# ADVERSE OUTCOMES AFTER COLPOSCOPY

by

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## **Abstract**

Little is known about the long term adverse outcomes following colposcopy. This thesis employs a mixed method approach to investigate the long term adverse impacts of undergoing this procedure.

Following a systematic review undertaken to explore the evidence base in terms of the potential impacts of colposcopy upon psycho-sexual functioning a two stage cohort study using questionnaires was undertaken employing quantitative and qualitative data collection tools.

Of particular interest was whether the level of colposcopic intervention (colposcopy, biopsy or loop excision) was associated with more pronounced levels of sexual dysfunction, higher levels of anxiety and depression and impaired quality of life.

There were no significant differences observed between women undergoing colposcopy, biopsy or loop excision for any of the outcome measures across both stages of the study. Age was the only predictor found to be associated with some of the outcomes measured.

The study concludes that the level of colposcopic intervention has no impact upon outcomes measured. Factors other than undergoing colposcopy are likely to explain any problems observed in this cohort.

# **Dedication**

In memory of Chris Flanagan Teresa Mary Mckeon & Lavinia Dorothy Flanagan

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## **CHAPTER 1: INTRODUCTION**

Screening for cancer and other conditions aims to 'identify preclinical disease by a relatively simple test' and ultimately to reduce mortality and improve patient quality of life. However, screening has the potential to do harm as well as good. A National Cervical Screening Programme has been in existence in England and Wales since 1988 and aims to provide a cost-effective programme to reduce morbidity and mortality rates from cervical cancer. Women between the ages of 25 and 65 are routinely invited to attend their general practice to undergo a test that involves a small brush removing a sample of cells from the transformation zone (TZ). This is the area of the cervix where the majority of abnormalities develop. The sampled cells are placed in a liquid solution and sent for laboratory examination. If mild to moderate abnormalities are identified, a referral is made to a colposcopy clinic.

Colpsocopy is an essential part of the NHS Cervical Screening Programme (NHSCSP). It is a detailed examination of the cervix (neck of the womb) and is performed by a doctor or qualified colposcopist.<sup>3</sup> Women are invited for a colposcopy following a referral generated via the National Cervical Screening Programme requesting further investigation of potential cell abnormalities discovered during routine cervical screening. Colposcopy clinics enable the diagnosis and treatment of CIN (Cervical Intraepithelial Neoplasia) in an outpatient setting.<sup>3</sup> There are approximately 406,000 colposcopy appointments each year in England and Wales of which 134,000 are new referrals (the remainder being follow-up appointments); 78% of these are triggered by screening.<sup>4</sup> The success

rate for treatment by colposcopy exceeds 90% and although it is a relatively safe procedure, there is evidence reported in 'best practice guidelines' that some post-procedure complications can occur - including short-term psychological impacts, obstetric effects and an increase in the incidence of cervical stenosis.<sup>5,6</sup>

Despite colposcopy being a relatively common procedure, little research has explored its potential long-term impacts upon psychological well-being, quality of life and sexual function. The long-term follow-up of women referred to colposcopy has mainly concentrated on establishing the rate of recurrence of CIN (the cell changes that can lead to potential abnormalities).

Studies related to the consequences of an abnormal smear, Human Papillomavirus (HPV) testing or colposcopy have not investigated the long-term experience of a defined cohort of women having undergone colposcopy stratified by level of treatment. Cohort studies have largely focused upon assessing the incidence of cervical stenosis;<sup>8</sup> the impact of colposcopy on subsequent pregnancies or the recurrence of CIN.<sup>9-12</sup>

It is timely to investigate how frequently these adverse impacts are experienced and to establish whether they have long-term consequences.

Furthermore, most of the existing research on the consequences of colposcopy has been based primarily on the use of qualitative methodologies or via small, underpowered, studies that focus solely on the time of the abnormal smear or colposcopy. None have had sufficient size to differentiate between post-procedure effects on women that experienced colposcopy purely for diagnosis and those that

underwent more 'invasive' treatments such as biopsy or loop excision. The need to establish the long-term psychological and sexual consequences of colposcopy itself has been acknowledged<sup>13</sup> and this study aimed to do so.

## 1.2 Aims and objectives

The primary aim of this study was to determine whether undergoing colposcopy and treatment for CIN has any long-term adverse psychological or sexual impacts.

Research question: Are there any long term adverse impacts of undergoing colposcopy?

Study objectives were to:

- 1. Undertake a systematic review of the available evidence regarding the psychosexual consequences of colposcopy and treatment for CIN.
- 2. Investigate the long-term effects of colposcopy upon women's quality of life.
- 3. Establish whether colposcopy has any long-term effects upon sexual function.
- 4. Characterise adverse sexual function by level of colposcopic intervention.
- 5. Determine the potential sociodemographic and/or clinical predictors of adverse outcomes following colposcopy i.e level of treatment/intervention, age and deprivation.

Overview of methodology

This thesis reports the findings of a cohort study designed to investigate the adverse psycho-sexual effects of undergoing colposcopy. Following a systematic review of the evidence for psycho-sexual consequences of colposcopy and treatment for CIN, the study utilised a two stage questionnaire to provide data to ascertain the potential clinical, sociodemographic and lifestyle factors that may influence whether or not women experience adverse outcomes following colposcopy, and to investigate the nature of any adverse outcomes experienced.

#### Systematic Review

A systematic review was undertaken of the available evidence relating to the adverse psycho-sexual impacts of undergoing colposcopy and treatment for CIN. The purpose of this was two-fold: to provide an overview of the current evidence base relating to these outcomes and to provide a reference point for the empirical data collected in the subsequent questionnaire element of this study.

#### Questionnaire

A cohort of women attending for colposcopy between 1<sup>st</sup> April 2008 and 31<sup>st</sup> March 2009 was identified from the hospital records at five colposcopy units across the West Midlands:

- Birmingham Good Hope (Heart of England NHS Foundation Trust)
- Birmingham Heartlands (Heart of England NHS Foundation Trust)
- Solihull Hospital (Heart of England NHS Foundation Trust)
- Birmingham Women's Hospital (Birmingham Women's NHS Foundation Trust)

Birmingham City Hospital (Sandwell and West Birmingham NHS Trust)

Women who had undergone colposcopy during the time period of interest were stratified into equal groups by level of intervention/treatment for both stages of the study. The numbers in brackets below indicate the proposed sample size in each group (stage one total n=1,050, stage two total n=630).

#### Stage one:

- 1. Colposcopy only no treatment or investigation (n=350)
- 2. Colposcopy with investigation/diagnosis e.g. punch biopsy (n= 350)
- 3. Colposcopy and treatment e.g. loop excision (n= 350)

#### Stage two:

- 4. Colposcopy only no treatment or investigation (n=168)
- 5. Colposcopy with investigation/diagnosis i.e. punch biopsy (n= 168)
- 6. Colposcopy and treatment i.e. loop excision (n= 168)

The initial study design included a control group, made up of age- and deprivation-matched women who had never attended for a colposcopy in order to ascertain the excess risk of adverse outcomes in the colposcopy group compared with controls. These control patients were to be identified from the patient list of a general practice in the West Midlands. However, this proved unfeasible due to the difficulty of recruiting GP practices to provide details of control patients for recruitment to the study (outlined in more detail in Chapter 5).

The first questionnaire (Q1) was relatively brief and aimed to establish the prevalence of sexual problems and quality of life of respondents. To complement quantitative data collection, Q1 also included a qualitative element; a blank page was provided within the questionnaire inviting women to note any further, unprompted comments about issues related to the topic area. Introducing this element enabled exploration of some of the issues that women considered to be important, generating qualitative data around women's experiences of the colposcopic procedure(s), adverse events experienced and general comments that participants felt were of interest or importance. Respondents to Q1 were asked to indicate whether they would be prepared to participate in a second, more detailed questionnaire (Q2) designed to collect demographic data alongside data related to a range of validated measures of sexual function, depression, anxiety and quality of life. Those who indicated a preference to receive the subsequent questionnaire were sent this shortly after their responses to Q1 were received.

Analysis of the questionnaire data was undertaken in two stages. Responder bias was calculated for both Q1 and Q2. Analysis of questionnaire one included calculation of the frequencies of responses to all questions in terms of respondent age, socioeconomic status and the treatment type undergone. Chi² tests were performed to investigate relationships between the variables of interest. More sophisticated analyses was undertaken for questionnaire two, including bivariate analyses of the presence or absence of female sexual dysfunction (FSD), scoring 'normal' or 'mild and above' on the depression and anxiety scales, comparison of means tests for the scores on the WHOQOL-BREF domains (physical, psychological, social and environmental). Bivariate analyses were undertaken for

the total scores on the Female Sexual Function Index (FSFI), HADS anxiety and depression scores to ascertain the significant predictors of the variance in scores. Any significant predictors were entered into a multiple regression model to ascertain the 'best' predictors of the score variation.

#### 1.3 Structure of thesis

Chapter two provides the background to the clinical features and epidemiology of cervical cancer and an overview of the NHSCSP. It also describes treatments available at colposcopy clinics, followed by a discussion of the treatment effectiveness and a summary of what is known about the adverse effects of cervical screening and colposcopy. Chapter three provides a systematic review of the literature pertaining to adverse psycho-sexual outcomes associated with colposcopy. Chapter four assesses the debates relating to the use of the terminology relating to sexual dysfunction within health research, touching on the some of the sociological and psychological issues pertaining to it. Chapter five provides an overview of the methodological approach including study design and study population. Chapter six presents the results from questionnaire one and summary of the findings. **Chapter seven** presents the results from questionnaire two along with a summary of the findings. Chapter eight presents the results from the qualitative element of the study and discusses these in the context of the wider literature. **Chapter nine** presents the discussion of the findings and includes study limitations along with the strengths of the study. It will also include suggestions for service improvement. Finally, **chapter ten** draws the study conclusions together including suggestions for future research.

### **CHAPTER 2: BACKGROUND**

The following chapter will present the clinical features and epidemiology of cervical cancer and describes the treatments available for CIN. It also discusses the evidence pertaining to the effectiveness of treatments for CIN and provides a summary of what is known in terms of the adverse physical and obstetric effects of cervical screening and colposcopy.

## 2.1 Prevalence and aetiology

Around 2,900 women are diagnosed with cervical cancer in the UK each year.

Overall, 2 out of every 100 cancers diagnosed in women are cervical cancers. It is the second most common cancer in women under 35 years old and is most frequently diagnosed following cervical screening. Around 4.4 million women are invited for screening every year and of these, around 24,000 have a 'severely' abnormal result (CIN 3).<sup>14</sup>

Table 2.1 Number of new cases and rates of cervical cancer UK, 2007<sup>15</sup>

	England	Wales	Scotland	N. Ireland	UK
Cases	2,276	184	284	84	2,828
Crude rate per 100,000 population	8.8	12.1	10.7	9.4	9.1
Age-standardised rate (European) per 100,000 population	8.0	11.3	9.8	9.3	8.4

## 2.2 Cervical cancer - clinical features and epidemiology

There are two types of cervical cancer, the most common of which is squamous cell cervical cancer. This develops from a skin-like cell that covers the cervix and accounts for approximately 90-95% of all cervical cancers. <sup>16</sup> Much less common is adenocarcinoma cervical cancer which develops from a glandular cell (a cell that makes mucus) within the cervical canal. The human papillomavirus (HPV) is the main cause of cervical cancer and out of the more than 100 known forms of HPV, types 16 and 18 are considered 'high risk' for cancer of the cervix. <sup>17</sup> Persistent or frequent infection with HPV type 16 or 18 increases the risk of developing precancerous cells and cervical cancer and it is estimated that HPV infection accounts for over 70% of all cases of cervical cancer detected. <sup>17</sup> Some types of HPV are passed on through sexual intercourse as well as non-penetrative sexual activity and girls aged 12 or 13 are now routinely offered a vaccine against HPV.

There are other known risk factors for cervical cancer. For example, herpes and HPV infection can double the risk of cervical cancer whist infection with Chlamydia and HPV can increase the risk by 80%. There is also evidence that smoking can increase the risk of developing cervical cancer, <sup>18</sup> and women with a weakened immune system (women with AIDS or HIV, or women on immunosuppressant drugs) have a higher than average risk of developing cervical cancer. <sup>19</sup>

Until recently, it was assumed that the link between the oral contraceptive pill and cervical cancer was number of sexual partners; the assumption being that women on the pill may be more likely to have multiple partners, or less likely to use barrier contraceptives. Evidence suggests that women who have used the pill for at least five years double their risk of developing cervical cancer.<sup>20</sup> This risk drops when

the pill is no longer taken. There would also appear to be a link between social deprivation and cervical cancer. Women living in more socioeconomically deprived areas have been found to have rates of cervical cancer three times higher than those living in less deprived areas.<sup>21</sup>

#### 2.2.1 Clinical Features

Unlike a number of other cancers, many women with cervical cancer will be asymptomatic. This is one of the primary reasons that screening is recommended, as screening can detect abnormalities and pre-cancerous cell changes that may otherwise take several years to manifest as signs or symptoms of the disease.

However, a number of non-specific symptoms may be an indication of the disease: intermenstrual bleeding; post-coital bleeding; postmenopausal bleeding (risk of cervical cancer increases with age); blood stained vaginal discharge and pelvic pain/dyspareunia.

Symptoms of advanced cervical cancer include renal failure, discomfort, leakage of urine or faeces from a fistula, lymph oedema, or severe haemorrhage.

## 2.3 The National Cervical Screening Programme - an overview

There has been a cervical screening programme in the UK since 1965. It was not until 1988 when a call and recall system was put in place that a systematic NHS Cervical Screening Programme (NHSCSP) was launched.<sup>22</sup> This system was

designed to ensure that maximum numbers of women are invited to attend cervical screening depending on their risk status (i.e. age).

The NHSCSP is nationally coordinated and locally managed. The call and recall system for each area holds the patient lists for all GP practices and sends these lists to each GP who is expected to check the records to ensure patient details (such as address and age) are correct. The call and recall system sends out all screening invitations and co-ordinates communication of reminders and results. Women are invited to attend their first routine screening appointment aged 25. Between the ages of 25 to 49, invitations are sent out every three years. Between the ages of 50-64, women are invited every five years and aged 65 and beyond, only those who have not been screened since the age of 50, or who have received recent results showing abnormalities are invited for screening. Women are invited five to six weeks prior to the date when the appointment is scheduled.

The GP practice is tasked with undertaking the test, which is sent for laboratory analysis. Following this, the laboratory sends the results to the GP, and checks that any results showing an abnormality are followed up by the practice. The colposcopy service receives referrals directly from the laboratory or primary care and undertakes further diagnoses and treatment if required. Following investigation and/or treatment, the colposcopy service discharges women back to the call and recall system.

The programme operates according to an initial screening invitation age of 25 following evidence that the incidence of cervical cancer in women under 25 is too

rare for screening below this age to be considered cost-effective. <sup>23,24</sup> The policy was formally reviewed in June 2009, partly due to public interest following the death of Jade Goody, a high profile 'celebrity' who was diagnosed and died of cervical cancer aged 27. Sasieni's review<sup>25</sup> examined the evidence for the efficacy of screening women under the age of 25 and concluded that 'cervical screening in women aged 20-24 is substantially less effective in preventing cancer (and in preventing advanced stage tumours) than is screening in older women. <sup>25</sup> In particular, the review concluded that cervical cancer is rare in younger women; there is no evidence that cervical screening works in women aged 20-24 because the women who developed cancer under the age of 25 were as likely to have been screened as unscreened; data available suggests that there is very low progression potential in women under the age of 25; there are harms and costs associated with screening women aged 20-24, and current evidence suggests that the harms outweigh the costs of screening women in this age group.

Screening was initially based on the Pap smear, developed in 1943 by George Papanicolaou. Following the 'phasing out' of the Pap smear, today, cervical screening in the UK uses liquid-based cytology. This means that the cells collected from the cervix are preserved in a liquid solution, rather than being transferred to a slide as was previous practice. This method has a number of advantages over the traditional 'smear test'. Firstly, it simplifies the process for the person taking the smear and improves the preservation of the cellular material. It is also takes less time for the laboratory to process the sample, so results can be returned to patients much sooner. Probably the most important improvement, certainly from a patient perspective, is that it reduces the number of inadequate smears. This

reduces the burden upon patients who may be unnecessarily recalled to provide a further sample.

Despite claims that cervical screening saves lives – over 4,000 in England per year,<sup>26</sup> it is not a wholly uncontroversial public health policy with concerns that is leads to over-treatment and may cause more harm than good. It should be noted that the evidence for the effectiveness of this programme has not been demonstrated through the means of randomised controlled trial. Raffle et al (1995) note that due to the fact that cervical screening is now widely practised, it is too late to be able to truly test its efficacy with a randomised control trial, thus 'we must live with the fact that we can never know for certain what contribution screening has made'.<sup>27</sup> Nevertheless, it would appear that screening for cervical cancer has had an impact upon both cervical cancer incidence and mortality rates.

As cervical screening programmes have become formalised within general practice and more recently incentivised in primary care through the Quality Outcomes Framework, there has been an increase in coverage to approximately 85%. This has resulted in a fall in the incidence of invasive cancer due to early diagnosis of pre-cancerous changes and other abnormalities that can be treated before disease progression.

## 2.4 Colposcopy services

Colpsocopy is an essential part of the NHSCSP. Colposcopy is a detailed examination of the cervix (neck of the womb) and is performed by a doctor or

qualified colposcopist in an outpatient setting. Women are invited for a colposcopy following a referral generated via the National Screening Programme requesting further investigation of potential cell abnormalities discovered during routine cervical screening. National guidelines for the NHS Cervical Cancer Screening Programme published in 2004 require that women who are diagnosed with mild cell changes (CIN 1) are referred for colposcopy after three positive tests.

The most recent NHS guidelines 'Colposcopy and Programme Management' have been adopted by colposcopic services in England and Wales.<sup>30</sup> There are approximately 406,000 colposcopy appointments each year of which 134,000 are new referrals.<sup>4</sup>

There are three reasons for referral to colposcopy:

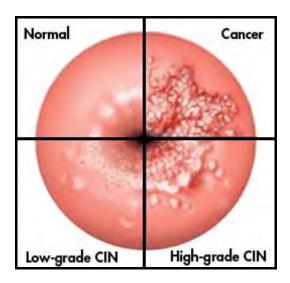
- The cervical screening results are not abnormal, but show that the laboratory was unable to report results. This may be because there are not enough cells to adequately assess whether the cervix is healthy or not.
- The cervical screening test has found evidence of possible cell abnormalities (dyskaryosis). This can serve as a warning that cervical cancer may develop in the future. These abnormalities are stratified into borderline or mild (CIN 1), moderate (CIN 2), or severe dyskaryosis (CIN 3).
- Women may be experiencing signs and symptoms related to the health of the cervix (abnormal bleeding, pelvic pain, unusually heavy discharge).

The subjectivity of judgement in diagnosing a cervical abnormality (exactitude is not possible) will mean that many women may undergo colposcopy unnecessarily. This should be borne in mind especially in the light of the evidence that colposcopy can have negative effects upon women's health and well-being and the fact that little is known of the long term adverse effects of colposcopy upon women's health. This would indicate that there is a need for a study to investigate whether there is a reduction in women's quality of life and in particular whether there is an effect upon women's sex life after colposcopy.

#### 2.4.1 Treatments for CIN

Treatments for CIN vary depending upon the grade of the neoplasia - namely Grade 1, 2 or 3. Figure 2.1 demonstrates the differences between a normal cervix compared with low grade and high grade CIN and cervical cancer. With CIN 1 (also referred to as borderline changes), cells often revert to 'normal' without any treatment and if this level of abnormality is identified, it is usually monitored by a repeat screening test six months later. However, after three borderline samples, women will be routinely referred for colposcopy. CIN 2 and 3, referred to as moderate or severe dyskaryosis (or carcinoma-in-situ) respectively are routinely referred for treatment with the aim of removing the abnormal tissue and cells or destroying the cells.

Figure 2.1.Cervical abnormalities<sup>31</sup>



Procedures to remove the abnormal area include a cone biopsy; large loop excision of the transformation zone (LLETZ) and hysterectomy, although this is not commonplace. Cone biopsy is used as a method of diagnosis and treatment where the area is of sufficient size. A laser is used to cut away a cone-shaped piece of the cervix which will be sent for analysis to determine the grade of CIN found in the cervix.

LLETZ is the most common method of treatment but methods employed may depend upon the facilities available in a particular NHS Trust as well as the clinician's decision as to what would be most appropriate given the age of the patient, or extent of disease. LLETZ is also known as LEEP (Loop electrosurgical excision procedure) and is usually performed under local anaesthetic, although general anaesthetic may be used if a significant area of tissue requires removal. A thin wire loop heated by an electric current enables the colposcopist to cut away the area of abnormality and also seals the tissue to minimise post-surgery

bleeding. The tissue is sent to the laboratory to ensure that all the abnormal cells have been removed. If the edge of the sample cells have no abnormality, no further treatment will be required. Otherwise, another colposcopy will be performed to ensure removal of the areas of abnormality.

Procedures to destroy the cells in the area of the abnormality include laser therapy; cold coagulation and cryotherapy. Laser therapy (also known as laser ablation) uses a laser to remove the area of abnormal cells and along with other excisional methods (LLETZ) is regarded as a procedure with lower morbidity than cold coagulation, which removes cells by heating the area of abnormality using a hot probe.<sup>32</sup> Cryotherapy, which uses a probe to freeze the abnormal cells, is not commonly used as it has a lower success rate than other treatments.

#### 2.4.2 Colposcopy procedure

Colposcopy is offered in an out-patient setting. At the colposcopy appointment, the nurse records the patient's medical history, explains the procedure and answers any questions the patient may have. The patient lies on a couch that supports the legs. The colposcopist warms and lubricates a speculum and places it in the vagina, to enable the cervix to be viewed. The colposcope, which works by enlarging the image and providing a view of the cervix in 3D, is used to enable a closer examination of the cervix (see Figure 2.2). An iodine solution is applied to the cervix using a cotton-wool ball and this is used to highlight any abnormal cells and enable the colposcopist to make a diagnosis. If no abnormalities are found, no

further investigation is required. However, if a diagnosis is made, a punch biopsy may be taken or treatment undertaken.

Figure 2.2 The colposcope



## 2.5 Adverse effects of cervical screening (fear of the smear)

Raffle *et al's* Bristol based study<sup>27</sup> aimed to analyse the rates of detection of cervical abnormalities and investigate the assumptions underpinning screening programmes. The assumption that 'abnormal cells' would only be found in the smears of women 'destined to die of cervical cancer' and that surgical treatment would prevent this is challenged, as Raffle *et al* suggest that such an assumption may lead to the misdiagnosis of cancer for women who may never go on to develop cancer despite the presence of some abnormalities of the cervix (i.e. overdiagnosis). The authors acknowledge that analysis and interpretation of cervical screening tests is not an exact science but 'a difficult and subjective task, and the

distinction between mildly changed and normal cells remains essentially arbitrary'.<sup>27</sup> It also noted that local treatment of CIN does not ensure the prevention of cancer in every case. Further to the issue of over-diagnosis and the acknowledged subjectivity of cervical screening, screening has also been argued to have a number of negative psychological impacts on women undergoing the procedure.

Women's experiences of cervical screening have been explored by commentators and researchers and the potential adverse effects of receiving an abnormal result are well described. 33-35 Women may have to confront issues around their own body image, mortality, self-efficacy and sexuality and receiving a positive result will raise the spectre of cancer as well as a fear that they may become stigmatised due to associations that have been drawn between cervical cancer and promiscuity. A 2006 Scottish study of the psychological effects of receiving a smear result of a low grade abnormality found levels of anxiety to be consistent with levels found in studies of women with high grade abnormalities. This study also identified particular sub-groups of women likely to be at higher risk of increased anxiety levels; including younger women, women with children, women who smoked and women who exercised more. 37

Feminist discourse emerged in the 1980's that challenged the 'interventionist medical model'<sup>38</sup> suggesting that the personal costs to individual women in terms of the side-effects of the screening procedure itself do not outweigh the public health benefits (fear of cancer; the invasive nature of the procedure, physical and

emotional trauma). Germaine Greer writing in 1999 stated that 'screening is many times more likely to destroy a woman's peace of mind than to save her life'.<sup>39</sup>

In order for a woman to make a fully informed choice about participating in cervical screening programmes (or indeed any screening programme), accurate information should be provided about the risks as well as the potential benefits. 40 In emphasising only the positive aspects of screening, Raffle states, we are ignoring individuals' autonomy and exacerbating feelings of anger that may be felt by patients who feel they have been 'let down by screening'. Patients may also become complacent, disregarding potential symptoms, in the erroneous belief that screening will offer full protection. It can also lead to problems for health service staff who may be blamed unreasonably for shortcomings that are systemic in the screening programme. There is, however, a clear tension that such transparency may discourage women to participate in screening. Raffle calls for more 'clarity at national level about the purpose of information about screening' which should enable answers to questions about 'the kind of information needed to achieve informed participation, and about how it should be framed and communicated'.

# 2.6 Effectiveness of treatment in preventing recurrence of CIN

Before summarising the evidence examining the known adverse consequences of treatment, this section will outline what is known about the effectiveness of colposcopically directed treatment for CIN in terms of its effect upon recurrence rates.

A systematic review published in 2000<sup>42</sup> looked at studies assessing the effectiveness of a variety of ablative and excisional treatments. The studies included did not detect any cases of progression to cervical cancer, but following the pooling of results, the median follow-up was 12 months, so conclusions about the long-term effectiveness of treatment are limited.

Soutter *et al* investigated the rate of invasive disease following ablative or excisional treatments. <sup>41</sup> The authors also assessed the risk of developing cervical cancer after treatment, using data from 2,116 women observed over a period of eight years (data combined from five UK studies). They noted that previous studies assessing the effectiveness of treatment did not exceed one-year follow-up. The cumulative rate of invasion eight years after treatment was 5.8 per 1,000 and the rate of invasive cancer 85 per 100,000 women years (95% CI: 60 to 119). They concluded that treatments for CIN reduce the risk of cervical cancer by 95% during the first eight years of treatment, but that even with long-term follow-up the risk of developing cervical cancer is five times greater than in the general population. Careful and systematic follow-up is recommended for this group.

So, there is evidence for the efficacy of treating CIN by colposcopically directed interventions, and the case for such intervention is clear. However, to provide a balanced view of the effectiveness of treatment, the following section will outline the literature that focuses upon the potential adverse effects of undergoing treatment.

# 2.7 Literature review: adverse outcomes after colposcopy - what is known?

Chapter three provides a systematic review of the available evidence for adverse psycho-sexual outcomes after colposcopy. This section provides an overview of the evidence for a broader range of adverse outcomes after colposcopy, outlining the psychological, physical and obstetric effects. It also summarises the evidence for the long-term psychological impacts for patients diagnosed with invasive cancer. Some of the studies relating to psycho-sexual function highlighted in this section are further explored in Chapter three.

