatient clinics and inpatient ward. Different consultant gynaecologists and gynaecology nurses ran the services.

It might be supposed that, given the individual nature of the two units that were in existence at the time of the study, there might be some procedural differences in patient care. For instance, some consultants may wish to delay hysterectomy in favour

of less invasive treatments. The timing of hysterectomy, in terms of patient age, together with differences in the sources of information about subsequent HRT use and the quality of such advice, could all affect HRT decisions. Did the consultants and nurses in one unit collectively differ from those in the other unit in their treatment of women?

The women in this study were seen, and had their surgery performed, by different consultants, so it may be supposed that they did not all receive exactly the same information. Consultants and healthcare professionals are supposed to give patients up-to date, accurate and individually tailored advice regarding treatment and medication options. The individual consultants whose patients are sampled in this study vary in age and by gender. They may have different consultation styles, and therefore different ways of relaying the same information.

There were both male and female gynaecologists working in both units, so not only individual, but also gender, differences could be examined. Are women gynaecologists more likely to give better levels of advice to women about HRT than their male counterparts? All gynaecologists work to clinical guidelines, and there should be concurrence in their advice; but is it possible that female gynaecologists are perceived by their patients to give better information? Do patients of female consultants, as Hall Roter and Katz (1988) suggest, adhere better to HRT treatment than those cared for by male consultants? Perhaps women doctors have a deeper understanding or increased interest in the relief of menopausal symptoms when compared to men. Female gynaecologists may, however, be influenced by their own view of menopause, which could affect the advice they give. Equally, male

gynaecologists will never personally experience the menopause and, as a result, may be more sympathetic to a condition that they have no personal experience of. Alternatively, the reverse may be true.

Different sources of the same information may lead to different levels of understanding and affect HRT use. This study examines which source of information the subjects rate as the primary source, and whether or not the patients' information requirements are met. Do nurses provide good quality information for women in hospital? Are leaflets useful, and are they used to reinforce verbal information? Which professional source of information is judged to be most effective by the women who receive it?

Information gleaned from other sources also affects decisions, and media influences are known to be strong. Although the press reports on the long-term effects of HRT came late into the timing of this study, they may still have had an effect on the study participants HRT decisions. The women in the study had their hysterectomies between 1992 and 2001, but were not approached to answer the study questionnaire until 2004-2005. It is therefore reasonable to question whether or not press reports and magazine articles influenced decisions made by women and their doctors, especially those undergoing hysterectomy in the later years of the study.

In order to examine whether the above mentioned variables affect women's HRT decisions following hysterectomy with bilateral oophorectomy, and the extent to which they influence such decisions, it was necessary to design a research study. The study would need to try and answer the original research questions posed at the end of

the preceding chapter. Accordingly, in the next chapter the study design and methods are described.

Chapter 3

Design and methods

This study is a retrospective cross-sectional survey of women's use of hormone replacement therapy following hysterectomy and bilateral salpingo-oophorectomy. It will examine the patterns of HRT use specifically in hysterectomised women. Although there has been a quantity of research literature published in the past, concerned with adherence with HRT, most studies have focussed on women with natural menopause, or have not separated the HRT users by hysterectomy status. The main aim of this study was to determine whether patterns of HRT use in hysterectomised women differ from those of HRT users in general. In order to explore this, the study will assess the number of women taking HRT following hysterectomy and the patterns of that use. The research questions posed in chapter one were as follows:

- How many women in this region of Scotland who have undergone elective hysterectomy with bilateral salpingo-oophorectomy for menorrhagia take HRT?
- When do they commence therapy?
- When do they stop therapy?
- Why do they stop?
- Are the reasons for early discontinuance different from those for late discontinuance?
- What factors affect HRT use? These have been discussed in chapter two and the study will determine if and indeed how they affect women with hysterectomy and bilateral oophorectomy.

Once the answers to these questions have been obtained, they will (in turn) help to elucidate the answer to the question:

- Do patterns of HRT use in women with hysterectomy and bilateral oophorectomy differ from those in HRT users in general?

In this chapter, the design and methods of the study will be detailed. The chapter is divided into three broad sections. After a short description of the local background to the study, the first section describes how the study was designed, in terms of data collection and analysis. The second section describes how the design was implemented, outlining the procedures used to identify and recruit the study subjects, and detailing how the study was conducted. Finally section three will consider the necessary legal and ethical requirements.

This study was conducted in a region of central Scotland. The study population consisted of women who had their operations carried out at either hospital A or hospital B, between 1/1/1992 and 31/12/2001. These two hospitals serve the local population and are together managed by the same NHS Trust. Although gynaecology services are now centralised in hospital A, at the time of this study patients were cared for in two distinct and separate units, each with their own medical and nursing staff. These two gynaecology units were run individually, with no cross-cover from nursing staff and the consultant gynaecologists worked cross-site only for occasional weekend on-call. The Department of Medical Records provided details of women suitable for inclusion in the study from both hospital sites.

3.1 Study design, data collection and analysis

3.1.1 Study design

This study was designed to examine HRT use in a group of women selected because they had undergone a specific operative procedure (in the same NHS Trust) for a specific complaint, before the average age of natural menopause at 51 years. It is otherwise non-biased in terms of participant characteristics as the women on the study were selected on these criteria alone with no account taken of their social background, financial income or who treated them.

According to Robson, (2001 p 49), surveys are designed to gather information in a standardised form from groups of people, often of a specific population, so producing a "snap shot" of that population in terms of generalised characteristics. In this case, the study population were the women in the region who underwent hysterectomy with bilateral oophorectomy, as patients of either hospital A or hospital B, between 1992 and 2001. This time-frame was chosen as the 10-year period prior to the commencement of the study to allow a retrospective examination of HRT use over the past 10 years. These women were elective admissions, and the specific reason for surgery was menorrhagia, that is heavy menstrual bleeding, a benign and common condition. So all study participants had undergone the same operation, for the same reason, within the specified time frame.

The study is cross-sectional as it samples women representative of those undergoing a particular operation for a specific reason. It is also retrospective, in that it examines decisions made in the past, and the factors which may have affected these decisions. The retrospective nature of the study is significant; and how the findings may be

influenced by the accuracy of recollection, and changes of opinion over time, will be considered in more detail in Chapter Five.

The research questions in this study are designed to ascertain who takes HRT following surgery, how long they take it for, and what influences their decisions to continue or cease therapy. Surveys are "well suited to descriptive studies" (Robson, 2001,p 49, as they can indicate common trends or opinions in a population, and usually employ a questionnaire as the method of collecting data. This study involved women being asked to complete a postal questionnaire (Appendix 3.1). Participants were asked what decisions they made, and what their experiences were in relation to their use of HRT. These responses were examined with the intention of revealing what factors may be associated with the use or non-use of HRT therapy, the duration of use, and the timing of discontinuance.

Given that the women in the study were no longer inpatients in hospital, a postal questionnaire was the best way in which to elicit their responses to these questions. The main advantages of using a postal questionnaire are that it is a relatively inexpensive method of data collection, in terms of both finance and time, and it offers the participants' greater anonymity (Kumar 1999, p 114). The first two factors were of importance to the researcher whose time and finance is limited. There are some logistic difficulties in contacting patients, some of whom had been treated many years previously, to request their participation in research studies. The voluntary nature of participation and the anonymity afforded by a questionnaire was an effective method of eliciting responses from this study population. A postal questionnaire allows a large number of subjects to be sampled quickly and, being relatively quick to

complete without face-to-face contact, may be more likely to elicit a response from subjects not willing to participate in more time-consuming studies. It also protects patient anonymity to an extent, in that demographic and health details may be known to the researcher, but the respondent need not actually meet the researcher in order to give her responses.

The study population was defined according to the following criteria:

- female.
- age 51 years or younger at the time of surgery
- elective total hysterectomy performed either abdominally or vaginally, with bilateral oophorectomy.
- surgery carried out in the study location between 1/01/1992 and 31/12/2001

The age limit was set as the researcher was interested in the experiences of those women becoming menopausal due to surgery rather than the more gradual transition to natural menopause. Fifty-one years is considered to be the average age of natural menopause, so women having surgery after this age are likely to have already experienced the menopausal transition.

The route used to perform the surgery has no relevance to the resulting hormonal profile, and by including both abdominal and vaginal hysterectomies, the number of women eligible for the study was increased.

The time-frame defines this particular population and, in view of the changes in HRT guidelines, care will be needed generalising the findings to women having hysterectomy with bilateral oophorectomy today.

The target sample for this study was the whole population, that is 100% of those women identified for inclusion. This represents a total of 362 women, which was fewer than expected, and probably related to coding issues (which will be addressed later in this chapter).

Women who had elective hysterectomy for malignant disease, or who had a prior medical history of breast cancer, were excluded. The reason for exclusion was that HRT use with either of these conditions would be contraindicated. Death, severe psychiatric illness, breast cancer diagnosed after surgery, and not now being resident in Scotland were the other reasons to exclude.

3.1.2 Data collection

The questionnaire is a popular method of data collection and, as previously mentioned, efficient in terms of finance and researcher time. However the construction of a good questionnaire is more difficult than it may appear to be. Robson (2001, pp 247-249) makes some suggestions, derived from research literature, as to how an efficient questionnaire can be constructed. He states that specific questions are better than general ones, that closed questions are better than open ones and that, although there are no particular rules on how to place the order of questions one should start with general questions and follow with specific. The order of questions is particularly important, as it is well recognised that the interpretation of

any given question can be influenced by the preceding question (Robson 2001, p 249). Robson also recognises that data collected via questionnaire may not be completely honest, and its accuracy is often subject to memory (p128). In this particular study, responses are also based on recollection of past events, which may be subject to less than accurate recall. Accuracy will depend on how long ago the event happened, and the saliency of that event. Bowling (2002 p305) suggests that asking about events occurring more than six months ago should be avoided, unless they are highly salient. It could be argued that hysterectomy, as major surgery, is a highly salient event but the subsequent HRT prescription is conceivably not.

The questionnaire is divided into four sections (Appendix 3.1). Each section is introduced to the respondent as to the context of the questions. The format of the questions was simple, with a choice of responses to be answered by ticking an appropriate response. The first section is concerned with the hysterectomy, and with the information given before and after surgery. The questions were designed to ascertain whether the patient was told of the risks and benefits of taking HRT, which particular factors were discussed, the source of the information, and whether or not the patient felt that they were sufficiently informed. Simple 'yes' or 'no' answers applied to most of the questions. In five of the questions, a choice of alternative responses was offered, with clear instruction as to the number of responses allowed.

The second section asked questions about taking HRT, both before and after surgery, the duration of use and the reasons for stopping. Again 'yes' or 'no' responses, or a choice between specific alternatives, were requested. The third section was more opinion-based, considered the patient's perception of risks versus benefits, and asked

if prescription charges influenced use. The fourth section requested simple demographic details, and asked whether the respondent had ever suffered a condition, which would prevent the use of HRT.

Finally, the respondent was asked if they would consider participating in an interview. A small number of women did agree to an interview but this part of the research was not ultimately undertaken. Originally, it was planned to interview those women who agreed to meet with the researcher in order to explore in further detail their responses, so providing a deeper understanding of their choices. The primary reason that this was not carried out was because a period of two years elapsed between the return of the questionnaires and the completion of the data analysis. This delay was caused by events personal to the researcher; and to approach these women again, after such a significant lapse of time, was considered unethical.

In order to identify any difficulties in the interpretation of questions asked in the questionnaire, a pilot study was necessary. Robson (2001, p 301) suggests that a "dummy run" should be carried out before gathering any sort of data, to identify flaws in the design. Initially, it was planned to pilot the study in another hospital, outwith Forth Valley, but this idea was rejected when it became apparent that separate ethical approval from the relevant NHS Trust would be necessary, so delaying the start of the study.

The questionnaire therefore was piloted on women undergoing hysterectomy in the gynaecology ward of hospital B, the then place of work for the researcher. This pilot revealed few problems with the questions asked. Some minor alteration to the format was made by the addition of clearer statements to indicate in what context/ stage of

treatment the questions should be answered, prior to the commencement of the main study. On reflection, a pilot undertaken elsewhere would have identified problems more effectively. Respondents unknown to the researcher may have identified any difficulties more openly than those who were approached by the researcher whilst they were patients in the ward. Another consideration would have to be that these women completed the pilot at the time of their hysterectomy, whereas the study subjects were asked to remember events from the past.

Some of the women completing the questionnaire had undergone surgery some years before, and the responses were all based on their recollection of events at the time. It is entirely possible that their responses are influenced by more recent information or that they were unable to recall clearly the events or opinions of the past.

Despite clear instructions and attempts to prevent ambiguity in the questions, it became apparent, once the responses were returned, that some of the questions had been ambiguous. The closed questions, to be answered by either 'yes' or 'no', did not produce any problems, but those with more than two choices sometimes elicited more than one response, even though the instruction to the respondent was to tick one response only.

One question that proved difficult was one in which the respondent was asked to rank their answers in order of importance. Robson (2001 p 248) suggests that the middle alternative should be avoided if intensity of an opinion is to be measured as people may use " medium" as a non-committal response. The researcher wished to identify the order of importance respondents chose for the benefits of taking HRT but a

number of women were assumed to consider the options as equally important as they gave the same rank to more than one answer.

3.1.3 Statistical Analysis of Data

SPSS was used to generate some descriptive statistics pertaining to the characteristics of the target study population as a whole (n=306) and of the returned sample (n=190). The purpose initially was to examine the target population as a whole, and to check if the demography of the returned sample, in comparison with target sample, was representative in terms of age, date of operation, socio-economic group and consultant in charge of care. In this way, provided that those subjects returning their questionnaires did not differ significantly from those subjects who did not, the information gleaned from the returned questionnaires could be treated as representative of the population in general.

Simple statistical tests were then used in the analysis of the data, in order to examine the association of independent variables and the HRT decisions women make.

Independent variables in this study include the age of the patient, the individual consultant, and the SIMD classification of the patient. Other examples are: the unit in which treatment took place, who gave HRT information, and whether or nor HRT had been taken prior to surgery. It is possible that any, or all, of these might have some association with the decision to take HRT. The dependent variables in the study include whether or not to take HRT in the first place; how long to take it for; when to stop, and why.

The t-test is used to analyse the difference between two sub-groups in the sample, defined by one independent variable, and determines whether there is a significant difference between the means of these two groups on a dependent variable (when the latter is a ratio or interval variable). In a normally distributed population, the null hypothesis would be that there is no significant difference between the two means. So, for instance, according to the null hypothesis there should be no difference between the mean age of women treated in two different hospitals, or according to which consultant who treated them, or whether or not they returned their questionnaire. The probability of finding the t value by chance, or by sampling error (assuming the null hypothesis is true) is then calculated. If this probability is very low, then the researcher is entitled, provisionally, to reject the null hypothesis, and assume that there is a difference between the two groups concerned. Conventionally, the accept/reject threshold of probability is set at .05.

Pearson's chi square measures the association, if any, between two categorical variables, such as SIMD and whether or not the questionnaire was returned, or the source of information and the unit where treatment was undertaken. A contingency table is constructed, and the test calculates the difference between observed and expected counts (on the assumption that the null hypothesis is true). If the difference between observed and expected counts is such that the probability of obtaining the observed values is low (with the threshold again set at .05), then the null hypothesis can, conventionally, be rejected. Interval and ratio variables such as age, or duration of treatment, can be re-coded into categorical variables, to allow chi square analysis. The hypothesis can be one-tailed, that predicts the direction of the association (for example, older women take HRT for shorter times) or two-tailed, where the direction

of the association is not predicted (for example, there will be a difference in length of HRT use associated with women's ages). Two-tailed tests are less likely to give false results, and have been used in the analysis of this data.

3.2 The implementation of the study, how the study population was identified, accessed and subsequently recruited, and the management of returned questionnaires

3.2.1 Identification of study population

The study population was identified by hospital computer record. The Medical Records department provided the researcher with a list of hospital unit numbers and dates of birth belonging to women who, according to their records, had undergone hysterectomy with bilateral oophorectomy, either by an abdominal or vaginal route, for menorrhagia within the time frame 01/01/1992 and 31/12/2001. At the time of any surgical procedure, a record is made of the patient (unit number), the reason for the surgery (the diagnosis code), and the operation performed (the surgical procedure code). These details can then can be used to identify the number of any particular operation performed for a specific diagnosis and the patient details. Each operation and each main diagnosis has its own code. It is possible, therefore, to distinguish a woman having had a hysterectomy for endometriosis from a woman who has had a hysterectomy for menorrhagia. In this way, only women who had undergone abdominal or vaginal hysterectomy with bilateral oophorectomy for menorrhagia could be recruited. There are three codes that indicate menorrhagia, one ceasing to be used after 1997, and they are listed below.

1. 6262 = excessive or frequent menstruation, menorrhagia, heavy periods, polymenorrhoea, menometrorrhagia. (Code 6262 used prior to 1997)
2. N920 = excessive, frequent and irregular menstruation with regular cycle.
3. N921 = excessive, frequent and irregular menstruation with irregular cycle.

There is one surgical procedure code for abdominal hysterectomy, one for vaginal hysterectomy, and (for some reason) two codes used interchangeably for bilateral oophorectomy, and these are as follows,

1. Q074 = Total abdominal hysterectomy.
2. Q089 = Vaginal hysterectomy.
3. Q221 or Q223= Bilateral oophorectomy.

The researcher screened the list, and those subjects over the age of 51 years at the time of operation were excluded.

Errors in coding do occur, and it was necessary for each case note to be checked prior to inclusion in the study. This was a very time-consuming exercise. Funding was not available to allow clerical staff to locate case notes for the researcher, so the researcher herself performed the actual retrieval of each case note. This involved many hours in the medical record file rooms locating case notes, a laborious task and not without difficulty at times owing to problems with misfiling, or lost or destroyed notes. It also took the researcher some time to become familiar with the method of case note retrieval using the terminal digit filing system used by the records department. In general case notes are kept until a patient is 25 years old, and

maternity notes are also kept for 25 years. However, notes are destroyed if the patient has not attended hospital for eight years. These records not used and those approaching eight years old are kept separately in what is known as secondary storage, located outwith the main records department. It was necessary for the researcher to visit secondary storage to view a small number of notes located there. Some of the identified notes were not available in file at the time the researcher was seeking access; other departments, such as outpatient clinics or inpatient wards, were using them. In these circumstances, the researcher was required to visit other departments in order to find and extract the necessary data. Once found each medical case note was examined, and the detail of each individual operation was checked against the recorded code. By personally examining the individual case notes, the researcher was sure that only relevant cases were selected. If reasons for exclusion were apparent, then those patients were not approached. Checks were also made to ensure that the selected women were all still living. From the eligible case notes, further details were collected and recorded on a data sheet (Appendix 3.2). These details included the patient's name and address and their registered general practitioner. The operation note was checked to confirm that the recorded diagnostic and operational procedure codes were correct, and that the patient had no medical history of breast cancer. The consultant gynaecologist in charge of their care was also noted.

A number of cases were lost to the study at this point as, for one reason or another, it was decided that they did not fit the study criteria. Unfortunately, some of the earlier case notes had been destroyed, and some operations had been incorrectly coded. The details of those excluded at this point are as follows,

The computer record identified 241 hospital A cases, 31 of which were removed for the following reasons:

Patient now deceased, n = 1

Case note destroyed, n = 6

Operation incorrectly coded, n = 4

Case note untraceable, n = 7

Case notes incomplete, n = 5

Patient no longer resident in Scotland, n = 3

Severe psychiatric history, n =3

Diagnosis of breast cancer, n = 2

Similarly the computer record identified 121 hospital B cases, and of these 19 were removed for the following reasons:

Patient now deceased, n = 1

Case note destroyed, n = 5

Operation incorrectly coded, n = 7

Case note untraceable, n = 2

Patient no longer resident in Scotland, n = 1

Evidence of psychiatric trauma related to Hysterectomy operation, n = 1

Diagnosis of breast cancer, n = 2

Once the target population was thus identified, the patients could be approached for recruitment to the study. The number of women in the target sample at this point was 312.

3.2.2 Access to and recruitment of study participants

A letter from the researcher was sent to each gynaecologist whose patients were identified as being possible participants in the study, asking for their permission to access and check the relevant case notes and approach the women for participation in the study (Appendix 3.3 (a) and (b)). All the gynaecologists approached were supportive of the study.

In order to comply with Data Protection and Caldicott Guardianship, the first approach to any patient must be from the clinical team involved with their care. A letter was drafted by the researcher, with the assistance of Dr X, and signed by each consultant gynaecologist to introduce the study and the researcher to each individual patient. In this letter, it was stated quite clearly that if the individual woman did not wish to take part in the study then she could telephone the Gynaecology office and ask for her name to be removed from the list of possible participants (Appendix 3.4).

A letter introducing the study and the researcher was also sent to the general practitioner with whom the identified potential participants were registered. This letter asked the general practitioner for permission to approach women in his care, and to identify those that he thought should not be approached. These doctors were asked to notify the researcher directly if they wished any of their patients to be excluded from the study. They were not asked to divulge the reason for wishing exclusion (Appendix

3.5). General practitioners referring to hospital A withdrew one patient from the study. Likewise General practitioners using hospital B also withdrew one patient. The reasons for withdrawing these two patients were not specified.

Participation in the study was, as previously stated, voluntary. Three patients from the hospital B cohort opted to withdraw themselves from the study at the time of first contact by following the instruction to communicate with the Gynaecology Department. One woman from the hospital A cohort also withdrew. The reasons for their non-participation were not explored.

Provided consent had not been refused within ten days, either by the general practitioner or the patient, the questionnaire was sent out. Given the losses already mentioned, the study numbers were reduced, with questionnaires being sent to 306 women. 208 were treated in hospital A; 98 were hospital B patients.

Accompanying the questionnaire was a letter of introduction, inviting participants to complete the questionnaire, and asking them to return a blank copy if they did not wish to participate: this would then prevent further contact with the researcher. The letter explained how long the questionnaire would take to complete, and gave a date by which it would be helpful to have it returned (Appendix 3.6). A patient information sheet also accompanied the questionnaire, explaining how the study participants had been chosen, outlining the purpose of the study, and emphasising confidentiality (Appendix 3.7). A self-addressed, postage-paid envelope was included for the return of completed or non-completed questionnaires. This ensured that the participants did not incur any expense, and was designed to assist a successful return rate.