The long-term physical and psychological consequences of invasive cancer are well described. As Psychological well-being scores in patients diagnosed with cancer remain lower than those of patients with other chronic illnesses or healthy subjects irrespective of age, cancer site or stage of disease, and it has been recommended that psychological interventions for patients facing cancer treatment should be provided as an integral component of cancer management.

Longitudinal studies assessing the consequences of hysterectomy in the treatment of early stage cervical carcinoma report a persistent negative impact on sexual interest. <sup>34,45</sup> Jensen *et al* utilised a validated self-assessment questionnaire (the Sexual function-Vaginal changes Questionnaire, (SVQ)) and found that radical hysterectomy appeared to have a persistent negative impact upon patients' sexual interest. <sup>45</sup> There is also evidence that other gynaecological procedures can impact negatively upon sexual functioning and concerns about impact on sexual function

can be particularly pronounced in younger women.<sup>46</sup> Zippe and colleagues evaluated sexual dysfunction after radical cystectomy (treatment for bladder cancer) and found that all domains of sexual function were affected by the intervention.<sup>47</sup>

Another study focusing upon the impact of hysterectomy upon sexual function also found that women experienced a reduction in their sex life following treatment, <sup>48</sup> although Jensen *et al* found that some of the postoperative problems subsided after six months. However, there is a paucity in the literature in relation to sexual function after hysterectomy and some of the studies report that sexual function may improve after surgery and may be associated with the relief from preoperative dyspareunia and dysmenorrhea. <sup>49</sup>

Treatment for CIN is associated with an excess of adverse obstetric outcomes.<sup>8-10</sup>

There is also evidence that women feel anxiety and fear following an abnormal smear, attending a colposcopy appointment, or being treated for CIN.<sup>33,44,50</sup>

Studies have found that the main reason women may not attend cervical screening in the first instance is that they believe it to be a test for cancer and fear a positive result.<sup>51,52,53</sup>

Diagnosis of CIN is also associated with a perceived threat to life and/or women's fertility, feelings of anger and resentment, <sup>35,54,55</sup> and effects upon body image and sexual functioning. Diagnosis can also have a stigmatising effect, <sup>56</sup> which may lead women to avoid screening in the future. Sexual health promotion messages have advised women that sexual activity at an earlier age can increase the risks

of developing CIN. The implications can lead women to fear being labelled as promiscuous, and thus avoid screening.

Women who have experienced colposcopy may also report adverse effects upon their sexual relationships. <sup>3,35,54,55,57-59</sup> McDonald *et al's* longitudinal study followed 20 patients through diagnosis and treatment with colposcopic biopsy showing 25% CIN 1, 45% CIN 2, and 30% CIN 3. After surgery, women reported that they felt less attractive and also reported reduced levels of sexual function. <sup>60</sup> Gath *et al* studied the emotional reactions of women attending colposcopy in Oxford and alongside using validated measures to assess the frequency, nature, severity and duration of emotional symptoms (including Present State Examination, General Health Questionnaire, Beck depression inventory), semi-structured interviews were conducted that found that women's sexual functioning was impaired following colposcopy. <sup>61</sup> Posner and Vessey's study found that 14% of women reported their sex life was not 'back to normal' 6 to 9 months after colposcopy and 19% of women's sex lives were adversely affected subsequent to treatment. <sup>34</sup>

Despite qualitative research suggesting the possibility of long-term adverse consequences of colposcopy,<sup>34</sup> little research has been undertaken to determine the generalisability of these findings or to quantify the prevalence of these adverse impacts. Quantitative studies have to date been small-scale, underpowered, and tend to be restricted to the time of the abnormal smear or colposcopy.<sup>60,61</sup> Furthermore, none have been of sufficient size to differentiate between women who underwent colposcopy purely for diagnosis and those who had treatment. The

need to establish the long-term psychological consequences of colposcopy has been acknowledged,<sup>55</sup> and a study of sufficient size and follow-up is required.

In the present study, cases were stratified depending upon whether patients were 'treated' at colposcopy, underwent investigation (biopsy) or had no treatment or investigation. This enabled assessment of (for example) whether patients who were 'treated' experienced an excess of adverse events to a greater extent than patients who underwent investigation alone or whether the type of treatment had no bearing on the extent of any adverse outcome experienced.

# 2.8 Physical and obstetric impacts of colposcopy and treatment for CIN

There is a relatively large body of evidence that has investigated the physical and obstetric impacts of undergoing colposcopy and treatment for CIN. Although the main focus of this thesis is to investigate the psychological and sexual impacts of undergoing colposcopy, in order to provide context and a summary of the clinical outcomes associated with the procedure, this section will consider the evidence that has explored the physical side-effects, obstetric impacts and incidence of cervical stenosis following colposcopy and treatment for CIN.

#### 2.8.1 Obstetric outcomes

The mean age of women undergoing investigation and treatment for CIN is around 30 years<sup>62</sup> and therefore it is important to ensure that treatments minimise any adverse obstetric outcomes for future pregnancies. Some studies have reported

no association between treatment and adverse obstetric outcomes, <sup>62,63</sup> whilst others have asserted that such links do exist. <sup>64-67</sup>

A systematic review and meta-analysis of the obstetric outcomes after treatment for CIN published in 2006 provides a useful summary of evidence relating to subsequent pregnancies.<sup>68</sup> Kyrgiou et al consider the effects of a range of conservative treatments for CIN including cold knife conisation, laser ablation, laser conisation, LLETZ or studies considering more than one treatment type upon obstetric outcomes. The study reviewed the available controlled observational studies (due to the nature of CIN and its development, no randomised controlled trials (RCTs) are available, nor are ever likely to be). Included studies focused upon comparing obstetric outcomes in pregnant women with or without a previous treatment intervention for CIN or stage 1 cervical cancer. The outcomes measured related to fertility outcomes including conception rates, number of pregnancies and time to conception. Maternal outcomes included pre-term births (<37 weeks), caesarean section rates, precipitous labour (<2 hours) and preterm spontaneous rupture of membranes (pPROM). Foetal outcomes measured included low birth weight, perinatal mortality and neonatal intensive care unit admission. All 27 studies included in the review were retrospective cohort studies. Some of the findings were hampered by small sample sizes and the problems inherent in retrospective studies. However, this analysis of the best evidence available at the time indicated that there are adverse pregnancy related outcomes following treatment for CIN. After LLETZ, the most commonly utilised form of excisional treatment, there was a significant increased risk of pre-term birth (Relative risk 1.70; 95% CI: 1.24 to 2.35, 156/1402 [11%] vs. 120/1739 [7%]); low birth-weight

(RR 1.82; 95% CI: 1.09 to 3.06, 77/996 [8%] vs. 49/1192 [4%], and pPROM (RR 2.69; 95% CI:1.62 to 4.46, 48/905 [5%] vs. 22/1038 [2%]). Similar associations were also found with cold knife conisation.

No pregnancy related risks were found in relation to ablative treatments (laser ablation). None of the included studies that focused upon fertility outcomes found any adverse effect on this outcome, although the authors note that the evidence is scant. In conclusion, the authors note that the excision of the transformation zone has a small but 'real increase in risk of pregnancy-related morbidity,' and that young women should be informed of this fact.

In 2007, Jakobsson and colleagues' retrospective cohort study (n=25,827) supported the findings of the 2006 meta-analysis and as it is substantially larger, it provides yet more evidence for the increased risks of obstetric outcomes for women undergoing excisional treatment for CIN.<sup>69</sup>

Following publication of this and subsequent large population based studies, <sup>66,71</sup> Arbyn and colleagues published a 'more comprehensive' review of the evidence paying particular attention to more serious outcomes - delivery before 32 weeks, birth weight under 2000g and perinatal mortality, for which data had been previously unavailable. Cold knife conisation was found to significantly increase the risk of perinatal mortality, severe and extreme preterm delivery, and low birth weight. Large loop excision, however, was not associated with the more severe spectrum of outcomes, although the authors did not rule out the fact that LLETZ may be associated with increase risk of pre-term birth. <sup>70</sup> The study findings

supported those from Kyrgiou *et al* and Bruinsma *et al* that ablative techniques are less likely to be associated with adverse obstetric outcomes than the more commonly utilised excisional treatments.

In 2011, Bruinsma and colleagues published an up to date systematic review and meta-analysis, motivated by the number of larger scale studies undertaken since the previous review.<sup>71</sup> Including data available from these studies provides a more comprehensive assessment of the adverse obstetric risks associated with treatments for CIN. The review highlights the three main sources of comparison for studies investigating the risk of pre-term birth:

- External comparison groups, namely women who gave birth at the same time who did not have a diagnosis of precancerous changes to the cervix;
- Internal comparison groups, comparing birth outcomes before treatment with births after treatment;
- Comparison of birth outcomes for women who had previous treatment for precancerous changes with outcomes for women who had a diagnosis of precancerous changes but who had not been treated.

The review investigates the impact of the type of comparison group on any association between treatment and subsequent preterm births (pre 37 weeks) and to see if the risk varies across treatment types (ablative or excisional). Overall, excisional treatments were associated with increased risk of preterm births, when

compared with an external (RR 2.19, 95% CI 1.93-2.49) or internal (RR 1.96, 95% CI 1.46-2.64) comparison group. In the case of women who were assessed but not treated the risk estimate was smaller (RR 1.25, 95% CI 0.98-1.58), suggesting intervention and treatment are higher risk factors for adverse obstetric impacts than women who underwent assessment alone.

This review adds to the previous debate as it provides evidence that ablative treatment may also be associated with an increased risk of preterm birth, albeit a smaller one than excisional treatments. It also highlights the importance of considering the types of comparison groups used in a study, noting the importance of treating studies with an external comparator separately from studies comparing women who have been assessed but not treated for precancerous changes to the cervix.

A subsequent Welsh study using a large data linkage method from routine healthcare databases was undertaken in 2011 and aimed to describe the risk of pre-term birth and low birth weight for women who had been treated for precancerous changes to the cervix. The study population were aged 20 to 39 and had attended for screening or referred for colposcopy over a three year period (n=157,634 negative smear group; n=8,731 colposcopy group; n=7,735 treatment group). The findings from the study indicate that for women undergoing colposcopy only and single excisional treatment, risk of pre-term birth (<37 weeks) increased significantly (OR 1.54; 95% CI: 1.32 to 1.80; OR 1.77; 95% CI: 1.47 to 2.13 respectively) when compared with women who had a negative smear test result. Rates of low birth weight were higher in women referred to colposcopy than

in the negative smear group. The authors found no increased risk of preterm birth or low birth weight between colposcopy only and treatment groups. However, when confounding factors were taken into account (women referred for colposcopy were generally younger at the time of birth, lived in deprived areas, were more likely to be smokers and had higher rates of previous obstetric problems), it is these factors that may plausibly explain the excess of obstetric problems.

A Finnish study published in 2011 examined the incidence of pregnancy after treatment for CIN for which there is little published evidence available. A matched cohort study compared pregnancy outcomes and incidence of pregnancy for women treated for CIN (n=6,179) and age and area matched women (n=30,436) and found that the pregnancy incidence rate was higher in the treated population than in the reference population. Despite this, the authors cite the evidence base that women treated for CIN are at increased risk of preterm birth, but conclude that women should feel reassured by the evidence that treatment for CIN does not reduce the incidence of pregnancies amongst this population.<sup>73</sup>

Kerri *et al* urge caution when considering the body of evidence investigating long-term consequences of treatments for CIN and in particular, pre-term birth, arguing that the nature of the evidence available e.g. many of the studies are retrospective and therefore prone to bias along with the fact that the causes of pre-term birth are complex and multi-factorial in nature and not fully understood should be borne in mind for practitioners working in the field.<sup>74</sup> It is also important to ensure that any potential adverse outcome - obstetric or otherwise - should be put in the context of

the level of abnormality observed and the likelihood that if left untreated could develop into cervical carcinoma.

## 2.8.2 Physical after-effects

It is known that there are physical side-effects following colposcopy and treatment for CIN. Luesley and colleagues (1990) published evidence from a prospective trial with six-month follow-up investigating the morbidity associated with treatment for CIN, using fine loop diathermy (LLETZ). As may be expected given the nature of treatment, mild bleeding occurred in 32% of cases (199/616), moderate bleeding in 8% of cases (51/616) and severe bleeding in three cases (3/616), although 59% experienced no post operative bleeding. Discomfort levels were relatively low with 85% of patients reporting no discomfort and only 1% reporting severe pain.

At six-month follow-up (n=557), 24 (4.3%) patients reported excessive bleeding (secondary haemorrhage) three weeks post treatment. Vaginal discharge was present in most cases post-treatment lasting for two weeks or less in 71% of cases (n=398/557). The period of discharge was prolonged in 5.6% of cases (n=31/557), lasting for six weeks or longer. Severe cervical stenosis (narrowing of the endocervical canal) was noted at follow-up in seven patients (1.3%).<sup>75</sup>

Bigrigg and colleagues followed 250 women who had been treated with LLETZ, three years post-treatment and found no differences in terms of fertility and effect upon menstrual cycles when compared with local controls.<sup>76</sup>

### 2.8.3 Incidence of cervical stenosis (CS) following treatment for CIN

As noted above, cervical stenosis (narrowing of the cervical canal) is one of the identified side effects following treatment for CIN. The studies examining the incidence of cervical stenosis are heterogeneous in terms of the method of treatment assessed, and to some degree, in terms of how cervical stenosis is defined.

Delmore *et al* reported results following 161 patients undergoing laser excision and 132 treated with cold knife conisation.<sup>77</sup> The study notes that 11% (n=6/132) of patients in the cold knife group were diagnosed with cervical stenosis (CS) compared to 4% (n=4/161) in the laser group. The authors note that this rate of cervical stenosis is higher than a previous study<sup>78</sup> reporting 1% and Gilbert *et al* who reported rates of 53%.<sup>79</sup> The reason for this variance would be appear to be related to the definitional (and clinical) differences in the use of the term 'cervical stenosis.

Overall, Delmore *et al's* study supports the evidence base that there are fewer complications with excisional techniques rather than ablative techniques. Baldauf and colleagues investigate the frequency of CS in patients treated either by loop electrosurgical excision (n=277) or laser conisation (n=255) and define CS as narrowing of the cervix to the extent that a 2.5mm dilator cannot be inserted.<sup>80</sup> 28 months after treatment, 38 cases of CS were diagnosed (n=26; 10.2% in laser group; n=12; 4.3% in the loop group). The study also investigated risk factors for CS and found that age (>50 years); location of the lesion (in the endocervical canal); height of excision (>20mm) and type of treatment method (laser conisation) were all factors associated with an increased risk of cervical stenosis. The authors

posit that any decreased risk of CS associated with loop treatment is due to the fact that the excision taken under loop is shorter than with laser ablation.

Suh-Burgmann *et al's* later study also investigated risk factors for cervical stenosis, focusing upon loop electro-surgical excision procedure alone and found a correlation between presence of CS and history of undergoing previous loop excision and volume of tissue removed (n=164) and the authors recommend that women who have previously undergone LEEP would benefit from counselling around their increased risk.<sup>81</sup>

Houlard and colleagues 2002 study focused upon the incidence of cervical stenosis after laser cone biopsy. This method enables detailed examination and diagnosis of cervical abnormalities. The study also assessed the risk factors for CS following the procedure. 238 patients were assessed at follow-up (37 +/- 26 months after surgery) and 40 patients (16.8%) were diagnosed with cervical stenosis. This incidence rate is greater than those seen in previous studies and authors suggest this may be due to the mean age of patients (36 years - higher than previous studies) as well as the varying definitions of cervical stenosis across studies. The fact that laser cone biopsy removes tissue at a greater height when compared with LEEP may also explain the higher rate of incidence in women undergoing cone biopsy. Risk of CS was found to increase in older patients; when excision depth increased; where the lesion was endocervical; when vaginal packing was required, and when a continuous laser beam was employed.

Despite the varying degrees of incidence cited across these studies, it is clear that cervical stenosis is a possible adverse event following investigation and treatment for CIN.

# 2.9 Chapter summary

The background to the study presented the rationale for undertaking the thesis and outlined what treatments are available. It also discussed the debate around the efficacy of the cervical screening programme and the evidence for the effectiveness of colposcopically directed treatments for CIN.

Furthermore, it summarised the body of evidence in terms of what is known about the adverse psychological, physical and obstetric consequences of undergoing colposcopy and colposcopically directed treatment for CIN. There is evidence that diagnosis of cervical abnormalities can have adverse psychological consequences and it would appear that there are some effects upon psycho-sexual well-being. There is evidence that women experience anxiety and fear following a diagnosis of a cervical abnormality, and that fear of cancer in particular is a prominent experience for these women. Undergoing colposcopy and treatment for CIN can also lead to adverse effects upon self-esteem and sexuality. Some studies indicate that diagnosis and treatment can lead to reduced libido and pain during sexual intercourse. These issues are explored further in Chapter three.

There are physical impacts of colposcopy, particularly post-operatively, and some evidence that women may experience a higher incidence of cervical stenosis

following treatment. The physical side-effects of undergoing treatment include bleeding and discomfort and vaginal discharge. It should be noted that the studies assessing the incidence of cervical stenosis were heterogeneous in nature, in particular in terms of how cervical stenosis is defined. One study defined CS as the narrowing of the cervix to 2.5mm whilst another study used 3mm as the cut off. Studies also varied in terms of the kinds of procedure investigated e.g. loop excision, laser cone biopsy the later of which found a higher incidence of CS due to the degree of tissue removal undertaken for this procedure.

In terms of obstetric outcomes, the most recent systematic review and metaanalysis of the evidence included the results from the three main comparator
groups utilised in the included studies. The review focused upon treatment and
subsequent pre-term birth and found that excisional treatments were associated
with an increased risk of pre-term births. Overall, studies indicate that there is
evidence that there are small, but nevertheless real risks in terms of the effect of
treatment upon obstetric outcomes. However, as highlighted by other studies,
confounding factors should also be taken into account when explaining any
increased risks observed. However, it is important that potential risks are
communicated to women who are considering having children.

Chapter three presents a systematic review of the psycho-sexual impacts of colposcopy and undergoing treatment. The findings from this review informed the design of the empirical stage of the study.

# CHAPTER 3: ADVERSE PSYCHO-SEXUAL EFFECTS OF COLPOSCOPY AND TREATMENT FOR CIN - SYSTEMATIC REVIEW

From the available evidence, what is known about the psycho-sexual impacts of undergoing colposcopy and treatment for CIN?

This chapter outlines the rationale, aim and methodology for conducting a systematic review of the literature addressing the adverse psycho-sexual consequences of undergoing a colposcopy in order to bring together the body of evidence related to these adverse impacts. The results of the review and discussion of the findings will be presented.

#### 3.1 Aim of review

Further to the obstetric and physical outcomes following colposcopy discussed in Section 2.7, there is evidence that women may feel anxiety and fear following an abnormal smear, attending a colposcopy appointment, or being treated for CIN. 34,50,82 Furthermore, there is evidence that colposcopy itself may be associated with sexual dysfunction. 3,35,54,13,57 However, little is known about the long-term effects of colposcopy upon women's psychological and sexual health and there are no published systematic reviews examining these effects on a cohort of women who have undergone colposcopy. Therefore, the primary aim of this systematic review was to bring together literature relating to colposcopy and its effect upon psychological health and sexual functioning in order to build an evidence base regarding the prevalence of adverse psycho-sexual outcomes after colposcopy (including anxiety, depression, and sexual functioning).

Studies investigating the efficacy of colposcopy for preventing the recurrence or progression of cervical intraepithelial neoplasia (CIN) were excluded from the review as the aim was not to assess the clinical effectiveness of treatments for managing cervical disease - the evidence base for this is well established. 32,62,83

Specific objectives of the review were:

- 1. To ascertain the effect of colposcopy on an exposed group
- 2. To consider the prevalence of these effects
- 3. To consider whether certain groups of women were more likely to experience adverse psycho-sexual outcomes following colposcopy

# 3.2 Methodology

Searches of a number of electronic databases were conducted for studies relating to the effect of colposcopy upon psycho-sexual functioning. The following databases were searched:

The Cochrane Library, Ovid MEDLINE (1948-2011), PubMed (2001-2011), EMBASE (1980-2011), PsycInfo (1967-2011). Citation searches of eligible papers were also undertaken to ensure that all relevant literature was included.

The search terms were selected following searches of the relevant literature pertaining to 'colposcopy' and treatment for CIN, and nomenclature in the field of psychological and sexual health; in particular, literature exploring the psychological

and sexual impacts of undergoing gynaecological treatment. Discussions with clinical practitioners were also undertaken to ensure that the most appropriate terminology was included. Search terms related to both the 'intervention' i.e. the procedures under investigation, and the relevant psycho-sexual outcomes measured in the studies returned by the searches.

Table 3.1 Search terms included in the review

Intervention		Outcomes	
Colposcopy Conisation Laser therapy Large loop excision LLETZ Loop electrosurgical excisional procedure	LEEP Laser conisation excision Laser conisation Laser ablation	Sexual dysfunction Sexual function Female sexual dysfunction Libido Desire Psycho-sexual Psychological Anxiety Depression Fear of cancer Emotional	Painful intercourse Dyspareunia Vaginal dryness Vaginal lubrication Body image Orgasm

The full search strategy is outlined in Appendix 1.

All citations returned by the database searches were downloaded into Reference Manager (Version 9). All duplicate citations were removed. Two independent reviewers (SF and SD) screened titles and abstracts for eligibility. Full papers were obtained for all studies that met eligibility criteria for the review, as well as those where consensus could not be reached on inclusion/exclusion criteria from title/abstract alone. A further three studies were identified via citation searches.

Data were extracted from eligible papers using a pre-defined data-extraction sheet (see Appendix 2) comprising information on study, authors, year and country of publication, study design and methods, population, results and conclusions.

Following data extraction, all eligible studies were quality assessed using a prespecified quality assessment proforma (Appendix 3). All eligible studies were assigned a quality assessment score and these scores were used to inform the results of the review. All relevant studies were included regardless of the quality assessment score they received as the aim of the review was to provide a summary of the available evidence to date, and both original qualitative and quantitative studies were included.

The review was designed in accordance with the PICO framework:84

Population - women who have undergone colposcopy

Intervention - colposcopy

Comparators - women who have not undergone colposcopy/level of colposcopic intervention

Outcomes - Psychological effects including anxiety and depression, sexual functioning

Inclusion criteria

Inclusion Criteria - Study design.

- Before and after studies using controls
- Before and after studies without controls
- Retrospective studies using controls (including historical controls)
- Retrospective studies without controls
- Systematic reviews

- Studies were included if they compared the effect of alternative treatment management options upon psycho-sexual function (e.g. see and treat versus surveillance).
- Studies whose purpose it was to measure the effectiveness of a particular intervention (e.g. information leaflet) aimed at reducing anxiety were included.
- Studies from any country were included in the search terms, so as to obtain the broadest overview of research in the field, regardless of geographical setting.

#### Exclusion criteria

- Studies examining obstetric or physical health outcomes exclusively (including incidence of cervical stenosis).
- Case reports
- Conference abstracts
- Correspondence
- Studies not available in English

For quality assessment (QA) of quantitative and qualitative studies the assessment tool presented in Appendix 3 was used as a guideline. Each paper was assessed against each criterion. If a paper was deemed to meet that criterion, it scored one point. If it did so partially, a score of 0.5 was assigned. If it did not

meet the criterion, it scored no points. The QA scores for each paper therefore ranged from 1 (very poor quality) to 10 (excellent quality). These are reported in Appendix 4.

#### Table 3.2 Quality assessment - Quantitative studies

- 1. Use of matched control or control (if a cohort study)
- 2. Sufficient description of the population
- 3. Whether study is prospective or retrospective (if a cohort study)
- 4. Sample size
- 5. Whether study provides sufficiently detailed outcome measures to allow conclusions to be made
- 6. How follow-ups are reported proportion followed up and length of follow-up.

Although the search strategy sought to include both qualitative and quantitative studies, these are considered separately in the elaboration of the findings.

# Table 3.3 Quality assessment - Qualitative studies<sup>85</sup>

- 1. Was the theoretical framework of the study and methods used always explicit?
- 2. Was the context of the research clearly described?
- 3. Was the sampling strategy clearly described and justified?
- 4. Did the sampling include a diverse range of individuals and settings, if appropriate, in order to enhance the generalisability of the analysis?
- 5. Was the fieldwork clearly described?
- 6. Were the procedures for analysis clearly described and justified?
- 7. Can the research material and the procedure for its analysis be inspected by an independent investigator?
- 8. Were triangulated methods used to test the validity of the data and analysis?
- 9. Were the analysis repeated by another researcher to test the reliability of the data and the analysis?
- 10. Was enough of the raw data (e.g. transcripts of interviews) presented in a systematic fashion to convince the reader that the interpretation of the investigator was based on the evidence and is not impressionistic?

# 3.3 Results of quantitative studies

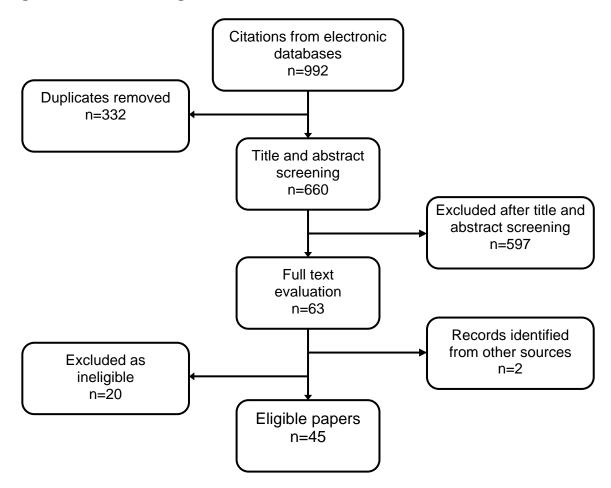
The search strategy identified 992 citations that were potentially eligible for inclusion in the review and these were transferred to Reference Manager. After removal of duplicates (n=332), the remaining 660 titles and abstracts were independently screened to determine suitability for inclusion. Disagreements about inclusion were resolved by discussion. A further 597 studies were excluded following title and abstract screening. 65 studies were deemed suitable for full-text assessment. A further three studies were identified via citation searches. Following full-text assessment, 45 studies were deemed eligible for inclusion and data extraction (Figure 3.1).

20 papers were excluded at the full assessment stage on the following grounds:

- Study focus on spectroscopy not colposcopy (n=1); discussion paper (n=1);
- Outcomes were measured prior to colposcopy (n=2);
- Correspondence (n=3);
- Review article (n=2);
- Not in English language (n=1);
- Not looking at effect of procedure, rather at risk factors for high state anxiety (n=1);
- Focus of the study HPV (n=1);
- Focus of study upon PAP smear (n=3);
- Not focused upon psycho-sexual outcomes (n=1);
- Focus upon physical effects (n=1);
- Measuring effect of psychological profile upon disease progression (n=1);

- Results reported elsewhere (n=1);
- Unable to access the full-text article (n=1).