3.2.3 The management of returned questionnaires

It is well recognised that response rates to postal questionnaires are often low, since many people do not return them, and those that do return them may have motivations differing from those who do not (Kumar1999, p 114). To minimise the effect of a self-selection bias in collected data, it is important to do everything possible to enhance the rate of return, so maximising the chance of obtaining data from the whole study population.

Robson (2001 pp 250) suggests that a number of factors can secure a good return rate. These include the use of quality stationary, stamped in preference to being franked, and personally addressed. All correspondence was made on good quality hospital-address headed paper, and sent by stamped first class postage to a named individual. Pre-survey letters are thought to increase return rates, but are also necessary to comply with data protection legislation. Clear information indicating the aim of the study, suggesting its importance, and assuring prospective participants of confidentiality also affect return rates. Robson also indicates that follow-up letters are the most effective way of increasing return rates from those who initially fail to return questionnaires. He suggests as many as three reminders may be used. In this study, however, only one reminder was sent, which included a further copy of the questionnaire and another stamped-addressed envelope (Appendix 3.8). The reminder was only sent to those women who had not returned their questionnaire by the date requested.

The return rate for hospital B was better than that for hospital A, with 76 completed questionnaires and 4 blank questionnaires returned - a rate of 81.6%. Given that only the completed questionnaires are of value, the useable return rate is 77.5%.

Of the 208 subjects from the hospital A cohort, 120 returned their questionnaires; but 6 of these were blank. This yields an overall return rate of 57.6%, and a useable return rate of only 54.8%. Kumar (1999, p114) suggests a 50% return rate is considered good, but Bowling (2002, p 264) suggests that over 75% is good, and points out that even then 25% of the sample have not responded, a proportion who may be different in some " important way" from those who do respond. There is no obvious reason for the disparity between the rates of return between the two cohorts.

Combining these figures it can be seen that, out of a total of 306 questionnaires sent out, 200 were returned, an overall return rate of 65.3%. However only 190 returns could be used, and therefore the overall useable return rate is 62.1%.

Data was collected from both primary and secondary sources. The primary source was responses to the questions included in the questionnaire. The secondary source was the data gathered from the medical records of the participants, such as date of birth, date of operation, name of GP, and name of hospital consultant.

The questionnaires were numbered to match the data sheet compiled at the time of the case note screening, so that when they were returned to the researcher at the Gynaecology office, it was possible to determine which woman had completed which questionnaire. It was therefore possible to match the demographic and other personal

details with the responses to the questionnaire. Once this had been completed the data was coded to anonymise the source and protect the participants' confidentiality, At this point, it was entered into the computer.

There were 116 questionnaires not returned, or returned blank. There is little value in these except to use the demographic data, which they contain, to investigate the similarities and differences between the returned data and the target sample as a whole. The only data used from these non-returned questionnaires were details of date of operation, age at operation, Scottish Index of Multiple Deprivation (SIMD) scores, and the consultant responsible for care.

When those who returned the questionnaire were compared with the target sample, it was found that those who returned their questionnaire were slightly older and from less deprived backgrounds. This is not totally unexpected. Published research has shown that response rates rise with increasing age, and that people from lower socio-economic groups are less likely to respond (Cartwright 1983, cited Bowling 2002, p 269). Cartwright, however, does not find differences in postal survey response rates by social class. The implications of this will further discussed in Chapter Four.

3.3 Ethical and legal considerations, issues of consent and necessary permissions sought prior to the commencement of the study

3.3.1 Ethical considerations

Before the study could begin, a number of permissions were required. The major consideration of any research study involving patients is one of ethical approval, and to this end an application was made to local Health Board's Ethics of Research Committee.

As this study was essentially based on voluntary participation, with no obligation to complete the postal questionnaire, the study participants were not at high risk of being exposed to discomfort, distress or much inconvenience. However, it was recognised that some subjects might feel obliged to participate for fear of jeopardising future health care in the local NHS Trust. To prevent this, it was made quite clear to prospective participants that any future health care would not be influenced by their decision whether or not to take part. Before any questionnaires were sent through the post, all potential recipients were checked against hospital data files of recorded deaths, in order to avoid the possibility of a mailing to a deceased person, causing distress to their family members. Patients were not approached in the immediate post-operative period, thus avoiding any potential sense of obligation to participate on their part.

Confidentiality was emphasised at the first point of contact, in the letter of introduction (Appendix 3.6), and data was edited, coded and securely stored. It will be disposed of in accordance with the Data Protection Act. As this was a voluntary study, no formal consent was obtained from each participant, the returning of the

questionnaire being non compulsory. A patient information sheet sent with each questionnaire explaining the purpose of the study, and emphasising the voluntary nature of their participation (Appendix 3.7). Consent of those involved in the clinical care of the study participants - their hospital consultant and general practitioner - was also sought (Appendices 3.3 and 3.5).

A second ethical committee was also approached for their approval of the study. As a student of the University of Stirling, it was necessary for the researcher to obtain ethical approval from the Departmental Research Ethics Committee. After some minor adjustments, both committees granted the study ethical approval.

The ethical committees also granted their approval for participants to be interviewed by the researcher after the questionnaires were completed. This was to be allowed providing the participants had indicated that they were willing to participate and had completed a formal consent to interview (Appendix 3.9). It was recognised by the researcher that, even if a respondent had opted to participate in an interview, it might be possible that asking women about hysterectomy, and its aftermath, could reactivate some distress if their experience in hospital, or their post-operative recovery, had been traumatic. In anticipation of this possibility, a clinical psychologist Mr Y was approached, and agreed to support the researcher if the women interviewed requested psychological support following their description of the hysterectomy and their hospital experiences. However as indicated earlier this part of the study was not carried out.

It is necessary not only to obtain ethical approval for hospital based research studies, but also to have permission from other individual members of the Health Board. Indeed, it is part of the granting of ethical approval that permission is sought from the relevant Clinical Director and/or Chief executive of the Trusts in which the work is to be carried out. To this end, the Chairman of the Women and Children's Unit, and the Medical Director and Caldicott Guardian for the Acute Hospitals NHS Trust were both approached. The Chairman gave his support to the study whilst the Medical Director and Caldicott Guardian gave permission for the release of non-anonymised patient information without patient consent from medical records to the researcher.

The study subjects were no longer under hospital gynaecological care and the study was retrospective, so subjects should not have felt obliged to participate for that reason. It was made absolutely clear to all potential participants, in the patient information sheet (Appendix 3.7), that any future health care would not be influenced by their decision to participate or not in the study. If a request was made to remove an individual from the list of possible participants, this was done.

The fact that the researcher was employed by the local Health Board and practising as a staff nurse in Gynaecology services would perhaps aid, rather than compromise, the study in terms of encouraging the return rate of questionnaires. Although the study may have involved women who had been directly under the care of the researcher at some time in the past, this fact should not put those women under any increased obligation to participate.

3.3.2 Legal considerations

To aid the researcher's understanding of her obligations under data protection and the law she met with the Lead Data Protection Officer for NHS Forth Valley, prior to the commencement of the study, to discuss how data would be collected and protected. Reference was also made to the local Data Protection and Confidentiality Policy for Personal Information, and the NHS Code of Practice on Protecting Patient Confidentiality, together with the Nursing and Midwifery Council's Code of Professional conduct regarding patient confidentiality. There are a number of legislative documents concerned with the protection of personal data, which determine what information may be accessed by a researcher and govern how such data is used. These include:

- Data Protection Act 1998.
- Caldicott Report 1997.
- Professional Ethics such as the NMC Code of Conduct
- Freedom of Information (Scotland) Act 2002.
- Human Rights Act 1998 (article 8)
- Computer Misuse Act 1990

The first three documents will be discussed in some detail, as they have the most practical relevance to the study.

The Data Protection Act 1998 became law in March 2000, and protects the rights of individuals when their data is being processed. This Act is only concerned with personal data - that is data, which would, alone or with the addition of other data also

known to the data controller, identify a living individual. There are eight main principles of the Data Protection Act, which ensure safe and lawful use of personal information. These principles are that information must be:

1. Fairly and lawfully processed.
2. Processed for one or more lawful purpose.
3. Adequate, relevant and not excessive.
4. Accurate and up to date.
5. Not kept for longer than necessary.
6. Processed in line with the data subject's rights.
7. Secure.
8. Not transferred outside the European Union, as Data Protection only applies to Europe.

On a practical basis for this study, all these principles were adhered to. The data was retrieved and used lawfully. The Health Board is registered for research purposes, and permission was gained from the Caldicott Guardian to access non- anonymised information. The only details gathered were those necessary for determining whether or not the subject was eligible for inclusion in the study in terms of age, diagnosis code and operational code. Demographic details such as name, address, postcode and general practitioner were collected to enable contact with prospective participants once their general Practitioner had granted permission.

All data has been processed in accordance with the rights of the data subjects, as the study participants were informed clearly in writing of the purpose of the study and

assured that their identity would be kept confidential by anonymising their questionnaire responses.

All identifiable data has been kept secure. At no time did the case notes leave the Medical Records Department file room, provided they were in file at the time of screening. Those case records located outside the file room were viewed at their location, i.e. outpatient clinic, and not removed by the researcher. Once collected, names, addresses and general practitioner details were removed from the data prior to processing and the individual subjects given a code number to protect their identity.

The Caldicott Report 1997 was commissioned by the Chief Medical Officer of England and chaired by Dame Fiona Caldicott to address concerns about how patient information was being used in the NHS in England and Wales. The report is mainly concerned with the security of details and the impact of new technology. The NHS in Scotland adopted it in 1999. The Caldicott Principles are much the same as those contained in the Data Protection Act, and are specifically designed to protect patient confidentiality due to the sensitive nature of medical records. They ensure that the use of patient identifiable data is justified, necessary and minimal. Only those who need to access patient identifiable information should have access to it and such information must be used lawfully. The report recommends that each health organisation should have a senior health professional to act as a guardian responsible for the safeguard of confidential patient information. The researcher met with The Caldicott Guardian for the NHS Trust after ethical approval for the study had been granted, and he gave his permission to access non-anonymised patient information.

In addition to the two sources of guidance above, as a nurse the researcher is also bound by the NMC's Code of Professional Conduct, which states clearly that patient information must be protected and only used for the purpose for which it was given.

The remaining three legislative Acts will only be discussed briefly for completeness. The Freedom of Information (Scotland) Act 2002 states that there exists a general entitlement of the public to know what information is held by any organisation about them and that, if requested, that information must be released to them. A formal request must be made, and must be dealt with by the organisation within 20 working days.

The right of the individual to have respect for their private and family life is law under the Human Rights Act article 8.

The computer Misuse Act 1990 addresses unauthorised access to computer material and is designed to safeguard computer held information. It forbids unauthorised access, which is punishable by imprisonment. On a practical basis, all computer held data for this study is coded and password protected.

Chapter Four Results

In this chapter the results of the study will be presented. After some observations about the extent to which the achieved sample can be taken as representative of the population, the variables which might be associated with HRT use (as discussed in chapter 2) are analysed; and, subsequently, the reasons why women stop HRT, and the point at which they do so, will be examined. Throughout the chapter, where appropriate, additional comment will be offered, although the main discussion will be left until chapter 5. To aid the reading of the text and tables in this chapter the following abbreviations have been used.

Hospital A (HA)

Hospital B (HB)

Scottish Index of Multiple Deprivation (SIMD)

4.1 Is the data collected from a sample, which is representative of the population as a whole?

The first objective of the statistical analysis was to determine whether the data collected from the questionnaires was representative of the whole target sample. The population as a whole consists of women undergoing hysterectomy with bilateral oophorectomy in the same NHS trust for menorrhagia. The target sample within this population was the 306 women to whom the questionnaires were sent, and the achieved sample was those women who returned their questionnaires. To determine if the data collected originated from women who are representative of the target population, a comparison between those who return their questionnaires and those who do not was made.

Demographic details were compared between the two groups to see if there were differences in patient age at the time of operation, or differences in the socio-economic group to which the women belonged. The unit where the operation took place, and the consultant in charge of care were also compared. It became apparent that:

- The mean age at operation is significantly different for the returned sample at 43.92 years compared with 42.80 years for those who did not return their questionnaires, (see Table 4.1).

Table 4.1 Comparison of the mean age at operation of those who returned the questionnaire and those who did not.

Return	n	Mean	Std. Deviation
Questionnaire returned	190	43.92	4.483
Questionnaire not returned	116	42.80	4.933

t-value 1.983
$p < .05$

- The return rate was significantly higher among those women treated in HB, with 77.6% returned from HB patients and 54.8% returned from HA patients. This may be explained by the fact that the original letter inviting participation was headed on HB notepaper and the patient information sheet stated that the researcher was a nurse in gynaecology at HB.

- The patients of some consultants return their questionnaires in greater number than the patients of others. The poorest return rate of 48.6% is seen for the consultant who performed the most operations and the best for the consultant who

performed the least operations. This may be explained by the fact that the consultant performing the least operations was new to the unit and had only operated on women in the recent past, whereas the consultant performing the most operations was a senior consultant who had been in post for some considerable time.

- There is a better return rate among those women with SIMD scores of 7-10, that is the less deprived. 71% of these women returned their questionnaires, compared with 58.2% of those in SIMD groups 1-6, as shown in Table 4.2.

Table 4.2 Comparison of the Socio-economic group of those who return the questionnaire and those who do not.

	Questionnaire not returned	Questionnaire returned	Total
SIMD 1-6 n % within SIMD 1-6	 89 41.8%	 124 58.2%	 213 100.0%
SIMD 7-10 n % within SIMD7-10	 27 29.0%	 66 71.0%	 93 100.0%
Total n % within SIMD 1-10	 116 37.9%	 190 62.1%	 306 100.0%

χ-square 4.472
$p < .05$

To summarise, the achieved sample over-represents women who were slightly older at the time of surgery and who have less deprived social backgrounds. There are

conflicting findings from studies trying to determine who does and who does not respond to surveys. Bowling (2002 p 269) acknowledges the difficulties in defining the characteristics of non-responders and suggests that the topic of the survey is partly responsible for the inconsistencies found. She quotes Cartwright (1983) who found that response rates to surveys vary with social class, but that these differences are *not* seen when postal surveys are used. Other researchers have found that socio-economic group is strongly associated with response rates to questionnaires. Turrell et al (2003) found in their survey of food purchasing behaviour that non-responders were older and less educated concluding that socio-economic position is a strong predictor of non-participation. Similarly, findings made by Van Loon et al (2003) support the socio-economic link, but these authors found that younger people are *less* likely to respond. Bowling (2002, p 269) however, states that research has shown that "among older people, response rates increase with increasing age". So the achieved sample in this study is in keeping with both Turrell and Van Loon's findings with regards to socio-economic status, but supports Bowling's statement on the association of increasing age and higher response rates.

Although a larger percentage of HB patients returned their questionnaire, fewer women were approached in Falkirk. A higher percentage of the *overall* returns were from HA patients, with 114 completed returns compared with 78 completed by HB patients.

The data collected from the achieved sample is now presented. Some general observations concerned with where, when and by whom the women were treated are made before an examination of which variables are associated with HRT use.

Number of cases per unit

Table 4.3 shows that hospital A (HA) performed more operations than hospital B (HB) over the ten-year period examined in the study. HA performed 60% of the total, while HB was responsible for 40%. This may be explained by the fact that the unit in HB was slightly smaller than that in HA, with 13 Gynaecology inpatient beds compared with 18 in HA.

Table 4.3 Number of cases by unit in the achieved sample.

	Frequency	percent
HB	76	40
HA	114	60
Total	190	100

When cases treated by individual consultant are analysed, it can be seen that a HA based consultant (H) is responsible for more than a quarter of all cases, performing 27.4% of all procedures. All consultant gynaecologists in each unit have slightly differing areas of specialist interest and clinical practice, and some have extensive administrative roles. This impacts on the time available to them for theatre cases. During the time frame of this study, one consultant retired (G), two took maternity leave (I and J), and one was newly recruited (C). This would obviously affect the number of cases each surgeon would perform. Table 4.4 details the number of cases treated by each consultant.

Table 4.4 Number of cases treated by consultant in the achieved sample.

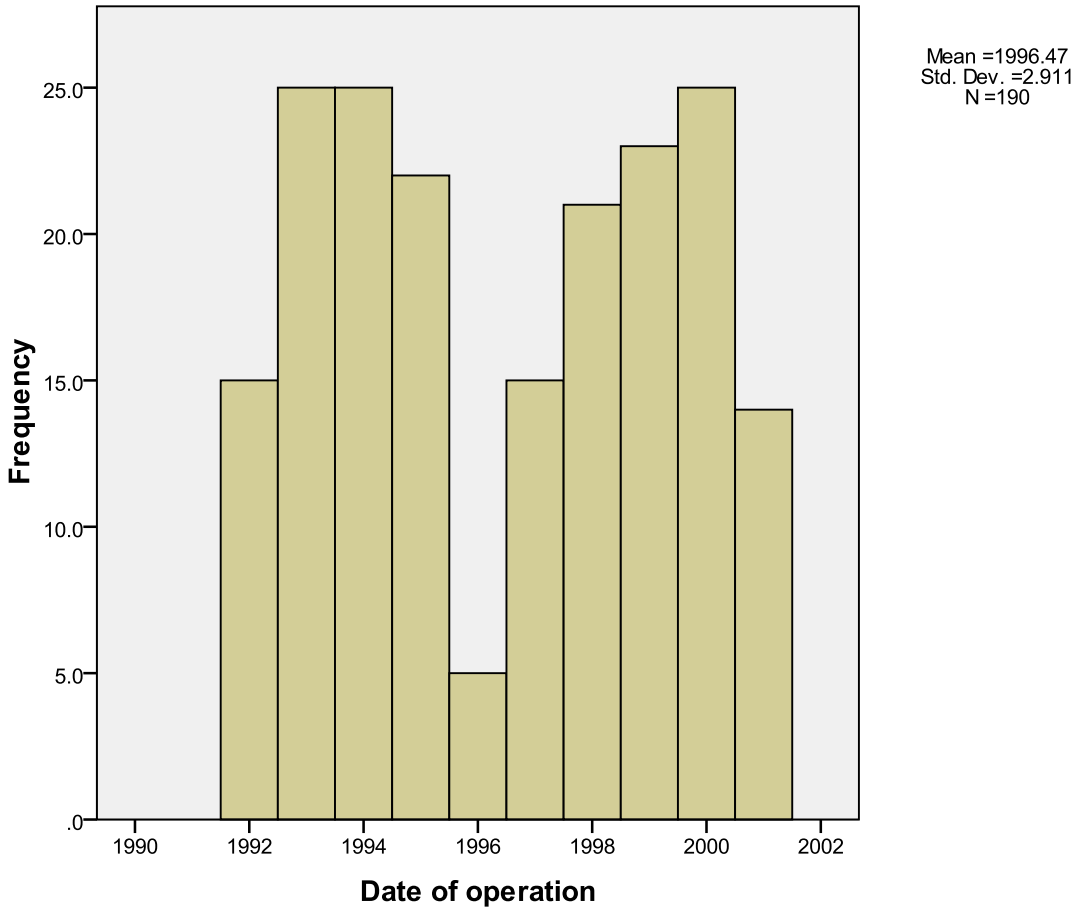
Consultant	Frequency	Percent
A	20	10.5
B	20	10.5
C	5	2.6
D	16	8.4
E	12	6.3
F	4	2.1
G	21	11.1
H	52	27.4
I	14	7.4
J	12	6.3
Other	14	7.4
Total	190	100.0

Date of operation

The distribution of returned questionnaires according to the year of operation is depicted in Figure 4.1.The numbers are roughly comparable for each year, with the exception of 1996.

The year 1996 has a very low return rate, and this must be looked at in context of the whole target population to see if there were actually fewer operations performed in this year. When the whole target sample was examined in terms of number of cases per year, it was clear that in 1996 fewer operations with the specified diagnosis codes, were performed according to statistical records. It was found that, in fact, only eight questionnaires were sent out to women whose operations had been in 1996. So the low number was not related to poor return rates but to very low target numbers.

Figure 4.1 Frequency of operation by year in the achieved sample.



This dramatic drop in numbers is difficult to explain except in terms of coding. It is possible that in this year the recorded diagnosis codes for these cases differed from

those selected for this study. If cases were coded with diagnosis codes other than 6262,N920, or N921 (see Chapter three) then they would have been excluded. The recorded diagnosis for any operation is linked to clinical findings prior to the operation, and selected from a pre-existing list of codes. Often there may be more than one diagnosis for the case, for example a hysterectomy may be performed to treat endometriosis or dysmenorrhoea which may co-exist with menorrhagia but as diagnoses have separate codes. This study has used only the main diagnosis code recorded to select study cases. So it is possible that the reason there were apparently fewer hysterectomies for menorrhagia in 1996, was that the operations were differently coded. It could be argued however that this would be the case in any of the studied years. There may be another possible explanation for the reduced numbers in 1996, again linked to coding. In 1996 two consultants joined the hospital. It may be that these new doctors did not perform so many total hysterectomies with bilateral oophorectomy for menorrhagia, preferring to follow a more conservative treatment or coded their operations with a different main diagnosis code, such as dysmenorrhoea. Munro (2007) acknowledges that it is difficult to measure the exact rate of hysterectomy for heavy bleeding, due to coding issues. Hysterectomy rates in the United States of America remain at much the same level, despite the advent of many medical and minor surgical treatments for heavy menstrual bleeding according to Munro (2007). In England, however, there has been a steady reduction in the numbers since 1995-1996, thought to be associated with increased rates of endometrial ablation and the use of the Mirena coil (Reid and Mukri 2005). Similarly the figures quoted by Bridgman and Dunn (2000), show falling hysterectomy rates since 1992-1993, with a dip in the numbers for the financial year 1995/1996.Again this is related to the alternative treatment, endometrial ablation being used more frequently in these years.

It is likely that fewer hysterectomies were performed in the year1996 in Forth Valley due to these national trends but also that variations in coding from year to year, have also played a part in the exceptionally poor numbers of target subjects for this particular year.

We now return to the variables considered in chapter two, in order to determine whether any of them are associated with the HRT decisions made by women in this study.

4.2 Is socio-economic status associated with HRT use?

Using the Scottish Index of Multiple Deprivation (SIMD), cases were ranked according to their postcode to be given a score according to their deprivation decile. The higher the score on a scale of 1 – 10, the less deprived in terms of current income, housing, health, education, skills and training, and employment the area is deemed to be. This system in some ways replaces the old Registrar General's classification for the purposes of determining socio-economic group, or level of deprivation.

In order to determine whether the achieved sample was representative of the population of the local area as a whole, a comparison was made of the representation of each decile in both groups. There are a total of 371 data zones within the local geographic area, each with its own decile. Likewise the 190 women who returned their questionnaires each belong to a decile based on their postal code. It is possible then to compare the percentage of the population belonging to one SIMD decile in the total population of the region with the percentage found in the achieved sample (Table 4.5). When this comparison is made, it is clear that the sample is roughly comparable

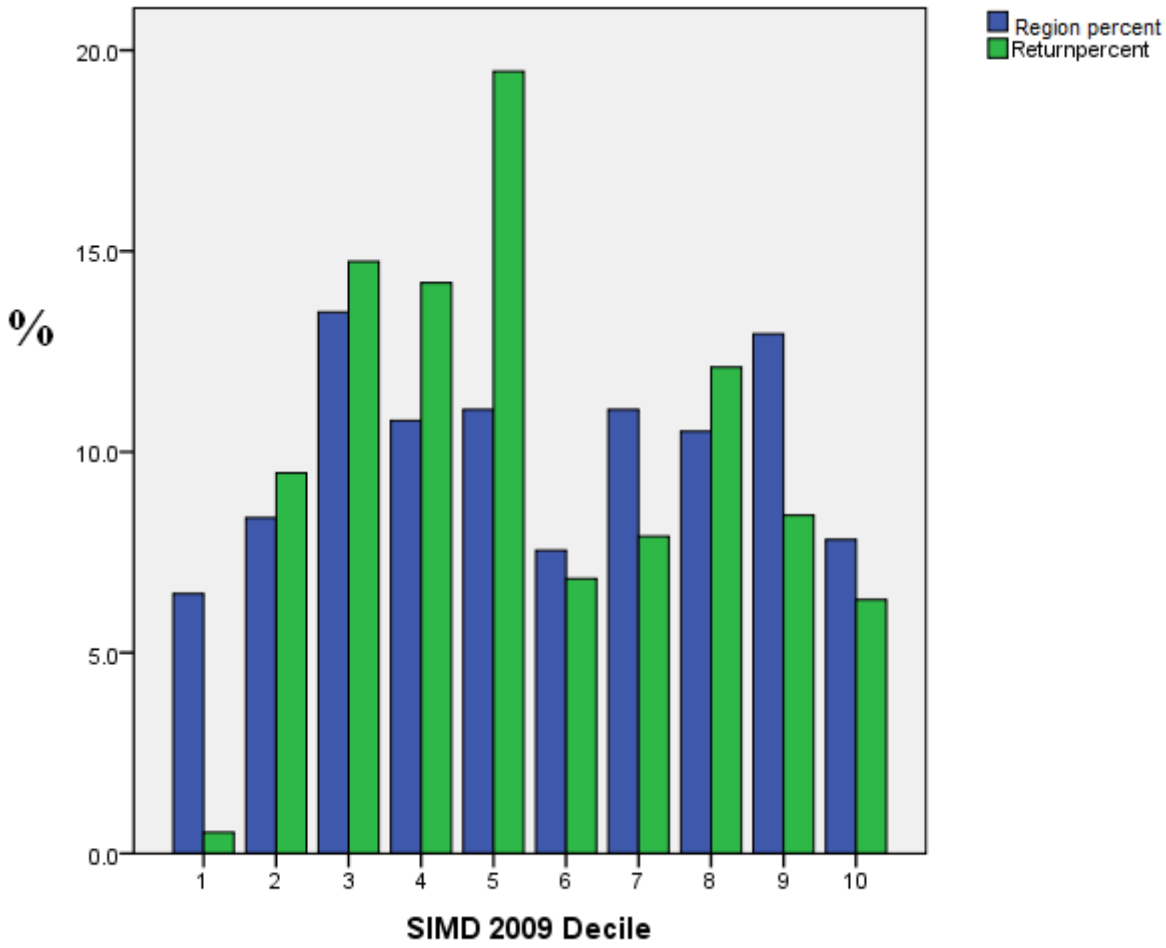
to the population of the local region as a whole, in terms of socio-economic background.

Table 4.5 and Figure 4.2 show that SIMD Group1 is particularly under-represented in the achieved sample and Group 5 is over-represented. Both these SIMD classes are grouped together as SIMD1-5, as the more deprived groups in the statistical analysis of the data obtained. So although there are fewer of the very poorest women in the sample, there are somewhat higher numbers of SIMD Group 5 women, who (for the purposes of this study) are still considered to be in the more deprived group.

Table 4.5 SIMD classification of achieved sample compared to the region as a whole.

SIMD	Whole Region		Achieved study sample	
	Frequency (n)	Percent(%)	Frequency (n)	Percent (%)
1	24	6.5	1	0.5
2	31	8.4	18	9.5
3	50	13.5	28	14.7
4	40	10.7	27	14.2
5	41	11.1	37	19.5
6	28	7.5	13	6.9
7	41	11.1	15	7.9
8	39	10.5	23	12.1
9	48	12.9	16	8.4
10	29	7.8	12	6.3
Total	371	100	190	100

Figure 4.2 Population of the whole of the region by SIMD classification compared with the sample achieved in this study.



The following five questions related to socio-economic group were addressed by the study:

4.2.1 Is socio-economic status associated with the age of the patient at the time of operation?

There is an association between socio-economic group and the age at which women undergo hysterectomy. When the whole target sample is analysed (n=360), differences in the mean age by socio-economic group are seen (Table 4.6). If the target sample is then divided into SIMD groups 1-5 and 6-10, there is a significant difference in the age at operation. For groups 1-5 the mean age is 42.92 years, while for the less deprived groups, 6-10 the mean age is 44.42 years (Table 4.7).

Table 4.6 Target sample mean age at time of operation by SIMD score.

SIMD	MEAN AGE	n	Std. Deviation
1	39.80	10	5.653
2	42.75	32	3.742
3	43.23	47	5.719
4	43.14	43	5.012
5	43.14	57	4.871
6	44.79	24	3.788
7	45.95	22	3.798
8	43.56	32	4.181
9	43.42	19	3.934
10	44.60	20	3.662
Total	43.49	306	4.682

Table 4.7 Target sample mean age at time of operation classified by SIMD groups1-5 and SIMD groups 6-10.

SIMD	n	MEAN
Age at operation		
SIMD 1-5	189	42.92
SIMD 6-10	117	44.42

t- value –2.905
p< .01

It may be argued that women from less deprived backgrounds with superior education may understand the issues surrounding early hysterectomy in terms of oestrogen loss more completely, and hence delay hysterectomy in favour of more conservative therapies. It has been shown that women from poorer backgrounds are more likely to have a hysterectomy before they become naturally menopausal, i.e. that they are younger than less deprived women (Cooper et al 2008).

When the data from the returned questionnaires is analysed, however, this socio-economic association with age at operation is not seen. The mean age at operation for SIMD groups 1-5 is 43.42 years, and for those classified in SIMD groups 6-10 it is 44.61 years. The difference between which is not statistically significant (Table 4.8).

Table 4.8 Achieved sample mean age at time of operation classified by SIMD groups 1-5 and SIMD groups 6-10.

SIMD age at operation	n	MEAN	Std.Deviation
SIMD 1-5	111	43.42	4.761
SIMD 6-10	79	44.61	3.989

t-value –1.805
p = 0.073

This can probably be explained in terms of sample size. It is assumed that, had more subjects returned their questionnaires, then the association between socio-economic group and age at operation would have shown in the achieved sample also.

4.2.2 Is the socio-economic status of the patient associated with hospital prescribing of HRT?

It might be expected that the social background to which the patient belongs has some effect on the level of information exchanged between doctor and patient during a consultation, and this in turn may affect HRT uptake. The Black report of 1980 found that middle class patients have consultations with their doctors of longer duration than those from poorer backgrounds. If the consultations are longer, is the information given more detailed, or different in any other way? This was examined in relation to the responses to the questions 3-10 in the questionnaire, concerned with information-giving and subsequent acceptance of HRT prescription. In this study, the socio-economic group of the patient does not seem to be associated with any of the responses to questions 3-10.

If the population is split at SIMD band 5, where bands 1-5 are the most deprived and bands 6-10 the least deprived, then there appears to be no effect of socio-economic status. This is true in terms of who mentioned HRT, before the operation, and whether or not symptoms of the menopause were discussed. SIMD has no effect on whether osteoporosis or heart disease protection is mentioned, or indeed on whether side-effects such as increased cancer and DVT risk are discussed. So discussions between women from less deprived backgrounds and their doctors do not differ significantly from those between more deprived women and their doctors, in terms of information given regarding risks/benefits of HRT. There is also no difference in terms of unit attended.

HRT is offered in hospital to women regardless of their SIMD status. Slightly more women in the lower SIMD groups, which are the most deprived, accept HRT when offered although this is not statistically significant in this sample. SIMD does not influence the likelihood of subsequent discussions with GPs regardless of whether or not the hospital provided HRT.

4.2.3 Do different socio-economic groups use different information sources in hospital?

It may be supposed that women from different backgrounds access information from different sources; however, this did not appear to be the case in the present study.

There is no association between the SIMD score of the patient and whether the doctor, nurse or HRT pamphlet is the main source of information about HRT. If the SIMD scores are split into two groups at band 4, the most deprived being groups 1-4 and the least deprived being groups 5-10, then the doctor is mentioned as a source by 28.2% of the most deprived women compared with 38.7% of the least deprived women. However, this is not a statistically significant result (p .096), and therefore it cannot be said that women from less deprived backgrounds are able to discuss this aspect of their care more confidently with their doctor. There is no difference in the numbers of women citing the nurse, or HRT pamphlet as a source of information when patients are classified by SIMD scores. It may be argued that nurses give the same information to all patients, or provide leaflets in lieu of personal advice; so variations by social class might be expected to be less evident. If the SIMD scores are more equally divided at 5, with the most deprived women in groups 1-5, and the least deprived in groups 6-10, then there is still no statistical association demonstrated.

There is no association between SIMD and whether or not the doctor is cited as a source of information; likewise there is no association between SIMD and whether of not the nurse or HRT pamphlet is cited. This would further confirm that the information sources used by the women in this study are not associated with SIMD.

4.2.4 Is socio-economic status associated with the duration of therapy? And is there any association between prescription charges and HRT use?

Are wealthier women more likely to use HRT for a longer time than women from less affluent backgrounds? And do prescription charges, or the eligibility for exemption certificates, affect HRT use by the women in this study?

Some association between socio-economic group and the timing of stopping treatment is seen. When the women are grouped by SIMD groups 1-5 and 6-10, the *least* deprived women appear to take HRT for longer, when all stopping times are considered. Overall there is only a close to significant result (p .061) found here. This effect is amplified if the timing of cessation of treatment is divided into two groups: 'up to 7 years' and 'beyond 7 years'. Table 4.9 shows that 77.5% of the most deprived women cease treatment within 7 years compared with 42.5% of the least deprived women. More than double the number (57.5%) of the least deprived women take HRT for more than 7 years, compared to only 22.5% of the most deprived. This is statistically significant.

If the timing of the cessation of treatment is divided into two different groups, 'up to 5 years' and 'more than 5 years', and if the respondents classified by SIMD5 the same

effect is seen, with more of the least deprived women taking treatment for longer (Table 4.10). Women from different backgrounds give the same reasons for stopping treatment.

Table 4.9 Women who stop HRT after up to 7 years of use, or after more than 7 years use, classified by their socio-economic group, SIMD 1-5 or SIMD 6-10.

When stopped	Most Deprived (SIMD 1-5) n %	Least Deprived (SIMD 6-10) n %	Total n %
Stopped up to 7 years	31 (77.5)	17 (42.5)	48 (60.0)
Stopped beyond 7 years	9 (22.5)	23 (57.5)	32 (40.0)
Total	40 (100)	40 (100)	80 (100)

χ-square 10.208
$p < .001$

Table 4.10 Women who stop HRT after up to 5 years of use, or after more than 5 years use, classified by their socio-economic group, SIMD 1-5 or SIMD 6-10.

When stopped	Most Deprived (SIMD 1-5) n %	Least Deprived (SIMD 6-10) n %	Total n %
Stopped up to 5 years	23 (57.5)	14 (35.0)	37 (46.2)
Stopped beyond 5 years	17 (42.5)	26 (65.0)	43 (53.8)
Total	40 (100)	40 (100)	80 (100)

χ- square 3.701
$p < .05$

It may be thought that prescription charges have an influence on the length of time a woman decides to continue with treatment, and that socio-economic group would reflect this aspect. Nearly 80% of the women answering said that they *did* pay for their HRT prescription.

When grouped by SIMD 5 (least deprived 6-10), 23.7% of the most deprived women and 17.9% of the least deprived women did not pay for their prescriptions. When this is cross-tabulated with the stopping times of 'up to' and 'more than' 5 years, no association is seen. Of those who *do not* pay for their medication, those who stop taking HRT at up to 5 years and those stopping at over 5 years do so in equal number. If those who stop after a longer period of time, 7 years or more, are compared to those who stop before this there is still no association with prescription charges. When asked if free prescriptions would make them more likely to take HRT, 75.4% of women said that it would not.

When asked if they discussed with their doctors their decision to stop, 65% said that they had done so. If the women are grouped by SIMD, there is no association between socio-economic group and the likelihood of this consultation taking place. This is true irrespective of whether SIMD 4 (least deprived SIMD 5-10) or SIMD5 (least deprived SIMD 6-10) is used to categorise the study population.

4.2.5 Do women from different socio-economic groups view the "risks versus benefits" of HRT therapy differently?

When the achieved study population was asked whether the benefits of HRT outweigh the side effects for them personally, 142 women (74.7%) answered in the affirmative. There is no statistical evidence that socio-economic group is associated with this response. The women were also asked to consider the benefits of HRT and rank, in order of importance, the prevention of menopausal symptoms, osteoporosis prevention and possible cardiovascular protection.

Table 4.11 shows that the relief of menopausal symptoms was ranked as most important by 31.5% of respondents, and a further 36% ranked this as of medium importance. The prevention of osteoporosis was thought to be most important for 26.3% of women, and a further 47.5% ranked this as of medium importance. Possible cardiovascular protection was thought to be most important for 15.6% of respondents, with a further 37.4% ranking this as of medium importance. (Some women did not clearly rank this question, as some gave joint importance to two or more choices; hence the intermediate classification of 1.5 and 2.5 in tables 4.11, 4.12 and 4.13.)

If the indication of joint importance of symptoms is considered, and the intermediate scores of 1.5 added to score 1, and 2.5 added to score 2, then the relief of menopausal symptoms appears to be most important to 38.2% of women. The prevention of osteoporosis is most important to 33% of women, and cardiovascular protection most important to 20.1%.

Table 4.11 Importance ranking by achieved sample of the benefits of HRT.

Importance ranking	Menopause symptoms n %	Osteoporosis protection n %	Heartdisease prevention n %
1.Most important			
% of Total	56 (31.5)	47 (26.3)	28 (15.6)
1.5			
% of Total	12 (6.7)	12 (6.7)	8 (4.5)
2.Medium importance			
% of Total	64 (36.0)	85 (47.5)	67 (37.4)
2.5			
% of Total	4 (1.7)	7 (3.9)	10 (5.6)
3. Least important			
% of Total	43 (24.1)	28 (15.6)	66 (36.9)
Total %	179 (100)	179 (100)	179 (100)

When SIMD scores are cross-tabulated with these ranked answers, we see some difference in the responses between women from different socio-economic groups.

If the respondents are divided by SIMD5, where the most deprived women are in groups 1-5 and the least deprived in groups 6-10, then there is a close-to significant difference in how the two groups rank the importance of the relief of menopausal symptoms. Table 4.12 shows a higher number of the least deprived women (35.1%), compared to 28.7% of the most deprived women rank relief of menopausal symptoms as most important (p .053). No statistical difference is seen in the way these two groups of women rank the importance of osteoporosis protection.

Table 4.12 Importance ranking of the relief of menopausal symptoms by deprivation score.

Importance of menopause symptoms	Most Deprived SIMD (1-5) n %	Least Deprived SIMD (6-10) n %	Total n %
1.Most important	29 (28.7)	27 (35.1)	56 (31.5)
1.5	10 (9.9)	2 (2.6)	12 (6.7)
2.Medium importance	31 (30.7)	33 (42.9)	64 (36.0)
2.5	3 (3.0)	0 (0)	3 (1.7)
3.Least important	28 (27.7)	15 (19.5)	43 (24.2)
Total	101 (100)	77 (100)	178 (100)

χ-square 9.331
p = 0.053

When the importance of cardiovascular protection is considered, there is a difference between the two groups of women. Of those most deprived, 20.6% ranked cardiovascular protection as most important, 33.3% as of medium importance, and 31.4% as of least importance. Those women who are least deprived appear to view the benefits differently. Only 9.1% consider cardiovascular protection as of most importance, 42.9% as of medium importance and 44.1% as of least importance. This is statistically significant (Table 4.13). This possibly may be explained by the

differences in perceived risk of a cardiovascular event, a possibility which will be considered in the discussion chapter to follow.

Table 4.13 The importance ranking of heart disease prevention by the achieved sample.

Importance of Heart Disease	Most Deprived (1-5) n	%	Least Deprived (6-10) n	%	Total n	%
1.Most important	21	(20.6)	7	(9.1)	28	(15.6)
1.5	8	(7.8)	0	(0)	8	(4.5)
2.Medium importance	34	(33.3)	33	(42.9)	67	(37.4)
2.5	7	(6.9)	3	(3.9)	10	(5.6)
3.Least important	32	(31.4)	34	(44.1)	66	(36.9)
Total	102	(100)	77	(100)	179	(100)

χ-square 13.446
$p < .01$

In conclusion, it may be said that there is a trend for women from less deprived backgrounds to be older at the time of hysterectomy than those from more deprived backgrounds. Although this is not evident in the achieved sample, the difference is statistically significant in the target sample. All women, regardless of background have the same discussions with their doctors, use the same information sources, and

have HRT offered to them. Women from less deprived backgrounds use HRT for longer and prescription charges do not influence the timing of discontinuance. The same reasons are given for discontinuance regardless of socio-economic group. There is some difference between socio-economic groups as to how risk-benefit is perceived.

4.3 Does the geographic location of the hospital in which the women were treated affect HRT use?

Are all women treated in the same way when comparing the two hospitals in the study? Obviously this question cannot be answered in simple terms, as there are many facets which need consideration. In each unit, different consultants and nursing teams care for patients, possibly in different ways. We now consider four differences, which might be apparent between the two units, in terms of what information the patient received, who gave it, and the timing of HRT prescription. We will also explore any individual or collective differences between consultants, as well as any possible gender differences.

4.3.1 Are there any differences between the two hospital units, in the information regarding HRT, given to patients?

It might be expected that there would be differences between the pre-operative consultations taking place in the different hospitals. This is considered because different consultants, who may differ in their information–giving in terms of detail and ease of understanding from the patient perspective, conduct the consultations.

One of the first questions in the questionnaire asked was: “was HRT was mentioned to you before you had the operation?” Table 4.14 shows that nearly three–quarters of the women who returned their questionnaires remember that HRT was a topic in their pre-operative discussion.

Table 4.14 Frequency of pre-operative discussion about HRT.

		Frequency	Percent
Valid	No	55	28.9
	Yes	129	67.9
	Total	184	96.8
Missing			
system		6	3.2
Total		190	100

When the 129 women who responded in the affirmative are differentiated by the hospital in which the operation took place, 75 cases were in treated in HB and 109 in HA. Cross tabulation shows HB with 72% of their patients being told about HRT prior to operation in comparison with 68.8% of patients in HA. This is not statistically significant.

So there is no difference between the two hospitals with respect to patient recollection of their pre-operative discussions about HRT.

Likewise, when considering information sources prior to surgery, there is no difference seen between units. Question 3 asked “who mentioned HRT before the operation?” 7.4% of women could not remember, 44.9% said that the hospital doctor had mentioned it, and only 16.9 % responded that their GP had counselled them.

However, 30.9% said that both the GP and the hospital doctor had discussed it with them. When this is examined in terms of unit attended, there is no difference between HA and HB. Although it would seem that HB GPs have a slightly higher proportion (21.8%) of their patients recalling a discussion prior to surgery compared with 13.6% for their HA counterparts, this difference is reduced if the number of women recalling GP input together with hospital doctor input is added together.

The questionnaire also asks whether or not symptoms of the menopause were mentioned and specifically if the benefits and side-effects associated with taking HRT were discussed (questions 4 and 5). When considering whether symptoms and benefits were mentioned, 66.7% of women recalled being told about the relief of menopausal symptoms (Table 4.15). 62.9% of women remember being told about osteoporosis prevention, (Table 4.16). 25.3% say they recall a discussion on cardiovascular protection (Table 4.17). Only 17.7% say that no benefits were mentioned.

When the units are compared, HA significantly tells more women about the symptoms of the menopause than does HB. Nearly three-quarters (73.6%) of HA patients recall the conversation, compared with 56.6% of HB patients (Table 4.15). This difference is seen again when considering whether osteoporosis prevention is mentioned (Table 4.16), and also if beneficial effects on the cardiovascular system are discussed (Table 4.17). The number of women being told about the possible beneficial effect of HRT on heart disease is much smaller than the numbers told of other benefits. This is presumably because that claim was disputed in the literature, and is now not thought to be of benefit. The number of women who state that they were not

told of any benefits of HRT is 11.8% of HA patients, and 26.3% of HB patients; this is also significant (Table 4.18).

There seems to be a difference then, between the two hospitals, in the amount of information being given to women regarding the benefits of HRT. HA provides information about the benefits of HRT to more women. The accuracy of data produced by recall however needs careful consideration.