Figure 3.1 PRISMA diagram



#### 3.3.1 Characteristics of included studies

The quality of the studies included varied considerably, as did the study designs, study populations and types of measures used (validated/non-validated/mixture of both). However, as there are no recent reviews with the aim of investigating psycho-sexual outcomes of colposcopy, all studies in the last 70 years that focused upon the psychological and/or sexual impacts of undergoing the procedure were included. Due to the heterogeneity of the studies included, meta-analysis and pooling of results was not possible. The approach taken here will first

describe the characteristics of the studies included before making comparisons between studies that to some degree are comparable.

#### Scope

All of the studies aimed to measure the psychological and/or sexual impacts of either colposcopy or related treatment procedures (LEEP, conisation). Five studies were qualitative by design and these will be discussed separately in Section 3.5.

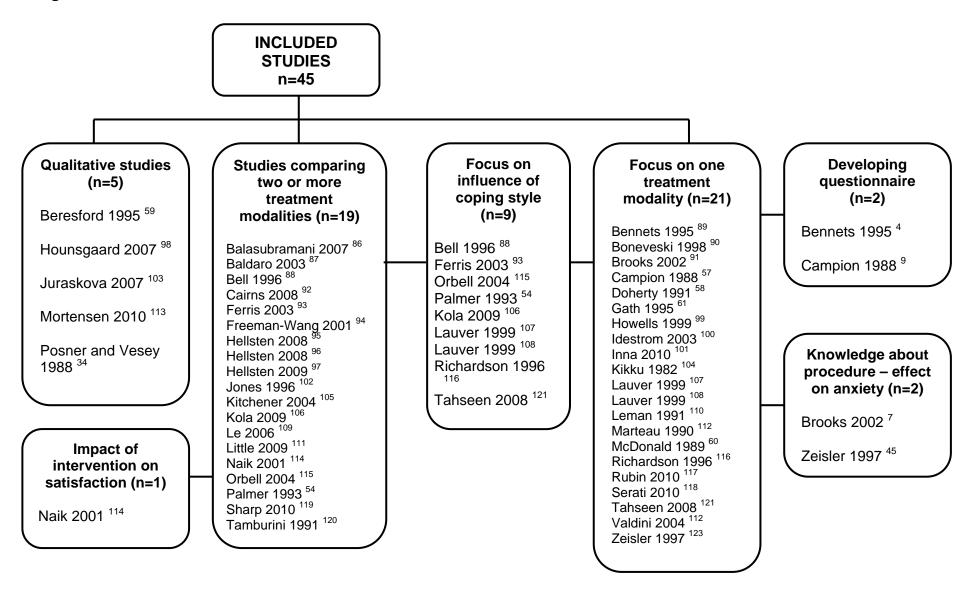
Of the included quantitative studies 19 studies compared psychological and/or sexual impacts between two or more types of colposcopically directed investigation or treatment. 86-88, 93-97,102,105,106,109,111,114,115,54,119,120

21 studies focused upon colposcopy only or one procedure only (e.g. LLETZ, conisation, biopsy). 57,58,61,89-91,99-101,104,107,108,110,112,60,116-118,121-123 Of these studies, two focused upon the development of a questionnaire to use with the population of interest - namely women undergoing cervical screening and treatment. 89,57 These have been included because in order to develop appropriate measures, they assessed the impacts of colposcopy upon their study sample. Nine studies also explored the influence of coping styles and its effect upon any adverse psychological outcomes. 43,54,88,93,106-108,115,116,

Two studies examined the influence of knowledge about the procedure upon levels of anxiety and adherence to follow-up<sup>91,123</sup> and eight studies assessed the effectiveness of interventions in reducing anxiety and one of these also looked at the impact of the intervention upon satisfaction levels.<sup>114</sup>

After giving an overview of the characteristics of all included studies, the findings of each sub group of studies will be assessed, so that comparable studies are considered together. A glossary of acronyms to accompany the studies presented can be found in Appendix 5.

Figure 3.2 Schematic of included studies



# 3.3.2 Study populations

The characteristics of study populations varied in terms levels of abnormality (grade of CIN), and how often patients had attended colposcopy. Some studies emphasised the level of abnormality as their main inclusion criteria, others focused upon the time of procedure and whether it was a first appointment or follow-up. Others looked at disease grade, when women attended, or the type of procedure undertaken. The terminology used to describe disease status was not consistent across studies.

One study specified that participants were diagnosed with high grade CIN <sup>86</sup> and two others that participants should have a diagnosis of CIN. <sup>54,58</sup> Hellsten *et al* include participants with a diagnosis of mild, moderate or severe CIN. <sup>96,97,98</sup> One study had participants with CIN 2/3, with a comparator group comprised of women with a diagnosis of microinvasive cancer. <sup>92</sup> Kitchener *et al* include participants with borderline/mild dyskaryosis, <sup>105</sup> whereas Bell *et al* include women with mild/moderate dyskaryosis and compare them with those with severe dyskaryosis. <sup>88</sup> Freeman-Wang *et al.* specify participants with moderate/severe dyskaryosis. <sup>94</sup>

Other study populations are described as those who had had an abnormal cytology result <sup>61,110,116</sup> mild abnormal smear, <sup>102</sup> epithelial abnormality <sup>91</sup>, and low grade cytology. <sup>111,114,118</sup> Lauver *et al* specify participants having had an abnormal smear with no previous history of colposcopy <sup>107,108</sup> and Richardson *et al* define the population as having been previously informed of abnormal smear result and requiring colposcopy and treatment <sup>34</sup>. Campion *et al* compare four groups including those with CIN and those without. <sup>57</sup>

Other studies specify patients with a recent abnormal smear/abnormal cervix result,<sup>93</sup> or having had two abnormal smears<sup>100</sup> and Zeisler *et al* specify participants as having a diagnosis of CIN following abnormal Pap and directed biopsy.<sup>122</sup>

A number of other studies focus their inclusion criteria upon participants who are attending their first colposcopy <sup>99,112,115,121</sup> and Bennetts *et al* compare first attenders with those who have had at least one colposcopy. <sup>89</sup> Tahseen *et al* do not specify whether participants are attending for the first time, merely that they are attending for colposcopy. <sup>120</sup> The remaining studies specify participants who underwent LEEP at least 3 months previously, <sup>101</sup> who underwent conisation, <sup>103</sup> underwent colposcopy in last 12 months with high grade CIN, <sup>106</sup> new colposcopy patients or patients undergoing LEEP, having undergone biopsy 6 weeks prior to LEEP, <sup>109</sup> sexually active patients who had undergone LEEP for CIN<sup>117</sup> or patients attending for conisation/Co<sup>2</sup>. <sup>119</sup>

#### 3.3.3 Outcome measures

25 studies utilised validated measures and 12 used non-validated measures (Table 3.4). Most studies focused upon anxiety, anxiety and depression, sexual function, fear about cancer and other psychological sequelae (see Table 3.5).

Table 3.4 Outcomes measured/method of administration

Author and Year	Outcomes	Validated Measures (Yes/No)	Administration Method
Kilkku <i>et al.</i> 1982	Sexual function, libido	No	Face-to-face
Campion et al.1988	Sexual Function	No	Face-to face
McDonald et al. 1989	Self-esteem/body image, sexual function	No	Postal
Marteau et al. 1990	Anxiety	Yes	Face to face
Doherty et al. 1991	Anxiety/general Health/ASQ *	Yes	Unclear
Lerman et al. 1991	Cancer worries/tension, mood, sexual interest	No	Telephone
Tamburin <i>i et al.</i> 1991	Depression, sexual function	Yes	Face-to- face/postal
Palmer et al. 1993	Anxiety, impact of invents, locus of control	Yes	Face-to-face
Bell <i>et al.</i> 1995	Depression, self-esteem, social adjustment, coping	Yes	Face-to-face
Bennetts et al. 1995	Beliefs/feelings, worries about infectivity, sexual relationships	Yes	Unclear
Gath <i>et al.</i> 1995	Depression, anxiety, psycho-sexual well-being	Yes	Face-to-face
Jones <i>et al.</i> 1996	Anxiety, fear of cancer, libido, relationships	No	Unclear
Richardson et al. 1996	ASQ, Anxiety, General health, POMS**, Evaluation of counselling	Yes	Face-to-face
Zeisler et al. 1997	Psychological distress	No	Postal
Bonevski <i>et al.</i> 1998	Anxiety/depression/sexual function	No	Telephone
Campion et al.1988	Sexual Function	No	Face-to-face
Howells et al. 1999	Anxiety/depression, psycho-sexual	Yes	Postal
Lauver et al. 1999	Uncertainty, coping styles	Yes	Telephone
Lauver et al. 1999	Coping styles	Yes	Telephone
Naik <i>et al.</i> 2001	Anxiety, satisfaction	No	Unclear
Brooks et al. 2002	Pre-post procedure anxiety, knowledge, satisfaction and adherence	No	Unclear

Author and Year	Outcomes	Validated Measures (Yes/No)	Administration Method
Baldaro et al. 2003	Anxiety and depression	Yes	Postal
Ferris et al. 2003	Depression, health beliefs, coping	Yes	Unclear
Idelstrom et al. 2003	Anxiety, worry	No	Postal
Kitchener et al. 2004	Anxiety, General Health	Yes	Face-to- face/postal
Orbell et al. 2004	Anxiety, emotions	Yes	Postal
Valdini et al. 2004	Anxiety/depression (PEAPS-Q***)	Yes	Face-to-face
Freeman-Wang et al. 2005	Anxiety	Yes	Unclear
Le et al. 2006	Anxiety/depression, PEAPS	Yes	Face-to- face/postal
Balasubramani <i>et al.</i> 2007	Anxiety	Yes	Postal
Cairns et al. 2008	Anxiety/depression, POSM	Yes	Postal
Hellsten et al. 2008	Sexual functioning	Yes	Face-to-face
Hellsten et al. 2008	Anxiety/depression/sexual functioning	Yes	Face-to-face
Tahseen et al. 2008	Worry, personality inventory, impact of leaflet on anxiety	No	Face-to- face/postal
Hellsten et al. 2009	Anxiety/depression/sexual functioning	Yes	Face-to-face
Kola et al. 2009	Anxiety, worry, distress, coping style, helpfulness of intervention	No	Postal
Little et al. 2009	Anxiety/depression	Yes	Postal
Inna <i>et al.</i> 2010	Sexual function	No	Face-to-face
Rubin <i>et al.</i> 2010	Uncertainty, coping, bi-polar profile, body image	Yes	Face-to-face
Serati et al. 2010	Sexual function	Yes	Face-to- face/postal
Sharp <i>et al.</i> 2011	Anxiety/depression, POSM, impact of events scale	Yes	Postal

<sup>\*</sup> ASQ - Abnormal Smear Questionnaire \*\*POMS - Process Outcome Specific Measure \*\*\* PEAPS - Q - Psychological Effects of having an Abnormal Pap Smear Questionnaire

Table 3.5 - Outcomes measured

	Anxiety	Depression	Sexual function	Libido	Self- esteem	Body image	Cancer/ Infectivity worries	Relation ships	Coping	Mood status/em otions	Impact of events	Satisfact ion	Knowledge	General Health	Worry/ Psycho- logical distress
Balasubramani et al 2007															
Baldaro et al 2003															
Bell et al1995															
Bennetts et al 1995															
Bonevski et al 1998															
Brooks et al 2002															
Cairns et al 2008															
Campion et al1998															
Doherty et al 1991															
Ferris et al 2003															
Freeman- Wang et al 2005															
Gath et al1995															
Hellsten et al 2008															
Hellsten et al 2008															

	Anxiety	Depression	Sexual function	Libido	Self- esteem	Body image	Cancer/ Infectivity worries	Relation ships	Coping	Mood status/em otions	Impact of events	Satisfact ion	Knowledge	General Health	Worry/ Psycho- logical distress
Hellsten 2009															
Howells et al 1999															
Idelstrom et al 2003															
Inna et al 2010															
Jones et al 1980															
Kilkku et al 1982															
Kitchener et al 2004															
Kola et al 2009															
Lauver et al 1999															
Lauver et al 1999															
Le et al 2006															
Lerman et al 1991															
Little et al 2009															
Marteau et al 1990															

	Anxiety	Depression	Sexual function	Libido	Self- esteem	Body image	Cancer/ Infectivity worries	Relation ships	Coping	Mood status/em otions	Impact of events	Satisfact ion	Knowledge	General Health	Worry/ Psycho- logical distress
McDonald et al															
Naik et al 2001															
Orbell et al 2004															
Palmer et al 1993															
Richardson et al 1996															
Rubin et al 2010															
Serati et al 2010															
Sharp et al 2011															
Tahseen et al 2008															
Tamburini et al 1991															
Valdini et al 2004															
Zeisler et al 1997															

The two main methods of administration of the data collection tools were by post or face-to-face, although four studies used the telephone. <sup>90,107,108,110</sup> Twelve studies posted questionnaires to participants <sup>60,86,87,92,99,100,106,111,112,118,</sup> and eleven used face-to-face interviews/administration of questionnaires. <sup>34,57,88,95,96,101,102,109,112,116,121,</sup> Remaining studies used either a mix of both face to face and postal administration or it was unclear from the paper how measures had been administered. <sup>54,58,61,89,91,93,94,102,105,114,117,119-121</sup>

## 3.3.4 Follow-up timescales

A wide range of follow-up time-points (see Table 3.6) were utilised, with most papers focusing either on the relatively short-term or the longer term, and a number of studies following up at various specific time points. Some studies administered measures prior to the procedure in order to provide a base-line measure of psychological sequelae. Other studies only partially specify, or did not specify time-frames.

Table 3.6 Follow-up timescales specified

Author and Year	Pre/Post follow-up		
Gath et al. 1995	4 weeks prior, 4 and 32 weeks post		
Baldaro et al. 2003	2 weeks prior procedure, and 3,6,12 months post		
Bell et al. 1995	1 week pre, 1 week post		
Palmer et al. 1993	6 <sup>th</sup> day after receiving diagnosis, 6 <sup>th</sup> day after treatment		
Author and Year	Pre (unspecified) and post follow-up		
Brooks et al. 2002	Pre (unspecified) and 2 weeks post procedure		
Howells et al. 1999	Pre colposcopy (unspecified) 6 months post colposcopy		
Kilkku <i>et al.</i> 1982	Pre procedure, 6 weeks, 6 months, 12 months post procedure		
Richardson et al. 1996	Pre-colposcopy/post colposcopy procedure, 3 and 6 months post treatment		
Freeman-Wang et al. 2005	Pre (unspecified) and post (day of treatment)		
Author and Year	Pre (day of procedure) and post follow-up		
Hellsten et al. 2008	Initial (day of procedure), 6 months and 2 years post		
Hellsten et al. 2008	Initial (day of procedure), 6 months and 2 years post		
Hellsten et al. 2009	Initial (day of procedure), 6 months and 2 years post		
Kitchener et al. 2004	Baseline (time of procedure), 6 and 12 months post		
McDonald et al. 1989	First visit, post surgery, 1 week after procedure, 3 weeks after procedure		
Serati et al. 2010	Time of LEEP, 6 months following procedure		
Lauver et al. 1999	After receiving abnormal Pap, day before procedure, day after procedure		
Lauver et al. 1999	After receiving abnormal Pap, day before procedure, day after procedure		
Author and Year	Day and post procedure (unspecified)		
Tahseen et al. 2008	Day of colposcopy (pre-procedure), after colposcopy (returned by post - not sure of time frame)		
Author and Year	Pre and post follow-up - unspecified		
Bennetts et al. 1995	Pre/post procedure (unspecified)		
Doherty et al. 1991	Pre/post treatment (unspecified)		
Ferris et al. 2003	Pre/post treatment (unspecified)		
Marteau et al. 1990	Pre/post procedure (unspecified)		
Valdini et al. 2004	Pre/post procedure (unspecified)		
Author and Year	Post follow-up - multiple time points		
Sharp et al. 2011	6 weeks after last procedure, 12, 18, 24 and 30 months after procedure.		

Little et al. 2009	6weeks, 3 years post procedure				
Rubin et al. 2010	After Pap result received, time after colposcopy, hearing results of colposcopy, 2-3 weeks, 4 months and 8th month after				
Author and Year	Post follow-up - one time point				
Idelstrom et al. 2003	5years after abnormal smear				
Jones <i>et al.</i> 1980	Post (30 months after colposcopy)				
Zeisler et al. 1997	At least 1 year after colposcopy visit				
Campion et al. 1998	Asked to recall about 6 months pre presentation, 6 months post				
Lerman et al. 1991	3 months after Pap result				
Balasubramani et al. 2007	1 week post procedure				
Bonevski et al. 1998	1 week post procedure				
Naik <i>et al.</i> 2001	1 week post procedure				
Orbell et al. 2004	1 week post procedure				
Author and Year	Unspecified				
Cairns et al. 2008	Post (unspecified)				
Inna <i>et al.</i> 2010	Post (unspecified)				
Kola et al. 2009	Unspecified				
Le et al. 2006	Before/after procedure (unspecified)				
Tamburini et al. 1991	Post (unspecified)				

# 3.3.5 Sample sizes

The sample size for included studies was variable, ranging from n=20 to n=4,439 with the mean sample size being n=345. These are presented in Table 3.7.

Table 3.7 Sample size

Author and Year	Total sample size	Sub-group
Little et al. 2009	n=4,439	Surveillance n= 2,223 Immediate colposcopy n= 2,216
Balasubramani <i>et al.</i> 2007	n=1,085	ST* n=136, DT** n=949 To undertake comparison n=136 ST, n=136 DT were matched on age, abnormality grade and deprivation
Orbell et al. 2004	n=1,085	(ST n=136, DD n= 949)
Sharp <i>et al.</i> 2011	n=989	Immediate LLETZ n=487, Biopsy and selective recall n=502
Kitchener et al. 2004	n=476	Choice n=233, No choice n=243
Ferris et al. 2003	n=413	Colposcopy n=150, Telecolposcopy n=263
Freeman-Wang et al. 2005	Pilot n=342 RCT=93	Diagnostic colposcopy n=251 Outpatient treatment n= 60, See and treat n=31 RCT Leaflet n= 45 Video n=48
Bennetts et al. 1995	n=350	-
Jones <i>et al.</i> 1980	n=345	Cytology n= 163, Colposcopy n=182
Idelstrom et al. 2003	n=242	-
Lerman et al. 1991	n =224	Normal pap n=118, Abnormal pap n=118
Richardson et al. 1996	n=219	Counselling plus leaflet n=104 Leaflet only n=115
Valdini et al. 2004	n=202	-
Hellsten et al. 2008, 2008, 2009	n=200	Cases n=100 LEEP n=46 surveillance n=61 Controls n=100 pre-smear
Howells et al. 1999	n=200	Leaflet n=100 Control n=100
Kola et al. 2009	n=151	Colposcopy n=86, LLETZ n=65
Bonevski et al. 1998	n=138	-
Brooks et al. 2002	n=122	-
Naik et al. 2001	n=118	Cases n=108, Controls n=7
Campion <i>et al.</i> 1998	n=106	Women referred for a colposcopy with an abnormal cervical smear n=30 Women traced as sexual partners of men with HPV who had evidence of cervical disease n= 26 As above but no cervical disease n=25 Traced as partners of men with urethritis and no cervical disease n=25
Gath et al. 1995	n=102	-
Baldaro et al. 2003	n=100	CIN LLETZ n=60, Hysterectomy n= 40
Inna et al. 2010	n=89	-
Rubin <i>et al.</i> 2010	n=88	-
Doherty et al. 1991	n=80	Pre-colposcopy n=25 Post-colposcopy n=25 Pre-laser n=15 Post laser n=15
Lauver <i>et al.</i> 1999 x 2	n=75	-
Serati et al. 2010	n=67	-

Author and Year	Total sample size	Sub-group
Kilkku et al. 1982	n=64	-
Tamburini et al. 1991	n=52	Traditional conisation n=25, C02 conisation n=27
Tahseen et al. 2008	n=50	-
Cairns et al. 2008	n=44	Microinvasive cancer n=18, CIN 2-3 n=26
Le et al. 2006	n=41	Colposcopy n=21, LEEP n= 20
Zeisler et al. 1997	n=40	Reported having insufficient info n=21 Reported having sufficient info n=19
Palmer et al.1993	n=40	Received news of abnormality n=20, Diagnosed with CIN n=20
Marteau et al. 1990	n=30	-
McDonald et al. 1989	n=20	-

Table 3.8 gives an overview of the results for included studies. It includes all quantitative papers regardless of the type of study, the outcomes being measured or the sample size reported.

Table 3.8 (overleaf) Overview of results

<sup>\*</sup> ST - See and Treat \*\* DT - Defer and Treat

Author and Year	Results
Balasubramani <i>et</i> al 2007	See and treat group felt more in control, more relief and less anxiety than defer and treat. See and treat less likely to attend 2 <sup>nd</sup> appt.
Baldaro <i>et al.</i> 2003	LLETZ and hysterectomy groups showed significant reduction in anxiety and depression at 3, 6,12 months compared with pre-operation group. 2 weeks before surgery 8 LLETZ (19.5%) showed anxiety while 10 (24.3%) presented with high levels of anxiety/depression. 12 months after surgery of women with pre-operative depression, 4 (9.7%) had negative mood status.
Bell <i>et al.</i> 1995	Sexual Function - overall the impact of an abnormal smear on sex life was relatively small. Reduced enjoyment was more common in colposcopy group and reduced interest in the surveillance group.  Distress higher among women with abnormal smear.  Anxiety/depression higher amongst those referred for colposcopy, but distress fell after treatment, but 20% remained highly anxious awaiting treatment. In surveillance - adverse psycho sequelae less acute but had more problems with social adjustment.
Bennetts <i>et al.</i> 1995	4 dimensions of distress identified: Experience of medical procedures - beliefs and feelings about abnormality and changes in self-perception/worry about infectivity and effect on sexual relationships.
Bonevski <i>et al.</i> 1998	n=52 - current decline in sexual interest. Of these, 13% indicated their interest had improved following colposcopy; 25% worsened; 62% not changed.  Depression experienced by 11% before colposcopy. Of women reporting depression after colposcopy, n=33 reported that this had not changed since appt.  Of women reporting not anxious following colposcopy, n=98, 23% were so before colposcopy.  Of women reporting anxiety following colposcopy, n=40, all reported it had either worsened (48%) or not changed (52%).
Brooks et al. 2002	Pre colposcopy - fear of cancer 30%; fear of complications 28%; fear of pain 23%; fear of infertility/SF 11% 50% (n=52/122) returned post-op questionnaire.  Mean fear score 7.3 (SE2.8, range 1-10); Mean anxiety score 7.8 (SE2.8, range 1-10)
Cairns et al. 2008	No significant difference in HADS <sup>(a)</sup> scores between groups (18% cancer/12% CIN depression scores) 35% anxiety in both groups.  No significant difference in POSM or concerns of ongoing follow-up.
Campion <i>et al.</i> 1998	Statistically significant adverse psycho-sexual sequelae associated with diagnosis and treatment of pre-invasive cervical intraepithelial disease.
Doherty et al. 1991	68% (n=54) - a little distressed, 21% (n=17) moderately distressed, 8% (n=6) severely distressed on at least 60% of the negative affect items with respect to abnormal result.  Affects of medical procedure 66% (n=53) found it a little distressing, 21% (n=17) moderately distressed, 9% (n-7) very distressed on at least 60% of 5 negative items
Ferris et al. 2003	Mild levels of anxiety/depression in both groups.  On health belief measure - both groups not excessively concerned about procedure, disease or consequences.  Significant proportion of telecolposcopy group considered high monitors compared with colposcopy. No significant diff between colposcopy and telecolposcopy in proportion of high blunters.  Colposcopy group less likely to have thoughts or fears about cancer and reported less pain.
Freeman-Wang et al. 2005	Pilot - see and treat had significantly more anxious than Group 1 or 2.  RCT - video significantly reduced anxiety of women attending for see and treat

Author and Year	Results
	In general, psychiatric morbidity was found to be transient and relatively minor. PSE scores not significantly higher than in community sample of 520 controls.
	Psycho-sexual function - (A) after receiving abnormal result - 1% increased frequency, 56% no change, 43% decreased frequency; 1%
	increased enjoyment, 63% no change, 36% decreased enjoyment: 24% reported deterioration with sexual relationship, the rest reported no
Gath et al.1995	change; 3% reported increased interest in sex, 60% no change and 37% reported decreased interest.
	(B) assessment three when asked to compare frequency of intercourse with 2 months before being asked to go to colposcopy clinic -
	proportions change considerably - 29% increased frequency, no change 52% and decreased frequency 19%; enjoyment increased for 7%, no
	change 62% and decreased 11%: 22% improved sexual relationship, 74% no change and deterioration 4%; Increased interest in sex 21%, no
	change 71% and reduced interest 8%.
	Initial anxiety/depression reduced over time.
Hellsten et al.	No difference in state anxiety for women treated by LEEP and those not.
2008	1/3 women still had fear of cancer in spite of lower 2 year state anxiety levels.
	No diff between groups may indicate it is receiving abnormal smear that causes anxiety/depression rather than procedure itself.
Hellsten et al.	Spontaneous interest in sex, frequency of intercourse and sexual arousal all significantly lower at 6 months compared with first visit and at 2
2008	years spontaneous interest in sex and frequency of intercourse remained low. No difference in sexual function between LEEP and non-LEEP
	group at follow up.
Hellsten et al.	Baseline mean for mental component on all mental health subscales of SF-36 (b) with statistically significant lower than normative data. At 2
2009	years, scores still significantly lower than normative. No difference between LEEP and non-LEEP in general QoL outcomes
	For whole study population on basis of STAI (c) were extremely anxious at initial visit and significantly less so at second visit, although elevated
	compared to population controls.
	TRAIT (d) - did not significantly changes between 2 visits. No significant difference in anxiety between leaflet and controls.
Howells et al.	Second visit anxiety/psycho-sexual scores similar in treated and untreated, although untreated had less spontaneous interest in sex.
1999	No significantly difference in initial STAI between 67 patients who did not attend follow-up and those who did.
	Psycho-sexual - First visit, leaflet group had more evidence of psycho-sex problems, by second visit, responses were comparable. Only
	significant difference control had problems with lubrication.
Ideletrons of of	N=184 experienced follow-up in a positive way. 72% considered they understood diagnosis.
Idelstrom <i>et al.</i> 2003	59% experienced worry and anxiety - 30% stating it had affected everyday life from between being informed of pap and further investigation.
2003	N=20 reported negative effect on sex life after treatment (correlated with less satisfaction at follow-up and negative influence on self-esteem)
Inna <i>et al.</i> 2010	Changes in frequency of sexual intercourse, dysmenorrhea and dyspareunia not statistically significant. Overall changes in overall satisfaction,
11111a 61 al. 2010	vaginal elasticity and orgasmic satisfaction statistically significant.
	Invite for colposcopy resulted in increased anxiety, but patients preferred this to surveillance.
Jones <i>et al.</i> 1980	Colposcopy patients higher fear of cancer, resentment of partner and reduced libido.
	Surveillance also raised anxiety
Kilkku <i>et al.</i> 1982	Significant decrease in no. of patients with dyspareunia. No change in libido, experience of orgasm, coital frequency orgasm, coital frequency,
	overall satisfaction with sex life.

Author and Year	Results
	No significant diff between arms for GHQ (e) and STAI at 12 months. Significant reduction in psycho-metric morbidity between baseline and 12
Kitchener et al.	months in both arms.
2004	Overall rates of default from protocol were same in each arm, but default that led to uncertain ascertainment of cervical pathology was greater
	in no choice.
	Reported high level of colposcopy related anxiety/worry. Those who reported fear of cancer, and concerns about fertility, colposcopy itself,
	embarrassment had higher anxiety levels than those not reporting these.
Kola <i>et al.</i> 2009	LLETZ perceived as stressful and more painful than colposcopy. There were associations between women's perceptions and certain
	interventions.
	Identified to distinct coping styles - 'blunters' who preferred idea of distraction based interventions and 'monitors' who preferred information
	based interventions
	Uncertainty about abnormal pap smear decreased over time.
	Negative mood scores reflecting psychological distress did not change over time.
_auver <i>et al.</i> 1999	Uncertainty about related positively to the coping strategy of catharsis as well to negative mood scores after receiving news and pre-
	colposcopy.
	Catharsis assoc with higher negative mood scores, but acceptance assoc with negative mood scores.  Helpfulness of relaxation and diversion was assoc with lower negative scores.
	Primary concerns involved not understanding pap result; cancer or infertility.
₋auver <i>et al.</i> 1999	Coping strategies most used and rated as most helpful - seeking support and distraction
	81% colposcopy significant anxiety/depression
	65% LEEP significant anxiety/depression
.e <i>et al.</i> 2006	Significantly more anxiety/depression in colposcopy group
	LEEP significantly less distressed and scored better than colposcopy on self-belief/cancer concerns and effects on sex life.
	Pap positive women statistically significant elevated worries about cancer, impaired moods, daily activities, sex interest and sleep.
erman <i>et al.</i>	Effects of positive result more pronounced among women who did not comply with follow-up.
991	Women who had completed follow-up (colposcopy) did not exhibit heightened worry, mood disturbance or sex interest problems compared with
	negative results (pap positive also more likely to be unemployed/less educational attainment)
ittle et al. 2009	Similar proportion of women anxiety/depression in both arms (similar characteristics)
Marteau et al.	Results - high anxiety in group
1990	Overall women significantly less anxious after procedure
	Concerns over cancer overrode all other concerns except during post-surgery visit at which time loss of attractiveness was paramount.
McDonald et al. 1989	Loss of sexual function high at all visits.
	Self-esteem - lowest and anxiety highest at initial and post visit.
	Positive body image highest at post-surgery
	All women in both groups felt anxious at time of clinic visit. After I week, majority of patients managed via one-stop felt slight anxiety and
Naik <i>et al.</i> 2001	controls remained anxious.
	All women said they would prefer one-stop if future abnormalities detected.

Author and Year	Results
Orbell et al. 2004	Diagnosis and cognitive appraisals significantly associated with emotion (accounting for between 3-15% of variance in different emotions. Women with CIN 2 or 3 undergoing ST were less anxious, less embarrassed and significantly more relieved compared with matched sample of women undergoing DT and perceived their first appt as more motivationally congruent.
Palmer et al. 1993	20 women interviewed at home 6-7 days after laser treatment reported 60% changes in their feelings about sexual activity.  Body and sexual relations suffer after diagnosis (because of CIN's posited causal relations with STD wart virus)
Richardson <i>et al.</i> 1996	High levels of distress on all measures in both groups pre-colposcopy and significantly post-colposcopy reduction in distress in both groups. No significantly diff in psychological functioning between 2 groups post colposcopy assessment. Minor diff at treatment and follow-up but following analysis these were interpreted as an artefact of baseline differences.
Rubin et al. 2010	Relationship between uncertainty and coping strategies was supported in the emotion-focused path, but not in problem-focused path.
Serati et al. 2010	(9 patients were excluded from final analysis as only completed sexual function questions before LEEP) In population - data showed overall sexual function was unchanged after LEEP, only 'desire' (sexual interest) became significantly worse.
Sharp <i>et al.</i> 2011	Over entire follow-up no significant difference between arms in cumulative prevalence or risk of significant depression or anxiety. 6 weeks post-procedure, distress did not differ between each arm. At later time points - 8-11% had significant depression and 14-16% had significant anxiety, but no difference between arms.
Tahseen et al. 2008	Prior to attendance - 36% very worried, 54% slightly worried, 10% not worried. All found leaflet helpful to variable degree. During colposcopy 30% found video helpful but a significant number (18%) found it increased worry.  Women with pre-existing high anxiety least satisfied with
Tamburini <i>et al.</i> 1991	Conventional group - 40% hypochondria; 32% on scale of depression; 20% hysteria. 4/25 worsening sex life; 3/25 social life; 4/25 worsening partner relationships.  CO <sup>2</sup> 14% hysteria/hypochondria 24% depression; 3/27 worsening social life; 6/27 worsening sex life; 3/27 worsening sex life.  Prior to attendance - 36% very worried, 54% slightly worried, 10% not worried. All found leaflet helpful to variable degree. During colposcopy 30% found video helpful but significantly number (18%) found it increased worry.  Women with pre-existing high anxiety least satisfied with interventions.
Valdini et al. 2004	Most distress caused - around fear of cancer and worries about miscarriage
Zeisler et al. 1997	Women with adequate info had less fear of cancer than inadequate info who also had increased distress. Group A - reported follow-up reinforced anxiety in comparison to group B. Compliance for regular attendance of screening significant better in B

<sup>(</sup>a) HADS - Hospital Anxiety and Depression Scale; (b) SF-36 - Health survey; (c) Spielberger State -Inventory; (d) Spielberger Trait Inventory; (e) GHQ - General Health Questionnaire

## 3.4 Discussion of quantitative studies

Although the studies included in this review assess psychological morbidity, sexual functioning or a combination of related sequelae, the breadth of methodologies adopted, population types and sample sizes across the studies restrict any discussions of the findings to a narrative approach. Due to the heterogeneity of the studies included, they will be grouped as follows to provide some means of comparison and to aid discussion of the results and conclusions.

- Studies measuring and comparing psychological and/or sexual outcomes between two or more treatment modalities.
- Studies measuring psychological and or sexual outcomes with no comparison between treatment modalities. It will include studies that are assessing impacts at various procedure stages.
- Studies measuring psychological and or sexual outcomes in terms of disease status of participants.
- Studies focused upon development and validation of a questionnaire to measure psychological and or sexual outcomes.

## 3.4.1 Studies comparing two or more treatment modalities

Most commonly, these studies focused upon outcomes based upon surveillance, whether by biopsy or colposcopy and treatment, <sup>86,95-97,106,109,114,115,119</sup> or via cytological surveillance and treatment. <sup>102,105,111</sup>

One study compared differences between conisation and Co<sup>2</sup> treatment, <sup>120</sup> between hysterectomy and LLETZ, <sup>87</sup> telecolposcopy and colposcopy <sup>93</sup> and one between biopsy, outpatient treatment and see and treat. <sup>94</sup>

Table 3.9 outlines the nine studies that compared biopsy or colposcopy with treatment, including studies that compared 'immediate treatment' with excisional or ablative methods with deferred treatment or surveillance via biopsy or colposcopy. This is followed by a narrative summary of these studies.

Table 3.9 Studies comparing biopsy/colposcopy versus treatment

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
Balasubramani 2007 <sup>86</sup> BJOG Do women with high grade CIN prefer see and treat option	UK	Prospective postal questionnaire Aim to compare experience of see and treat LLETZ (ST) and defer and treat Biopsy (DT). Measuring anxiety (STAI) and subsequent behaviour. Questionnaire sent 7 days after procedure	Total n=1,085 (see and treat = 136; 949=defer and treat, but to undertake comparison n=136 ST, n=136 DT were matched on age, abnormality grade and deprivation). High grade CIN referred for first visit to colposcopy 136=(ST), 136=(DT)	ST's felt more in control, more relief and less anxiety than DT's. ST's less likely to attend 2 <sup>nd</sup> appointment.	ST is psychologically beneficial and may be preferred by women with CIN 2/3	Short term follow up – 7 days. Issues of over- treatment?	9
Hellsten 2008 95  BJOG 2 year follow-up of anxiety/depressi on for colposcopy	Sweden	Prospective cohort study Aim to see if there are any long lasting elevated anxiety levels in women attending colposcopy (also examines depressive mood). STAI (at initial visit and 2yr), MADRS-S at all visits. Psychological interview (not clear when completed?)	n=100 women with mild moderate, severe dyskaryosis invited for colposcopy. All had punch on first visit and treated either by LEEP (n=46), or 6 monthly colposcopy (n=61) depending on severity. Questionnaire	Initial anxiety/depression reduced over time. No difference in state anxiety for women treated by LEEP and those not. 1/3 women still had fear of cancer in spite of lower 2 year state anxiety levels. No difference between groups may indicate it is receiving abnormal smear that causes anxiety/depression rather than procedure itself.	Referral for colposcopy does not cause long-lasting anxiety/depression. Sub-group with initially highest depression scores at 2 years still had significant higher depression/anxiety scores.	Small sample, but in general a good quality study	8

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
			completed at initial visit, 6 months and 2 year follow-up. n=100 controls (pre-smear) to establish population reference levels				
Hellsten 2008 96 BJOG Longitudinal study of Sexual function in colposcopy - 2 year	Sweden	Prospective cohort study - as above. To assess levels of psycho-sexual problems in women referred for colposcopy. psycho-sexual Questionnaire administered at all 3 visits (based on Campion, modified by Howells). Study compares LEEP and non-LEEP	As above	Spontaneous interest in sex, frequency of intercourse and sexual arousal all significantly lower at 6 months compared with first visit and at 2 years spontaneous interest in sex and frequency of intercourse remained low. No difference in SF between LEEP and non-LEEP group at follow up.	2 years after referral for colposcopy, women still had effect on SF - less spontaneous interest and lower frequency. No relationship between treatment of CIN by LEEP and reduced SF	Small sample, author acknowledges that maybe be difficult to determine SF with a questionnaire. Swedish population - may have different colposcopy practices	8
Hellsten et al 2009 97 Euro J of Obs & Gynae & Repro Biology Longitudinal study of QoL - 2 year	Sweden	Prospective cohort study - Long term follow up aim to assess QoL. Study design as above. Paper reports results from the SF-36 which includes domain about emotional well-being. SF-36 has a mental component summary and is used as a compliment to STAI and	As above	Baseline mean for mental component on all MH subscales of SF-36 with statistically significantly lower than normative data. At 2 years, scores still significant lower than normative.  No diff between LEEP and non-LEEP in general QoL.	Women experienced long- lasting negative effects upon mental health (but not on physical). Although no diff between LEEP and non- LEEP (so maybe it is the knowledge of having an abnormality rather	Small sample, author acknowledges that maybe be difficult to determine SF with a questionnaire. Swedish population - may have different colposcopy practices	8

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
		MADRS-S. SF-36 most valued measure of subjectively expressed mental health whereas STAI and MADRS-S are symptom oriented			than procedure itself that causes distress)		
Kola 2009 <sup>106</sup> Euro J of Obs & Gynae & Repro Biology	Ireland	Retrospective postal survey Aims to compare intra procedural stress between colposcopy and LLETZ and assess patient's perceptions of possible non-pharmocological interventions to reduce stress. Secondary aim to ascertain patients' perceptions of utility of possible interventions. Measures anxiety/worry/distress (not validated, but based on existing literature). Effect of coping style upon levels. Perceived helpfulness of suggested intervention (did not undergo, but asked to rate usefulness).	Women having undergone a colposcopy during previous 12 months. n=151 (aged 20-60) with high grade CIN. n=86 Colposcopy n=65 LLETZ	Reported high level of colposcopy related anxiety/worry. Those who reported fear of cancer, and concerns about fertility, colposcopy itself, embarrassment had higher anxiety levels than those not reporting these.  LLETZ perceived as distressing and more painful than colposcopy. There were associations between women's perceptions and certain interventions. Identified to distinct coping styles - 'blunters' who preferred idea of distraction based interventions and 'monitors' who preferred information based interventions	Colposcopy elicits high level of anxiety. See and treat LLETZ experience greater psychological consequences than colposcopy	Not sure how long after treatment Questionnaire sent to patients. Non-validated measures	6
Le 2006 <sup>109</sup>	Canada	Prospective	Patients seen for	81% colposcopy significant	Recommends face-	Small sample size	7
Int J of Gynae		comparing Colposcopy	new colposcopy	anxiety/depression	to-face education		
Cancer		vs. LEEP -	assessment and	65% LEEP significant	and support after		

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
Psychological morbidities prior to LLETZ		anxiety/depression levels between groups and effectiveness of nursing based counselling. Patients completed HADS and PEAPS pre- procedure. After colposcopy, one-to-one teaching and clinic nurse counselling	those scheduled for colposcopy or LEEP offered participation. LEEP patients had previously undergone biopsy 4-6 weeks prior to procedure. n=21 colposcopy n=20 LEEP	anxiety/depression Significantly more anxiety/depression in colposcopy group LEEP significantly less distressed and scored better than colposcopy on self- belief/cancer concerns and effects on sex life.	colposcopy may reduce subsequent distress		
Naik 2001 <sup>114</sup> Euro J of Obs and Gynae	UK	Prospective study aims to assess feasibility of offering one-stop colposcopy clinic for low grade abnormalities. If so, is combination of immediate info of biopsy result and treatment helpful in reducing anxiety and improving satisfaction levels. Self-completed Q (not validated) for anxiety	n=108 with low grade abnormalities Control group managed by standard procedure n= 7	All women in both groups felt anxious at time of clinic visit. After I week, majority of patients managed via 1-stop felt slight anxiety and controls remained anxious. All women said they would prefer 1-stop if future abnormalities detected.	One-stop is a feasible management option for women with low-grade abnormalities	Main focus is feasibility of 1-stop.	5
Orbell 2004 115 Brit J of Health Appraisal theory and emotional sequelae of first visit to colposcopy following an abnormality	UK	Aims to evaluate the role of cognitive appraisal components in explaining reaction to colposcopy. Secondly comparing psycho sequelae of see and treat (ST) V diagnose and defer (DD).	n=1,085 attending first colposcopy (ST=136, DD=949)	Diagnosis and cognitive appraisals significantly associated with emotion (accounting for between 3-15% of variance in different emotions). Women with CIN 2 or 3 undergoing ST were less anxious, less embarrassed and significantly more relieved	Diagnosis, motivationally congruent experiences and low emotion- focused coping potential are most important determinants of	Well reported study	8

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
		Questionnaire - STAI; Emotions/Appraisals assessed derived from Smith. Questionnaire sent within 7 days of colposcopy		compared with matched sample of women undergoing DT and perceived their first appt as more motivationally congruent	anxiety after colposcopy ST increased motivational congruence		
Sharp 2010 119 J Brit Cancer Long-term psycho-social impact of alternative management policies	UK	RCT - comparing 2 alternative management policies. Baseline - depression/anxiety scores taken pre- colposcopy HADS, IES completed 6 weeks after last procedure - then 12, 18, 24, 30 months post recruitment - HADS and POSM. Prevalence of significant depression, anxiety and distress and medium POSM scores compared between arms.	n=989 (age range 20-59) with low grade cytology randomised to LLETZ n=487) or 4 punch biopsy (with immediate recall for LLETZ if showed CIN 2/3) n=502.	Over entire follow-up no significant difference between arms in cumulative prevalence or risk of significant depression or anxiety. 6 weeks post-procedure, distress did not differ between each arm. At later time points - 8-11% had significant depression and 14-16% had significant anxiety, but no difference between arms.	There is no diff in long-term or short-term psycho outcomes of immediate LLETZ vs. punch biopsy/selective recall.	Long-term follow up	10

Biopsy/colposcopy surveillance versus treatment

The nine studies focusing upon two treatment modalities (biopsy or colposcopy surveillance vs. treatment (or deferred treatment) were of relatively high quality, scoring six or above on quality assessment. <sup>86,95,96,97,106,109,114,115,119</sup> Four studies were UK based <sup>86,114,115,119</sup> and the remainder were from either Europe <sup>95,96,97106</sup> or Canada. <sup>109</sup>

Balasubramani *et al* <sup>86</sup> using the State-Trait Anxiety Index (STAI) found that women treated via see and treat (ST) felt more in control, a greater sense of relief and less anxiety following the procedure than the defer and treat group (DT) who were monitored by biopsy. For this population (women with moderate to severe CIN), the authors conclude that ST has better psychological outcomes. As the authors note, this could be due to patients feelings that they have a larger stake in decisions being about their treatment (women had a choice of whether to have DT or ST). Furthermore, immediate treatment may avoid any anxiety based upon fear of treatment progression that may have been experienced by the DT group.

The issue of potential over-treatment for those treated immediately, when they may have experienced disease regression without treatment is also raised. The authors suggest that this is minimised if ST is reserved for those patients with high-grade disease. As this study follows women up within a short time frame following the procedures, it may be useful in terms of understanding how best to configure services for this particular patient group in terms of minimising procedural related

stress and anxiety, but its short time frame does not provide evidence of the long term impacts of either modality.

Hellsten et al 95-97 follow the same cohort of 100 women having had biopsy on an initial visit and who are treated either by LEEP or 6 monthly colposcopic surveillance (dependent upon disease severity). 100 control patients (pre-cytological surveillance) are identified to provide reference levels for the treated population. These three twoyear follow-up studies focus upon anxiety and depression levels, 95 sexual function outcomes, 96 and emotional wellbeing. 97 The studies are well designed and provide long-term data when compared with other similar studies. They utilise validated or modified measures for data collection. Questionnaires were completed at three time points (at initial visit, six months and 12 months after visit). No significant differences were found between the LEEP and the non-LEEP group and any initial anxiety or depression levels reduced over time. A sub-group of women with the highest initial depression scores were found to have significantly higher anxiety and depression scores after two years. Study findings suggest that the lack of difference between the two treatment modalities cannot account for the anxiety and depression scores observed. The authors postulate that initial anxiety levels may be attributed to concerns about disease status rather than treatment itself.

Sexual problems appeared to be present at six months following the procedure compared to the initial visit, and after two years there remained reduced spontaneous interest in sex and frequency of intercourse, which indicated that treatment for or diagnosis of CIN does have a longer-term impact upon some domains of sexual function. However, there were no differences noted between LEEP and non-LEEP

groups.<sup>96</sup> In order to measure subjectively expressed mental wellbeing, the SF-36 was used to compare the LEEP, non-LEEP and population controls.<sup>97</sup> The SF-36 is a short measure administered to measure the health status of patients. No differences were found between LEEP and non-LEEP groups, but mental well-being scores at two years were significantly lower in cases than controls.

These studies suggest that it is unlikely that the type of procedure that a woman undergoes is itself a predictor of adverse events, although there may be some longer term effects upon sexual functioning and emotional well-being. Hellsten *et al* conclude that colposcopy does not seem to result in long-lasting anxiety or depression.

Kola *et al*<sup>106</sup> compared see and treat LLETZ with colposcopy for women with high grade CIN and aimed to assess levels of anxiety, worry and distress of women undergoing the procedure (non-validated measures, but adapted). Questionnaires were sent retrospectively, but it is unclear how long after a procedure participants returned the questionnaire. It examined patients' perceptions of the usefulness of possible interventions and the effect of particular coping styles upon levels of perceived helpfulness of the interventions. It found that participants with higher levels of anxiety were more likely to report fear of cancer, fertility concerns, fear of colposcopy itself and higher levels of embarrassment.

The study indicates that see and treat LLETZ patients experienced more negative psychological outcomes than those undergoing colposcopy surveillance. This is in

contrast to the findings of Balasubramani *et al.* However, Balasubramani *et al.* measure state trait anxiety that may subside after a potentially traumatic procedure is over. Kola *et al.* also measure factors such as fear of cancer and concerns about future fertility that may remain for a prolonged period after a patient is treated. As Kola *et al.* do not use validated measures and it is unclear when follow-up took place, it is difficult to compare across these studies.

Le *at al*<sup>109</sup> compare new colposcopy patients with those scheduled to undergo LEEP or colposcopy (who underwent biopsy 4-6 weeks prior to appointment) and uses HADS to measure anxiety and depression and PEAPS (to measure psychological effects of receiving an abnormal Pap result) before and after the procedure. The follow-up questionnaire was accompanied by a one-to-one teaching session and nurse counselling. The small sample size limits the generalisability of the findings, but the authors found significantly higher levels of anxiety and depression in the colposcopy group than the LEEP group (colposcopy 81%, LEEP 65%, p=<0.050). The LEEP group also appeared less burdened by fears of cancer and effects upon their sex life. The authors argue that one of the reasons for this may be that patients attending for LLETZ had had previous support and information provided, which may account for reduced levels of anxiety and depression in this group. The fear of the unknown in the colposcopy group could be a contributory factor in raising levels for these patients. They conclude that providing patients with information and support prior to treatment may be psychologically beneficial.

Naik *et al* <sup>34</sup> focus upon women with low-grade abnormalities and compare psychological morbidities between women managed by a 'one-stop' clinic (underwent biopsy and received results of biopsy on same day), and those managed by standard practice. It is not entirely clear from the paper what 'standard procedure' entails although it is plausible that the control group did not receive their biopsy results on the day of the clinic appointment. Non-validated anxiety measures were used to measure anxiety levels at the time of the clinic visit. One week following 'one-stop', the majority of patients felt less anxiety than those managed by standard procedure. As this study had a further aim to assess the feasibility and acceptability of 'one-stop', they report that all women treated by one-stop as well as those managed by standard procedure stated that they would prefer a 'one-stop' procedure and conclude that for women with low-grade abnormalities, this option appears to reduce levels of anxiety.

A well-designed, robust RCT study by Sharp *et al* <sup>119</sup> uses a similar population to Naik *et al* (focusing on women with low grade abnormality), and compares patients randomised to LLETZ (n=487) or to surveillance via four punch biopsies (with recall to LLETZ if CIN2/3 is indicated n=502). The study findings were part of a trial to assess the benefits and harms of using see and treat, or defer and treat and found no differences between both procedures in terms of detection rates for CIN or in their cost-effectiveness. The study utilises validated measures (HADS, IES (Impact of Event Scale)), POSM (Process Outcome Specific Measure) providing baseline data (pre-procedure), 6 weeks, 12, 18, 24, and 30 months post-recruitment to enable short and long-term follow-up.

Over the entire period of follow-up, the study found no significant differences between arms in terms of the risk of significant depression (OR=0.78, 95% CI 0.52-1.17) or anxiety (OR=0.83, 95% CI 0.57-1.19), although at later time points 8-11% had significant depression and 14-16% had significant anxiety levels, with no differences found between arms.

The authors conclude that there is no difference in short or long-term psychological morbidities between the two approaches. These findings contrast with Balasubramani *et al*, Kola *et al*, Le *at al* and Naik *et al* but these studies all have a variety of follow-up time-points and used different scales. Sharp *et al* ensured that the initial six week follow-up would have taken place after both groups had been treated unlike in Balasubramani *et al* when the DT group would not yet have been treated. This study also benefits from the measurements of base-line scores for anxiety and depression, and a larger sample size, and its findings seem comparable with Hellsten *et al*.

Although Orbell *at al* <sup>35</sup> evaluate the role of cognitive appraisal in explaining reaction to colposcopy, they also compare psychological outcomes between a matched sample of patients undergoing see and treat and diagnose and defer (biopsy) n=136 in each group. The authors found that women undergoing ST were less anxious, less embarrassed and significantly more relieved than those in the DD (diagnose and defer) arm (anxiety mean score = 41.08 vs. 43.98; embarrassment mean score = 1.18 vs 1.28; more relief mean score = 2.68 vs. 2.11). The study seems to support

the findings in Le *et al* and Balasumbramani *et al* that indicate that women undergoing ST are less likely to experience psychological morbidities.

These studies provide data on the potential short/long term impacts of undergoing colposcopy and do so by comparing outcomes of women being 'treated' and those undergoing surveillance. Due to varying follow-up timescales and the variety of measures used, it is impossible to draw firm conclusions. However, studies focusing upon longer term follow-up <sup>95-97,119</sup> found no differences between outcomes for the treatment of surveillance groups. These studies conclude that any adverse outcomes are typically short-lived and there are minimal long-term psycho-sexual outcomes following colposcopy and treatment for CIN.

Table 3.10 outlines the four studies that compared cytological surveillance and colposcopically directed treatment. The table is followed by a narrative summary of these studies.