Table 4.15 Frequency of recalled discussion about menopausal symptoms by location of treatment.

		HB n %	HA n %	Total n %
Menopausal symptoms mentioned	Not mentioned	33 (43.4)	29 (26.4)	62 (33.3)
	Yes, mentioned	43 (56.6)	81 (73.6)	124 (66.7)
Total		76 (100)	110 (100)	186 (100)

χ-square 5.885
$p < .05$

Table 4.16 Frequency of recalled discussion about osteoporosis by location of treatment.

		HB n %	HA n %	Total n %
Osteoporosis mentioned	Not mentioned	38 (50.0)	31 (28.2)	69 (37.1)
	Yes, mentioned	38 (50.0)	79 (71.8)	117 (62.9)
Total		76 (100)	110 (100)	186 (100)

χ-square 9.169
$p < .01$

Table 4.17 Frequency of recalled discussion about heart disease by location of treatment.

		HB n %	HA n %	Total n %
Prevents heart disease	Not mentioned	63 (82.9)	76 (69.1)	139 (74.7)
	Yes, mentioned	13 (17.1)	34 (30.9)	47 (25.3)
Total		76 (100)	110 (100)	186 (100)

χ-square 4.535
$p < .05$

Table 4.18 Frequency of no benefits of HRT being recalled by location of treatment.

		HB n %	HA n %	Total n %
No benefits mentioned	Benefits were mentioned	56 (73.7)	97 (88.2)	153 (82.3)
	Benefits were not mentioned	20 (26.3)	13 (11.8)	33 (17.7)
Total		76 (100)	110 (100)	186 (100)

χ-square 6.473
$p < .05$

Associated risks and side-effects of any medicine need careful consideration when a patient and her doctor are discussing long- term prescription. A total of 181 women answered the question about side-effects (9 cases were missing). It would seem that discussing risks is not done as effectively as discussing benefits. Table 4.19 shows 65.2% of all patients responded that no side effects of HRT were discussed with them.

Table 4.19 Frequency of side-effects not being discussed by location of treatment.

		HB n %	HA n %	Total n %
Side effects mentioned or NOT mentioned.	Side effects mentioned	20 (27.8)	43 (39.4)	63 (34.8)
	Side effects not mentioned	52 (72.2)	66 (60.6)	118 (65.2)
Total		72 (100)	109 (100)	181 (100)

χ-square 2.603
$p = 0.114$

Specifically, when asked if an increased risk of breast cancer was discussed, 69.1% of all patients answered negatively (Table 4.20). Meanwhile, Table 4.21 shows that 87.8% of all patients do not recall being told about increased risk of blood clots (DVT).

Table 4.20 Frequency of cancer risk being discussed by location of treatment.

		HB n %	HA n %	Total n %
Cancer side-effect mentioned	Not mentioned	53 (73.6)	72 (66.1)	125 (69.1)
	Yes, mentioned	19 (26.4)	37 (33.9)	56 (30.9)
Total		72 (100)	109 (100)	181 (100)

χ-square 1.159
p = 0.326

Table 4.21 Frequency of DVT risk being discussed by location of treatment

		HB	HA	Total
DVT risk discussed	Not discussed n % within unit	 65 90.3	 94 86.2	 159 87.8
	Yes, discussed n % within unit	 7 9.7	 15 13.8	 22 12.2
Total	n % within unit	72 100	109 100	181 100

χ-square .663
p = 0.491

It is clear that there is no difference between the individual units when discussing the possible side effects of HRT.

There is also no statistical difference seen between HB patients and HA patients in terms of where their information comes from - whether nurse, doctor or HRT pamphlet, (Tables 4.22, 4.23 and 4.24.) The nurses in HA are cited as a source of information more often than nurses in HB, but not significantly.

Table 4.22 Frequency of nurse cited as information source by location of treatment

		Nurse **not** mentioned as source n %	Nurse mentioned as source n %	Total N %
UNIT	HB	45 (63.4)	26 (36.6)	71 (100)
	HA	53 (54.6)	44 (45.4)	97 (100)
Total		98 (58.3)	70 (41.7)	168 (100)

χ-square 1.289
p = 0.272

Table 4.23 Frequency of doctor cited as information source by location of treatment.

		Doctor **not** mentioned as source n %	Doctor mentioned as source n %	Total n %
UNIT	HB	49 (69.0)	22 (31.0)	71 (100)
	HA	66 (68.0)	31 (32.0)	97 (100)
Total		115 (68.5)	53 (31.5)	168 (100)

χ-square .018
p = 1.000

Table 4.24 Frequency of pamphlet cited as information source by location of treatment.

		Pamphlet **not** mentioned as source n %	Pamphlet mentioned as source n %	Total n %
UNIT	HB	44 (62.0)	27 (38.0)	71 (100)
	HA	62 (63.9)	35 (36.1)	97 (100)
Total		106 (63.1)	62 (36.9)	168 (100)

χ-square .067
p = 0.872

4.3.2 Does the unit attended for treatment affect the uptake of HRT?

Moving on from the pre-operative consultation, the next two questions were designed to ascertain how many women leave hospital with a prescription for HRT. 187 women answered the question "were you offered HRT in hospital before you went home?" 89.3% said that they were, and 10.7% said that they were not.

Table 4.25 Frequency of HRT offered in hospital by location of treatment.

		HB n %	HA n %	Total n %
HRT offered in hospital	Not offered	7 (9.5)	13 (11.5)	20 (10.7)
	Yes, offered	67 (90.5)	100 (88.5)	167 (89.3)
Total		74 (100)	113 (100)	187 (100)

χ-square .196
p = 0.810

It would be usual practice to commence HRT in the early post- operative phase, providing no contraindications to such therapy had been found at the time of surgery. This is reflected in the figures above (Table 4.25).

Only 167 women answered the question as to whether they accepted that offer of HRT in hospital. This is because 20 cases had previously said that they had not been offered HRT and therefore the question was not applicable to them. 98.2% of 167 women accepted the offer of HRT (Table 4.26).

Table 4.26 Overall frequency of HRT acceptance whilst in hospital.

Accept HRT in hospital?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	3	1.6	1.8	1.8
	Yes	164	86.3	98.2	100.0
	Total	167	87.9	100.0	
Missing	N/A	20	10.5		
	System	3	1.6		
	Total	23	12.1		
Total		190	100.0		

HA and HB have similar percentages of women offered HRT whilst in hospital (Table 4.25), and of those who accept that offer (Table 4.27). Therefore it can be said that although women perhaps do not have an exhaustive explanation of the risk-benefit ratio of HRT prescription given by their Gynaecologist, the vast majority are content to commence therapy after their hysterectomy.

Table 4.27 Frequency of HRT acceptance whilst in hospital by location of treatment.

		HB n %	HA n %	Total n %
Accept HRT in hospital	No	2 (3.0)	1 (1.0)	3 (1.8)
	Yes	65 (97.0)	99 (99.0)	164 (98.2)
Total		67 (100)	100 (100)	167 (100)

χ-square .896
p = 0.565

Of the 163 women who responded to question 8, which asks about further discussion with the GP, 74.8% discussed HRT with their GP when their hospital prescription required renewing. Patients are encouraged to do this. The first form of medication may not be the most suitable, and another preparation may be more appropriate, or there may be transient side-effects, which will settle with perseverance. There is no association between which unit the operation took place in, and whether or not these women were more or less likely to speak to their GP (Table 4.28).

Table 4.28 Frequency of subsequent GP HRT discussions by location of treatment, if hospital had provided HRT.

		FDRI n %	SRI n %	Total n %
Discuss with GP if hospital provided	No	18 (27.7)	23 (23.5)	41 (25.2)
	Yes	47 (72.3)	75 (76.5)	122 (74.8)
Total		65 (100)	98 (100)	163 (100)

χ-square .370
p = 0.583

Twenty-four women did not have HRT prescribed in hospital. Nearly all these women discussed HRT with their GP after discharge from hospital (Table 4.29). All but one of them subsequently had it prescribed by their GP (Table 4.30). Where the operation took place has no effect on this, and GP's referring to HA, are just as likely to discuss HRT, and prescribe it for these women, as their HB counterparts (Table 4.29 and Table 4.30).

Table 4.29 Frequency of subsequent GP HRT discussions by location of treatment, if hospital had not provided HRT

		HB n %	HA n %	Total n %
Discuss with GP if hospital did not provide	No	2 (20.0)	0 (0.0)	2 (8.3)
	Yes	8 (80.0)	14 (100)	22 (91.7)
Total		10 (100)	14 (100)	24 (100)

χ-square 3.055
p = 0.163

Table 4.30 Frequency of GP prescribed HRT by location of treatment.

		HB n %	HA n %	Total n %
GP prescribed if hospital did not prescribe	No	0 (0)	1 (7.1)	1 (4.2)
	Yes	10 (100)	13 (92.9)	23 (95.8)
Total		10 (100)	14 (100)	24 (100)

χ-square .745
p = 1.0

As would be expected then, the majority of women in the study left hospital with a prescription for HRT. Those women who did not subsequently consulted their GP, who then prescribed it for almost all of them. This may be explained in that on occasion it is necessary to wait for definitive histology results before prescribing HRT. Once these are known, and HRT can be safely prescribed, the patient may already be at home and in the care of her GP.

4.3.3 Does the individual consultant in charge of care affect HRT use?

It may be assumed that different consultant Gynaecologists have different views when deciding at what age a hysterectomy is the treatment suitable for their patient. The age of the patient will affect HRT use. From the data collected, it appears that the average age at operation does vary between consultants.

Using data from the achieved sample, two consultants appear to operate on slightly younger women. Consultant H operates on women with an average age of 42.58 years and Consultant D on women with an average age of 42.44years. Other consultants operate on women at an average age of between 43.00 years and 46.80 years (Table 4.31).

Table 4.31 Mean patient age at time of operation by consultant.

Consultant	Mean Age	n	Std.Deviation
A	45.05	20	4.019
B	43.35	20	4.522
C	46.8	5	2.280
D	42.44	16	3.076
E	46.67	12	3.774
F	43.00	4	4.320
G	45.71	21	3.481
H	42.58	52	5.203
I	43.64	14	4.088
J	43.92	12	3.579
Other	44.21	14	5.409
	43.92	190	4.484

Table 4.32 illustrates that consultant H operates at a significantly younger age than do his colleagues.

Table 4.32 Mean age at time of operation of patients treated by consultant H, compared to patients treated by other consultants.

		n	Mean age	Std. Deviation
Age of patient at operation	Consultant H	52	42.58	5.203
	All others	138	44.42	4.088

t-value -2.564
$p < .05$

When consultant H and consultant D are compared (together) against their colleagues, the difference becomes even more significant ($p < .001$). The mean age of their patients at operation is 42.54 years compared to the mean age of their colleagues' patients is 44.68 years (Table 4.33).

Table 4.33 Mean age at time of operation of patients treated by consultants H and D combined, compared to patients treated by other consultants.

		n	Mean	Std. Deviation
Age of patient at operation	Consultants H and D	68	42.54	4.768
	All others	122	44.68	4.143

t-value -3.226
$p < .001$

When the target population (n=306) is examined in Table 34, the same trend is seen, suggesting that this is a real phenomenon, not just an artefact of the achieved sample. Consultant's D and H together operated on 127 women with an average age of 42.67 years, which is significantly younger than the women treated by the other consultants.

Table 4.34 Mean age at time of operation of patients in the target sample treated by consultants H and D combined, compared to patients treated by other consultants.

		n	Mean	Std Deviation
Age of patient at operation	Consultants H and D	127	42.67	4.590
	All others	179	44.08	4.672

t-value -2.618
$p < .01$

It is of note that one of these consultants worked in HA and the other in HB; thus both hospitals had one consultant operating on slightly younger women. It is also interesting that this finding appears to be linked personally with these two consultants, and is not based on their gender.

Looking again at the target population (n = 284, because 22 procedures were performed by locum consultants whose gender is not known), it was found that male consultants operate on women with an average age of 43.49 years. Their female colleagues operate at an average age of 43.6 years, a difference that is not statistically significant. The average age of patients undergoing hysterectomy who returned their questionnaires is slightly older. For those in the care of male consultants the mean is 43.57 years, and for those in the care of female consultant gynaecologists the mean is 44.77 years. This is also not a statistically significant difference. So it is the individual consultant gynaecologist, rather than the gender of the gynaecologist, that appears to be associated with the age of the patient at time of operation.

The source of any information given to patients will probably have an effect on how well that information is understood and remembered. It is still probably true to say that many patients are happy to comply with treatment, purely on the basis that it is what is recommended by their doctor. There has been much discussion in the press concerning the safety of HRT in recent years. This has made women more aware of the possible side–effects of treatment and the new advice given to women in terms of how long treatment should continue. The women in this study were treated before the results of the American Women's Health Initiative were published in the national press, and therefore their responses may not reflect the impact of these findings.

When asked "who" or "what" was the major source of information regarding the taking of HRT, 182 women responded. 30.8% of women said that the doctor was their main source of information in hospital, whilst 31.9% chose the nurse and 28% the HRT pamphlet. Combinations of doctor-plus-pamphlet and nurse-plus-pamphlet account for the remaining 9.3% of cases. It has to be said, at this point, that although respondents were asked to choose just one source, the answers obtained often included more than one choice. The data has been analysed accordingly. If a respondent had indicated that the source of information was both the doctor and a pamphlet, then the answer was included in both categories.

When the doctor, nurse and HRT pamphlet input are considered in terms of a collective approach, then the figures change slightly. Looking at whether the doctor is mentioned as a source of information, either alone or in conjunction with the other sources, then 34.6% of women respond in the affirmative (Table 4.35). 39% of women recall the nurses, either alone or with other sources, as the supplier of

information (Table 4.36) and 36.8% remember an HRT pamphlet (Table 4.37). It is clear, then, that nurses are an important source of information, and that information pamphlets are useful.

When individual consultants are considered in relation to which sources of information their patients cite, some individual differences emerge. The number of patients recalling the doctor as a source of HRT information ranges from just 9.1% to 60%. Only 9.1% of Consultant E's patients mention the doctor as a source (Table 4.35), but 90.9% of these same patients say that they obtained information from an HRT pamphlet (Table 4.37). Consultant C mentions HRT to 60% (Table 4.35) of patients and none of these patients cite a pamphlet as a source of information. However, 40% mention the nurse as a source (Table 4.36). Twenty-five percent of consultant F's patients mention the doctor as a source, 50% mention the nurse, and 25% the HRT pamphlet. Consultant G's patients recall the nurse as the main source of information (61.9%), while 19% mention the doctor and 28.6% the pamphlet. Likewise 63.6% of patients under the care of consultant J also mention the nurse. The women in the care of consultant H obtain information from all three sources in roughly the same proportions, doctor 38%, nurse 38% and HRT pamphlet 36%. The use of the HRT pamphlet as a source of information is shown to be significantly different by consultant (Table 4.37), whereas whether or not the doctor or the nurse is mentioned displays individual differences but no statistical difference. So some consultants use pamphlets more than others to relay information to their patients, again displaying differences of an individual nature.

Table 4.35 Frequency of doctor cited as source of HRT information by consultant providing care.

Consultant	Doctor not cited		Doctor cited		Total	
	n	%	n	%	n	%
A	14	(73.7)	5	(26.3)	19	(100)
B	12	(66.7)	6	(33.3)	18	(100)
C	2	(40.0)	3	(60.0)	5	(100)
D	9	(60.0)	6	(40.0)	15	(100)
E	10	(90.9)	1	(9.1)	11	(100)
F	3	(75.0)	1	(25.0)	4	(100)
G	17	(81.0)	4	(19.0)	21	(100)
H	31	(62.0)	19	(38.0)	50	(100)
I	9	(64.3)	5	(35.7)	14	(100)
J	8	(72.7)	3	(27.3)	11	(100)
Other	4	(28.6)	10	(71.4)	14	(100)
Total	119	(65.4)	63	(34.6)	182	(100)

χ -square 16.691
$p = 0.081$

Table 4.36 Frequency of nurse cited as source of HRT information by consultant providing care.

Consultant	Nurse not cited n	%	Nurse cited n	%	Total n	%
A	10	(52.6)	9	(47.4)	19	(100)
B	12	(66.7)	6	(33.3)	18	(100)
C	3	(60.0)	2	(40.0)	5	(100)
D	11	(73.3)	4	(26.7)	15	(100)
E	8	(72.7)	3	(27.3)	11	(100)
F	2	(50.0)	2	(50.0)	4	(100)
G	8	(38.1)	13	(61.9)	21	(100)
H	31	(62.0)	19	(38.0)	50	(100)
I	9	(64.3)	5	(35.7)	14	(100)
J	4	(36.4)	7	(63.6)	11	(100)
Other	13	(92.9)	1	(7.1)	14	(100)
Total % within consult	111	(61.0)	71	(39.0)	182	(100)

χ -square 16.096
p = 0.097

Table 4.37 Frequency of pamphlet cited as source of HRT information by consultant providing care.

Consultant	Pamphlet not cited n %	Pamphlet cited n %	Total n %
A	14 (73.7)	26.3% (5)	19 (100)
B	11 (61.1)	38.9% (7)	18 (100)
C	5 (100)	0.0% (0)	5 (100)
D	10 (66.7)	33.3% (5)	15 (100)
E	1 (9.1)	90.0% (10)	11 (100)
F	3 (75.0)	25.0% (1)	4 (100)
G	15 (71.4)	28.6% (6)	21 (100)
H	32 (64.0)	36.0% (18)	50 (100)
I	8 (57.1)	42.9% (6)	14 (100)
J	7 (63.6)	36.4% (4)	11 (100)
Other	9 (64.3)	35.7% (5)	14 (100)
Total	115 (63.2)	36.8% (67)	182 (100)

χ -square 18.859
$p < .05$

If the individual consultants are considered in terms of whether their patients recall being told about HRT prior to surgery, individual differences are seen. There is a range of between 60.0% and 100% of patients confirming that pre-operative discussions about HRT took place. Some consultants seem to be most effective in giving this information, with an overall total of 70.1% of all patients recalling these discussions. However there is no statistical evidence to suggest that some consultants

are better than others at delivering information, or that their patients are better than others at recalling such information are. Likewise, there is no statistical difference between individual consultants in the length of time their patients expect HRT treatment to last.

It would seem, then, that there are some differences in how different consultants relay information to their patients - or at least how it is recalled by their patients - but that whatever strategies are used they are equally effective.

4.3.4 Does the gender of the consultant in charge of care influence HRT use?

If the consultants are divided by gender, it is seen that male consultants operated on 125 patients whilst the female consultants operated on 45 patients. 14 cases were lost for statistical analysis, as locum consultants whose gender could not be determined had performed the operations. There is no association between the gender of consultant and whether or not they discussed HRT prior to surgery. 66.4% of male consultants and 75.6% of female consultants have this conversation with their patients but the difference is not significant. Therefore, neither the different consultants nor the gender of the consultant affects whether or not HRT is mentioned prior to surgery. As stated previously gender is not implicated in the slightly earlier age at which two consultants operate.

There is also no association between the gender of the consultant seen in hospital and whether or not the patient recalls who, out of a choice of hospital doctor, GP or both, provided a pre-operative discussion about HRT (there is no data collected on the gender of the G.P consulted).

When the gender of the individual consultant is considered, it is seen that there is no association with whether or not the patient is told about symptoms of the menopause or about osteoporosis prevention. Likewise, the gender of the individual consultant seen is not associated with whether or nor cancer risk is discussed or if DVT risk is mentioned. The figurers for no side effects being mentioned are identical for both male and female consultants at 65.9%.

If, as reported by Hall and Roter (1988), the recall of information by patients is associated with female physicians, then the gender of the consultant may affect the way that information is given to patients. This does not appear to be the case in the present study. Of the 168 valid responses (14 cases removed as gender of consultant not known) 32.5% of women in the care of male consultants and 28.9% of women in the care of female consultants, cited the doctor as a source of HRT information. The number of women citing the nurse as a source of information is equally close, with 41.5% of the male consultants' patients and 42.2% of the female consultants' patients responding in this way. It appears that the female consultants use an HRT pamphlet more often than their male colleagues. Nearly forty- seven percent (46.7%) of women in the care of a female consultant mentioned an HRT pamphlet as a source compared with 33.3% of those women cared for by a male consultant. This however is not statistically significant.

The gender of the hospital consultant is not associated with whether or not a woman is offered HRT whilst in hospital, or whether the offer is accepted. Nor is it associated with the length of time women expected to take HRT for. Likewise, the patients of

female consultants are no more likely than those of male consultants, to discuss HRT with their GP when their prescription needed renewal. Of the small number of women who did not have HRT commenced in hospital (n =24), most, as previously mentioned, had it prescribed by their GP. This prescribing is not influenced by the gender of the consultant in charge of their hospital patient care. There is no association between the gender of consultant and whether or not this particular group of women speak to their GPs.

We have examined the data collected in this study, in terms of " outside influences" on women's HRT decisions. That is to say how the individual consultant or unit attended might affect patient choice. We now consider the possible inherent differences in the women in the study in terms of age and previous HRT experience.

4.4 How do inherent differences in the study population, in terms of patient age and prior use of HRT, affect HRT use after hysterectomy?

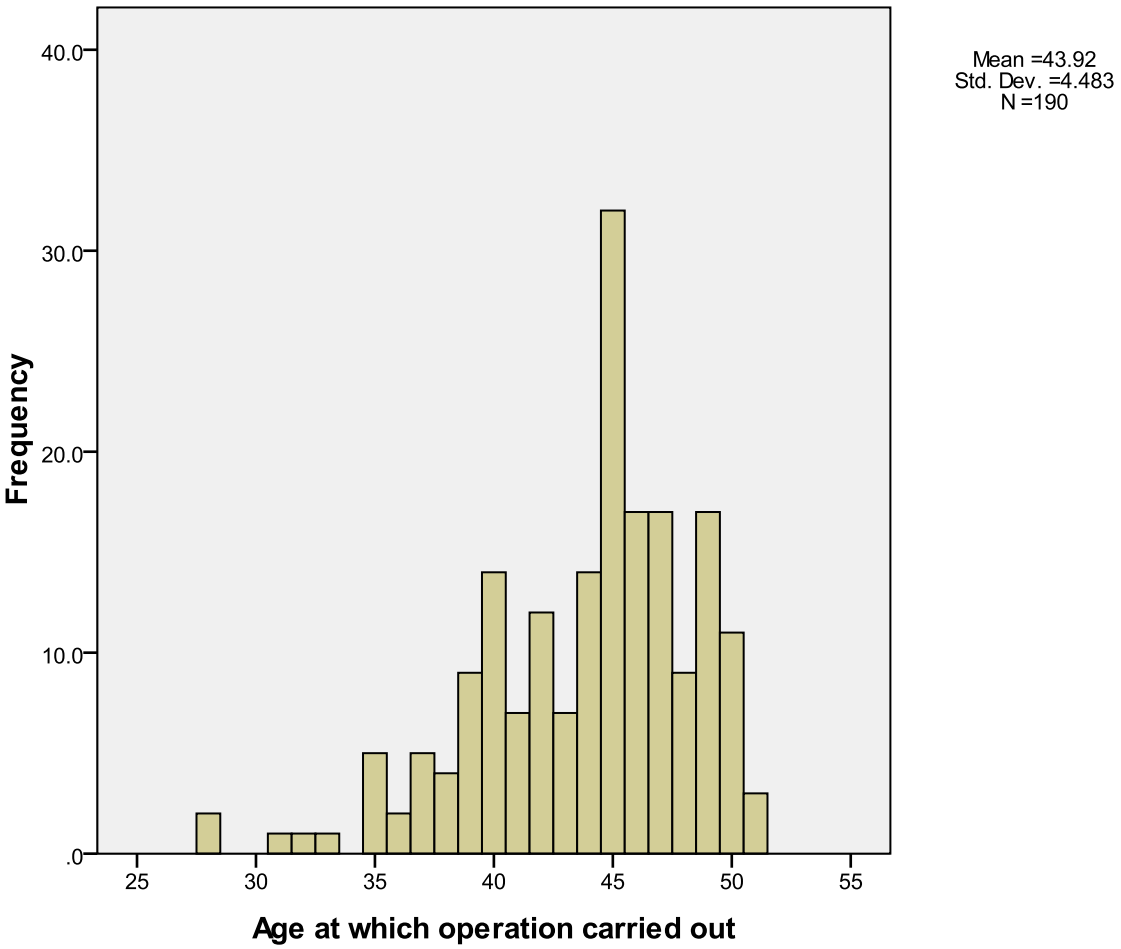
4.4.1 Age at time of operation

The mean age at the time of operation is 43.92 years, the youngest woman being 28 years old and the eldest woman 51 years old (the upper age limit for the study).

It can be seen in figure 3 below, that the age of operation increases gradually, peaking at age 45, then declining to 51 years. This would be expected, as surgeons would be reluctant to perform this operation in younger women without very specific reason. Most women will have completed their families by their 40s and be entering the perimenopausal phase of their lives by their late 40s. It would be reasonable to suggest that women in their mid-to-late 40s who experienced menorrhagia would be

suitable for hysterectomy, and would therefore choose this option with the support of their Gynaecologist.

Figure 4.3 Frequency distribution of patient age at time of operation.



There is little difference between the mean ages at operation between the two units. The average age at operation in HA cases 43.65 years, and in HB cases 44.32 years. This is not significant.

The age of the patient is not associated with the source of their information. No age differences are found, in the use of doctor, nurse or HRT pamphlet.

Part of the discussion surrounding HRT prescription is the length of time the patient should expect to take the preparation for. 183 women answered the relevant question. The majority of women, 112 cases, expected to take HRT for more than 7 years (Table 4.38). This is linked to the age of the women at the time of their operation and, as expected, the younger women expected to take HRT for a longer time (Table 4.39).

Table 4.38 Expected duration of HRT use

How long expect to take HRT	Frequency	Percent	Valid percent
Less than 1 yr	5	2.6	2.7
1-5 years	35	18.4	19.1
5-7 years	31	16.3	16.9
More than 7 yr	112	58.9	61.2
Total	183	96.3	100.0
Missing	7	3.7	
Total	190	100.0	

Table 4.39 Increasing expected duration of HRT use and decreasing mean age of women at time of operation.

How long expect to take HRT	Mean age at operation	n	Std.Deviation
Less than 1 yr	46.60	5	2.702
1-5 yrs	45.17	35	3.374
5-7yrs	44.97	31	4.363
More than 7 yrs	42.95	112	4.717
Total	43.81	183	4.500

If the women are divided into two groups, those who expect to take HRT for up to 7 years (mean age 45.18), and those who expect to take for more than 7 years (mean age 42.95), a statistical difference in the mean age is found. In both groups, the taking of HRT for the expected time would take the patient up to around the natural age of menopause at 51 years (Table 4.40).

Table 4.40 Mean age of women taking HRT for up to 7 years and for more than 7 years.

How long expect to take HRT	n	Mean age at operation	Std.Deviation
Up to 7 years	71	45.18	3.777
More than 7 years	112	42.95	4.717

t-value 3.368
$p < .001$

There is no evidence that women having their operations in the later 1990s/2000 expected to take HRT for a shorter duration, which would be a predicted result as these women were treated prior to the publication of the Women's Health Initiative study.

It may be expected that, if a woman had taken HRT prior to her operation, this may influence her response when asked how long she expected to take it for. Table 4.41 shows that women who take HRT prior to surgery are significantly older than women who do not.

Table 4.41 Mean age at time of operation of women who have taken HRT prior to surgery and those who have not.

Age at operation	n	Mean age at operation	Std.Deviation
Taken HRT before operation	31	46.13	3.649
Not taken HRT before operation	157	43.50	4.533

t-value 3.035
p <. 01

One would assume that, as older women, the pre-operative users should expect to take HRT for a shorter time. This, however, does not seem to be the case. The data shows that the majority (67.9%) of those women who had taken HRT before their operation still expect to take it for more than 7 years. This is not statistically significant because 59.7% of women who had not taken HRT prior to surgery also expected to take HRT for more than 7 years, (Table 4.42).

Table 4.42 Cross tabulation of expected duration of HRT use of up to, or beyond 7 years and prior use of HRT.

Expected duration of HRT use	Not taken HRT before operation		Taken HRT before operation		Total	
	n	%	n	%	n	%
Up to 7 years	62	(40.3)	9	(32.1)	71	(39.0)
More than 7 years	92	(59.7)	19	(67.9)	111	(61.0)
Total	154	(100)	28	(100)	182	(100)

χ -square .656
p = 0.529

The purpose of question 12 in the questionnaire was to determine for how long *after* their operation the women expected to take HRT. It is possible that this question was not sufficiently clearly specified, and therefore difficult to interpret. It is also possible that, at the time of this study, women were actually expecting to take post-operative HRT for a longer duration than is now currently recommended, regardless of their age.

4.4.2 Prior use of HRT and duration of therapy

Most women have not taken HRT prior to their operation (83.1%). Of those 16.9% who have taken HRT before, most are over 45 years old. Only 8.4% of women aged up to 44 years had taken HRT before, while 23.6% of women aged 45 years and older had done so. Table 4.43 again demonstrates a relationship between increasing age and pre-operative HRT use, which is expected.

Table 4.43 Cross tabulation of age band up to 44yrs and over 45 yrs with prior use of HRT.

Age band at operation	Not taken HRT before operation n %	Taken HRT before operation n %	Total n %
Up to 44 years	76 (91.6)	7 (8.4)	83 (100)
45 years plus	81 (76.4)	25 (23.6)	106 (100)
Total	157 (83.1)	32 (16.9)	189 (100)

χ -square 7.598
$p < .01$

There is little association between prior HRT use and women's expected duration of use. Of those aged under 45 years who had not taken HRT before, 72.4% expected to take HRT for more than 7 years, while only 47.4% of the over 45 year-olds did. Similarly 83.3% of the younger women who had taken HRT prior to surgery expected to take HRT for more than 7 years. This confirms that younger women expect to take therapy for longer. However, 63.6% of those women who had taken HRT prior to surgery and were over 45 years old also expected to take HRT for over 7 years (Table 4.44), perhaps reflecting the longer use of HRT recommended by doctors at the time of these operations.

Table 4.44 Cross tabulation of age band, and pre-operative HRT use with expected duration of post-operative HRT.

Taken HRT before	Expect to take < 1 yr n %	Expect to take 1-5 yrs n %	Expect to take 5-7 yrs n %	Expect to take > 7 yrs n %	Total n %
No					
Up to 44	1 (1.3)	10 (13.2)	10 (13.2)	55 (72.4)	76 (100)
45 plus	2 (2.6)	21 (26.9)	18 (23.1)	37 (47.4)	78 (100)
Total	3 (1.9)	31 (20.1)	28 (18.2)	92 (59.7)	154 (100)
Yes					
Up to 44	0 (0)	1 (16.7)	0 (0)	5 (83.3)	6 (100)
45 plus	2 (9.1)	3 (13.6)	3 (13.6)	14 (63.6)	22 (100)
Total	2 (7.1)	4 (14.3)	3 (10.7)	19 (67.9)	28 (100)

HRT before No χ -square 10.020 $p < .05$

HRT before Yes χ -square 1.663 $p = 0 .645$

The findings above perhaps give evidence of a flawed question, compounded by the small case numbers in the study. It is impossible to know whether the older pre-operative users actually did expect to take HRT well into their fifties, or whether they

have added their preoperative treatment time into their calculated expectation of therapy duration. Today, it would be expected that the older women would anticipate a shorter time of HRT therapy after their operation; but this is not seen in this study.

In general, most of the women in this study expect to take HRT for more than 7 years, which may be a reflection of the advice they received at the time of their surgery. As previously mentioned, neither the individual consultant who cares for them nor the gender of that consultant, influences this.

Of the 32 women who had taken HRT before their operation, only 30 disclosed the length of time they had taken it for. The time taken ranges from 2 to144 months. 86.7% of women had taken it for 45 months or less. The ages of the 4 women who had taken HRT for 5 years or longer ranged from 45 to 50 years old. The woman who said she had used HRT for 144 months prior to surgery was 48 years old at the time of operation, which means she was 36 years old at the time of commencement of therapy. This is unusual, in that she must have taken HRT for some twelve years pre-operatively, and then had a hysterectomy for menorrhagia. This may perhaps indicate a coding problem with the diagnosis code which defined inclusion in the study or, more likely, that there has been some ambiguous interpretation of the question.

When asked if they were still taking HRT, 107 women (56.3%) said that they were. These numbers are obviously from the returned sample and not just the women who had taken HRT prior to surgery. The length of time taken ranges from 18 to 192 months. The woman who reports 192 months of therapy is the same woman who reported 144 months of therapy pre-operatively. Over three-quarters (77.6%) of

women had taken therapy for up to 10 years. This is probably a reflection on the timing of this investigation.

When the source of the prescription is analysed, it is seen that the hospital prescribed medication is taken for an average of 88.46 months, whilst the GP-prescribed HRT averages 101.55 months. This is not a significant difference, and the numbers of GP-prescribed first prescriptions is small (n = 11). Although it would seem that primary care medication is taken for longer duration this can be explained: it is the primary care prescriber who manages the patient once she is no longer under the care of the hospital consultant.

4.4.3 Does taking HRT prior to operation affect the recollection of HRT discussions at time of hysterectomy?

It might be supposed that, had a woman taken HRT before her surgery, she would recall the earlier consultation concerning this prescription more fully than the discussions in hospital post-operatively. The discussions with women who have previously taken HRT concern the difference in preparation required after oophorectomy, rather than detailing of risks and benefits. The side-effects of treatment should have been detailed in previous consultations. Of the 20 women who said that they were not offered HRT while in hospital only 6 (30%) had taken HRT prior to their surgery. HRT taking prior to surgery does not negatively influence the offer of HRT post-operatively (Table 4.45). There must be some other explanation for why these women do not recall the offer or were not offered HRT whilst in hospital.

Table 4.45 Cross tabulation of pre-operative HRT use and recalled offer of post-operative HRT.

		Not taken before surgery	Taken before surgery	Total
HRT offered in hospital	**No**			
	n	14	6	20
	% within HRT offered in hospital	(70.0)	(30.0)	(100)
	%within Taken HRT before op	(9.0)	(20.0)	(10.8)
	Yes			
	n	142	24	166
	% within HRT offered in hospital	(85.5)	(14.5)	(100)
	%within Taken HRT before op	(91.0)	(80.0)	(89.2)
Total	n	156	30	186
	% within HRT offered in hospital	(83.9)	(16.1)	(100)
	% within Taken HRT before op	(100)	(100)	(100)

χ-square 3.187
p = 0.102

Of the 30 women who had used pre-operative HRT and revealed the source of their information about HRT, the doctor is cited as a source by 43.3% of them. The nurse by 33.3%, and an HRT pamphlet by 36.7%. The women who had not taken HRT prior to their operation surprisingly mention the doctor as a source in fewer numbers. Only 33.1% cite the doctor as a source, 40.4% mention the nurse, and 36.4% an HRT pamphlet, (Tables 4.46, 4.47 and 4.48).

Table 4.46 Cross tabulation of pre-operative HRT use, with the doctor cited as a source of HRT information.

Taken HRT before operation	Doctor not mentioned	Doctor mentioned as source	Total
No			
n	101	50	151
% within taken before operation	(66.9)	(33.1)	(100)
Yes			
n	17	13	30
% within taken before operation	(56.7)	(43.3)	(100)
Total			
n	118	63	181
% within taken before operation	(65.2)	(34.8)	(100)

χ-square 1.152
p =0.300

Table 4.47 Cross tabulation of pre-operative HRT use, with the nurse cited as a source of HRT information.

Taken HRT before operation	Nurse not mentioned	Nurse mentioned as source	Total
No			
n	90	61	151
% within taken before operation	(59.6)	(40.4)	(100)
Yes			
n	20	10	30
% within taken before operation	(66.7)	(33.3)	(100)
Total			
n	110	71	181
% within taken before operation	(60.8)	(39.2)	(100)

χ-square .524
p = 0.543

Table 4.48 Cross tabulation of pre-operative HRT use, with pamphlet cited as a source of HRT information.

Taken HRT before operation	Pamphlet not mentioned	Pamphlet mentioned as source	Total
No			
n	96	55	151
% within taken before operation	(63.6)	(36.4)	(100)
Yes			
n	19	11	30
% within taken before operation	(63.3)	(36.7)	(100)
Total			
n	115	66	181
% within taken before operation	(63.5)	(36.5)	(100)

χ-square .001
p = 1.000

Although these differences are not significant, they are interesting. It might be expected that women receiving HRT for the first time would have longer and more memorable discussions with their hospital doctor, but this does not seem to be the case. They do, however mention the nurse in higher numbers. It may be supposed that those women who had taken HRT prior to their operation would have a clearer understanding of the principles of HRT, having discussed this with their GP at the time of prescription. This may mean that they need less information, and that the nurse cannot give the information they need - such as preparation changes - adequately. Although the study questionnaire specifically asks about the source of information in hospital, it may be that women who take HRT prior to operation remember a doctor as the source, and perhaps have less recollection of where these discussions took place. It is clear that HRT literature is used equally by both groups of women.

In the following and final section, we will consider what the study can tell us about the information women receive (according to their own reports), about HRT, and the timing of discontinuance, together with the reasons they give for stopping treatment.

4.5 Is patient information satisfactory?

If we accept that satisfactory information received by the patient, and the confidence women have in the source of such information, are paramount in their decision making process, then it is encouraging to see that the majority of women (98.2%) accept HRT when it is offered in hospital (Table 4.26). However, when asked if they had sufficient information before leaving hospital to make their decision, only 61.1% of women said that they had. Of the women who chose not to accept the offer of HRT (only three cases), two said that they had sufficient information (Table 4.49). That there were so few of these women makes it difficult to draw a conclusion here; but it might be said that, overall, the level of satisfactory information- giving needs to be improved.

Of the women who said that they *did not* have sufficient information, 37.4% still accepted HRT (61 cases).

This means that over one third of hospital patients accepted a prescription for HRT without feeling that they had sufficient information to make such a decision.

Table 4.49 Cross tabulation of HRT offered in hospital with sufficient information given.

INHOSP * Before home from hospital, enough info Crosstabulation

			Before home from hospital, enough info		
			No	Yes	Total
INHOSP	Offered, but not accepted	Count	1	2	3
		% within INHOSP	33.3%	66.7%	100.0%
	Offered and accepted	Count	61	102	163
		% within INHOSP	37.4%	62.6%	100.0%
	Not offered	Count	10	9	19
		% within INHOSP	52.6%	47.4%	100.0%
Total		Count	72	113	185
		% within INHOSP	38.9%	61.1%	100.0%

χ-square 1.696
p = 0 .428

Of the women for whom the hospital did not prescribe HRT (n=24), 91.7% discussed HRT with their GPs, who prescribed for all but one case. Slightly more than half (54.5%) of these women felt that they did not have sufficient information given to them in hospital. Again, the numbers are small, and no statistical significance can be attributed.

When benefits of treatment are considered it would be expected that, if the perceived benefits outweighed the side–effects of such treatment then therapy would continue for a longer period of time. Of the 180 cases that answered both questions 16 and 21, 103 were still taking HRT and 77 were not. 98.6% of those who were still taking thought that the benefits of treatment outweighed the side – effects, fewer than 2% did not agree. More than half (53.25%) of those who had stopped therapy also agreed that benefits outweighed side -effects. This could be explained by the fact that some of the women in this study might have been advised to cease therapy for reasons other than side –effects, such as lengthy duration of treatment. However, those women who

continue to take HRT are of the opinion that the benefits of treatment offset the side–effects (Table 4.50).

Table 4.50 Cross tabulation of benefits of HRT use with continued or discontinued use.

Still taking HRT?	**No** Benefits do **not** outweigh side-effects		**Yes** Benefits do outweigh side-effects		Total	
	n	%	n	%	n	%
No	36	(46.8)	41	(53.2)	77	(100)
Yes	2	(1.95)	101	(98.05)	103	(100)
Total	38	(21.1)	142	(78.9)	180	(100)

χ-square 53.126
p .000

When asked if, before they left hospital, they had sufficient information regarding HRT, 110 out of 180 (61.1%) patients said that they did. Of those women who mentioned the doctor as a source, 77.8% say that they had sufficient information, (Table 4.51), whereas only 60.6% of women who mention the nurse as a source say that they had sufficient information (Table 4.52). The statistical analysis shows that a significant number of the women who had enough information cited the doctor as a source; but the nurse input is not significant. When HRT pamphlets are considered (Table 4.53), 52.3% of those women who had enough information mentioned the pamphlet as a source. This is a disappointing result from a nursing perspective. Nurses see health education, information giving and patient choice as an integral part of their role. However, in this study there is no real evidence that this is occurring in relation to HRT prescription.

Table 4.51 Cross tabulation of sufficient information given and doctor cited as a source of HRT information.

Before home from hospital, enough information?	Doctor **not** cited as source		Doctor cited as source		Total	
	n	%	n	%	n	%
No	56	(47.9)	14	(22.2)	70	(38.9)
Yes	61	(52.1)	49	(77.8)	110	(61.1)
Total	117	(100)	63	(100)	180	(100)

χ-square 11.329
$p < .001$

Table 4.52 Cross tabulation of sufficient information given and nurse cited as source of HRT information.

Before home from hospital, enough information?	Nurse **not** cited as source		Nurse cited as source		Total	
	n	%	n	%	n	%
No	42	(38.5)	28	(39.4)	70	(38.9)
Yes	67	(61.5)	43	(60.6)	110	(61.1)
Total	109	(100)	71	(100)	180	(100)

χ-square .015
$p = 1.000$

Table 4.53 Cross tabulation of sufficient information given and pamphlet cited as source of HRT information.

Before home from hospital, enough information?	Pamphlet **not** cited as source n	%	Pamphlet cited as source n	%	Total n	%
No	39	(33.9)	31	(47.7)	70	(38.9)
Yes	76	(66.1)	34	(52.3)	110	(61.1)
Total	115	(100)	65	(100)	180	(100)

χ-square 3.318
p = 0.081

4.6.When do women stop HRT therapy?

When those women who had stopped taking HRT are examined, it transpires that 80 women stopped at periods of between two months and more than 10 years after starting it. The most (n = 31) stopped after taking treatment for between 7 and 10 years. Nine women ceased treatment within one year of starting, and 37 women had stopped within 5 years. Over half the women (43) women took HRT for more than 5 years, and one woman for more than 10 years (Table 4.54).

If, then, we consider that 38.8% of those women who had stopped therapy, did so at between 7 and 10 years of HRT use, this is a slightly longer duration of treatment than is currently recommended. This might be thought to be related to the age of the patient at the time of operation. However, if the mean age is calculated for those women ceasing therapy at the intervals given on the questionnaire, there is no association between age and when therapy is ceased. The mean age of women taking HRT for up to 3 years is 44.0years, and for those taking it for more than 3 years it is

45.16 years. It would be expected that the older the patient is at the time of hysterectomy then the shorter the duration of post-operative HRT therapy. However, this is not statistically demonstrated in the present study, possibly owing to the small number of cases stopping in the early post-operative period.

Table 4.54 Duration of HRT use with stopping times.

If stopped, when

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Less than 3 months	2	1.1	2.5	2.5
	3-6 months	3	1.6	3.8	6.3
	6 months to a year	4	2.1	5.0	11.3
	1-2 years	8	4.2	10.0	21.3
	2-3 years	7	3.7	8.8	30.0
	3-5 years	13	6.8	16.3	46.3
	5-7 years	11	5.8	13.8	60.0
	7-10 years	31	16.3	38.8	98.8
	more than 10	1	.5	1.3	100.0
	Total	80	42.1	100.0	
Missing	n/a	108	56.8		
	System	2	1.1		
	Total	110	57.9		
Total		190	100.0		

4.7 Why do women stop HRT therapy?

The main reasons for stopping were examined, and over a quarter (26.6%) said that the main reason was the advice of the doctor. Side–effects of treatment led to discontinuance in 21.5% of women, and 13.9% of women thought that they had taken it for long enough. When the advice of the doctor, the patient's feeling that they had taken it for long enough, and side effects are combined then discontinuance is explained for 72.2% of women. As previously indicated, there is no association between socio-economic group and the reasons given for discontinuance.