Table 3.10 Comparing cytological surveillance v colposcopically directed treatment

First author;	Country	Study design and methods	Population	Results	Authors	Comments	QA
year; journal					conclusion		Score
Freeman-Wang 2001 94 BJOG Anxiety levels in women attending colposcopy clinics for treatment for cervical intraepithelial neoplasia: a randomised trial of written and video info	UK	Assessing effectiveness of video in reducing anxiety using STAI.  2 stages - Pilot assessing anxiety levels in 3 groups - 1 diagnostic colposcopy; 2. out-patient treatment;  3. see and treat clinic.  Stage 2 - RCT between  Leaflet or video and leaflet.  Received prior to their see and treat appt. Anxiety measured at attendance for see and treat	Pilot - 3 groups: Group 1=251 Group 2=60; Group 3=31 Women with mod/severe dyskaryosis. RCT - after loss to follow-up Leaflet n= 45 Video n= 48	Pilot - see and treat had significant more anxiety than Group 1 or 2. RCT - video significant reduced anxiety of women attending for see and treat.	High degree of anxiety in patients attending diagnostic colposcopy. Video successful in reducing anxiety in see and treat.	Including as it provides results of anxiety in women attending colposcopy, although aim is to assess effectiveness of intervention	3
Jones 1996 <sup>102</sup> J R Soc Med The mildly abnormal cervical smear	UK	Cohort Comparing anxiety levels between surveillance v colposcopy after first smear for women with mild abnormal smears. At end of study all offered colposcopy appt and to complete Q to recall previous emotional events (30 months post colposcopy) Not validated measures, but asking about anxiety as well as fear of cancer, resentment of partner, loss of libido	n=163 cytology surveillance n=182 colposcopy	Invite for colposcopy resulted in increased anxiety, but patients preferred this to surveillance. Colposcopy patients higher fear of cancer, resentment of partner and reduced libido. That said, surveillance also raised anxiety	Colposcopy increased anxiety, but was more satisfactory (maybe due to reassurance from having been treated). So surveillance seems better for anxiety.	Not clear about measures used - not validated. Recall bias as being asked to think back about previous reactions	3
Kitchener 2004  105  BJOG  RCT of  cytological	UK	RCT of 6 monthly cyto-surveillance or to make choice between CS or colposcopy in managing mildly abnormal smears. Followed up for 1 year.	n=476 women with borderline/mild dyskaryosis. Choice=233,	No significant difference between arms for GHQ and STAI at 12 months. Significant reduction in psycho-metric morbidity between baseline	Choice did not impact favourably or harmfully upon psych	Looking at the effect of choice upon psycho outcomes,	8

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
surveillance V patient choice and Colp		No choice - repeat smear at 6/12 months and if normal returned to routine (if abnormal at 6, then LLETZ performed).  Questionnaire in this arm - completed baseline, prior to repeat smear at 6months, after repeat smear at colposcopy, if carried out, and at 12 months.  Choice arm - those choosing CS managed as above. Colposcopy managed as protocol. Q - taken at baseline and after initial colposcopy, if chosen before and after 6mth and at 12 months. Questionnaire - GHQ, STAI (choice arm also questionnaire about why made particular choice).	no-choice=243	and 12 months in both arms. Overall rates of default from protocol were same in each arm, but default that led to uncertain ascertainment of cervical pathology was greater in no choice.	outcomes. If patient anxious, allowing them to choose may be favourable because it will reduce default rates for this group	but provides data of rates of caseness for STAI and GHQ.	
Little (Tombola Group) 2009 111 BMJ Cytological surveillance compared with immediate referral for colp	UK	Nested RCT. Aim- effectiveness of surveillance (6 monthly n=2,223) V immediate referral to colposcopy (n=2,216). 3 year follow-up Main focus - measuring incidence of CIN, but also measuring significant anxiety/depression (HADS) at 6 weeks and in 3 <sup>rd</sup> year.	Women with low grade cytology (aged 20-59)	Similar proportion of women anxiety/depression in both arms (similar characteristics)	No clear benefit immediate colposcopy compared with surveillance in terms of psychological outcomes	Although the main focus of study is incidence of CIN, including as it also focused upon psycho sequelae.	10

Cytological surveillance vs. colposcopically directed treatment

In the three studies comparing cytological surveillance and colposcopically directed treatment, one was of poor quality<sup>102</sup> (quality score=3) and two were of higher quality<sup>105,111</sup> (QS=8;10). One further study that compared biopsy with outpatient treatment and see and treat scored 3 points on the quality score.<sup>94</sup>

Jones *et al* <sup>102</sup> focus upon the impact of cytological surveillance versus colposcopy after first smear upon anxiety levels. This study uses a relatively large sample size (n=163 cytology, n=182 colposcopy) but does not use validated measures. The study, which also asks about fears about cancer, libido and sexual relationships, found these more likely to be adversely affected in the colposcopy arm. However, despite elevated levels of anxiety in the colposcopy arm, these patients found immediate colposcopy more satisfactory compared with the surveillance arm. The study concludes that in terms of anxiety levels, cytological surveillance is a preferable treatment option. However, as is acknowledged by the authors, surveillance also raises anxiety. This study is retrospective in design, asking participants to recall anxiety levels at the time of colposcopy. This may have resulted in the introduction of recall bias as is common with these types of studies.

Kitchener at al <sup>105</sup> compare anxiety levels for patients with mild/borderline dyskaryosis undergoing six-monthly cytological surveillance (CS) and patients offered a choice of CS or colposcopy. The study concludes that having a choice of management options did not impact upon psychological outcomes. A reduction in psychological morbidities between base-line and at 12 month follow-up were found and are unsurprising as state levels of anxiety are likely to be reduced once treatment has been completed.

As well as the study comparing biopsy recall and immediate LLETZ, 119 the TOMBOLA group report results of an RCT that was partially designed to examine the impact of cytological surveillance in primary care compared with immediate referral for colposcopic examination upon anxiety and depression. Similar proportions of women reported anxiety and depression in both arms and so there would be appear to be no psychological benefit from undergoing immediate colposcopy compared with cytological surveillance.

Freeman-Wang *et al*'s <sup>94</sup> two stage study assesses the effectiveness of using a video in reducing anxiety by comparing three management options: diagnostic colposcopy; outpatient treatment and a see and treat clinic. The first stage measures patients' anxiety levels following their respective appointments and found that women attending the see and treat clinic were significantly more anxious than those attending alternative management (diagnostic colposcopy p=0.019; outpatient treatment p=0.013) despite this group receiving a booklet, information leaflet and explanatory letter (diagnostic biopsy group received booklet and those needing treatment received booklet and supplementary information leaflet), although the numbers across the group are not comparable (Group 1 n=251, Group 2 n=60, Group 3 n=31). However, all STAI scores across the three groups indicated high levels of anxiety. The study would seem to support the findings of Jones *et al*<sup>102</sup> who found higher anxiety levels in the treatment arm. It would also appear that the provision of information does little to reduce anxiety for this group.

The larger, well designed studies comparing immediate treatment with deferred treatment seem to indicate that it is not the actual procedure *per se* that is the cause

of anxiety and depression with Hellsten *et al* and Sharp *et al* finding no differences between treatment arms. Of course this is not to say there are no adverse psychological affects of undergoing treatment for CIN, but that any adverse effects are unlikely to be caused by the 'wait and see' and the 'see and treat' modalities.

Table 3.11 summarises the data extracted for the remaining three studies included in this section. One study compares patient acceptance of and psychological outcomes for women experiencing telescolposcopy (for those living in a distant site) and colpsoscopy. 93 Women were assessed pre- and post-treatment, although different measures (non-validated) were administered post-treatment as the focus of the posttreatment questionnaire was to ascertain acceptance levels of the procedures. The study found mild levels of depression and anxiety in both groups pre-treatment (validated measure used) and found that the psychological profile of patients undergoing alternative treatments were different, with telecolposcopy patients more likely to be monitors compared with colposcopy patients. The study concludes that each treatment type had similar satisfaction levels (high) and comfort levels. The only question on the post-treatment questionnaire to measure any kind of psychological impact was in terms of fear of cancer and the colposcopy group were significantly less likely to hold such fears. The study adds little in terms of evidence to this review, primarily because the main focus is upon acceptability of an alternative treatment method. This is reflected in the post-treatment measures that do not address psychological impacts other than issues around fear of cancer.

Baldaro *et al* <sup>87</sup> although comparing psychological reactions to LLETZ to those of hysterectomy, provides data on the sequelae pre- and post-treatment of patients

undergoing LLETZ. The study found elevated levels of anxiety two weeks prior to treatment, with a quarter of patients showing high levels of anxiety (n=10), but found a significant reduction in anxiety and depression at 3,6, and 12 month follow-up indicating that there are no long term psychological impacts of undergoing LLETZ. The study is limited by its small sample size (n=60) but would seem to support findings from other studies with a long-term follow-up on measures of anxiety and depression.<sup>95</sup>

One study, 120 compares psychological and sexual impacts of patients treated with either CO2 laser as an outpatient (a relatively new treatment type at the time the paper was published) and standard care - inpatient conisation. The study is of poor quality, with a small sample (n=52) in total and the results are not well-reported, although it concludes that patients treated by the 'new' procedure had less anxiety about their disease and better quality of life than the conventional group. Although findings from these studies are equivocal, there would appear to be little difference in terms of impacts irrespective of treatment modalities.

Table 3.11 Conisation vs. Co<sup>2</sup>; hysterectomy vs. LLETZ; telecolposcopy vs. colposcopy

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
Baldaro 2003 87 J of Psycho Research Psychological distress of conservative and non- conservative uterine surgery	Italy	Aim to evaluate psychological reaction to conisation (its incidence) - compares group with hysterectomy.  Pre and post Questionnaire - 2 weeks prior to op and 3,6,12 months after.  Measure - Italian version of Symptom Questionnaire (SQ) - 4 scales - anxiety, depression somatic and hostility.	n=60 with CIN undergoing LLETZ n=40 hysterectomy	Both LLETZ and hysterectomy group showed significant reduction in anxiety and depression at 3, 6, 12 months compared with pre-operation. 2 weeks before surgery 8 LLETZ (19.5%) showed anxiety while 10 (24.3%) presented with high levels of anxiety/depression. 12 months after surgery of women with pre-op depression, 4 (9.7%) had negative mood status.	LLETZ determines good psychological prognosis in the short/long term	Short and long term follow-up. Validated measures	5
Ferris 2003 93 J Am Board Fam Pract Patient acceptance and the psychological effects of women experiencing telecolposcopy and colposcopy	USA	Comparing telecolposcopy and colposcopy on psychological outcomes. Measures completed before colposcopy (or telecolposcopy) - PRIME-MD (anxiety); CES-D (depression); MBSS (coping styles - monitoring or blunting) 12 item health beliefs and concerns. Post colposcopy (or telecolposcopy) completed 23-item - including satisfaction, cancer concerns etc.	Colposcopy n= 150 Telecolposcopy n= 263 Recent abnormal smear/abnormal appearance on cervix/returning for surgery or follow-up	Mild levels of anxiety/depression in both groups. On health belief measure - both groups not excessively concerned about procedure, disease or consequences. Significant proportion of telecolposcopy group considered high monitors compared with colposcopy. No significant difference between colposcopy and telecolposcopy in proportion of high blunters. Colposcopy patients less likely to have thoughts or fears about cancer and reported less pain.	Main conclusion is around the efficacy of using telecolposcopy as an alternative to colposcopy - satisfactory and time/money saving.	How long before/after colposcopy were measures taken? Not same measures used after procedure as before.	7

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
Tamburini 1991 120 The Cervix and the lower genital female tract Psychological aspects of conization	Italy	Aim- evaluate QoL (including psychological/ sexual) of patients treated with CO2 laser conisation (out-patient) compared with QoL observed in previous study in patients treated with conventional conisation (in-patient). Measures -Questionnaire on social and sexual relationships; Minnesota Multiphasic Personality Inventory. Completed immediately after follow-up visit. Co2 group at time of interview had been treated min 3 months/max of 12 months previously, Conventional group - had been treated minimum 12months/maximum 18	n=25 patients who had undergone traditional conisation for CIN III in 1979 completed Q on a follow-up visit. All these patients completed and returned Questionnaire n=27 patients who had undergone CO2 conisation between 1989- 1991returned completed Questionnaire, although only 21 participants completed MMPI section.	Conventional group - 40% hypochondria; 32% on scale of depression; 20% hysteria. 4/25 worsening sex life; 3/25 social life; 4/25 worsening partner relationships. CO2 14% hysteria/hypochondria 24% depression; 3/27 worsening social life; 6/27 worsening sex life; 3/27 worsening sex life	No significant difference in sex life, social life, partner relationship, but CO2 patients appear to have less anxiety about their disease and had better QoL than conventional group	Old study - 1979 Conisation not performed today. Poorly reported results.	3

#### 3.4.2 Studies focusing upon one cohort

This section will focus upon studies that focus only on one cohort or treatment modality (n=17). Table 3.12 outlines the data extracted for each of these studies. Again, the studies vary in terms of follow-up time scales, disease stage, method of administration and types of measure and study quality. 11 studies scored five or below on quality assessment. <sup>60,90,91,100,104,107,112,117,121-123</sup> Six studies were of relatively higher quality (scoring 6 or above). <sup>54,61,99,101,108,118</sup> Five studies were UK based <sup>99,100,112,116,121</sup> two from Australia, <sup>90,123</sup> two from Europe <sup>104,118</sup> and six from the USA. <sup>91,107,108,60,117,122</sup>

Boneveski *et al* <sup>90</sup> use non-validated measures to determine the short term effects (anxiety, depression and sexual function) experienced by 138 women attending colposcopy, following women up within a week of colposcopy with a telephone interview. As well being asked about anxiety and depression following colposcopy they were asked how they rated their levels prior to colposcopy.

Participants were asked whether anxiety, depression and reduced sexual interest were present before colposcopy, better since colposcopy or worse since colposcopy. The presentation of results is unclear, but seems to indicate that anxiety and disinterest in sex had either worsened or remained the same since colposcopy. Depression was less marked prior to colposcopy, and for those experiencing depressive symptoms pre-colposcopy, there were no changes after colposcopy. The study is poorly designed and reported, and given its short-time frame for follow-up

and lack of validated measures, it is difficult to draw satisfactory conclusions in terms of any long term effects of colposcopy. It would seem plausible that depression levels remain unchanged in those who were depressed prior to the procedure as depressive symptoms can be enduring. One would expect elevated levels of anxiety prior to colposcopy, but may expect these to reduce post procedure. A reduction in sexual interest in the short-term after undergoing an invasive procedure may also be expected.

Brooks *et al* <sup>91</sup> measure pre-visit anxiety and found that 30% of their sample (30/122) experienced fear of cancer, 28% fear of complications, and 23% fear of alteration of sexual function. However, this study's main aim was to measure the association between levels of anxiety pre-colposcopy with knowledge, satisfaction and adherence to follow-up. Interestingly, the authors found a correlation between higher levels of pre-visit knowledge and higher levels of fear, although those who had more knowledge pre-procedure were also less likely to default from follow-up. It may be argued that for some women, knowing more about the nature of their diagnosis and potential treatment may raise anxiety levels, giving greater opportunity to ruminate on potential adverse experiences or outcomes. However, to improve default rates, which can be marked in follow-up patients, access to better information may reduce poor adherence with follow-up.

Gath *et al* <sup>61</sup> observed psychiatric morbidity in a cohort of 102 patients assessing rates four weeks prior to colposcopy assessment (they had received results indicating an abnormality) following them up 4 and 34 weeks post colposcopy. The

study used validated measures and community controls to measure PSE (Present State Examination) scores. The study demonstrates that overall any psychological or sexual morbidities are relatively transient. Sexual problems were more pronounced prior to treatment which may be explained by concerns about engaging in intercourse prior to colposcopy. The study would seem to support the view that any adverse psychological or sexual effects diminish over time.

Howells *at al's* <sup>99</sup> before and after study measured state-trait anxiety and psychosexual functioning (validated and modified measures) pre-colposcopy and six months post procedure. As seen in other studies, pre-colposcopy levels of state anxiety were elevated at the initial visit although significantly reduced at follow-up. Trait anxiety was not found to be significantly different at either visit. The authors found that those treated at colposcopy experienced less spontaneous interest in sex than those who were not treated. The study's main aim was to assess the usefulness of a leaflet designed to reduce anxiety, with 100 women receiving the leaflet and 100 controls who did not. As observed in *Brooks et al*, the leaflet appeared to increase psychosexual problems at the first visit, supporting the theory that information provision can lead to increased adverse psychological outcomes. However, by the second visit, both groups were similar. The authors conclude that sending a leaflet in isolation (i.e. without further counselling) is not of benefit in the population.

A five year follow-up study focusing upon the experiences of women with abnormal Pap smears who had also undergone subsequent treatment, found that 72% experienced follow-up in a positive way. Fifty nine percent had experienced worry

and anxiety, and 20% reported that treatment had had a negative effect upon their sex life. The study is limited by the fact that it asked women to recall their reactions at the time of an event that took place a number of years previously, rather than whether they had any current psycho-sexual problems. This may have resulted in recall bias.

Inna *et al* <sup>101</sup> examine the effect of LEEP upon sexual function (using a non-validated measure) in 89 women who had undergone LEEP three months previously. Although administered at one time point, women were asked to recall pre-procedure sexual function as well as post-procedure function. As the authors found statistically significant changes in overall sexual satisfaction, orgasmic satisfaction and vaginal elasticity, rather than predominantly physiological changes (dyspareunia, dysmenorrhea, frequency of intercourse), they posit that any adverse effects from the procedure are likely to be psychological in origin. The emphasis of this study would seem to be largely upon clinical gynaecological effects that may lead to poor sexual function, however due to the nature of female sexual dysfunction, it is difficult to disentangle the physical from the psychological.

The earliest study included in the review (1982), investigating the effect of conisation upon sexual function is poorly designed and reported. The study interviews women before procedure (it is not clear if this is on the day of procedure) and 6 weeks, 6 and 12 months post-operation and finds little difference in libido, orgasm, frequency or satisfaction before and after procedure. There is scant detail of the measures used (although they appear to be non-validated), and there is no control to measure levels

of sexual problems in the general population, so it is difficult to ascertain whether preprocedure scores for cases were representative.

Two studies by Lauver *et al* <sup>107,108</sup> focus upon understanding women's concerns about smear abnormality, <sup>108</sup> to identify coping strategies to manage concerns. <sup>107</sup> Participants were telephoned pre-procedure and completed a questionnaire before colposcopy and post colposcopy. These studies use a small sample with 75 patients undergoing a telephone interview and 40 completing a pre-colposcopy questionnaire and 35 completing a post-colposcopy questionnaire. Primary concerns were found to relate to cancer, fertility and not understanding the nature of the abnormal result. The authors found that dependent upon particular coping styles, some women may benefit from seeking social support, or engaging in displacement activities to reduce procedural anxiety.

A further study with a similar scope<sup>121</sup>, aimed at finding a correlation between levels of anxiety and the perceived helpfulness of interventions to reduce anxiety, rather unsurprisingly found that women prone to higher levels of anxiety were less satisfied with interventions offered. Zeisler *et al* <sup>123</sup> compared levels of distress between women who perceived that they had received adequate information regarding their diagnosis and those who felt they had not. In this small study (n=40) women who felt they were inadequately informed had significantly increased levels of distress than the group who felt they had been better informed.

Rubin *et al* <sup>117</sup> also looked at coping strategies in a cohort of women with low grade abnormality (n=88) and relationships between this and uncertainty about illness and knowledge and adaption in reaction to smear result and subsequent investigations. The authors conclude that uncertainty about illness exists for women undergoing the cervical screening and treatment pathway. It is likely that such uncertainty may result in increased anxiety, although it is not reported by the authors.

Marteau *et al's*<sup>112</sup> study would seem to support the evidence that levels of anxiety are high in women when measured immediately prior to colposcopy, but are significantly less so immediately after procedure. This study is poorly designed and reported, and although it utilised a validated measure (STAI), the small sample size (n=30) means that the results are far from robust, despite its conclusions appealing to commonsense. There are also no normative data reported to account for pre-colposcopy anxiety levels.

McDonald *et al* <sup>60</sup> sample 20 women attending colposcopy, and used 4 time-points for data collection (initial visit - biopsy; one week later - results of biopsy; third visit - before surgery; three weeks after surgery). Non-validated measures were used and focused upon cancer fears, which was found to be pronounced at all visits aside from post-surgery; sexual function problems that were high at all visits; self-esteem was lowest and anxiety highest at initial and post-surgery visits. The findings of the study are limited again by sample size, but it provides an interesting picture of the psychological fluctuations that may accompany the pathway from diagnosis to post treatment.

Richardson *et al*'s<sup>116</sup> primary aim is to focus upon the effectiveness of interventions (information and counselling) by randomising 219 patients to receive either leaflet (n=104) or leaflet plus counselling (n=115). However, the study also provides data using a psychological measure (validated) over a six-month follow-up period. As seen in Marteau *et al*, high levels of distress were found in both groups preprocedure which were significantly reduced post-procedure. The study found no incremental benefit in offering cognitive behavioural counselling over and above the benefit found in the information group alone.

Serati *et al* <sup>118</sup> is the only study in the review to utilise the Female Sexual Function Index (FSFI) to compare sexual function at time of LEEP and six months post procedure. A relatively small sample (n=67) and lack of control make results difficult to generalise, although the results indicate that overall, sexual function was unchanged at six months aside from sexual desire, which became significantly worse (p=0.02) which seem to support findings in Gath *et al*.

Valdini *et al* <sup>122</sup> used PEAPS to explore the factors associated with distress in a population of 202 women undergoing colposcopy and main concerns focused upon worry about getting cancer and fear of death.<sup>89,91</sup>

Conclusions from higher quality studies appear to indicate that any psycho-sexual morbidities following colposcopy are relatively transient in nature.

Table 3.12 Studies focusing upon one cohort

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
Boneveski 1998 <sup>90</sup> J of Obs abnd Gynae Women's experience of having a colposcopy examination	Australia	Cohort Aim - assess satisfaction levels, unmet needs and consequences of colposcopy. Measures - short-term consequences including anxiety, depression, sexual function Also looking at satisfaction with care received. Computer aided telephone interview. Measures 'derived from validated measures'.	n=138 attending for colposcopy contacted within a week of clinic visit to complete telephone interview	n=52 - current decline in sexual interest. Of these, 13% indicated their interest had improved following colposcopy; 25% worsened; 62% not changed. Depression experienced by 11% pre-colposcopy. Of women reporting depression after colposcopy, n=33 reported that this had not changed since appt. Of women not anxious following colposcopy, n=98 (23%) were so before colposcopy. Of women reporting anxiety following colposcopy (n=40,) all reported it worsened (48%) or not changed (52%).	Anxiety, disinterest in sex had worsened or not improved after colposcopy	Only taken 1 week after procedure - short-term. Non- validated measures utilised	4
Brooks 2002 91 J of Lower Genital Tract Disease Association of knowledge anxiety and fear with adherence to follow-up for colposcopy.	USA	Aim-evaluate association of pre-visit anxiety and post-visit knowledge, satisfaction and adherence to follow-up. Questionnaire administered prior to appt and 2 weeks after appointment for colposcopy. Questionnaire not validated - based on 'literature and judgments' from focus group.	n=122 presenting for colposcopy with epithelial abnormality. 98% participated in self-admin questionnaire. Follow up, only 50% returned post-op questionnaire. (83% African American)	Pre colposcopy - fear of cancer 30%; fear of complications 28%; fear of pain 23%; fear of infertility/sexual function 11% 50% (n=52/122) returned post-operative Questionnaire.  Mean fear score 7.3 (SE2.8, range 1-10)  Mean anxiety score 7.8 (SE2.8, range 1-10)	Higher pre-visit knowledge associated with greater fear as well as adherence to follow-up. Recommends - acknowledgment of role of anxiety/baseline knowledge, logistical concerns may reduce anxiety, promote adherence.	Poor quality - non-validated measures. Confused about aims.	5

First author;	Country	Study design and	Population	Results	Authors	Comments	Quality
year; journal		methods			conclusion		Score
Gath et al 1995 61  Journal of Epidem and Comm Health Emotional reactions in women attending a UK colposcopy clinic	UK	Observation study Women underwent a psych assessment at 3 time points - 4 weeks before clinic appt, 4 weeks after and 32 weeks after apt. Measures - Standard psychiatric interview; present state examination; 4 self rated mood scales - Beck depression scale, Leeds depression scale and Leeds anxiety scale. Psycho-sexual functioning was measured by asking about frequency of intercourse, enjoyment of intercourse, interest in sex, any changes following treatment.	n=102 New attenders to a colposcopy clinic over a 12 month period. Women had been found to have a abnormal smear at routine screening, or at follow up of previously inconclusive smear.	In general, psychiatric morbidity was found to be transient and relatively minor. PSE scores not significantly higher than in community sample of 520 controls.  Psycho-sexual function - (A) after receiving abnormal result - 1% increased frequency, 56% no change, 43% decreased frequency; 1% increased enjoyment, 63% no change, 36% decreased enjoyment: 24% reported deterioration with sexual relationship, the rest reported no change; 3% reported increased interest in sex, 60% no change and 37% reported decreased interest.  (B) assessment three when asked to compare frequency of intercourse with 2 months before being asked to go to colposcopy clinic -proportions change considerably - 29% increased frequency, no change 52% and decreased frequency 19%; enjoyment increased for 7%, no change 62% and decreased 11%: 22% improved sexual relationship, 74% no change and deterioration 4%; Increased interest in sex 21%, no change 71% and reduced interest 8%.	In terms of SF - women reported increased sex problems at time of being informed of abnormal smear - not surprising as would have felt more anxious. However, by final assessment, levels of SF return to normal levels. After abnormal smear, investigation by colposcopy generally associated with low levels of anxiety/depression	Relatively small sample - follow up only 32 weeks	6

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
Howells 1999 <sup>99</sup> BJOG Is provision of info leaflet before colp beneficial?	UK	Prospective randomised study. Assessing usefulness of leaflet before colposcopy, designed to reduce anxiety/psycho-sexual morbidity. Measures - STAI/TRAI and psycho-sexual Q (Campion modified) completed before colposcopy and 6 months after colposcopy (leaflet group completed further questionnaire about the leaflet)	n=200 undergoing colposcopy for first time, abnormality no greater than moderate dyskaryosis. n=100 leaflet n=100 control	For whole study population on basis of STAI were extremely anxiety at initial visit and significantly less so at second visit, although elevated compared to normal women(?).  TRAI - did not significantly changes between 2 visits. No difference in anxiety between leaflet and controls. Second visit anxiety/psycho-sexual scores similar in treated and untreated, although untreated had less spontaneous interest in sex. No significant difference in initial STAI between 67 patients who did not attend follow-up and those who did.  Psycho-sexual - First visit, leaflet group had more evidence of psycho-sex problems, by second visit, responses were comparable. Controls had lubrication problems.	Sending leaflet is not of benefit I isolation, but of benefit in reducing psychosexual function.	It may in fact cause anxiety - see leaflet group increased psychosexual dysfunction.	6
Acta Obstet Gynecol Scand Women's experience of coping with a positive Pap smear	Sweden	Prospective cohort Aim to evaluate women with repeated CIN1 by describing their experiences as well as evaluating how examinations, treatment and follow-up affected them. Questionnaire administered 5 years after first abnormal	n=242 having had 2 abnormal pap smears and who had undergone colposcopy/ biopsy	n=184 experienced follow-up in a positive way. 72% considered they understood diagnosis. 59% experienced worry and anxiety - 30% stating it had affected everyday life from between being informed of pap and further investigation. n=20 reported negative effect on sex life after treatment (correlated with less satisfaction at follow-up and negative influence on self-	Feeling vulnerable when undergoing investigation, but no influence on follow-up. Diagnosis created worry and negative experiences, may be improved if more education at time of screening. No remaining anxiety	Not clear about data collection methods. Non- validated survey. Recall bias	5