If the respondents are classified by whether they stopped therapy at up to, or after, 5 years, then a difference is seen in the reasons given for stopping. In those women who stopped therapy at any time up to 5 years, the most common reason given for their discontinuance was side-effects (36.1%), and not liking the idea of hormones in a further 11.1%. In those women who stopped after 5 years, the most common reason was the advice of their doctor (35.7%); a further 23.8% said that they felt that they had taken treatment for long enough. Only 9.5% of the later discontinuers cited side-effects as their reason. This is significant in statistical terms (Table 4.55). This can be explained in one or both of two ways. First, those women troubled by the side-effects of treatment would be expected to stop therapy before those who were unaffected. Second, doctors would be more likely to recommend ceasing treatment once patients had taken HRT for a longer period of time.

If there was some further reason for stopping therapy out with the given choices on the questionnaire, women were asked to state that reason. Most (68.4%) gave no further reason. The additional reasons, when given, were varied, including the development of breast lumps (2.5%), diagnosed with breast cancer (1.3%), breast tenderness (1.3%), migraine headaches (1.3%), worries about cancer and DVT risk (1.3%) and the effect of the media (3.8%).

Table 4.55 Main reasons for stopping HRT at up to 5 yrs and after 5 yrs use.

Main reason for stopping (% within when stop)	Stopped up to 5 years		Stopped after 5 years		Total	
	n	%	n	%	n	%
Doctor's advice	6	(16.7)	15	(35.7)	21	(26.9)
Didn't need	1	(2.8)	2	(4.8)	3	(3.8)
Taken long enough	1	(2.8)	10	(23.8)	11	(14.1)
Side effects	13	(36.1)	4	(9.5)	17	(21.8)
Didn't help	1	(2.8)	2	(4.8)	3	(3.8)
Didn't like hormones	4	(11.1)	0	(0)	4	(5.1)
No symptoms	1	(2.8)	3	(7.1)	4	(5.1)
Advice + taken long enough	0	(0)	2	(4.8)	2	(2.6)
Advice+ side effects	2	(5.6)	3	(7.1)	5	(6.4)
Side-effects + taken long enough	1	(2.8)	0	(0)	1	(1.3)
Side effects + didn't help	3	(8.3)	1	(2.4)	4	(5.1)
Side effects + didn't like hormones	1	(2.8)	0	(0)	1	(1.3)
Didn't help+ didn't like hormones	1	(2.8)	0	(0)	1	(1.3)
Didn't help+ cost	1	(2.8)	0	(0)	1	(1.3)
Total	36	(100)	42	(100)	78	(100)

χ-square 28.560
$p < .01$

Although there were no questions specific to media influence, it was anticipated that media influence would have featured in the responses to Question 19, which asked respondents to state their main reason for stopping HRT. In the event, however, it was not cited frequently. When asked to state any further reasons for stopping HRT 3.8% of responders quoted media influence. This was the largest "other" reason. The media is cited by 6.4% of all the women who stop HRT as having some effect on their decision to cease therapy.

Those women who had cited side effects as a main reason for stopping HRT were asked to specify what those side-effects were, from five choices specified alternatives. The side–effects most commonly cited were weight gain (13.8%), worries about increased breast cancer risk (10.3%), and headaches (3.4%). Many women had indicated more than one side-effect; weight gain is cited by 60.2% of respondents, headaches by 44.5% and worries about breast cancer by 30.8%. Weight gain is cited as a side-effect in 85% of women who stop therapy at up to 5 years, and by only 50% of those who continue therapy beyond 5 years (Table 4.56). Headache is cited by 65% of those who discontinue therapy before 5 years, and by only 25% of those who continue beyond 5 years (Table 4.57).

Table 4.56 Cross tabulation of Weight gain cited as a reason to stop HRT with timing of discontinuance at up to or beyond 5 years.

Weight gain	Stopped up to 5 yrs		Stopped after more than 5 yrs		Total	
	n	%	n	%	n	%
Weight gain not cited	3	(15.0)	4	(50.0)	7	(25.0)
Weight gain cited	17	(85.0)	4	(50.0)	21	(75.0)
Total	20	(100)	8	(100)	28	(100)

χ-square 3.733
p = 0.077

Table 4.57 Cross tabulation of Headache cited as a reason to stop HRT, with timing of discontinuance at up to or beyond 5 years.

Headache	Stopped up to 5 yrs		Stopped after more than 5 yrs		Total	
	n	%	n	%	n	%
Headache not cited	7	(35.0)	6	(75.0)	13	(46.4)
Headache cited	13	(65.0)	2	(25.0)	15	(53.6)
Total	20	(100)	8	(100)	28	(100)

χ-square 3.676
p = 0.067

Breast tenderness is cited by 35% of early discontinuers, and by only 12.5% of later discontinuers. More early discontinuers (25%) than late discontinuers (12.5%) cite DVT risk as a reason for stopping HRT. Although none of these results is statistically

significant, a trend is seen which, had the study numbers been larger, may have produced a significant result.

When cancer risk is examined, the reverse pattern emerges, in that 62.5% of women taking HRT for more than 5 years cite increased cancer risk as a reason for discontinuing treatment. Only 35% of early discontinuers mention this as a reason to stop (Table 4.58).

Table 4.58 Cross tabulation of cancer risk cited as reason to stop HRT, with timing of discontinuance at up to or beyond 5 years.

Cancer risk	Stopped up to 5 yrs		Stopped after more than 5 yrs		Total	
	n	%	n	%	n	%
Cancer risk **not** cited	13	(65.0)	3	(37.5)	16	(57.1)
Cancer risk cited	7	(35.0)	5	(62.5)	12	(42.9)
Total	20	(100)	8	(100)	28	(100)

χ-square 1.765
$p = 0.183$

Again although not statistically significant it is an interesting result that may have been more evident with a larger study sample, or with greater numbers of early discontinuers.

These results will now be discussed in further detail and in comparison with previously published material in the final chapter.

Chapter five

Discussion

The original aim of this study was to determine if women undergoing hysterectomy with bilateral oophorectomy have patterns of HRT use, which are specific to them when compared to HRT users in general. Many of the published studies in this area have considered menopausal women as a homogenous category, and have not evaluated women with surgical menopause as a distinct group, to be investigated separately.

This chapter will discuss the findings detailed in the previous chapter in terms of the differences, if any, found between the women in this study and previously published literature on HRT use by women in general.

To begin, some observations regarding the age of the study subjects are made before the findings of this study are discussed under three main headings. The prevalence and duration of HRT use found in women with surgical menopause will be considered first, followed by the socio-economic factors associated with that use. Finally any effects of the location of treatment will be discussed, before general conclusions from the study are drawn.

The women in this study are older in general than women in some previous American based studies. Brett and Maddens (1997) quote a mean reported age at menopause of 45.9 years age in their American population of both naturally and surgically menopausal women, and of 40.1 years for those who had bilateral oophorectomy. The

women in their study who had experienced natural menopause did so at a mean age of 47.5 years. In the U.K. Maresh at al (2002), found a median age at hysterectomy was 45 years, but do not quote a mean age for concomitant bilateral oophorectomy, nor do they limit their population by clinical indication for surgery. The mean age in the achieved sample of surgically menopausal women in this region of Scotland is 43.9 years. In the target sample the mean age is slightly younger at 43.5 years. So the Forth Valley women are older on average than some surgically menopausal (with BSO) women, but younger on average than Brett and Madden's general menopausal population. This older age at surgery, (and therefore of menopause), may be linked to the original reason for that surgery. All the women in this study had surgery for menorrhagia, and as such would be treated after less radical alternative therapies had been exhausted, rather than as urgent cases requiring immediate surgery for possible malignancies. Lewis et al (2000), states that the peak rate for hysterectomy in the U.S is between 40-44 years, but that the peak rate of concomitant bilateral oophorectomy is later, at 45-54 years. These figures relate to operations carried out for a variety of indications, rather than solely benign menorrhagia with an upper patient age limit of 65 years. The mean age at operation therefore will be older due to this age limit, with oophorectomy more likely with increasing age. The women in this study were no older than 51 years at the time of hysterectomy so the mean age at operation is predictably younger than Lewis found, and yet older than the women described by Brett and Maddens.

The main findings from this study are now discussed.

5.1 The prevalence and duration of HRT use in women with hysterectomy and bilateral oophorectomy.

Women with surgical menopause are more likely to take HRT, and to take it for a longer time, than HRT users in general. When they stop therapy, they cite some of the same reasons as other users but are more likely to stop on the advice of their doctor.

Finley at al (2001) quote a prevalence rate for HRT use of 40% in their American peri and post-menopausal women aged between 50 and 70 years old, and a further 17% of the women in their study have used HRT in the past. However they along with other authors, suggest that surgical menopause greatly increases the likelihood of taking HRT when compared to natural menopause. In another American study, Brett and Maddens (1997) found that 71% of surgically menopausal women took HRT.

Maclaren and Woods (2001) found that 56% of women with surgical menopause were taking HRT compared with 39% of peri-menopausal or naturally menopausal American mid-life women .The age range of women in their study is 40-65 years, and this will explain the lower rate, as many of the older women would have discontinued use by the time of their survey. If the women who had started therapy but discontinued it are added to those still taking HRT, then a figure close to 75% is obtained. This study does not determine oophorectomy status, so it may well be that the remaining 25% (approximately) of women did not have their ovaries removed and therefore did not require post-operative HRT. In the United Kingdom Griffiths and Convery (1995) find similar rates of HRT use in women with hysterectomy and bilateral oophorectomy. Of the women in their general practice in Stockton -on –Tees that were under 52 years old and had had a hysterectomy with bilateral oophorectomy,

71% were taking HRT and a further 8.4% had taken it in the past. Only 50.6% of their women had commenced therapy immediately after surgery. They report 20.6% of women had never taken HRT, a finding which may be explained by the specific reason for surgery. If the operations had been carried out for reasons other than benign menorrhagia, then HRT may not have been appropriate.

Almost all women (98.2%) in the region studied who have hysterectomy with bilateral oophorectomy at less than 51 years of age start HRT in the early postoperative period. This figure is higher than quoted by the authors mentioned. This high rate is associated with the benign indication for surgery and the young age of the patient. Only 9 women stopped therapy within a year of starting treatment.

Women in this study have taken HRT for a longer time than is currently

recommended. The duration of use for this population would confirm earlier findings that hysterectomy with oophorectomy is associated with long-term HRT use.

The current advice to women taking HRT after hysterectomy with bilateral oophorectomy for benign indications is to continue therapy for five years or until the age of natural menopause, and then discuss with a doctor- but probably stop at that point. Many of the women in this study had taken HRT for longer than this, with more than half of those who had eventually stopped reporting that they had used therapy for more than five years. Hope and Rees (1995) found 51% of their lapsed users stopped HRT much earlier, after less than a year; and Den- Tonkelaar (2000) found, in a mixed population of past and present HRT users, that 74.4% of past users aged 30-75 had stopped HRT within 2 years. Maclaren and Woods (2001) quote a median of five

years' use in women aged 40-65 years, with 25% taking HRT for 10 years or more. In all these studies, many of the women had not had a surgical menopause, which may account for the higher rate of early discontinuance.

Hysterectomy is associated with longer duration of HRT use (Brett and Maddens 1997, Den- Tonkelaar 2000), which would explain why most of the women in the current study expect to take HRT for more than seven years. At the time of questioning, the majority of these Scottish women were still taking HRT, and the duration of use varied from eighteen months to sixteen years, (if HRT use prior to surgery, characteristic of some women, is included). Of these women, 77.6% had used treatment for up to ten years. In this study, there were 80 women who had stopped therapy and 38.8% of them had used HRT for between seven and ten years. Women who stopped treatment within one year of commencing totalled just 11.25% of all those who stopped, and account for only 5.4% of those who started HRT in hospital.

The *expected* duration of treatment is linked to the age of the patient. Overall, younger women anticipate longer treatment, as they are oestrogen deficient for a longer time compared to older women. It is interesting, then, to find that there is no evidence to suggest that those women who had taken HRT prior to surgery expect to take HRT for a shorter time post-operatively, although they are statistically older than those women who have not taken pre-operative HRT. This suggests that the decision to take HRT after hysterectomy, and the ultimate duration of use, is unaffected by prior use of hormones. Post -surgery HRT is a different form of treatment with the change from combined therapy to oestrogen- only therapy. Perhaps women consider pre- and post

hysterectomy HRT, as separate entities, and do not worry about the additional length of time in oestrogen treatment of the two put together. (Alternatively, as previously mentioned, this result may be the product of a flawed question).

Likewise, in this study, patient age is apparently not a factor in the actual timing of HRT discontinuance. This is also not expected, and may be linked to the small number of early discontinuers. At the time the women in this study were treated, the recommended duration of HRT treatment had no clear limit. A woman aged 48 years at operation for instance may have expected to continue treatment indefinitely, so her expectations may have been indistinguishable from those of a much younger woman who would also anticipate long-term use.

Hysterectomised women stop HRT for largely the same reasons as women with an intact uterus. In this study, the most common reasons for stopping HRT were either on the advice of the doctor (26.6 %) or the side-effects attributed to treatment (21.5%). These figures are higher than those found in other studies for rates of discontinuance on medical advice, but lower than those found for side- effects. Discontinuance on medical advice has been found to account for 22% of women by Maclaren and Woods (2001), 22.9% by Newton at al (1997), and in18.8% of study subjects by Den-Tonkelaar and Oddens (2000). Side- effects of treatment account for 31.8% of discontinuance, according to Den-Tonkelaar and Oddens, for 26.6% according to Newton et al (1997), and for 42% in the Maclaren study.

Considering medical advice first, it is interesting to note that a greater number of the women in this study consulted with their doctor (prior to stopping treatment) than was the case in previous studies of HRT users in general. Hope and Rees (1995) found that 38% of women did not consult their doctor before stopping treatment, while Newton et al (1997) found that many more women (53.8%) stopped without medical advice. Only 35% of the Scottish women studied ceased treatment on their own. This figure is not, perhaps as low as might be expected, given that the original prescription for treatment was received at the time of hospitalisation, as a medical recommendation rather than a treatment option. It is perhaps more likely that these women feel the need to discuss stopping treatment, and the possible consequences of ceasing treatment more keenly than women experiencing natural menopause. It is also possible that consultations about HRT with surgically menopausal women are more straightforward than consultations with women who are naturally menopausal. For younger surgically menopausal women HRT is truly a "replacement" treatment for prematurely lost oestrogen, whereas it can be viewed as "additional" oestrogen support for a failing natural supply in women without hysterectomy and bilateral oophorectomy. Women with intact uteri need also to consider the potential side effects of combined HRT and the potential for bleeding problems. With this in mind, there may be less ambiguous information given to women after hysterectomy and bilateral oophorectomy, and they, in turn, find consultations more satisfactory. Bond and Bywaters (1999) highlight the dissatisfaction of some peri-menopausal/ naturally menopausal women regarding HRT discussions with their doctors, but exclude surgically menopausal women from their study as they recognise that women with hysterectomy and bilateral oophorectomy have fewer grounds to refuse HRT.

Women who are early discontinuers of therapy give reasons for stopping which are different from those of women who discontinue therapy later. Buist et al (1999) suggest that long- term HRT use may be closely related to women's beliefs about therapy and the interaction they have with their doctors. Women stopping within five years cite side- effects and not liking the idea of hormones as the main reasons for stopping, whereas women stopping later do so on medical advice and because they feel they have taken it for long enough. Only 9.5% of late discontinuers cite side-effects as a reason to stop. This would be expected. If side-effects were a problem they would probably appear early in treatment; and, if not resolved they might prove intolerable in the short term. Once treatment were established with no experience of side-effects, therapy would be more likely to continue until advised to stop on medical grounds. Concerns about taking hormones has been shown to be linked to never using HRT, (Mansfield and Voda1994), and to account for its discontinuance in about 15% of users (Den Tonkelaar and Oddens 2000). It is cited by 11.1% of women who ceased therapy before five years in this study.

If side-effects are considered, then many of the reasons given for discontinuing therapy in these women are the same as those found in previous studies of women regardless of hysterectomy status. Side-effects related to menstrual bleeding, which feature as reasons to discontinue treatment in women with natural menopause, will not be discussed as surgically menopausal women are not troubled by these symptoms. Weight-gain, headache and worries about breast cancer are the side-effects that concern these surgically menopausal women.

Weight- gain was the most commonly cited side- effect in this study, with 13.8% of women who had ceased treatment stating that this specific side effect was the reason for their decision. Many more women (60.2%) indicated that weight gain was *partly* responsible, together with other side effects, for their discontinuance. Hope and Rees (1995) found that 21% of current HRT users and 27% of lapsed users knew that weight gain was a possible side effect of treatment, but they do not claim that weight gain alone statistically makes women more likely to stop therapy. Den-Tonkelaar and Oddens (2000) found that weight gain was implicated in HRT discontinuance for 30.7% of their subjects, but also cites an endocrine study which shows that HRT does not in fact increase body weight when compared to placebo (Espeland et al 1997).

According to Den-Tonkelaar and Oddens (2000), headache accounts for 5.7% of women stopping HRT; and according to Newton et al (1997) it functions as a reason to change HRT regimens in 4.1% of women. In the current study it is given as a reason by 3.4% of those women stopping treatment. It is however mentioned as being *partly* responsible for stopping, together with other side effects by 44.5% of these women.

Concerns about increased risk of breast cancer affect 10.3% of the women in this study, and are given as a primary side- effect leading to discontinuance. Together with other side effects, these worries influence the decisions of 30.8% of women. Newton et al (1997) found "fear of cancer" was the reason to quit treatment in 15.4% of their past users, but do not specify which particular cancer. Long-term risks such as cancer are quoted by Hope et al (1998) to account for discontinuance in 18% of the women

in their study, with 70% of these discontinuers specifically mentioning breast cancer risk. Fear of breast or endometrial cancer, is the reason for stopping HRT in 10% of mid-life women according to Maclaren and Woods (2001.)

So it would appear that, in women with surgical menopause, the side-effects/ worries that prompt them to stop taking treatment are the same as those that trouble HRT users in general. The impact of any one individual side- effect on discontinuance is relatively small, but when women are troubled by more than one side effect then stopping therapy is explained in higher numbers of women.

As Hope and Rees (1995), found that current users of HRT were more able to tolerate side-effects than were lapsed users, it was anticipated that this study might show that there are differences in the reasons women give for stopping therapy at different times. This has proved not to be the case. There are however some trends that may have been more evident in a larger study. Women who discontinue treatment within five years report their reasons as weight gain, headache, breast tenderness and worries about DVT in greater numbers than those women whom take HRT for more than five years. Those women who take HRT for more than five years, cite breast cancer worries as their reason for stopping in greater number than earlier discontinuers. These differences are however not statistically significant.

5.2 Socio-economic factors associated with HRT use in women with hysterectomy and bilateral oophorectomy.

Socio-economic group may be associated with the timing of hysterectomy, but in contrast to findings from menopausal women in general, it is not associated with the degree of uptake or the likelihood of continuation of therapy in women with surgical menopause. There is some evidence to suggest that women from different socio-economic backgrounds perceive the risks and benefits of HRT use differently.

It is suggested by the Scottish Government findings of 2007, in the second chapter of their publication "Growing up in Scotland. A study following the lives of Scotland's children", that younger mothers tend to be from less affluent areas. If then, by comparison, less deprived women delay having their children until they are older, this could affect their decisions when considering the timing of hysterectomy. Settnes and Jorgensen (1996) found that, in Denmark, less educated women were more likely than educated women to have a premenopausal hysterectomy, and Cooper et al (2008) found similar trends when studying women in Britain and Australia. It is not possible, on the basis of this study, to say that Scottish women from lower socio-economic groups are more likely to have hysterectomy at a younger age, because the socio-economic distribution of the achieved sample does not accurately reflect the socio-economic structure of the regional population generally. (This is particularly apparent in the most deprived category SIMD 1 which is under-represented: see Figure 2 in chapter 4). It is, however, possible to say that if women from higher socio-economic groups are less likely to have hysterectomy at an earlier age, then the women from more affluent backgrounds who do have surgery are likely to be older when that surgery takes place, and this is what is found in the study.

In the target sample there is a difference of 1.5 years in the mean age at hysterectomy between women in SIMD groups 1-5 (most deprived) (42.9 years) and 6-10 (least deprived) (44.4) years.

It is also important to recognise that these more affluent women, who had their operations when they were older also returned their questionnaires in greater numbers so are disproportionately represented in the achieved sample.

Socio-economic group is not associated with access to HRT treatment, nor the likelihood of uptake in women with surgical menopause, but women from less deprived backgrounds tend to use HRT for longer. Women use the same information sources regardless of socio-economic status.

It has been suggested that socio-economic group strongly affects the likelihood of HRT use (Finley et al 2001), but evidence from this study would suggest that these trends are not so evident in women with surgical menopause. Finley et al (2001) found that wealthier peri- and post-menopausal women were three times more likely to use HRT than were poorer women in the USA. This is not seen in the surgically menopausal women of this Scottish study. Finley's findings may be linked to the ease of access patients have to advice regarding HRT. Consultations with GPs about preventative medicine are known to take place less frequently if the patient belongs to a lower social class (Goddard and Smith, 2001), so perhaps the wealthier women in Finley's study were consulting their physicians in greater numbers, and with greater

adherence, than the poorer women. This is particularly likely in view of the differences in health care funding between the USA and Scotland.

All the women in this study should have had the opportunity to discuss the use of HRT with health professionals as part of their hysterectomy care. They will have had the discussion "brought to them" rather than having to seek out advice on menopausal symptoms from their GP. There is no evidence that these discussions differ according to the socio-economic group to which the patient belongs, suggesting that the advice given to this group of women does not vary in content, and equity of care is implied. The recommendation of a health professional has been positively linked to HRT use (Finley et al 2001), and it is likely that these recommendations are just as effective in surgically menopausal women. In any case, HRT use following hysterectomy and bilateral oophorectomy for a woman under 51 years of age is less controversial than for peri or postmenopausal women with intact uterus. So it may be easier for all women, regardless of socio-economic group, to accept therapy after surgery.