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
		smear. Questionnaire not validated - based upon 'knowledge from previous studies and reference literature.'		esteem).	after 5 years, but 8% reported remaining negative influence on sex life		
Inna 2010 <sup>101</sup> J Sex Med Sexual function after LLETZ	Thailand	Aim - to examine effect of LEEP on overall sexual satisfaction and other specific aspects of sexual function in women with dysplasia.  Questionnaire administered at one time point (after procedure) and asked about pre and post procedural sexual function.  1. Questions about freq of sexual intercourse, dysmenorrhea, dyspareunia, post-coital bleeding  2. Overall satisfaction with sex intercourse, sexual desire, vaginal lubrication/elasticity, orgasmic satisfaction, patient/partner satisfaction, anxiety - rated on 6 point Likert scale.  Not validated - but designed by research team to suit population.	n=89 women who had undergone LEEP at least 3 months previously	Changes in frequency of sexual intercourse, dysmenorrhea and dyspareunia not statistically significant Overall changes in overall satisfaction, vaginal elasticity and orgasmic satisfaction statistically significant.	Authors conclude that unlikely that LEEP caused problems as any of the statistically significant differences relate more to psychological rather than physiological aspects	Different to Hellsten which measured psychological aspects of sexual function. Inna main focus is on physiological aspects. Recall bias Asian pop - not generalisable ?	7

First author;	Country	Study design and methods	Population	Results	Authors	Comments	Quality
year; journal Kilkku 1982 104 Gynae Oncol Sexual function after conisation	Finland	Women undergoing conisation interviewed - about libido and sexual function.  Methods not clearly explained.	64 patients who had conisation during 6 month period. Interviewed before op, 6wks, 6mnths and 12 months post-op.	Found significant decrease in no. of patients with dyspareunia. No change in libido, experience of orgasm, coital frequency orgasm, coital frequency, overall satisfaction with sex life.	Seems to be saying sex problems no worse pre-op than post-op	Very poor quality - crude non- validated measures.	Score 1
Lauver 1999 <sup>107</sup> J of Women's Health and Gender-based medicine. Women's uncertainties, coping and moods regarding abnormal pap	USA	Aims - understand women's coping process with abnormal smear and colposcopy.  Examining influence of coping processes upon how individuals deal with stress/reaction to screening results.  Problem-focused/acceptance=ass ociated with positive experiences, but emotion-focused or avoidance has also helped reduce anxiety for women with abnormal pap smears.  Initial telephone interview (n=75), Follow-up Q before colposcopy (n=40) and n=35 completed post colposcopy Q.  Measure - Uncertainty in Illness Scale - 17 items out of 23 (6 excluded as	Women with abnormal smear requiring colposcopy, no previous history of colposcopy. Initial telephone interview (n=75), Follow-up Questionnaire before colposcopy (n=40) and (n=35) completed post colposcopy Questionnaire.	Uncertainty about abnormal pap smear decreased over time.  Negative mood scores reflecting psychological distress did not change over time.  Uncertainty about related positively to the coping strategy of catharsis as well to negative mood scores after receiving news and pre-colposcopy.  Catharsis associated with higher negative mood scores, but acceptance associated with negative mood scores.  Helpfulness of relaxation and diversion was assoc with lower negative scores.	Clinical interventions can address women's uncertainty and promote coping strategies to reduce psychological distress among women with abnormal cervical screening results.	Small sample size. Focus upon coping styles.	4

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
		not deemed appropriate). Further 7 items used in prior studies related to abnormal smear. Coping processes assessed - patients reporting their use of coping strategies.					
Lauver 1999 108 JOGNN Women's experiences in coping with abnormal Papanicolaou results and follow-up colposcopy	USA	Longitudinal descriptive study - telephone interviews after pap result and Questionnaire day before and after day after colposcopy Aim to delineate primary concerns women associate with abnormal pap results and colposcopy and to identify coping strategies. Telephone interview - open-ended questions re coping style (used in previous research). Questionnaire - asked again to think about main issues that troubled them	n=75 with abnormal pap needing colposcopy completed telephone interview; n=40 pre colposcopy Questionnaire; n=35 - post colposcopy Questionnaire No previous history of colposcopy	Primary concerns involved not understanding pap result; cancer or infertility. Coping strategies most used and rated as most helpful - seeking support and distraction	Nursing interventions should be considered to improve women's understanding of meaning of pap, and encourage women to seek social support and distraction while awaiting colposcopy	Non-validated measures. Focus upon coping strategies rather than measuring specific adverse sequelae.	6
Marteau 1990 112 BJOG Anxieties in women undergoing colp	UK	Aim to measure level of distress in women referred for colposcopy and examine contributing factors to anxiety.  Questionnaire administered before and after appt.	n=30 (age range 20-53) attending for first colposcopy	Results - high anxiety in group Overall women significant less anxious after procedure		Poorly reported/desi gned. Not clear about results. Nor sure how long after procedure	1

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
		STAI, and asked about specific anxieties in relation to 1. colposcopy itself, 2. what may be found, 3. perceived seriousness of problem.				the survey was administered.	
McDonald 1989 60 Gynae Oncol Impact of CIN diagnosis and treatment on body image and self-esteem	USA	Longitudinal study. Baseline data on self- esteem and body image from fist visit and post surgery Questionnaire on 4 visits Initial visit (biopsy) 1 week later (results of biopsy) Colposcopy/treatment 3 weeks after surgery Questionnaire - 3 sections 1- demographics 2- rate concerns with cancer, loss of SF, loss of reproduction, loss of attractiveness, medical procedure, partner rejection, STI's 3 - 7 items - adjective generation technique - self, body, medical condition, feelings towards partner, perception of how partner feels about her and her body. Not validated	n=20 (age range 15-40) attending colposcopy clinic	Concerns over cancer overrode all other concerns except during post-surgery visit at which time loss of attractiveness was paramount.  Loss of sexual function high at all visits.  Self-esteem - lowest and anxiety highest at initial and post visit.  Positive body image highest at post-surgery	Psychological problems associated with CIN are present even prior to diagnosis	Small sample Short-term follow-up Non- validated measures Baseline anxiety likely to be raised at first visit, so not a true baseline - No controls	5

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
Richardson 1996 <sup>116</sup> British Journal of Health Psychology Evaluation of cog-behavioural for distress associated with abnormal smear	UK	Prospective RCT looking at effect of provision of info and cog behavioural counselling on psychological adjustment.  Measures - ASQ STAI, GHQ, POMS administered precolposcopy, post-colposcopy, pretreatment, post-treatment and 3 and 6 month follow-up. Also a counselling evaluation Survey after colposcopy.	Women who had previously been informed of abnormal cervical smear result and subsequently required colposcopy and treatment. 219 randomized into either counselling plus leaflet (n=104) or leaflet only n=115).	High levels of distress on all measures in both groups precolposcopy and significant post-colposcopy reduction in distress in both groups.  No significant diff in psychological functioning between 2 groups post colposcopy assessment.  Minor difference at treatment and follow-up but following analysis these were interpreted as an artefact of baseline difference.	Cognitive-behavioural counselling plus info does not appear to have any incremental benefit over provision of information alone.		6
Rubin 2010 117 J of Lower Genital Tract Perceived uncertainty. Coping strategies	USA	Correlational study Aims to investigate relationships among uncertainty, knowledge, coping strategies and adaptation in young women having an abnormal pap and determine changes over time - i.e. on receiving news of pap; after colposcopy; receiving results of colposcopy; 4 <sup>th</sup> month follow-up pap; 8 <sup>th</sup> month follow-up colposcopy. Measured uncertainty at all time points and study also designed to	88 non-pregnant women who had HPV on a mildly abnormal pap	Relationship between uncertainty and coping strategies was supported in the emotion-focused path, but not in problem-focused path.	Presence of uncertainty over time was established in this pop. Statistically significant relationships were confirmed among uncertainty, emotion focused coping strategies and adaption in this group.	Concerned with relationships between psychological states rather than psycho outcomes per se.	5

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	Quality Score
	Italy	determine relationships between previous knowledge; uncertainty; coping strategies (emotion and problem focused) and adaption (body attitude, moods, promptness of follow-up). Mishall Uncertainty in Illness Scale; Ways of Coping checklist; Bipolar profile of Mood States; My Body Right Now Questionnaire.	n_67 covuelly	(O nationto wore evaluded from		Woman'a SE	
Serati 2010 <sup>118</sup> J Sex Med Impact of Loop on FSF	Italy	Questionnaire study FSFI utilised at time of the LEEP and 6 months after. Comparisons drawn between pre and post LEEP questionnaire.	n=67 sexually active women undergoing LEEP for CIN lesions	(9 patients were excluded from final analysis as only completed sexual function questions before LEEP).  In population - data showed overall sexual function was unchanged after LEEP, only 'desire' (sexual interest) became significantly worse.	LEEP does not affect women's sexuality, when compared to before LEEP.	Women's SF may have been affected by diagnosis. Need base- line that pre- dated diagnosis - control group required. Small sample	6
Tahseen 2008  Euro J of Obs and Gynae and Reproduction Psychological distress associated with colp	UK	Prospective study Aims to understand factors associated with anxiety in relation to colposcopy and seek opinion on interventions designed to reduce such risks. Anxiety levels recorded	n=50 first colposcopy appointment	Prior to attendance - 36% very worried, 54% slightly worried, 10% not worried. All found leaflet helpful to variable degree. During colposcopy 30% found video helpful but significant number (18%) found it increased worry. Women with pre-existing high anxiety least satisfied with	Higher the index of anxiety - less likely they are to find interventions helpful. Research should focus upon very anxiety women	No information on measures used. No control group	4

First author;	Country	Study design and	Population	Results	Authors	Comments	Quality
year; journal		methods			conclusion		Score
		upon arrival at clinic and		interventions.			
		given Questionnaire to					
		complete after					
		colposcopy (- not sure					
		how long after they were					
		expected to return					
		questionnaire.					
Valdini 2004 122	USA	Aim to illicit factors	202 Caribbean	Most distress caused - around	Fear of cancer and		3
J of Lower		associated with distress	Latino	fear of cancer and worries about	dying		
Genital Treat		in Latina pop.	colposcopy	miscarriage			
Disease		PEAPS-Q administered	patients				
Measurement of		in 2 parts - before and					
colp-assocaited		after procedure (doesn't					
distress		state how long)					
Zeisler 1997 <sup>123</sup>	Austria	Aim to evaluate the	n=40 attending	Women with adequate info had	Women should have	What is	3
Oncology		psychological distress of	colposcopy	less fear of cancer than	adequate info as it	sufficient to	
Reports		women after receiving	clinic with CIN I	inadequate information who also	improves	one person	
Psychological		abnormal pap.	(having had	had increased distress. Group A -	psychological	may be	
burden of		Questionnaire sent to	abnormal pap	reported follow-up reinforced	outcomes and	insufficient to	
women with		women at least one year	and directed	anxiety in comparison to group B.	improves compliance	another.	
mild CIN		after their last colposcopy	biopsy).	Compliance for regular		Poorly	
		visit.	Divided into	attendance of screening		designed	
		Questionnaire - short -	Group A (n=21)	significantly better in B		study.	
		non-validated	women who				
			reported they				
			hadn't received				
			sufficient				
			information				
			Group B -(n=19)				
			had sufficient				
			information				

## 3.4.3 Comparing populations in terms of disease status

This section will discuss those studies that report adverse psycho-sexual consequences in terms of disease status, (n=5). Table 3.13 outlines the data extracted for these studies.

Five studies compared psychological outcomes between women with varying stages of disease progression, or who were disease free. Two studies scored five or below on quality assessment <sup>57,110</sup> with the remaining three studies of higher quality (scoring six or above). <sup>54,88,92</sup> Four studies were undertaken in the UK <sup>57,88,92,117</sup> and one study was from the USA. <sup>110</sup>

Bell *et al* <sup>88</sup> compared women with mild/moderate dyskaryosis (under cytological surveillance, Group 1 n=75); women with severe dyskaryosis (first abnormal smear - referred for colposcopy, Group 2 n=75) and women with negative cytology (Group 3 n=73) using validated measures. These were administered face-to-face on one occasion (Group 1 and 3) where administration took place one week before and one week after colposcopy. It is not clear at what time point Group 2 questionnaires were administered. The study found that overall, the impact of abnormal smear upon patients' sex life was relatively small, although those undergoing colposcopy were more likely to experience reduced enjoyment. Distress was higher in women with an abnormality when compared with controls. Anxiety and depression levels were higher amongst those referred for colposcopy presenting with severe dyskaryosis, but fell following treatment, and the surveillance group in general had fewer psychological problems than the colposcopy group. Although this study focuses upon women in

terms of abnormality, it is not clear whether it is the level of abnormality that may cause adverse effects or the treatment modality. It does seem to indicate that receiving an abnormal result has some adverse psychological outcomes. Unlike studies that suggest that surveillance can have greater negative psychological consequences, <sup>86</sup> this study seems to suggest that the treated group were at greater risk of such outcomes.

Cairns *et al* <sup>92</sup> compare women treated for CIN 2/3 with women being treated for micro invasive cancer using validated measures and matched on age and year of treatment. It is not clear how long after treatment women were followed up. They found no significant differences on the HADS or POSM scores. Anxiety levels were the same in each group - 35% with a score greater than or equal to eight. This study provides reassurance for those undergoing treatment for micro invasive cancer, but as there is no control for the CIN group, the results in terms of the CIN group are more difficult to interpret.

Campion *et al* <sup>57</sup> assess six aspects of sexual behaviour in four patient groups undergoing colposcopy that demonstrated varying levels of disease status. The two stage assessment took place via interview at initial appointment. At this stage, a detailed history was taken and patients were asked to explore six aspects of their sexual life in the preceding six months. Follow-up took place after patients had received the 'all-clear' and they returned five to six months after baseline. They were asked to complete the same questionnaire with reference to the preceding 5 to 6 months. The authors found significant adverse psycho-sexual sequelae associated with diagnosis and treatment for CIN (Hellsten *et al*), which given the relatively long-

term follow-up, indicates that such effects can be more enduring than found in other studies.<sup>61</sup>

Lerman *et al* <sup>110</sup> compare women with a normal Pap result (n=106) and those with an abnormality requiring colposcopy (n=118) and found that the latter group had significantly elevated worries about cancer, impaired moods and effects upon their sex life and these were more pronounced in women who defaulted from initial follow-up.

Palmer *et al* <sup>54</sup> used validated measures to investigate the psychological effects of treatment for CIN, administering a questionnaire and interview with 20 women who had received news of abnormality and 20 women diagnosed with CIN. The study employed a short term follow-up (6 to 7 days post treatment or in the case the first group, 6 to 7 days after receiving result of abnormality). Women in the CIN group reported higher levels of psychological sequelae than the control group. It is unclear whether these impacts arose from the diagnosis itself or treatment or both, although the authors posit that given the data from the post-treatment interview, issues around the impact of diagnosis were pronounced.

It is difficult to draw satisfactory conclusions from these studies about the nature or severity of psycho-sexual impacts. Where elevated worries are observed, it is uncertain if these arise from being diagnosed with an abnormality or whether adverse impacts can be attributed to treatment itself.

Table 3.13 Comparing populations in terms of disease status

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Total
Bell et al <sup>88</sup> 1995 Preventative Medicine Psychological response to cervical screening	Scotland, UK	Cross sectional - cohort Women interviewed at home and psychological adjustment was assessed Structured sociological interview covering sociodemographic information - past experiences etc  1. HADS 2. Self esteem measure 3. Maudsley personality inventory 4. Social adjustment 5. Coping strategies Sexual function	1. n=75 women with mild or moderate dyskaryotic smears, under cytological surveillance for up to 9 months (interviewed on one occasion?); 2. n=75 women referred for Colposcopy after first ever abnormal smear showing severe dyskaryosis (interviewed on 2 occasions - 1 week before, 1 week after colp); 3. n=73 controls with negative cytology (interviewed on one occasion?).	SF - overall the impact of an abnormal smear on sex life was relatively small. Reduced enjoyment was more common in colposcopy group and reduced interest in the surveillance group.  Distress higher among women with abnormal smear than controls.  Anxiety/depression higher amongst those referred for colposcopy, but distress fell after treatment, but 20% remained highly anxious awaiting treatment. In surveillance - adverse psycho sequelae less acute but had more problems with social adjustment.	Positive smear maybe psychologically traumatic for a significant minority, irrespective of management style.  In contrast to Campion et al this study suggests less marked impact upon sex life, although this is a younger group and changes they found were evident only after biopsy/ LEEP	No base line data. Cross-sectional, so not long term. Short term follow up. Not clear when group 1 and 3 interviewed.	6
Cairns 2008 92 Int J Gynecol Cancer Impact of microinvasive cancer of cervix on women	UK	Comparing concerns of women with microinvasive cancer and those with high grade CIN (CIN2/3). Population based, casecontrol. Postal Q using HADS	18 with micro- invasive cancer vs. 26 CIN 2/3 (age and year of treatment matched) diagnosed between 2000-	No significant difference in HADS scores between groups (18% cancer/12% CIN depression scores) 35% anxiety in both groups. No significant difference in POSM or concerns of ongoing follow-up	No difference is treatment of cancer vs. CIN.	Comparators are cancer and CIN. To identify cancer patients had to go back to 2000 were	7

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Total
		and POSM - not sure how long after procedure questionnaire sent	2006.			some may be 6 years post diagnosis, so adverse effects may well have subsided.	
Campion et al 1988 <sup>57</sup> Br J Obstet Gynaecol	UK	Before and after questionnaire assessing 6 aspects of sexual behaviour before presentation and 6 months after treatment	n= 30 women referred for a colposcopy with an abnormal cervical smear; n=26 women traced as sexual partners of men with HPV who had evidence of cervical disease, n=25 as above but no cervical disease n=25 partners of men with urethritis and no cervical disease)	Statistically significant adverse psychosexual sequelae associated with diagnosis and treatment of preinvasive cervical intraepithelial disease.	Need for supportive counselling to help reduce anxiety	Small sample size	4
Lerman 1991 Adverse psychological consequences of positive cytologic screening	USA	Aim to explore relationship of cervical cancer screening, positive and negative pap results and psychological status. 3 months after Pap smear result - 10 minute structured telephone interview.  Measures - adapted from either Mental Health	n=106 women with normal pap result compared with n=118 requiring colposcopy due to abnormality. Population - lower-income minority	Pap positive women statistically significant elevated worries about cancer, impaired moods, daily activities, sex interest and sleep. Effects of positive result more pronounced among women who did not comply with follow-up. Women who had completed follow-up (colposcopy) did not exhibit heightened worry, mod disturbance or sex interest problems compared with negative results. (Pap positive also more likely	Health education targeted to psychologically vulnerable may reduce psychological distress.	Recall bias Only one time-point Younger, black population	5

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Total
• · •		Inventory and previous work - non validated. Data gathered on sociodemo status, screening history etc. Psychological variables - frequency of worry about cervical cancer; impairment of daily activities, tension and mood in past month; sexual interest; sleep.		to be unemployed/less educational attainment)			
Palmer et al 1993 <sup>54</sup> Br J Clinical Psychol Understanding women's responses to treatment for cervical intra- epithelial neoplasia.	UK	Cohort - questionnaire Includes Qualitative semi-structured Interviews with women. Aim to investigate emotional effect of treatment for CIN using a control group (diagnosis only). Measured - anger, health locus of control, impact of events. Visited at home 6 <sup>th</sup> day after receiving diagnosis and 7th day after treatment. Validated measures - Impact of events scale, STAI, Locus of control scale	Total n=40. Group 1 n=20 women who had received news of cervical abnormality Group 2 n=20 diagnosed with CIN. To examine effects of treatment group 2 compared on 2 occasions - after diagnosis and after laser treatment	20 women interviewed at home 6-7 days after laser treatment reported 60% changes in their feelings about sexual activity. Body and sexual relations suffer after diagnosis (because of CIN's posited causal relations with STD wart virus)	Women experience psychological and psycho-sexual problems after diagnosis and treatment for CIN	Small sample, short-term follow up, so answer received may be related to impact of treatment rather than long lasting effect of diagnosis upon sexuality, qualitative	6

# 3.4.4 Studies focusing upon the development and validation of a questionnaire

Two studies<sup>89,58</sup> focus upon the development of a questionnaire to measure the psychological effects of receiving an abnormal smear result and subsequent treatment and both were found to be reliable for use with this population. Table 3.14 outlines the data extracted from these studies.

Table 3.14 Studies focusing upon the development and validation of a questionnaire

First author;	Country	Study design and	Population	Results	Authors	Comments	QA
year; journal		methods			conclusion		Total
Bennetts 1995 89  J Clin Epidem PEAPS-Q: a questionnaire to measure the psychosocial effects of having an abnormal pap smear	Australia	Outlines the development and validation of Questionnaire to measure psycho effects of abnormal pap.  2 groups - 1. Received notification of abnormal pap attending 1 <sup>st</sup> colposcopy.  2. Had been followed up by at least one colposcopy.  PEAPS-Q administered before colposcopy (except for Q about experience of colposcopy - completed post-procedure).  GHQ administered also for validation of PEAPS-Q.	Group 1, n=93 Group 2, n=257 - this group was divided into first follow-up group (6mths) and second women having other than first follow-up.	Four dimensions of distress identified - Experience of medical procedures - /beliefs and feelings about abnormality and changes in self-perception/ worry about infectivity and effect on sexual relationships.	PEAPS-Q is a valid measure of psychological morbidity	Main focus on validation of Q, but does give results for domains of distress.	8
Doherty 1991 58 J Psychosom, Obstet. Gynaecol Assessment of the psychological effects of an abnormal cervical smear result and subsequent medical procedures	UK	Uses Q - Abnormal Smears Q - to examine affective and cog reactions to abnormal smear and subsequent procedures. 4 groups Measures - STAI, GHQ, ASQ	n=80 attending colposcopy clinic or outpatient theatre for laser. Had been previously informed of abnormal smear and diagnosed with CIN. 4 groups - precolposcopy (n=25) Post colposcopy (n=25), Pre-laser (n=15), post laser (n=15)	68% (n=54) - a little distressed, 21% (n=17) moderately distressed, 8% (n=6) severely distressed on at least 60% of the negative effect items with respect to abnormal result. Medical procedure - 66% (n=53) found it a little distressing, 21% (n=17) moderately distressed, 9% (n=7) very distressed on at least 60% of 5 negative items	ASQ is useful standardised tool for assessing degree of distress	Not clear when followed up. Main focus validation of ASQ	3

### 3.4.5 Summary - Quantitative studies

The first section of the systematic review focused upon the quantitative studies that looked at the psychological and/or sexual impacts of undergoing colposcopy or treatment for CIN. Due to the heterogeneity of the study designs, follow-up timescales and populations, the studies were grouped to enable a more coherent overview of the findings. The over-arching finding from the studies comparing biopsy/colposcopy surveillance with treatment was that there were no differences in outcomes between these groups. The higher quality studies concluded that any adverse outcomes were short lived in nature. Similar findings were observed with the studies comparing cytological surveillance and colposcopically directed treatment.

Studies focusing upon one cohort, rather than comparing across intervention modalities also indicated that any psycho-sexual morbidities were transient in nature. Studies that compared populations in terms of disease stage/status were less equivocal in their findings as it was difficult to disentangle the impact of receiving a diagnosis of an abnormality from the treatment itself. The main findings are discussed in more detail in Section 3.6.

### 3.5 Qualitative results

The next section will present the findings from the five qualitative studies included in the review. The data extracted from these qualitative studies are presented in Table 3.15.

**Table 3.15 Qualitative studies** 

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
Beresford 1986 59 Colp and Gynae Laser Surgery The emotional impact of abnormal pap smears on patients referred for colposcopy	Canada	Qualitative interviews after colposcopy (undertaken by clinical psychologist) including some Likert questions to rate concerns. Open-ended questions 'what was it like for you?' using experiential humanistic theory. Lasting 30 minutes	n=50 with CIN (various grades) referred for colposcopy directed biopsies following abnormal pap smear.	Four major areas of concern identified Fear of cancer - 100% of patients (70% severe intensity); Fear of reproductive loss/sexual function (68%) Fear of procedure itself (65%) Fear of bodily betrayal (62%)	Suggestions for improvements - physicians inform of result directly; descriptions of pap smears; written information	Poorly reported. Vague methodology given for data gathering and reporting results.	2
Hounsgaard 2007 98 Euro J of Oncol Nursing Facing possible illness detected through screening	Denmark	Qualitative study - to gain knowledge about women's perceptions of illness - based upon detected abnormal screen. Observation/Interviews + fieldwork. Theoretical underpinning - Ricoeur theory of 'critical interpretation. Participants followed over 2 year period at various stages in their treatment.	n=12 with diagnosis of potential illness n=7 required treatment n= no treatment (monitored by pap)	Main themes identified - feeling healthy/being healthy + potentially ill at the same time. Being a patient and suffering. Diagnosis of abnormality caused participants to feel anxious. Anxiety subsided 6 months after treatment. Non-treated group anxiety flared at check-up times.	Biomedical model juxtaposed with patients experience - patients feeling they have early stage cancer despite (pre- stage Vs actual cancer	Fits in with Quant studies comparing impact of different treatments, giving a useful theoretical overview	6
Juraskova 2007 <sup>103</sup> Psycho- Oncology What does it mean - uncertainty, trust, communication	Australia	Qualitative Semi-structured telephone interviews (Grounded theory). Aim to identify factors that influence women's experience of diagnosis and treatment and whether these continue long term. Follow-up - immediately	n=21 (aged 24- 54) women with CIN who had LLETZ (varying degrees of CIN)	Main themes identified Pre-treatment - shock, fear anxiety exacerbated by feelings of uncertainty. Post-treatment - negative replaced by positive - relief, empowered, main concerns - risk of developing cancer/reproductive probs. Feeling loss of trust in body. Communication - Attitudes towards	So, initial relief, but still fear of cancer. Study suggests negative impacts can be enduring	Fits in with literature r.e. cancer fears	6

First author; year; journal	Country	Study design and methods	Population	Results	Authors conclusion	Comments	QA Score
		post-treatment 8 months post-treatment		partner - positive and negative.  Doctor communication - easier to cope if positive experience with Doctor			
Mortensen 2010 <sup>113</sup> J Public Health Qual study of women's anxiety and info needs	Denmark	Focus groups and individual interviews	12 women with diagnosis of cervical dysplasia within last 3 months of having had conical section in last 6 months. Age range 25-35	Participants considered CD to be a highly distressing condition and experienced monitoring as a worrying delay before regression of lesions or treatment. Fear of cancer - not proportionate to stage of dysplasia, but determined by degree of knowledge regarding condition. Unlike other STI's, information regarding HPV did not result in stigmatisation as 'perception of disease dominated by cancer fears.	Important to address women's fears, need for information and communication with medical professionals about CD after diagnosis after diagnosis, irrespective of stage of disease.	Not clear when interviews or focus groups took place.	8
Posner & Vesey 1988 <sup>34</sup> Kings Fund Prevention of cervical cancer: the patients view	UK	Telephone - semi- structured	153 colposcopy patients	Women experience upset on receipt of abnormal smear. Knowledge deficit and fear of cancer are contributing factors to upset.	Need to address knowledge deficit to improve patient experience.	Rather too prescriptive in terms of questions asked. Not necessarily truly qualitative, but nevertheless an early, important study.	5

Four of the included qualitative studies were identified following the search strategy outlined in Section 3.4.<sup>59,98,103,113</sup> One further study was identified via a citation search for relevant studies.<sup>34</sup> Two studies were of poor quality, scoring five or below on quality assessment<sup>59,34</sup> with the remaining three scoring six or above. <sup>,98,103,113</sup>Two Danish studies were included, <sup>98,113</sup> and one study from Australia, Canada and the UK respectively. <sup>103,59,34</sup>

Beresford *el al's* <sup>59</sup> study aims to explore the particular emotional concerns that may arise following diagnosis of cervical abnormality. The authors interviewed 50 women with a diverse range of CIN disease grades. The participants were relatively young, with 58% being under 30 years of age. The quality of the study is hampered by a lack of explanation or detail in terms of the sampling strategy, description of data collection, analysis and discussion of the findings. The main results are expounded with the use of quotations, although these were limited and this hampered the authors' ability to demonstrate fully the conclusions being drawn. Four main themes are described by the authors, identifying the main areas of concern to be:

- Fear of cancer (100%)
- Fear of reproductive problems (68%)
- Fear of the procedure itself (65%)
- A sense of body betrayal (62%)

The first three themes have been routinely identified in the quantitative literature as well as the other qualitative studies. The notion of 'body betrayal' is attributed to the feelings that women, especially younger, ostensibly healthy women, may experience

in learning that they have an illness. Fear of reproductive problems could also be a particular concern in the age demographic where many women will not have had children and good reproductive health will be of considerable importance to them. However, there is scant discussion of these findings, diminishing the impact of the study. The authors suggest a number of service improvements, but do not justify these recommendations in the light of their results.

Hounsgaard *et al's* <sup>98</sup> study is comparatively well designed and provides a clearer methodology and exploration of their findings. Their aim is not to focus upon providing a framework for a general understanding of illness, but rather to understand the perceptions of illness for those women involved in the study. The study is longitudinal in design following women over a period of months and again the sample is relatively young (mean age 32 years) with no history of serious illness, with a diagnosis of moderate to severe cervical abnormality. The theoretical framework (phenomenological), study design, context, methodology and analysis plan are well described. The design is such to explore the progression and changes in participants' experience of illness over a period of time, taking into account the various stages of pre-treatment, treatment and post-treatment. Three main themes arose from data analysis:

- Notions of being healthy and potentially ill
- Being 'a patient' and suffering
- Being unable to work and suffering

These themes are presented in the context of the wider literature and the authors conclude that receiving an abnormal smear result is a significant event that raises worries about mortality, but such events may also be seen as opportunities for personal growth. The authors discuss these themes in the context of the biomedical model versus the patient/lay model of illness. Many women undergoing cervical screening are under the misapprehension that cervical screening is a test for cancer. Health care professionals need to take into account the lay person's knowledge and understanding of the kinds of treatment they are undergoing. This study provides a useful thematic overview of the kind of concerns this population have - fear of cancer and of painful treatments and as identified in Beresford *et al*, the unsettling position of feeling well, whilst being diagnosed with an illness.

Juraskova *et al* <sup>103</sup> have a slightly different focus in that they aim to identify factors that may influence how women experience diagnosis and treatment and to see if these continue in the long-term. Women were recruited at various time-points (immediate post-treatment up to eight months post-treatment) and with a range of abnormalities. The interviews were conducted via telephone, as patients lived within a wide geographical area. The context and methodology are adequately described and a grounded theory approach is used to aid analysis. Results are presented clearly and quotations are used to illustrate the themes that emerge and these are discussed in the context of pre- treatment and post-treatment:

- Uncertainty
- Trust in the body
- Communication

During the pre-treatment phase, the overriding feelings are of shock, fear and anxiety bought about by a sense of uncertainty. Following treatment, women experience a sense of relief and empowerment, although concerns persist about having/getting cancer, and worries about future fertility. A sense of feeling a loss of trust in one's body is a prominent theme, and women's experiences are ameliorated by a positive relationship with the doctor performing the procedure.

Mortensen *et al* <sup>113</sup> used a focus group and interview approach for data collection to examine the experiences of women (aged 25 to 35) with varying disease status and those treated by conisation and those who were not. The authors also investigated whether knowledge of human papillomavirus as the cause of dysplasia had any bearing on women's perception of disease. The context, methods and results are well presented and analysis was undertaken using a discourse theoretical approach. The main themes identified were as follows:

- 1. Discrepancy between severity of dysplasia and level of anxiety experienced. For some women with lower grade disease who had not been conised, levels of anxiety were more pronounced when compared to those with higher grade disease who had been treated. This may indicate that the mere diagnosis of dysplasia is of concern irrespective of severity. As seen in Balasubramani *et al*,<sup>86</sup> Naik *et al* <sup>114</sup> and Orbell *et al* <sup>115</sup> being treated at the outset can have more positive psychological outcomes.
- 2. This notion is reinforced by the fact that those who were treated felt a sense of reassurance. These women had also received more information than the untreated group which was also found to be reassuring. This is in contrast with

- other quantitative studies that do not to support the notion that greater levels of information and knowledge have a bearing upon positive psychological outcomes (Freeman-Wang *et al*,<sup>94</sup> *Howells et al* <sup>99</sup>).
- 3. Effect of information about the role HPV role as a cause of dysplasia. Women who did not know about HPV were concerned about getting cancer, whereas those who had learned about its role in cancer did not feel stigmatised or overly concerned about the fact that it was a sexually transmitted disease.
- 4. As seen in Juraskova *et al*, women's levels of concern were dependent upon the rapport with the medical professional and the amount of information they had received. The contrast between the medical and lay language model were highlighted (Hounsgaard *et al*) with women's anxiety levels being exacerbated by the use of terminology to describe their disease 'precursor to cancer,' and 'precancerous legion'.

In conclusion, the authors highlight the importance of realising the fears that women experience regardless of disease stage and the need to ensure that adequate information is provided and that health care professionals have the ability and interpersonal skills to communicate effectively with patients.

Posner and Vesey's large qualitative study<sup>34</sup> investigating the psychological, psychosexual and physical impacts of undergoing cervical screening and subsequent treatment was the first of its kind to explore women's experiences. They used 'semi-structured' interviews with 153 colposcopy patients and although the aim of the study is to explore experiences, the study is limited by the nature of data collection as the interviews are underpinned by a list of prescriptive questions that may introduce

concepts and issues that may not have arisen had the questions not been phrased in such a manner, leading to the possibility of researcher bias. Nevertheless, the study is important as it is a thorough exposition of women's responses and raises a number of important aspects of the experience of diagnosis and treatment for CIN as well making a number of recommendations for treatment providers.

Women's emotional upset on receiving an abnormal smear result was found to be a recurring theme and knowledge deficit around the nature of their diagnosis and fear of cancer were contributing factors to this upset. The study presented previously unreported experiences of the pain associated with treatment of the cervix that hitherto, had been poorly recognised in the field of gynaecological medicine. The sense of relief that can follow treatment is also raised as positive aspect of women's experiences. Information accompanying treatment also helped move women away from feelings of fear and distress.

The findings from the qualitative studies all seem to suggest that fear of cancer and fears around future fertility are prominent issues for women. Five of the studies interview younger women, <sup>34,59,98,103,113</sup> and therefore, concerns about reproductive health are unsurprising. Fear of cancer is a recurring theme through most of the studies cited in this review (quantitative and qualitative) and the contrast between lay and medical language around diagnosis of cervical abnormality appears to be a cause of confusion for patients who mistakenly conflate CIN and cancer.

Feelings of body betrayal also feature in the qualitative literature and such feelings are likely to be compounded by the largely asymptomatic nature of cervical disease.

Unlike other serious illnesses, there is often little or no warning of the fact that women are living with a cervical abnormality. This clearly has a disarming effect upon how women relate to their own bodies.

As we see with many interactions between patients and health care professionals, a great deal of importance is placed upon the ability of the professional to show compassion and care towards a patient as well as the importance of providing the patient with adequate and timely information that can help patients feel more at ease and less anxious. As commented previously, some of the quantitative literature is less than conclusive with regards to the benefits of having adequate information and its effect upon anxiety and levels of worry with two studies reporting that it may have the opposite effect <sup>94,99</sup> and other studies highlighting that adequate information can reduce anxiety levels. <sup>91,123</sup>

#### 3.6 Discussion

#### 3.6.1 Summary of the main findings

The purpose of this review was to provide an overview of the studies measuring the potential adverse impacts upon psychological and psycho-sexual well-being following screening and/or treatment for CIN. As outlined, study aims and design, methodology and follow-up time-frames are insufficiently homogeneous to enable a meaningful meta-analysis of the results to be drawn. The quality of the studies included range from the poorly designed to higher quality, robustly designed studies.

It is difficult to draw over-arching conclusions, but it is clear that there are a number of potential adverse effects that may arise from undergoing colposcopy. The main areas of interest would appear to be how enduring these are; whether they are dependent upon the management style offered to women and whether participant's psychological profile has any influence upon outcomes.

The studies focusing upon comparing two treatment modalities concluded that either see and treat was preferable to defer and treat, or defer and treat was preferable to see and treat. The studies concluding there were no significant differences between either management approach tended to be of better quality and in the main had a longer period of follow-up. In cases where see and treat was deemed to be preferable, the reasons given were that patients felt more in control and that anxiety was reduced due to the fact that they felt that their abnormality had been treated.

Studies indicating that surveillance may cause lower levels of psychological burden found that patients treated immediately may experience more anxiety relating to future fertility and effects of treatment upon sexual performance. The studies that found no significant differences between treatment and surveillance groups acknowledged that women do experience adverse effects including loss of libido and higher anxiety and depression scores in the short term, but that these are largely transient. The lack of difference between the groups is more likely to be explained by the fact that it is the nature of the diagnosis and feelings about 'body betrayal' that account for psychological sequelae, rather than the treatment itself.

Studies focusing upon one treatment employed either long-term or short-term follow-up. The more robust studies looking at long-term follow-up found that any increased psychological morbidities tended to be transient in nature. Studies asking women about particular fears and anxieties associated with colposcopy found that fear of cancer and fear about future fertility featured prominently as found in the qualitative literature.

Overall, it would appear that diagnosis of cervical abnormalities and follow-up treatment (whether immediate or deferred) can cause elevated levels of anxiety and problems with sexual functioning to a greater or lesser degree, but in general, these are unlikely to persist in the long-term.

In general, anxiety levels would appear to be largely transient, being raised post-diagnosis and pre-treatment but subsiding once treatment is complete. Sexual functioning problems appear to be more enduring, although in general, long term studies suggest that these too dissipate over time. Further, it would seem important to consider the influence of the particular psychological and coping profiles upon how a patient experiences diagnosis and treatment. Studies that take into account the psychological profile of participants importantly acknowledge that how individual women respond to diagnosis and treatment will be largely dependent upon any premorbid psychological or psycho-sexual difficulties they may have as well as how they typically manage health-related problems.

It would seem that a balance between benefits and harms needs to be struck. Being able to predict which women are likely to experience less adverse events depending

upon the treatment type offered is likely to be dependent upon a number of factors that it may be difficult to control for - personality types, coping style and stage of disease.

The evidence related to the psychosexual impacts of undergoing colposcopy or treatment for CIN is heterogeneous in nature. There are adverse impacts identified from the literature, but overall, such impacts are relatively transient in nature.

#### 3.6.2 Limitations of this review

Although the aim of this review was to investigate the adverse psychological and psycho-sexual sequelae associated with diagnosis of and/or treatment for CIN, the heterogeneity of included studies in terms of sample size, study design, follow-up time points and use of measures means that the generalisability of the results is difficult to establish. Furthermore, a number of studies were undertaken outside of the UK and therefore the extent to which the findings are applicable to the UK is limited.

Treatment options available for the diagnosis of cervical abnormalities/management of CIN have changed over the years. It is plausible that newer management techniques reduce the extent of adverse events for women undergoing surveillance of treatment. As the year of publication for included studies ranges between 1988 and 2010, this fact needs to be borne in mind when interpreting the findings and recommendations for future service provision outlined in earlier studies.

#### 3.6.3 Conclusions

The current evidence available examining the potential adverse psycho-sexual outcomes of treatment for CIN are heterogeneous in scope, design, setting, population and quality. These facets of the evidence limit the ability to draw unequivocal conclusions about the extent of adverse events associated with colposcopy and treatment for CIN. This review has confirmed the need to undertake a well-designed and sufficiently powered study to investigate any potential long-term adverse effects arising from colposcopically directed investigation and treatment.

# CHAPTER 4: FEMALE SEXUAL DYSFUNCTION - A CONTESTED NOTION

What are the current debates related to the existence of female sexual dysfunction?

One of the primary aims of this study was to ascertain the effects of undergoing colposcopy or treatment for CIN upon women's sex life. As the measure employed to explore 'sexual function' seeks to categorise women with or without 'sexual dysfunction,' it is important to highlight the potential pitfalls of categorising sexual problems as a 'dysfunction'. This chapter will focus upon the development of female sexual dysfunction (FSD) as a clinical diagnostic tool and will outline some of the arguments that both support and challenge its use within medicine.

Female sexual dysfunction is a contested concept. Some commentators argue that medicalisation and the 'need to treat' female sexual function is a misguided standpoint. The motivation to 'treat' FSD became prominent following the 'treatment' of erectile dysfunction with pharmaceuticals (Sildenafil). This led to the growth of interest in the area of 'treating' 'female arousal disorders.' It is argued that this a problematic proposition, not least because female (and male) sexuality are complex and multi-faceted phenomena. Sexuality may be considered in physiological terms but the psychological and emotional aspects of the phenomena are also integral to 'sexuality'. Furthermore, there are also important cultural and political aspects of sexuality.

'Dysfunction' is a value laden term and carries with it the sense that a person's sexual behaviours or desires are somehow malfunctioning. The literature pertaining to the creation of the concept of FSD and the arguments that challenge the 'reductionist' model of how best to understand human sexuality will be described. The first characterisation of the 'female sexual response' cycle was posited by Masters and Johnson in 1966. 124 It was classified as consisting of four phases - excitement, plateau, orgasm and resolution. In 1979, Kaplan 125 proposed a three phase model (desire, arousal and orgasm) and this later became the basis for the Diagnostic and Statistical Manual of Mental Disorders (4th edition). 126

Laumann and colleagues' work in the late 1990's <sup>127</sup> focused upon sexual dysfunction (SD) in men and women and characterised it by 'disturbances in sexual desire and in psycho-physiological changes associated with sexual response cycle of men and women'. Laumann *et al* acknowledged that epidemiological data is scant, but noted that the recent interest was sparked by two main areas of 'progress': increased understanding of neurovascular mechanisms of sexual response, and the availability of new drugs. These factors led to more people requesting help and Laumann *et al* realised the potential benefit of providing epidemiological data to explore the prevalence and predictors of SD. They postulated that such data would help to develop the kinds of services required and how best to deliver these.

The authors also argued that the 'changing cultural values' and 'demographic shifts' have influenced an increase in 'sexual concerns'. Laumann *et al*'s paper analysed data from the National Health and Social Life Survey 1992 (NHSLS)<sup>140</sup> to address these issues. This survey collected data on aspects of sexual behaviour including

problems and dysfunctions, health and lifestyle variables and socio-cultural predictors. The NHSLS analysed interviews with 1,410 men and 1,749 women (age range 18 to 59 years). Findings were presented according to seven dichotomous response items, looking at symptoms in past 12 months relating to:

- Lacking sexual desire
- Arousal difficulties (erection/lubrication)
- Inability to climax
- Anxiety about sexual performance
- Premature climax
- Pain during intercourse
- Not finding sex pleasurable

The main outcome measures were the risk of experiencing SD as well as other negative concomitant outcomes. The prevalence rates of SD for women were 43%. SD was found to be associated with age and educational attainment, with those achieving high levels of attainment half as likely to experience sexual problems. It was noted that women of different racial groups experienced different levels of SD for example, black women experienced lower levels of sexual desire, whereas Hispanic women experienced a lower rate of problems with sexual desire. SD was also found to be more common among men and women who had poor physical/psychological/emotional health and those who had had negative experiences within particular sexual relationships. The authors concluded that SD is a real and important public health concern and they acknowledged the role that

emotional/psychological problems may contribute to the experience of such problems.

Jennifer Berman, professor of urology at the University of California, along with Laura Berman and Irwin Goldstein, <sup>128</sup> published a paper outlining the classifications and definitions of FSD agreed at the 1998 AFUD (American Foundation of Urologic Disease) consensus panel. The paper also outlined the aetiologies of FSD before considering some of the treatments available. Berman's approach explores sexual (dys)function from a predominantly medical perspective focusing upon hormonal and physiological changes. However, in conclusion she also acknowledges the importance of 'psychosocial' evaluations of sexual dysfunctions as well as the importance of a collaborative approach between therapists and physicians. She also makes clear that FSD is distinct from male dysfunction. This is an important acknowledgment, although the tone of the article is largely devoted to approaching female sexuality from a medical/physiological angle.

Moynihan's paper<sup>129</sup> questions the motivations behind defining a disorder - namely Female Sexual Dysfunction (FSD), presenting the arguments in the debate from the pro-medical to the non-medical end of the spectrum. He indicates that in order to market similar drugs for women, a 'clearly defined medical diagnosis' is required before clinical trials for potential medications could go ahead.

The 'milestone paper' 'Sexual dysfunction in the United States: prevalence and predictors' (Lauman et al) estimated prevalence of FSD for women between 18 to 59 as 43% although concerns were raised - if women answered yes to only one of the

seven questions they were characterised as having FSD. Sandra Leiblum believed FSD to be far less prevalent and has argued that the figure of 43% has contributed to the over-medicalisation of women's sexual dysfunction. Similar concerns were raised by Dr John Bancroft, director of the Kinsey institute, who believed the term 'dysfunction' to be highly misleading. He noted that inhibition of sexual desire may be healthy and appropriate in many circumstances.<sup>131</sup>

Moynihan explains that the focus of male sexual dysfunction was upon erectile dysfunction, a physically measurable condition. To be able to 'measure' female dysfunction in order to 'treat' it, researchers like Goldstein were cited as developing animal modes of 'vaginal engorgement insufficiency'. Goldstein used data from other studies concerned with comparing testosterone levels of 'normal' women with those of his patients and reported at a Pfizer sponsored conference (December 2002) that women with FSD might have 'specific defect in steroid synthesis'. Goldstein cites the 43% prevalence of FSD and is steadfast in his belief that it represents 'dysfunction' rather than 'difficulties' as suggested by Liebman and other commentators.

Furthermore, Goldstein vociferously defends the importance of the collaboration between the pharmaceutical industry and medicine in 'treating' 'this new disorder.

In contrast to Goldstein, Moynihan sited the work of Tiefer *et al* in promoting a 'women-centered definition of sexual problems: 'discontent or dissatisfaction with any emotional, physical, or relational aspect of sexual experience,' with sociocultural, political/economic, psychological or medical causes. Tiefer aruged that sex cannot be defined in the context of the medical model that looks at health and sickness. To do so is to commit a category error. In conclusion, Moynihan indicated that there are

some benefits of the medical model of FSD in the sense that it humanises the doctor/patient relationship, leads to effective/safe drugs, and increases public and research attention about the complexity of FSD.

John Bancroft's 2002 paper further urged caution in the 'treatment' of sexual function in women. 130 He contextualises the 'Viagra phenomenon' and how it has become relevant to women's sexuality. He argues that although Viagra has enabled millions of men to improve erectile function, and this may be a positive for many women, there may be some women for whom this is not such a cause for celebration.

Furthermore, he charts the brief history of how female sexuality has, at times throughout history, been suppressed. The Victorian era in particular conflated female sexual enjoyment with malady and madness. Following this period, the phenomenon has been largely ignored until the permissive era of the 1960's when women's burgeoning sexual freedoms were realised with the introduction of the oral contraceptive. More recently, there has been increased attention paid to not only the potential harms caused by steroidal contraceptives, but also to the impact of procedures like hysterectomies upon female sexual health.

Bancroft urges caution in terms of how we conceive sexual function, initially citing the differences in male and female sexuality. He notes that male and female sexuality have become more similar of late (sexual freedom) but that whereas men's sexuality has been largely 'directed and shaped but not suppressed by social determinants' women's sexual expression should be viewed more profoundly through the prism of socio-cultural changes. Male sexuality is more clearly understood in relation to hormone levels, whereas female sexuality and desire would appear to be multifactorial or less predictable in terms of hormonal levels and physiological factors. The

connection between orgasm and reproductive function is fundamental for men, but not so for women. Bancroft discusses the sexual response cycle as the underpinning theory for much of the recent sex therapy. This theory has been widely criticised by feminists as it would seem to equate the male and female response to sex as well as suggesting that a 'normal' sexual response for a women would be characterised by achieving orgasm through intercourse. It seems to ignore the fact that for women, this may be only one aspect of their sexuality. Furthermore the underlying assumption that men and women have an 'equal' relationship may not be a reflection of certain societal norms where gender equality may not be a reality. Sex therapy, he suggests, also seems 'in the dark' when it comes to understanding the interface between the 'psychological processes and the physiological mechanisms involved in sexual response.'

Bancroft's final point focuses upon the use of 'sexual dysfunction' as an appropriate description for phenomena that may be better described as a 'sexual problem.' It is important to contextualise and understand that a diminished female sexual response maybe due to the relationship a women has and the fact that it just does not excite her. It seems curious to describe such a response as a dysfunction. Bancroft acknowledges that there are women for whom a pharmacological intervention will be appropriate, but it is important that these interventions are not the default setting for managing sexual problems.

In 2003, Bancroft published the results of a study whose aim was to assess the prevalence of distress about sexuality amongst women and examine the predictors of such distress. Notably, his use of the term 'distress' is a move away from the

medicalised language of 'dysfunction'. 131 A telephone survey was conducted in the USA with 987 white/Black African women (aged 20 to 65) who had been living for at least six months in a heterosexual relationship. A quarter of women reported 'marked distress' about their relationships or sexuality and the best predictors of this were their sense of general emotional well-being and emotional relationship with their partner during sexual activity. Bancroft suggested that these predictors do not fit well with the DSM-IV criteria for SD in women. Furthermore, he posited that the data discussed by Laumann *et al* was gathered using a very crude tool that does not explore responses beyond a yes/no categorisation. Surely women may interpret the questions differently and without looking at what is behind the responses it is difficult to assign a 'diagnosis.'

Cynthia Graham, an academic who like Bancroft and Moynihan, is cautious of the use of pharmaceuticals to treat female sexual problems, also comments about the concern felt by her and other commentators about the utility of the term 'female sexual dysfunction'. <sup>132</sup> In response to the increasing concern about the medicalisation of female sexual function she notes that recent research has focused upon challenging the medical model's focus upon 'correct genital performance,' and instead positing the importance of relationships and the emotional responses to sexual situations. Like Bancroft, she challenges the 43% prevalence rate of SD as it is based upon responses to very limiting questions. She notes that it is important to be able to distinguish between 'transient' sexual difficulties that may be the result of situational stresses (adaptive rather than dysfunctional) and longer term dysfunctions that may arise from illness, physical trauma or the effects of medications.

Unlike Laumann, Graham is uncomfortable with the close associations between sexologists and the pharmaceutical industry and sees the need for wider outcome research to evaluate the effectiveness of psychological interventions to treat sexual problems.

This chapter highlights the debates around the notion of female sexual dysfunction. The aim of the study reported in this thesis was to establish whether undergoing a colposcopy, or being treated for CIN carries with it an excess risk of female sexual dysfunction. Commentators have questioned the utility in attempting to 'diagnose' female sexual dysfunction when female sexuality is such a complex issue involving the interplay between various psychological, social, cultural, environmental and physical factors. It is important that this is borne in mind when drawing conclusions about how many women in this cohort have FSD. Although the Female Sexual Function Index (FSFI) is the 'best' yet measure of female sexual problems, the limitations of its use in this study are outlined in Chapter 5.

### **CHAPTER 5: STUDY METHODOLOGY**

# 5.1 Study design - an overview

What methods were employed to investigate the long term impacts of undergoing colposcopy or treatment for CIN?

This chapter will outline the methods used in the cohort study reported in this thesis and will include details of the study design, population, and details of recruitment.

Following the systematic review, which assessed the existing evidence base of the adverse psycho-sexual impacts of colposcopy, the main element of primary data collection for this research was the undertaking of a cohort study, with women who had undergone colposcopy within a defined period (stratified by level of intervention) in order to assess the impact of colposcopic interventions on psychological health and sexual functioning.

Data were collected via a two stage questionnaire survey administered by post. Data on a number of sociodemographic variables (age, deprivation, ethnicity) were obtained, in addition to information relating to the quality of life and sexual function derived from a number of validated measures incorporated into the questionnaires used.

Women who underwent colposcopy between 31<sup>st</sup> March 2008 and 1<sup>st</sup> April 2009 were identified from the records of participating hospitals in the West Midlands. The main outcome measures utilised were HADS (Hospital Anxiety and Depression

Scale) to measure anxiety and depression;<sup>133</sup> FSFI (Female Sexual Function Index) to measure sexual function<sup>134</sup> and WHOQOL-BREF (World Health Organisation Quality of Life - brief version) to measure quality of life.<sup>135</sup> Results were analysed by linear and logistic regression (using SPSS) in order to assess the best predictors of experiencing problems.

Ethical approval for the study was obtained from The Black Country Research Ethics Committee on 15<sup>th</sup> March 2010. REC reference number: 10/H1202/9.

# 5.2 Quantitative data collection using questionnaires

The study utilised postal questionnaires to collect both quantitative and qualitative data. Questionnaires enable statistical information to be calculated from the data collected and allow investigation of any associations between the variables being studied. In this study, the primary associations of interest were whether the level of treatment, age or socioeconomic status had any significant association with sexual function, psychological health and quality of life outcomes.

Questionnaire one collected basic data around sexual function, satisfaction with relationships, and general physical and psychological health. This questionnaire also included an open comment section to enable participants to provide other information or comments about the topic area that do not readily emerge from closed questions. Questionnaire two was sent to women who had agreed to participate in the second stage of the survey and collected more detailed information of outcomes and the predictors of adverse outcomes following colposcopy.

## **5.3 Study Population**

### 5.3.1 Colposcopy unit selection

The initial study design outlined recruitment from five colposcopy units - three from within the West Midlands (Birmingham Women's Hospital, Good Hope Hospital and City Hospital); one unit in Oxford (John Radcliffe) and one unit in Wales (Wrexham). However, it was estimated (given the assumptions about the response rate) that sufficient numbers of patients could be recruited from five units in the West Midlands. These units cover a wide geographical area providing a mix of more affluent and socioeconomically deprived populations, adding to the representativeness of study participants. The five participating units were as follows:

- Birmingham Good Hope (Heart of England NHS Foundation Trust)
- Birmingham Heartlands (Heart of England NHS Foundation Trust)
- Solihull Hospital (Heart of England NHS Foundation Trust)
- Birmingham Women's Hospital (Birmingham Women's NHS Foundation Trust)
- Birmingham City Hospital (Sandwell and West Birmingham NHS Trust)

#### 5.3.2 Population profiles of participating colposcopy units

Sandwell and West Birmingham

City Hospital is run by Sandwell and West Birmingham Primary Care Trust (PCT) and is situated in and serves an ethnically diverse population. Its patients are drawn from relatively deprived areas across West Birmingham.