There is evidence to suggest that, in this region of Scotland, socio-economic group does have some effect on the duration of HRT use, with women from less deprived backgrounds using HRT for a longer time. This would confirm findings from a large Swedish study (Persson et al 1997), and one from four general practices in the England, (Den Tonkelaar and Oddens 2000), both of which examined the characteristics associated with long-term (over 6 years) HRT use in women with both natural and surgical menopause. Den Tonkelaar's findings are consistent with the Persson study but are not statistically significant. These authors state that high educational level is associated with long-term use, and Den Tonkelaar and Oddens

(2000) suggest that women of greater intelligence may " have been more aware of the risks of osteoporosis and were probably more likely to comply with their own decisions"(Den Tonkelaar and Oddens 2000 p 511), so implying that these women "make up their own minds".

If women from higher socio-economic groups take HRT for longer, and are more likely to consult their GP about preventative medicine, it might be expected that they also consult their GP in greater numbers when deciding to cease treatment. Thirty–five percent of the women in this study did not discuss their decision with their doctor, a rate that is similar to that reported in some studies of the general menopausal population (38% in Hope and Rees 1995), but lower than the rate found in other studies (53.8% in Newton et al 1997). These papers did not examine possible associations between socio-economic statuses, but there is no evidence in the current study that it affects the likelihood of consultation.

The women in the current study, regardless of their socio-economic group, use the same sources to inform them about HRT. So, if it is not the source of the information that influences the uptake or duration of therapy, possibly it is the interpretation of such information that makes a difference. This is implied by Den-Tonkellar's (2000) suggestion that better educated women may have a greater understanding of the treatment, which in turn may lead to longer-term use.

Women from different socio-economic backgrounds view the risks and benefits of HRT differently. Most women (74.7%) from the current study believed that the risks associated with HRT were outweighed by the benefits; and this finding is unrelated to

socio-economic status. There are, however, some differences associated with socio-economic group when the importance of these benefits is considered. More women from the lower socio-economic groups consider that cardiovascular protection is the most important benefit of HRT. There is, however, no difference between women from different backgrounds in how important they rate osteoporosis protection; and, although more women from less deprived backgrounds rate the relief of menopausal symptoms as of primary importance, this is not statistically significant. So women from deprived areas agree with women from more affluent areas about the importance of symptom relief and osteoporosis protection, but they are more likely to believe that cardiovascular protection is also important.

The primary benefits of HRT have always been the relief of menopausal symptoms and osteoporosis protection, although cardiovascular protection was also thought to be a possible benefit at the time these Scottish women were taking HRT. There may be a possible explanation for the difference found in how cardiovascular protection was rated, either in the timing of the survey, or more significantly in the way different socio-economic groups perceive personal risk. In terms of survey timing, it is possible that women from the more affluent socio-economic groups were more aware of the findings of the Women's Health Initiative, and knew that this benefit had been largely discredited at the time they were asked to complete the questions. This might explain why only 9.1% ranked cardiovascular protection as their most important benefit. It does not explain why 42.9% ranked it as of medium importance. In terms of perceived personal risk, it may be that lower socio-economic groups feel at greater risk of a cardiovascular event, and therefore rate possible cardiovascular protection of HRT more highly. It is well known that coronary heart disease is more prevalent in lower

socio-economic groups, and low control beliefs are thought to contribute to these higher rates (Bosma et al 2004).

A perceived lack of control, together with a perceived susceptibility to any health threat, is central to many models that try to explain health-related behaviours. The health belief model (Becker et al 1977) emphasises personal susceptibility, while Leventhal's common sense model places great importance on lay beliefs when trying to predict health decisions. If an individual believes that they are at risk of developing cardiovascular disease through familial traits, or as a consequence of life-style, then it would not be surprising if they rated the prevention of such disease more highly than somebody who considered themselves at lower inherent risk. The belief that that HRT may protect against heart disease, as well as relieving menopausal symptoms, and preventing osteoporosis, may have led some women to think that out of these three benefits, that cardiovascular disease is the most serious affliction and therefore the most important condition to prevent. At any rate, women from different backgrounds all take postoperative HRT, but their beliefs in the benefits of such treatment differ.

It is unfortunate that, when the questionnaire was devised, no question specific to the risks of treatment was included, as this would, with hindsight, have been interesting. As it is, it is not possible to say how these women would rank the importance of their risk of breast cancer or DVT.

When considering the possible effect of prescription charges, it is interesting to see that there is little difference in the numbers of women who are in receipt of free prescriptions when comparing the least and the most deprived groups. The assumption

would be that more deprived women are more likely to have free prescriptions; but, although more women from the most deprived backgrounds do not pay for medication, their number is not statistically greater than for less deprived women. One possible explanation for this may be the SIMD classification of the study population. SIMD is not designed to classify individuals but rather the area in which they live. It is entirely possible for women who are not income-deprived to live in an area of higher deprivation. In the recent publication of SIMD (Scottish Government 2009) it is stated that 64% of income-deprived people live outside the most deprived areas. Whatever their background, as designated by SIMD, most women say that free prescriptions would not make them more likely to take HRT. Since these women were surveyed, prescription charges in Scotland have been abolished.

5.3 The impact of the location of treatment on HRT use in women with hysterectomy and bilateral oophorectomy.

There is no evidence, in this study, to suggest that the two hospitals diverge in their practice in such a way as to impact on patterns of HRT use. However there is evidence that information given to patients could be improved.

There are differences between hospitals in the information given to patients concerning the benefits of HRT, but the hospital attended for treatment has no association with the subsequent use of HRT after hysterectomy. The medical staff in both hospitals discuss HRT with their patients prior to surgery, and women report no significantly different information sources contingent on where they are treated. Discussions related to the relief of menopausal symptoms, and osteoporosis protection is recalled by two thirds of all the women in the study.

A greater number of women seen by medical staff at hospital A recall discussions about the benefits of taking HRT when compared to those women attending consultations at hospital B. So hospital A appears to be more effective than hospital B at informing women of the benefits of treatment. Although there is a statistical difference in the data here, its reliability is possibly questionable as it is dependent on patient recollection. It is possible that benefits are remembered and risks forgotten. Further concerns over reliability of recall are evident when the risks of treatment are considered.

Apparently, the potential risks of treatment with HRT are not always discussed with patients, with 65.2% of women saying that side-effects were not referred to. This is hard to believe and needs to be explored further. The study subjects were asked to recall a conversation, which took place (in some cases) a considerable length of time before the survey, and which is consequently liable to be inaccurately recalled. It is entirely possible that, in a consultation with her doctor, a woman opting for elective hysterectomy with bilateral oophorectomy, will focus on the benefits of the operation rather than on possible post-operative side-effects. Similarly, the doctor when discussing the need for HRT will focus on the relief of premature menopause rather than the small likelihood of the patient experiencing any serious side-effects of treatment. The overall risk-versus-benefit balance in these consultations will favour HRT prescription, and this may explain why women do not remember being informed of the risks of treatment. There is no difference between the two hospitals in the information given to patients about risks of treatment.

If the patients attending hospital A receive better information about the benefits of treatment then it might be expected that they are more likely to take HRT post-operatively. This is not the case. Both hospitals offer HRT to a high percentage of their patients, and those patients have almost the same uptake level, at 99% of hospital A patients and 97% of hospital B patients.

The fact that there appears to be no significant difference in the timing of HRT prescription, and that similar numbers of women leave both hospitals with that prescription, would indicate that both units adopt similar practice. In this respect, at least, there does not appear to be a "postcode lottery", perhaps because the same health authority governs both hospitals.

There may be no significant differences between the two hospitals in their management of women undergoing hysterectomy, but there is evidence of differences in the timing of treatment, dependent on which consultant is seen. There are two consultants who operate on significantly younger women. One of these doctors works in HA, the other in HB. Had they both worked in the same hospital, some statistical difference between the hospitals might have been seen. As it is, there is no significant difference in patient age at operation by hospital. One of these two consultants also performed more than a quarter of all cases, a fact which supports the observation of Gupta & Manyonda (2006) that hysterectomy rates for benign disease vary between consultants in the same hospital. These differences appear to be idiosyncratic, and not based on gender.

Patient satisfaction with medical consultations has been shown to be linked to the communication style of the doctor (Hall et al 1994), and differences in communication style are found according to gender (Hall et al 1994 cited Roter at al 1999). The patients of female physicians are associated with higher rates of adherence to treatment than the patients of male physicians (Hall, Roter & Katz 1988 cited Roter et al 1999). This study does not support the claim that a physician's gender is associated with the uptake or continued use of HRT by their patients. The gender of the consultant has no effect on the timing of hysterectomy, or the content of pre-operative discussions about HRT. Nor does it determine whether HRT is offered in hospital, or whether this offer is accepted. In this respect the surgically menopausal women in this study are no different than midlife women in general. Maclaren and Woods (2001) found no statistical association between physician gender and HRT use, although in their study, HRT use was more likely in women who saw male doctors. Some authors have found that women prefer to see female doctors (Schmittdiel and Selby et al 1999), but patient preference for physician gender was not explored in the current study. It may well be that women prefer female gynaecologists, but there is no evidence from this study to suggest that the care from male gynaecologists is any different than that provided by their female colleagues. This would concur with the suggestion by Christen et al (2008) that patient satisfaction and adherence to treatment is influenced by the communication style of the doctor and not by the gender of that doctor alone.

On the basis of this study, it could be argued that patient information about HRT needs to be improved in this NHS trust. Although 98.2% of the women in this study

accept HRT when it is offered to them in hospital, not all of them thought that they had sufficient information to make the decision to start long-term medication. Of those who accept treatment, 62.6% consider themselves well enough informed. Equally, of the three women who did not accept HRT in hospital, two said that they had sufficient information for their purposes. However, over one third (37.4%) of the women said that they *did not* have enough information. So women appear to take treatment whilst acknowledging they have too little information on which to base their decision.

In this study, *not* having enough information did not deter women from taking HRT when it is offered to them. Women in the immediate post-operative stage were apparently prepared to commence treatment on the advice of the doctor, even though they now believe that they needed more information. Of the women who said that they *did* have sufficient information, most mention the doctor as a source of that information, perhaps confirming that patients are more likely to remember what doctors say. Nurses are certainly mentioned as an information source; however, they are not remembered by more of the women who believe they had sufficient information when compared to the women who believed they did not have enough information. It could therefore be said that doctors do a better job than nurses do in giving information to these women. As previously discussed, physician recommendation is known to be associated with HRT uptake generally (Finley 2001). The fact that women remember the doctor as the source of their HRT information may be further evidence to support this, with these surgically menopausal women not differing from HRT users in general in this respect.

Those women who continue to take HRT in this study are, as expected, of the opinion that the benefits of taking treatment outweigh the possible risks. This confirms the findings of Den –Tonkelaar and Oddens (2000) in past or present HRT users in general. Over half of the women, who had stopped therapy also thought that benefits outweighed risk, which suggests that the long-term user is content with therapy but ceases treatment on medical advice.

5.4 OVERALL CONCLUSION

In all probability, the decision to take HRT after hysterectomy with oophorectomy is a relatively easy one, compared to the decision that must be taken by naturally peri-menopausal or menopausal women. After surgery, women face " instant menopause" and are therefore advised to take HRT to prevent menopausal symptoms and to protect their bones against osteoporosis. The relative risks of treatment, including breast cancer and venous thrombosis, in these comparatively young women, are small as HRT is considered to replace a prematurely lost oestrogen supply rather than supplement or extend that supply after a natural menopause. These risks are perhaps offset by the fact that women with premature menopause are at higher risk of osteoporosis than women experiencing menopause naturally. There are no concerns for the surgically menopausal woman in terms of the return of menstrual bleeding, or the risk of endometrial cancer, as they have no uterus. Bleeding and concerns about cancer risks are known to be reasons for stopping treatment in HRT users in the general. For women who do not like the idea of exogenous hormones, HRT after surgery may be considered acceptable due to its compensatory role. Naturally menopausal women who dislike hormones may think treatment unnatural and or unnecessary, but for surgically menopausal women any concerns about taking

"unnatural" exogenous hormones may be outweighed by the argument that HRT in these circumstances is not "extra" but "replacement". If there are fewer issues surrounding treatment then discussions between medical staff and patients are easier and outcomes more predictable. This is certainly consistent with the findings in the present study.

Following hysterectomy with oophorectomy, nearly all women in this study take HRT on the advice of their doctors. This is expected and is consistent with previous findings that treatment is associated with hysterectomy and oophorectomy (Den-Tonkelaar and Oddens 2000). HRT is offered and accepted by women regardless of their social background, and irrespective of the medical professional consulted. The association between HRT use and higher social status found in studies of generalised HRT users, (Persson et al 1997, Finley et al 2001, and Maclaren and Woods 2001), is not evident in these surgically menopausal women. Many of the women in this study have taken HRT for a longer time than is found in the general HRT- using population, and this may be in part due to prescribing advice at the time. They stop treatment for many of the same reasons as women with natural menopause do, but are more likely to consult their doctor prior to stopping. They cite side-effects of treatment less often than general users and weight gain is the most common complaint associated with discontinuance. Weight gain is also reported as an undesirable side–effect by HRT users in general (Den- Tonkelaar and Oddens 2000). All women tend to use the same information sources, yet there are some differences, associated with socio-economic status, in how the information about risks and benefits is perceived; cardiovascular protection was rated more highly by women from more deprived backgrounds. Over one third of women said that they had insufficient information prior to starting HRT.

It is this last observation that has some interest in terms of any clinical applications resulting from this study.

If the discussion about post-operative HRT is straightforward, why do some women say that they did not have enough information? Although they start treatment, the fact that they consider themselves not adequately informed raises questions about the effectiveness of these discussions. Is it because there are fewer side-effects to discuss, and the argument for treatment stronger in cases of surgical menopause that impacts in these discussions? If the consultation focus is that of replacement of a prematurely lost natural hormone rather than the addition of hormones to relieve menopausal symptoms, then perhaps doctors do not put the same emphasis on the side-effects because they are fewer and less serious. A naturally menopausal or peri-menopausal woman can choose HRT to relieve menopausal symptoms; a surgically menopausal woman is positively encouraged to take HRT.

The consultations, then, are essentially different for the two groups of women.
From the patient's perspective, the recollection of what information has actually been given is perhaps less than full. Discussions about HRT take place at a time when major surgery is being contemplated or has just been performed, and it would be understandable if recollections were not completely accurate. It is important to know that, regardless of whether adequate information was given, these women say that they were not sufficiently informed. Nurses were cited in this study as a source of information, but not as a particularly memorable or effective one. One possible reason for this may be that nurses are subject to time constraints, and do not have time in an acute setting for lengthy discussions. Alternatively, they might not have been

confident in their own understanding of HRT and might therefore have felt unable to answer questions knowledgably.

This latter possibility is particularly relevant to the present study because of the emerging controversy and changing recommendations (with respect to HRT use) at the time some of these women were treated.

It is clear from this study, that when making their decisions about HRT, these women were content to follow the advice of their doctors, but they wanted more information. It is essential that the information given to them is accurate and up to date. Part of the problem for these, and indeed other, HRT users has been how to interpret the research findings, as they emerged. It may be supposed that it was difficult for women taking HRT, at the time, to understand how they might be affected personally. There is something to be learned from the career of HRT, which has implications for medical and nursing practice.

McKinlay (1981) says that "no government should support through public funding for general public use any service, procedure or technology, the effectiveness of which has not been, or cannot be demonstrated" (p 402). As discussed earlier, the effectiveness needs to be established by experimental studies, for example RCTs. If "doctors and nurses are the gatekeepers of innovation" (Wright 2005 p1096), then there is a duty to ensure that only treatments with proven efficacy are promoted.

One proposal is that the pharmaceutical industry should continue to be obliged to make very clear statements of efficacy and clinical indications for use when new

medicines are licensed for the market. Claims of secondary benefits, such as (in the case of HRT) CHD prevention, should not be made until proven. Early release of any data obtained showing possible detrimental effects of treatment should also be publicised more readily. This, however, is probably unrealistic, given the financial investment made by the pharmaceutical industry in the development of new medicines, and the need for accurate data collection. It can be argued that, if all new innovations were not marketed until long-term data were available, then it may be impossible to collect data from large-scale studies, and it could take decades to prove a treatment to be both effective and safe. This clearly would stifle innovation and progress in medicine. The media also have a responsibility to report accurate information and, as previously discussed, the power of sensationalism is clearly evident in the general press.

All nurses should have an understanding of how new drugs are tested in clinical trials, and most importantly, an awareness of the power of the pharmaceutical industry and the influence of the media. As Wright (2005) advises, medicine prescribing by doctors and nurses should not be influenced by the media or the pharmaceutical industry but by empirical evidence.

The Royal College of Nursing, as the largest professional union for nurses in the UK, representing some 400,000 members, "promotes excellence in practice and shapes health policies" (RCN website 2011). It aims to lobby government to develop and implement policies that improve patient care. The RCN has a number of priorities when considering the maintenance and development of services provided by both the NHS and the private sector. These include maintaining staffing levels, protecting

time for the training of nurses as part of professional development, protecting the nation's health by providing public health information, investing in specialist nurses, and sustaining health care investment. All these influence the effectiveness of nurses' clinical role in regard to helping women with their HRT decisions. Maintaining staffing levels permits time to spend on proper discussion with patients to individualise their care. Formal training, networking and private study allow the nurse to be confident and informed in practice, thus able to impart up-to-date, individualised care. Using the consultation time for a holistic assessment of the patient allows for other health information to be given, and provides an opportunity to engage in health screening.

The RCN National Menopause Nurse Group was formed as a sub group of the RCN Women's Health Forum in 2003. The objectives of this group were to develop the clinical role of nurses working in menopausal health, promote education on menopause related issues to all nurses, and to encourage a multidisciplinary approach to menopause care. To ensure safe and effective practice, the group developed a national competency framework. Published as "*An integrated career and competence framework for nurse and health care support workers working in the field of menopause"* (RCN Competences: 2009), it is designed for use by nurses working within menopause services, and elsewhere. It is recognised that nurses working in menopause health work in many different settings, in both primary and secondary care, and that their roles vary according to their setting. The framework is useful to all nurses involved in women's health, but specifically ensures competency in those nurses involved in menopause care at a more specialist level.

Specialist menopause nurses, with this extended training, have a role in helping women with more difficult HRT decisions. The women in this study might have had their information needs met if the discussion about HRT had been undertaken by a specialist nurse, at a time when the women themselves were less pressured by decisions to be made regarding major surgery, or in the immediate post-operative period. These discussions could instead perhaps, take place as an extended part of the pre-operative assessment. This assessment takes place after the decision to have surgery has been made, yet before the operative procedure has taken place. Then, allowing for some time for reflection, a follow up discussion prior to discharge on the ward, or at the post-operative visit in clinic could be made. Alternatively, information evenings for women waiting for hysterectomy could be held by suitably qualified nurses, as happens in some of the major teaching hospitals, for example Birmingham Women's NHS Foundation Trust. The information would best be given without time constraint and supported by literature to take home. Other women contemplating HRT also need to be given quality information, tailored to their individual need, by a competent practitioner, in order to make their decision.

There is a role here for written, hysterectomy-specific information in leaflet form for women to read and keep following their operation. In the NHS Trust where this study was conducted, written HRT information is given to patients in this form but the leaflet used contains broad-based information for women regardless of the origins of their menopause, be they peri-menopausal, naturally menopausal, or surgically menopausal. If this information was specific to women undergoing hysterectomy with bilateral oophorectomy, and if the risks and benefits were stated with particular

reference to this group of women, then their information needs may be better met, and the information in question more consistently retained.

In recent times, the role of the specialist nurse has been under threat as posts have been left unfilled due to budget cuts. A recent article in the Sunday Observer, entitled "Diabetics are put at risk as NHS cuts specialist nursing posts", written by health correspondent Denis Campbell, reported a doubling of unfilled diabetic specialist nurse posts within the UK in the last year (Campbell 2011 p 8). The RCN's Frontline First campaign, designed to protect services, predict that at present there are more than 1500 nursing and midwifery posts under threat in Scotland (rcn.org.uk 2011). Quality of care can only be maintained by adequate staffing levels, and the protection of specialist nurse posts is of great importance. All areas of health care are affected by investment in their service. Women's health is no exception; if funding is not to be increased, it needs protecting at the current level, and the nursing profession needs to lobby for such protection.

Chapter six Limitations

6.1 The limitations of this study

The final chapter will acknowledge and discuss a number of the study's limitations, which will be considered under the following three headings,

Research study design

Data source

The researcher

6.1.1 Research design

Three questions, relating to the design of the study, need to be addressed.

1. Can the findings of this study be generalised to a wider population?

2. Are the findings affected by unpredicted exogenous influences?

3. Do issues around recollection influence responses?

6.1.1.1 Can the findings of this study be generalised to a wider population?

This is a very modest study of patients treated in two general hospitals. These hospitals, approximately 8 miles apart, serve a relatively small area in central Scotland. The target number of possible participants was 306 women, of whom only 190 returned questionnaires that were useable. So the study draws on the opinions of a small, and conceivably biased, sample of women in a small geographical area. Consequently, it could be criticised for being too small and local to support generalisations. Although the socio-economic status of the respondents is roughly

comparable to the population of the region as a whole, there are two SIMD classifications in particular, which are not representative of the population as a whole. The most deprived group (SIMD 1) is significantly under-represented and so the opinions of the poorest women are not known, and the opinions of SIMD 5 women are over-represented. As HRT use is known to be associated with higher socio-economic group in HRT users in general, the lack of data collected from women with lower socio-economic status may have contributed to the high rate of uptake and the long duration of treatment found in this study. The small size of the sample is also implicated in the findings related to the age of the patient at the time of operation. In the target sample women from more deprived backgrounds (SIMD 1-5) are significantly younger when they have surgery compared to women from less deprived backgrounds. This statistical association between age and time of hysterectomy is not found in the achieved sample. The mean age of the achieved sample is significantly older than that of the women who did not respond to the questionnaire. The advice given to a patient regarding the duration of HRT use after surgery varies depending on patient age; and, as the achieved sample does not accurately represent the younger woman, the findings regarding duration of treatment cannot be generalised to the population as a whole.

6.1.1.2 Are the findings affected by unpredicted exogenous influences?

There may also be some question as to the relevance- in 2010- of data that refers to events which happened some years ago, as medical treatments change and indications for drug therapy vary in the light of continued research. Some of the findings may be relevant to this particular group of women, and to other women who were treated within the same time frame; but because of changes in HRT use, they cannot be

generalised to a wider population of women having hysterectomies now. This point applies primarily to the duration of therapy because the women in this study took HRT for a longer time than is currently recommended. Some women in their late 40's having hysterectomies today may not start HRT immediately after surgery, but rather wait to see if they are affected by menopausal symptoms. If they do start, they will probably expect to take it until they were 50, and then reassess.

Robson (2001, p 70) discusses the validity of research findings, using Cook and Campbell's (1979) list of possible threats to such validity. They note that various external influences can affect research findings. One of these influences is historical context. This may particularly affect this study, as there was a great deal of discussion about HRT use in both the medical and general press just as the questionnaires were being sent out to participants. Publicity if this kind may have prompted the study subjects to re-examine their reasons for taking HRT, or it may have informed them of risks and benefits of which they had been previously unaware. It is impossible to be sure that these press reports affected survey responses but it is certainly a distinct possibility.

6.1.1.3 Do issues around recollection influence responses?

This is a retrospective study, over a 10-year period, involving women who had surgery between January 1992 and December 2001. Consequently, some of the study participants had undergone their surgery some considerable time before they were asked to participate. This will inevitably result in some problems with the recollection of past events and, in general, the reliability of the respondents' memories is obviously open to question. It is difficult for anyone to be certain where knowledge

originates from and this is particularly true when it is accrued over time and the topic is the subject of publicity in the press. Not only did the study ask women to remember events in the past, it asked questions about a medication that had received significant media attention. For this reason, it is difficult to be sure that the responses made reflect accurate memories, and that they have not been reconstructed on the basis of more recent information.

The problem of obtaining reliable information applies to this study for other reasons too. The data was obtained using a postal questionnaire, and there are corresponding concerns regarding the accuracy of responses. It is recognised that problems exist in even the best designed questionnaires because they are completed quickly, and not always truthfully. In addition, the women in this study were questioned by someone associated with the medical team who had cared for them in the past, possibly influencing the responses given. If, as Robson (2001 p128) suggests, people sometimes respond "in a way that shows them in a good light", then they may not reveal their true feelings to those who treated them. It is likely that sampling a group of patients with whom the researcher had no previous connection would have produced more robust data.

6.1.2 Data source

The relatively small number of patients in this study is due, in part, to difficulties experienced in the accessing of patient records. If this task had been easier and quicker to achieve, then study numbers may have been increased.

The researcher checked case notes individually, to determine eligibility, and 37 possible subjects were lost to the study because their case notes were incomplete, untraceable, destroyed or incorrectly coded. The incorrectly coded records are of particular interest, and may be partially implicated in the apparent drop in the 1996 figure for hysterectomy as a treatment for menorrhagia. If notes are incorrectly coded, then the recorded rate of hysterectomy with bilateral oophorectomy will be inaccurate. Moreover, it is reasonable to assume that if notes are incorrectly coded for one operation then other operations may be similarly miscoded. To ensure that all possible participants were identified would have required the researcher to check all hysterectomy notes, regardless of the clinical indication for surgery, over the 10-year period. Clearly this would have been a lengthy process. Time constraints also prevented exhaustive tracing of lost case notes.

It is worth adding that the clinical indication for surgery in this study is exclusively menorrhagia. Study numbers could also have been increased if the indication had been widened to include other benign conditions.

The design of the questionnaire is central to the quality of the data obtained. Once the responses were returned, it was clear that the questions were not all without ambiguity. For example, Question 12 would have been clearer if it had specified that it was asking about taking *post-operative* HRT. Further, more substantive data on the reasons for stopping treatment may have been elicited by a more exhaustive and specific list of reasons, or by allowing the respondent to complete the question in her own words. These difficulties in interpretation were not evident in the pilot, perhaps due to where the pilot was conducted.

Face- to- face interviews with study subjects who agreed to such questioning would have produced the most detailed data about the reasons women stopped treatment. The decision not to proceed with this part of the study was again the result of time considerations, as discussed at the end of Chapter Three under “Ethical and legal considerations”.

6.1.3 The researcher

Robson (2001) states that the “ trustworthiness of the data depends to a considerable extent on the technical proficiency of those running the survey”(p125). This was the first time the researcher had undertaken a research study. Many of the limitations of this study are therefore linked to inexperience, and much has been learned with the benefit of hindsight.

For example, the study could have been improved if the researcher had broadened the subject base in terms of the clinical indication for surgery. The primary reason that this was not done was to keep the subject population as uniform as possible, and to exclude any condition making post-operative HRT less straightforward.

The questionnaire could have been improved in terms of format, with clearer instructions to the respondents. The ambiguities in the questionnaire may have been highlighted had the pilot study been performed using subjects from another hospital or indeed from a different clinical area within gynaecology.

Owing to personal circumstances, this study has taken some considerable time to complete. This has had a negative effect in terms of the relevance of the study. HRT is viewed somewhat differently today, when compared to the 1990s, so the data obtained here is perhaps less relevant than it might have been if the study had been completed quickly, and without the concerns raised by the WHI study. The impact of the WHI study, along with media influences on HRT use, was not explored in any depth, and this is regrettable. The reason for this is that the questionnaire was designed prior to these reports being published, and ethical approval already granted. Further ethical approval would have been necessary if additional questions had been added, so delaying the commencement of the study.

Nevertheless, this study has given the researcher an appreciation of the difficulties of conducting research, and the subsequent management and interpretation of data. It has given an interesting insight into practice at her place of work, extended her knowledge of the issues surrounding HRT prescription in general, and those relevant to HRT following hysterectomy with bilateral oophorectomy in particular.

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APPENDICES

Appendix 3.1 Questionnaire

COMPLIANCE WITH HORMONE REPLACEMENT THERAPY AFTER ELECTIVE HYSTERECTOMY AND THE REASONS WOMEN GIVE FOR CONTINUANCE OR DISCONTINUANCE.

QUESTIONNAIRE

This questionnaire is designed to find out how many women take hormone replacement therapy (HRT) after having a hysterectomy, and for how long they take it. It does not matter which type of HRT you take, tablet, patch or implant.

It also includes questions about the information you were given and the reasons you have for taking it or not taking it.

Finally, it asks some details about yourself, and also if you might be prepared to be interviewed by the researcher to explain your opinions further.

THE FIRST QUESTIONS ARE ABOUT YOUR HYSTERECTOMY AND THE INFORMATION YOU WERE GIVEN BEFORE AND AFTER SURGERY. PLEASE ANSWER AS FAR AS YOU CAN RECALL.

1.When did you have your operation? Month…….. Year……

2. How old were you when you had your hysterectomy?
……..Years.

3.Was HRT mentioned to you before you had your hysterectomy? (please tick)
Yes

No

If yes, please tick **one** of the following answers

a) Yes, by my family doctor
b) Yes ,by the hospital doctor
c) Yes ,by both family and hospital doctors
d) Cannot remember

4.As far as you can recall were any of the following benefits of HRT mentioned?
(please tick all that were mentioned)

a) Helps the symptoms of the menopause e.g. Hot flushes
b) Helps prevent osteoporosis in later life
c) May help prevent heart disease.
d) No benefits mentioned

5.As far as you can recall were any of the following side effects of HRT mentioned?
(please tick all that were mentioned)

a) Increased risk of breast cancer.
b) Increased risk of blood clots (DVT)
c) No side effects mentioned

6.Were you offered HRT in hospital before you went home? (please tick)

a) Yes
b) No

If you answer yes to this question please answer the next 2 questions
If you answer no to this question please go to question 8.

7.Did you accept HRT when offered it in hospital? (please tick)

a) Yes
b) No

8.If the hospital did provide HRT, Did you discuss HRT with your family doctor when your prescription from hospital needed renewing?(please tick)

a) Yes
b) No

9.If the hospital did **not** provide HRT, did you discuss HRT with your family doctor after you went home? (please tick)

a) Yes
b) No

10.If the hospital did **not** provide HRT did you have HRT prescribed for you by your family doctor after you went home? (please tick)

a)Yes
b)No

11.What was the main source of the information you were given in hospital ?
(please tick one answer)

a) Doctor

b) Nurse

c) HRT pamphlet

12.How long did you think you would have to take HRT for? (please tick)

a) Less than 1 year?

b) About 5 years?

c) More than 5 years?

d) More than 7 years?

13.Before you went home from hospital did you feel you had sufficient information about HRT to make your decision to take it or not take it?

a) Yes
b) No

THE NEXT QUESTIONS ARE ABOUT TAKING HRT AND THE REASONS YOU MAY HAVE FOR EITHER CONTINUING TO TAKE IT OR FOR STOPPING TAKING IT.

14. Had you taken HRT at any time before you had your operation?
(please tick)

a) Yes
b) No

15.If the answer is yes then how long did you take it for approximately?
……..Years, …….Months

16.Are you still taking HRT? (please tick)

a) Yes
b) No

If you have **answered yes** to this question then please go to question 21

17.If you have stopped taking HRT when did you stop? (please tick one answer)

a) Less than 3 months of starting it?

b) Within 3 and 6 months of starting it?

c) Within 6 months and one year of starting it?

d) Within 1 and 2 years of starting it?

e) Within 2 and 3 years of starting it?

f) Within 3 and 5 years of starting it?

g) Within 5 and 7 years of starting it?

h) Within 7 and 10 years of starting it?

18.When you stopped did you discuss your decision with your doctor beforehand?

a) Yes
b) No

19.What was your main reason for stopping? (please tick **one** only)

a) Doctors advice

b) Didn't need it anymore

c) taken it for long enough

d) Side effects

e) Didn't help the symptoms

f) Didn't like the idea of taking hormones

g) Didn't have any symptoms of the menopause

h) Cost of prescription

If there is any other reason you stopped taking HRT could you detail it in the space provided.

20. If you answered “side-effects” to question 19,could you please indicate which side-effects influenced your decision.(please tick)

a) Weight- gain
b) Headaches
c) breast tenderness
d) worries about increased breast cancer risk
e) worries about DVT

THE NEXT QUESTIONS EXPLORE YOUR OPINIONS ON THE EFFECTS OF HRT, AND THE CURRENT PRESCRIPTION CHARGES MADE.

21.Do you believe that, for you the benefits of HRT outweigh the side effects?(please tick)

a) Yes
b) No

22.For you what do you consider the most important beneficial effects of HRT? Please rate the following three effects in order of importance to you , where

1= most important
2=medium importance.
3= least important.

Prevents menopausal symptoms e.g. hot flushes ☐
Vaginal dryness/ urinary problems
Irritability

Helps prevent osteoporosis ☐

May help prevent heart disease ☐

23.Do you have to pay for your HRT prescription?(please tick)

a) Yes
b) No

24.Would free prescription make you more likely to take HRT?(please tick)

a) Yes
b) No

THE FINAL QUESTIONS ARE ABOUT YOU AND ALSO TO FIND OUT IF YOU MAY BE WILLING TO MEET WITH THE RESEARCHER FOR INTERVIEW.

25.What is your date of birth

26.What is your post code [first 3 characters]

27.Do you suffer now or did you at any time in the past, from a medical condition, which the doctor said was a reason not to take HRT?

Yes

No

28.If yes, what was / is that condition?

Thank you very much for taking the time to complete this questionnaire.

I am hoping to talk to a number of women about their experiences and opinions .If you would be prepared to meet with the researcher to discuss your answers in more detail please tick the box and enter your name address and telephone number in the space provided. Ticking the box does not mean the researcher will visit you without prior arrangement.

☐

NAME;

ADDRESS;

TELEPHONE NUMBER;

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.
IT WOULD BE MOST HELPFUL IF YOU COULD RETURN IT TO ME BY ……

A STAMPED ADDRESSED ENVELOPE IS ENCLOSED.

Appendix 3.2

HRT COMPLIANCE STUDY

FIONA BEST WARD

NAME ……

ADDRESS ……
……
……

D.O.B. ……..

UNIT NUMBER ……..

G.P. ……..
……..

RESPONSIBLE CONSULTANT

1 ☐ 7 ☐
2 ☐ 8 ☐
3 ☐ 9 ☐
4 ☐ 10 ☐
5 ☐ 11 ☐
6 ☐ 12 ☐

DIAGNOSTIC CODE ☐

OPERATIONAL PROCEDURE CODE ☐

DID/DOES THIS PATIENT HAVE A HISTORY OF BREAST C.A.

YES ☐ NO ☐

Appendix 3.3 (a) Letter to all consultant gynaecologists at hospital A

GynaecologyWard
All Consultant Gynaecologists
Hospital A

Dear Consultant Gynaecologists

Compliance with hormone replacement therapy after elective hysterectomy and the reasons women give for continuance or discontinuance
ERC Study No: (789)

I am writing to ask for your support in the above study. The study is to be carried out by the author, Fiona Best Staff Nurse, as part of an MSc by Research. The aim of the study is to answer the following related questions:

1. How many women in the NHS trust who have undergone elective hysterectomy with bilateral oophorectomy for menorrhagia take HRT?
2. When do they commence therapy?
3. When do they stop therapy?
4. Why do they stop?
5. Are the reasons for early discontinuance different form those for late discontinuance?
6. Does socio-economic group influence HRT use in the region?

Participants will be selected from in-patient records at hospital A and hospital B for the time period January 1992 to December 2001. Subjects will be under 51 years of age at the time of operation and women who had undergone surgery for malignancy or who have a medical history of breast carcinoma will be excluded. The study has been approved by the Ethical Committees of both Stirling University and the NHS Board (ERC Study Number 789)

I ask firstly for your permission to check your patients' case notes to ensure that they do indeed fit the inclusion criteria and secondly for your permission to subsequently send selected patients a postal questionnaire to complete at home. A copy of the questionnaire is appended. I confirm that the General Practitioner of each subject will also be approached for their permission prior to any contact being made with patients. If you wish any further details of the study please contact me at the above address
Thank you very much for your assistance.
Yours sincerely Fiona Best Staff Nurse

Appendix 3.3 (b) Letter to all consultant gynaecologists at hospital B

Gynaecology ward

All Consultant Gynaecologists
Hospital B

Dear Consultant Gynaecologists

Compliance with hormone replacement therapy after elective hysterectomy and the reasons women give for continuance or discontinuance
ERC Study No: (789)

I am writing to ask for your support in the above study. The study is to be carried out by the author, Fiona Best Staff Nurse, as part of an MSc by Research. The aim of the study is to answer the following related questions:

1. How many women in the NHS trust who have undergone elective hysterectomy with bilateral oophorectomy for menorrhagia take HRT?
2. When do they commence therapy?
3. When do they stop therapy?
4. Why do they stop?
5. Are the reasons for early discontinuance different form those for late discontinuance?
6. Does socio-economic group influence HRT use in the region?

Participants will be selected from in-patient records at hospital A and hospital B for the time period January 1992 to December 2001. Subjects will be under 51 years of age at the time of operation and women who had undergone surgery for malignancy or who have a medical history of breast carcinoma will be excluded. The study has been approved by the Ethical Committees of both Stirling University and the NHS Board (ERC Study Number 789).

I ask firstly for your permission to check your patients' case notes to ensure that they do indeed fit the inclusion criteria and secondly for your permission to subsequently send selected patients a postal questionnaire to complete at home. A copy of the questionnaire is appended. I confirm that the General Practitioner of each subject will also be approached for their permission prior to any contact being made with patients. If you wish any further details of the study please contact me at the above address.

Thank you very much for your assistance.
Yours sincerely Fiona Best Staff Nurse

Appendix 3.4 Letter of introduction from consultant gynaecologist

Department of Gynaecology

The Gynaecology Office Telephone No:

Dear

This letter relates to the hysterectomy operation you had some time ago. We are trying to find out how many women use HRT (hormone replacement therapy) after hysterectomy, and would very much like your help.

Staff Nurse Fiona Best from the Gynaecology Department will contact you soon, by letter, to see if you are happy to help. If you agree, you will be given a short confidential questionnaire to fill in and return.

If you like, we will tell you what we have found at the end of the study.

If you do not wish to be contacted by Fiona, would you please telephone the above number and ask for your name to be removed from the list of possible participants.

Thank you for reading this letter.

Yours sincerely

Consultant Gynaecologist/Obstetrician

Appendix 3.5 Letter to GP

Gynaecology ward.

Dear Dr

I am writing to inform you of a research project I am undertaking concerning women who have undergone elective hysterectomy with bilateral oophorectomy for menorrhagia and their use of HRT. It is a voluntary study involving the answering of a postal questionnaire. The aim of the study will be to answer the following related questions:

1. How many women in the NHS trust who have undergone elective hysterectomy with bilateral oophorectomy for menorrhagia take HRT?

2. When do they commence therapy?

3. When do they stop therapy?

4. Why do they stop?

5. Are the reasons for early discontinuance different from those for late discontinuance?

6. Does socio-economic group influence HRT use in the region?

Participants will be selected from in-patient records at hospital A and hospital B the time period January 1992 to December 2001. Subjects will be under 51 years of age at the time of operation and women who had undergone surgery for malignancy or who have a medical history of breast carcinoma will be excluded. The study is part of an MSc by Research and has been approved by the Ethical Committees of both Stirling University and the NHS Board (ERC Study Number 789) If you have any patients who have had this operation for menorrhagia and in your opinion should not be approached for participation in this study, would you please inform me at the above address (before) so that I may exclude them from the study.
Thank you very much for your assistance.

Yours sincerely

Fiona Best
Staff Nurse

Appendix 3.6 Covering letter to patient for questionnaire

Dear

Do women use hormone replacement therapy after hysterectomy? How long do they take it for and why do they stop?

I am writing to you to ask if you would consider completing the short questionnaire enclosed. I am hoping to discover what women think about the use of Hormone Replacement Therapy (HRT), and if they use it.

Before you decide if you can help me, it is important that you understand what is involved; so I have enclosed some information about the study, so that you will be able to understand what is involved.

The study is entirely voluntary and your personal details will not be identifiable to anybody other than the researcher (that is, myself). Once your answers to the questionnaire have been received they will be confidential, and all collected answers will be destroyed at the end of the study.

The questionnaire should take no more than 15 minutes to complete.

While I realise that there is no direct benefit to yourself, if you take part in this study, I would be very grateful if you felt able to participate as I believe that the information you can give is of great value, and could be used by nurses when planning future gynaecology care. I would be happy to send you a copy of the findings of the study, once it is complete.

It would be most helpful if you could return the completed questionnaire by …….

If you choose not to take part in the study, please return the uncompleted questionnaire in the envelope provided in order to ensure that you are not contacted again.

Thank you for taking the time to read this letter, and I look forward to hearing from you.

Yours sincerely,

Appendix 3.7 Patient information sheet.

Gynaecology Department Address
Gynaecology office telephone no;

Study Title

Do women use hormone replacement therapy after hysterectomy? How long do they take it for and why do they stop?

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.
As you will probably be aware, there is an increasing amount of information about Hormone Replacement Therapy (HRT). The purpose of this study is to find out how many women take HRT after having a hysterectomy, with the removal of their ovaries; how long they take it for; and why and when they stop taking it. The reason this is important is that we would like to improve the service we give to women in the region having this type of operation; and in order to do this, we need to understand fully what experiences such women have had in the past.

You have been chosen as one of approximately 360 women who had this operation at some time between 1992 and 2001, at either hospital A or hospital B.The consultant in your case has given me permission to write to you.

The study is entirely voluntary, and it is up to you to decide if you wish to take part. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. A decision not to take part will not affect the standard of care you will receive from any hospital at any time in the future.

The study involves the completion of the enclosed questionnaire only, and this should take no longer than 15 minutes to complete. However, you may wish to consider being interviewed as well. If you agree to this, you will be asked to sign a standard consent form agreeing to the interview, a copy of which you will be given to keep. Interviews will be arranged at a time and place convenient to you and may last approximately one hour. The questions you will be asked will be about your opinions of HRT, and your experiences of it; the reasons you take it or the reasons you don't. The questionnaire has a box you can tick if this is something you would be prepared to consider.

In the event of an interview taking place, it will be possible for you to request access to a psychologist, should you feel that there are any unresolved issues arising out of your HRT treatment (this is standard interview practice).

I realise there is no direct benefit to yourself in taking part in this study; however, women in the future may be able to benefit from the findings of this study. I should also emphasise that you will incur no expenses as a result of taking part in the study.

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed, so that you cannot be recognised from it.

The results from this study will form the basis of an MSc thesis that may be published in the future. No individual participant in the study will be identified.

Fiona Best, a Staff Nurse in Gynaecology at hospital B is carrying out this research project. The Ethics Committees of both the local Health Board and the University of Stirling have approved it. There is no collaboration with any pharmaceutical company.

Should you wish to contact me for further information, I can be reached at the above address and telephone number.

Please keep this sheet for your records if you decide to participate.

Appendix 3.8 Reminder letter

Gynaecology Ward

Telephone no.

Dear

Sometime ago I sent you a questionnaire and some information regarding a study I am conducting into women's use of HRT after hysterectomy. To date I do not appear to have received your reply. I now enclose a duplicate copy of the questionnaire in case the original was lost. I would be most grateful if you felt able to complete it, but if you do not wish to do so return the blank questionnaire to me and I will ensure that you are not contacted again.

Thank you for reading this letter.

Yours faithfully,

Fiona Best, Staff Nurse.

Appendix 3.9 Consent to interview

COMPLIANCE WITH HORMONE REPLACEMENT THERAPY AFTER ELECTIVE HYSTERECTOMY AND THE REASONS WOMEN GIVE FOR CONTINUANCE OR DISCONTINUANCE

CONSENT TO INTERVIEW.

I hereby consent to an interview, which may be tape recorded for research purposes.

I understand that I am free to withdraw at any point in time, without giving any reason, and am under no obligation to answer any question put to me by the researcher. I also understand that all my answers will be treated confidentially, and that any recordings will be destroyed at the end of the study.

I confirm that I have been informed of the availability of a qualified counsellor if I should wish to use such a consultation.

Signed ……

Date ……