#### Birmingham Women's Hospital

Birmingham Women's hospital is a centre for excellence providing care and treatment for women and their families across the West Midlands. As such, it provides services for women across a wide range of ethnicities and women from both affluent and deprived areas.

#### Heart of England NHS Foundation Trust

Heart of England NHSFT is one of the largest trusts in England and serves a diverse population across the West Midlands. Three of the participating colposcopy units form part of HEFT:

- Good Hope hospital serves North Birmingham including the more affluent area of Sutton Coldfield alongside parts of east Staffordshire. It has a catchment population of 450,000.
- Heartlands hospital serves a diverse, multi-ethnic inner city community and is the flag ship hospital of the Trust.
- Solihull hospital serves the relatively affluent area of Solihull, alongside the more deprived area of North Solihull.

## **5.4 Recruitment**

#### 5.4.1 Inclusion criteria

Women aged 25 to 65 who had undergone colposcopy at least 12 months previously (April 2008 to March 2009), recruited from the five participating centres outlined in Section 5.3, stratified by level of intervention:

- 1. Low risk group colposcopy only: no treatment or investigation (n=350)
- Medium risk colposcopy with investigation/diagnosis i.e. punch biopsy (n=350)
- 3. High risk colposcopy and treatment i.e. loop excision, or cone biopsy (n=350)

The study initially sought to include a control group of women aged 25 to 65 who had never undergone colposcopy (n=1,050). These controls would have been age and deprivation score matched to the cases (1:1 ratio) (IMD 2007 used as a proxy measure for deprivation). This proved impossible, given a number of limitations that are outlined in Section 5.4.6.

#### 5.4.2 Exclusion criteria

Cases: Women who had undergone treatment that was not colposcopically directed (e.g. women who may have been treated by hysterectomy). Excluding these women maximised the probability that any observed adverse effects following a colposcopy would be due to the colposcopy itself and not attributable to other procedures.

In order to access the study population of interest, contact was made with the lead consultants at the colposcopy units via letter and e-mail. The study protocol and

study details were included in order to describe the project and its aims. Meetings were arranged with each lead consultant to discuss the project in more detail, including matters of case identification. The following data were obtained for each patient, either by SF, where this was permitted by the terms of the Trust R&D approvals, or by an appropriate member of the clinical team.

Patient name

Hospital number

Address (including post-code to identify IMD)

Age

Date of first referral

Date of colposcopy

Diagnosis

Intervention type

- Colposcopy and no investigation/treatment
- Colposcopy and investigation (i.e. punch biopsy)
- Colposcopy and treatment (i.e. cone biopsy/LEEP/LOOP excision)

An Excel spreadsheet was created populated with the required fields, with each potential patient assigned a unique university identifier. Due to differences in patient record maintenance and access regulations at each participating Trust, the recruitment procedure and process for facilitating patient mailings differed slightly at each Trust. The procedures for identifying patients and inviting them to participate in the study in each Trust are outlined in Section 5.4.3.

### 5.4.3 Recruitment of patients - Birmingham Women's NHSFT

Despite R&D approval being granted for the study, the R&D department had some concerns about granting a research passport or letter of access to enable SF to work on site under the direction of the clinical team to facilitate patient mailings directly. Therefore, to enable case identification to take place and to allow the mail outs of questionnaire one to potential participants, Birmingham Women's NHSFT provided the support of a research midwife (RM) to undertake this role, who was given a spreadsheet pre-populated with the relevant fields for which data were required. The RM interrogated the hospital record systems to identify eligible patients, and recorded the patient details on the Excel spreadsheet (proforma presented in Appendix 6). Each patient's record was assigned a unique university identifier to ensure that the correct patient could be identified throughout the study. Study packs were provided to the RM so that the mailings could be directly facilitated from the Trust site. These comprised the following items:

- 1. Letter of invitation. The letter of invitation displaying the trust logo and an electronic signature from the lead consultant (Appendix 7)
- 2. Patient information sheet (Appendix 8)
- 3. Questionnaire 1 with assigned patient ID number (Appendix 9)
- 4. Pre-paid envelope for return of questionnaire by respondent
- 5. Envelope to send pack to patient

Mailings were undertaken in a series of batches over a period of seven months. As the mail-outs were undertaken, the RM sent a copy of the spreadsheet with all columns completed, but with identifiable information (name, address and date of birth details) removed so that progress with mailings could be monitored whilst maintaining anonymity and confidentiality. A postcode was provided to enable an IMD quartile to be assigned for each patient. The age for each patient was also provided. Study responders returned the questionnaire directly to the University of Birmingham, providing their contact details if they wished to receive the follow-up questionnaire (Q2) (Appendix 10). All non-responders to the initial mailing of questionnaire one received a reminder after three weeks.

### 5.4.4 Recruitment of Patients - Sandwell and West Birmingham NHST

R&D approvals and a letter of access were provided by SWBNHST and permission was granted by the lead consultant to provide onsite administrative support to undertake mail-outs for patients of City hospital. All patient identification was undertaken by the colposcopy secretary who selected patients using the criteria outlined above. SF printed and posted the study packs from the unit and a copy of the spreadsheet (with identifiable data removed) was taken back to the University on an encrypted memory stick.

#### 5.4.5 Recruitment of patients - Heart of England NHSFT

R & D permissions were granted along with a research passport to enable case identification and mail-outs to be undertaken directly by SF. Patient lists were provided on behalf of the lead Consultant by a nurse colposcopist listing all eligible patients for the three participating hospitals within the trust - Good Hope Hospital,

Heartlands Hospital and Solihull Hospital. Some delays were encountered in terms of IT access to patient records, but as per R&D permissions from Heart of England NHSFT, all patient identification - accessing patient names and addresses from the lists provided - was completed by SF.

Table 5.1 Time-line for approvals and recruitment

	Timeline for Ethics/R&D approvals and patient identification
9 <sup>th</sup> September	Contact made with SWB R&D informing of forthcoming
2009	project and requesting permission to name them as lead R&D site.
8 <sup>th</sup> January 2010	Ethics application submitted
1 <sup>st</sup> February 2010	Ethics Meeting
15 <sup>th</sup> March 2010	Ethical approval granted
15 <sup>th</sup> March 2010	Informed SWB R&D of ethical approval decision.
16 <sup>th</sup> March 2010	Research Passport signed off by University of
00   M   - 0040	Birmingham.
22nd March 2010	Contact made with relevant R&D departments to inquire
	about relevant information required for R&D permission at each site.
End April 2010	Responses received from all sites outlining information required. Delay occurred due to late responses from a number of R&D sites.
End April 2010	All relevant information sent to each R&D site.
May-July 2010	Further delays due to absence and sickness of R&D
July 2040	staff.
July 2010	R&D approval granted - Heart of England, Sandwell and West Birmingham, Coventry and Warwickshire.
September 2010	Approvals granted BWH, Worcestershire PCT.
September 2010	Recruitment of Worcestershire general practices
0	commenced (see Section 5.4.6).
October 2010 -	Patient recruitment commenced - BWH (all patient
end date	identification undertaken by Research Nurse at the unit,
	as BWH R&D would not allow SF to access identifiable
	data. All mail-outs had to be undertaken when RN had

	availability to do so).
November 2010	Patient recruitment commenced City Hospital (difficulties
	in arranging on-site meetings with consultants and
	limited access to appropriate IT resources to undertake
	mail-outs).
March 2011	Patient recruitment commenced - Good Hope and
	Solihull
April 2011	Patient recruitment commenced - Heartlands

The original aim was to identify 1,050 women from across the five participating hospitals' information systems; 350 women from each risk group (low, medium, high).

It was envisaged that 70 women would be required per risk group per hospital, so that each unit would provide 210 women in total. However, due to the poor response rates observed in the early stages of the questionnaire mailing, a larger number of women were mailed in each group to increase the study sample size (colposcopy only n=864; biopsy n=592; loop excision n=626). The final numbers of respondents are outlined in Chapter six.

### 5.4.6 General Practice Selection and Recruitment - study limitation

As described in Section 1.2, the initial aim for the study was to access an age and deprivation matched control group of women who had never attended colposcopy. This was planned in order to ascertain the degree of sexual dysfunction in the general population and to assess whether there was any excess risk of sexual dysfunction in the population that had undergone colposcopy or other investigations.

In order to recruit control participants for the study, general practices were approached within Worcestershire PCT. Potential practices were identified via the Midlands Research Practices Consortium (MidReC). This service consists of a

network of over 600 general practices, covering a representative population of over four million residents of the West Midlands. 138 68 GP practices in Worcestershire PCT were identified from the MidReC database. 14 practices were originally contacted by letter and a provided with a one-page summary of the protocol, introducing the aims and background to the study. It also outlined the research methods and the role that the practice would be asked to perform for the research. A reply slip and Freepost envelope were included, enabling practices to communicate their willingness to participate, decline participation or request further information about the study. Practices not wishing to participate were not contacted again. Non-responding practices received one reminder.

#### Practice involvement was outlined as follows:

- To provide a list of all women on the practice list aged 25 to 65 years (name, address and date of birth) who had never attended for colposcopy
- 2. To check this list so that women who it would be inappropriate to approach could be excluded (e.g. if the GP felt that inclusion may cause distress, or if a patient was considered to lack the mental capacity needed to enter the research study). Women who have had previous gynaecological malignancy were also excluded
- Provide a practice letterhead to enable the questionnaire to be accompanied by a covering letter from a GP in the practice

Financial reimbursement for practice time was available for performing these tasks.

One general practice in Redditch responded to the invitation to participate as a recruitment centre and following a meeting with one of the general practitioners and a

research nurse attached to the practice, they agreed to assist in accessing control patients from their list. Exploratory searches were performed using the practice data system to see if the required number of practice patients would be eligible to participate in the study. These searches suggested that around 3,890 patients were potentially eligible from the practice list.

Unfortunately, despite initial agreement to act as a patient identification site, and despite receiving full ethical approval for the questionnaires to be sent to general practice patients, the practice decided that it would be inappropriate to mail the questionnaire to patients without undertaking in-depth checks to also exclude women who may have been the victim of a sex crime. It seemed that the motivation for this was that receiving such a questionnaire may have impaired the patient/practitioner relationship. The limiting implications of this are discussed in further detail in chapter nine.

Following this, Research and Development (R&D) permissions were sought to facilitate access to practices within other Birmingham-based PCTs. Expression of interest letters were sent to six 'research friendly' practices in Birmingham. Despite attempts to fast track approvals, the study timescale was such that it became unfeasible to undertake recruitment of a control population for the study, taking into account the practice time required to identify patients, to match each case with a suitable control and to undertake the mail-outs and reminders to potential participants.

Concerns over response rates were also factored into the decision not to recruit controls. Response rates for the case population were well below the original forecast. Questionnaires had been sent to double the original number of colposcopy

patients anticipated to maximise the response rate. It was anticipated that in order to recruit an adequate number of age and deprivation matched control group patients, questionnaires would have to be mailed to at least three times the original number proposed - largely due to the fact that women who had never undergone colposcopy may have not seen the value in completing a questionnaire measuring quality of life, and particularly questions of a sexual nature. The decision was made that the study would continue, recruiting only women who had undergone colposcopy or treatment for CIN, and with normative published data acting as a proxy for control patients.

## 5.5 Sample Size

Each year, the five collaborating colposcopy units have 12,400 colposcopy appointments. 6,693 individuals were estimated to be eligible for inclusion within this study (i.e. excluding follow-up, non-attendance, cancellation). Eligible women comprised those treated (11.5%), not requiring treatment (65%) and those having investigation (e.g. biopsy) but no further treatment (23.5%). Data were based upon colposcopy records of three participating colposcopy units. The mean age at colposcopy is 38 years (range 17 to 82) and the background (no colposcopy) prevalence of FSD (female sexual dysfunction) was assumed to be 15%. 139

To estimate a doubling in the risk of FSD, from 15 to 30%, 160 participants were required in each group (90% power, 5% significance). The smallest group (high risk) comprises 730 women per annum. Conservatively assuming a questionnaire response rate of 50%, 350 in each group would be approached. Due to the lower than anticipated response rate for the study, the final sample of responders to Q2

(which was used to calculate the prevalence of FSD) was as follows: colposcopy only n=119; biopsy n=76; loop excision n=84. Given these figures, it was estimated that rather than estimating a doubling of FSD risk it would be possible to estimate 2.6 times the risk of FSD (from 15-39%) for the cohort (at 90% power and 5% significance). The limiting aspect of the sample size is discussed in chapters nine.

### 5.6 Data collection tools

The questionnaires used in the study were designed to establish:

- The prevalence of sexual problems amongst women who have undergone colposcopy, in order to ascertain if colposcopy has an adverse effect upon women's sexual life (sexual functioning).
- The prevalence of physical and psychological health problems amongst
  women who have undergone colposcopy. Again, this enables us to ascertain if
  colposcopy has an adverse effect upon women's physical and psychological
  health.
- Demographic details as potential confounders/predictors of psycho-sexual and physical outcomes.

### 5.6.1 Questionnaire one (Q1)

Questionnaire one was relatively brief and aimed to establish the prevalence of sexual problems using six questions used in the National Survey of Sexual Attitudes

and Lifestyles 2000<sup>140</sup> that relate to sexual functioning and Quality of Life (QoL) scores. It also contained an open question with space provided for participants to provide any further comments about issues raised on the questionnaire. Participants were also invited to consent to take part in the second survey.

The focus of Q1 was to measure patients' perceptions about aspects of their physical, emotional, sexual well-being and satisfaction levels in terms of their current relationships. Physical, emotional and social well-being are routinely used as the focus of quality of life assessment. Although the questionnaire did not use stand alone validated measures, it used adapted questions from the SF36, a short and multi-purpose measure of health outcomes.<sup>141</sup>

Consideration was given to utilising the EQ-5D (EUROQOL Group 1990) as a measure of five dimensions: mobility, self-care, usual activity, pain and discomfort, anxiety and depression. However, despite EUROQOL providing a short standardised measure of health related outcomes, it has been criticised due to the low response rates that it can yield in a number of populations and is highly skewed and relatively insensitive. Furthermore, issues around mobility and self-care were unlikely to be relevant to the population age range from which this sample was drawn (most attenders at colposcopy are aged 30-40).

Questions relating to general physical and emotional health were adapted from the SF-36 and are presented in Figure 5.1.

Figure 5.1 Questions relating to physical and emotional health

1. In general, would you say that your health is (Please circle)	e one option)						
Excellent Very Good Good	Fair	Poor					
2. In the <u>past 12 months</u> , have you had any of the following daily activities <u>as a result of your physical health</u> ? ( <i>Please</i>		ork or other regular					
Felt less able to carry out normal tasks	Yes	No 🗌					
Were limited in the kind of work or other activities you have undertaken	Yes	No 🗌					
3. During the <u>past 12 months</u> , have you had any of the followas a result of any emotional problems (such as feeling deplox)							
Accomplished less than you would like	Yes 🗌	No 🗌					
Didn't do work or other activities as you usually would do	Yes 🗌	No 🗌					
4. During the past 12 months, how much of the time have your physical OR emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? ( <i>Please circle one option</i> )							
All of the time  Most of the time  Some of the time	A little of the time	None of the time					

The SF-36 is a reliable measure which has been demonstrated to be more sensitive to lower morbidity rates, 141 but as it had 36 items, it would not have been appropriate for inclusion in the first questionnaire. The first question asks participants to consider how they would rate their general health and from the wording, the expectation was that they would be rating their perceptions on the day of questionnaire completion. Participants were asked to consider whether in the past 12 months they had experienced any problems undertaking regular activities (i.e. carrying out normal tasks/limited in the work or activities undertaken) as a result of their physical health. Similarly, the survey asked if their regular activities had been impeded by their emotional health. The next questions focus upon the impact of physical or emotional health upon respondents' social activities, again using a 12-month timeframe. The SF-36 also asks people to rate their health in the past four weeks. As this study aimed to explore the longer term adverse outcomes of colposcopy, it was deemed more appropriate to ask participants to give an overview of the previous 12 month period. This was thought to avoid the likelihood that respondents would report relatively recent or transient problems.

Six questions from the National Survey of Sexual Attitudes and Lifestyle (Natsal)<sup>140</sup> were employed to measure psycho-sexual problems including physiological problems. Natsal is a UK based scientific study of sexual behaviour, originally established in the context of the HIV/AIDS epidemic, to gather information about sexual lifestyles. It is the largest scientific study of its kind since the 1940's and 1950's.

The Natsal questions cover a broad range of sexual problems identified from the literature 124,147 and cover the main domains of female sexual problems - desire, arousal, orgasm, pain, distress. Natsal report that just over half of women (53.8%) reported at least one of these problems lasting at least one month; most commonly a lack of sexual interest. 139 It is acknowledged that a dichotomous format to answer questions of this nature does not provide an adequate level of sensitivity, and it does not provide a measure of female sexual dysfunction (FSD). This was measured in the second study questionnaire (Q2). Furthermore, women were not asked if they had a current partner at the time of completing questionnaire one which would have excluded responders from completing this section of the questionnaire. It does, however, provide a measure of whether participants who were sexually active felt they had a problem. As shown in Figure 5.2, it asks women to consider the previous three months or longer. As there is no consensus upon how long a difficulty should last before it becomes a 'problem', three months was considered to be a reasonable balance between avoiding capturing transient difficulties, and short enough to avoid missing severe, but relatively short-lived episodes.

#### Figure 5.2 Questions related to sex life

8. In the past year have you experienced any of the following for three months or longer? (Please tick the box that applies most to you)

Lacked interest in having sex?

Felt anxious just before having sex about your ability to perform sexually?

Were unable to come to a climax (experience an orgasm)?

Have come to a climax (experienced an orgasm) too quickly?

Experienced physical pain during intercourse or sexual activity?

Have had trouble lubricating?

Two Likert scales were also used to measure overall satisfaction with sexual life and overall satisfaction with relationships measured at the time of questionnaire completion (see Figure 5.3). These were employed as a broader measure of sexual satisfaction. Responses here provided a more impressionistic view of a participant's perception of their sexual life and can add context with which to aid interpretation of the six preceding questions.

Figure 5.3 Satisfaction with sex life and relationship

9. On a scale of one to ten, with 1 being most dissatisfied and 10 being most satisfied, how would you rate your satisfaction with your sexual life? (Please circle the number that applies most to you) 1 2 3 5 6 7 9 10 Most Neither Most dissatisfied satisfied satisfied nor dissatisfied

10. On a scale of one to ten, with 1 being most dissatisfied and 10 being most satisfied, how would you rate your satisfaction with your relationship? (*Please circle the number that applies most to you*)

1 2 3 4 5 6 7 8 9 10 Most Neither Most dissatisfied satisfied satisfied nor dissatisfied

The final section of the questionnaire provided participants with the opportunity to raise any other issues that they feel are relevant or important to them. The results from this are analysed in Chapter 8.

The second questionnaire described in section 5.6.2 included questions designed to elicit demographic data - age, social/educational level, ethnicity, lifestyle factors and health related factors. It collected more detailed information on outcomes and the predictors of adverse outcomes using a number of validated measures.

### 5.6.2 Questionnaire two (Q2)

Q2 collected detailed demographic information and details of outcomes and the predictors of adverse outcomes shown in Table 5.2. The purpose of the second questionnaire was to collect a range of data including ethnicity, level of educational attainment, smoking status, problematic licit and illicit substance use, sexual orientation, relationship status, method of contraception (if applicable), number of children, history of obstetric problems, history of gynaecological problems (e.g. dysmenorrhea), history of sexually transmitted infection, long term health problems, and frequency of visits to the general practitioner. Alongside these data, three validated measures were employed to measure female sexual dysfunction, anxiety and depression levels and quality of life.

**Table 5.2 Outcomes and predictors** 

Outcomes	Quality of Life, sexual functioning, anxiety and
	depression
Exposures	Colposcopy
Modifiers	Level of Colposcopic intervention: low/medium/high
	risk, age and deprivation 137
Other	Sociodemographic factors: Ethnicity, 148 relationships,
sociodemographic/health	education
related factors of interest	Lifestyle factors: smoking, alcohol, problem drug use
	Health-related factors: obstetric history, history of
	sexually transmitted disease, number of visits to GP,
	physical health problems

The following validated measures were used to measure sexual function, levels of anxiety and depression and quality of life:

- 1. Female Sexual Function Index (FSFI) which provides information about women's sexual functioning.<sup>134</sup>
- 2. The Hospital Anxiety and Depression (HADS) scale to assess levels of anxiety and depression. HADS has been found to perform well in assessing the symptom severity and caseness of anxiety disorders and depression in both somatic, psychiatric and primary care patients and in the general population.<sup>133</sup>
- 3. Quality of life was measured using the WHOQOL-BREF incorporating physical health, psychological health, social relationships and environmental factors. 135

Each of these three scales are described in greater detail in the forthcoming sections.

The Hospital Anxiety and Depression Scale is a relatively short well-validated scale that has been demonstrated to perform well in a general population as well as a hospital setting. It comprises 14 statements pertaining to generalised anxiety (n=7) and depression (n=7), see Figure 5.4. The outcomes indicate anxiety/depression levels with a range of 'normal', 'mild', 'moderate' and 'severe.' A lower score indicates that responders are in the 'normal' range in terms of anxiety and depression.

Although widely utilised and validated for the general population, much of the literature pertaining to prevalence rates of anxiety and depression investigate rates

from a population exposed to a particular disease or disorder. HADS was originally designed for use with patients who are physically ill. In the absence of matched control data to provide the prevalence rates of anxiety and depression in the general population, normative prevalence data will be referenced to provide context to the findings from the current study.

Figure 5.4 Anxiety and depression questions

Please consider the following statements and tick the box which most applies to you. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which best describes your present feeling. (*Please tick one box only for each question*).

	All of the time	Most of the time	Some of the time	Hardly ever	Never
25. I feel tense and wound up					
26. I still enjoy the things I used to enjoy					
27. I get a sort of frightened feeling as if something awful is about to happen					
28. I can laugh and see the funny side of things					
29. Worrying thoughts go through my mind					
30. I feel cheerful					
31. I can sit at ease and feel relaxed					
32. I feel as if I am slowed down					
33. I get sort of frightened feeling like butterflies in the stomach					
34. I have lost interest in my appearance					
35. I feel restless as if I have to be on the move					
36. I look forward with enjoyment to things					

37. I get sudden feelings of panic			
38. I can enjoy a good book or radio or TV programme			

The maximum score for both the anxiety and depression domains is 21, with the following ranges: normal 0 to 7; mild 8 to 10; moderate 11 to 15, and severe 16 to 21.

The Female Sexual Function Index (FSFI) is a brief multidimensional scale (19 items) for assessing sexual function in women, and has six domains relating to desire, arousal, lubrication, orgasm, satisfaction and pain. It is based upon activity in the past four weeks (see Figure 5.5). A score of between one and five was assigned to the domain question relating to desire (a score of one indicating no problems and a score of five indicating the highest degree of problem in this area). The remaining domains were scored in the same manner, although a score of zero was applied if responders were not engaged in sexual activity. A score  $\leq$  26.55 indicates the presence of FSD. Total scores of  $\leq$  26.55 indicate the presence of sexual dysfunction. When analysis of the results from the FSFI was undertaken, a sensitivity analysis was completed removing women who had reported no sexual activity. The purpose of this was to ensure that 'no sexual activity' was not treated as a sign of 'dysfunction' of women in the cohort. This limitation of the measure is discussed in more detail in chapter 9.

Chapter four discusses the literature pertaining to FSD in greater detail, but the available population prevalence data of FSD are outlined below. There is little consensus in terms of the prevalence rate of FSD in the general population. The heterogeneity of measures used, the use of inconsistent definitions of 'sexual dysfunction', differing population age ranges, gender, and timescales that the

measures ask participants to rate the length of time over which they have had difficulties (one week, one month, three month, six months) have all influenced this lack of precision.

Mercer *at al*<sup>139</sup> undertook a survey exploring the sexual function problems of a large sample (n=11,161) of men and women aged 16 to 44. The study measured the main dimensions of sexual dysfunction as defined by the ICD-10 and utilised by National Health and Social Life Survey<sup>147</sup> in the USA including sexual desire, lack of enjoyment/interest, genital response problems, orgasmic dysfunction, painful sex and excessive sexual drive. The study found that 15.6% of women had experienced persistent sexual problems in the previous year (persistent defined as lasting for at least six months).

A more recent study<sup>150</sup> sampled 1,489 women in the UK (aged 18 to 85) and utilised the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale (FSDS) to assess symptom severity and degree of distress. The study found that 5.8% of women reported recent sexual dysfunction and 15.5% lifelong sexual dysfunction. The later finding would seem to support the findings from Mercer *et al*, although Mercer *et al* reported 'persistent' problems as those experienced in the previous six months. Furthermore, the authors report that the most common independent predictor of FSD (lifelong or recent) was relationship dissatisfaction (OR 1.2 to 4.5). When focusing upon lifelong FSD, the authors found that experience of abuse, increased anxiety and obsessive compulsive behaviour were the most common predictors. These findings support the notion that female sexual dysfunction should be interpreted in the context of emotional and social factors and goes some

way to support the idea whether a diagnosis of a 'dysfunction' can be applied to a problem that is multifaceted - relating to partnership status, emotional health as well as physiological concerns.

The NHSLS study reports FSD rates of 43% in a sample of 1,749 US women aged 18 to 59 measuring the presence of a 'problem' in the previous 12 months. This study also found associations between age and educational attainment. Sexual problems were found to decrease with age except for those reporting problems with vaginal lubrication. The authors speculate that younger women are more likely to have multiple partners, longer periods of inactivity and inexperience all of which may contribute to increased anxiety around sex. Women educated to a higher level were less likely to experience sexual problems.

## Figure 5.5 The Female Sexual Function Index

In the first questionnaire we asked you some questions relating to your sexual feeling and responses during the last 3 months. We would like to ask some more questions that are a little more detailed. We realise that this is a particularly sensitive and private matter. Your responses will be treated in the strictest confidence.

In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

**Sexual intercourse** is defined as penile penetration (entry) of the vagina.

**Sexual stimulation** includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

**Sexual desire or interest** is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

### Over the past 4 weeks, (Please tick one box)

39. How <b>often</b> of	did you feel sexua Almost always or always	I desire or interes Most times (more than half the time)	st? Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
	0	0	0	0	0
40. How would y	ou rate your <b>leve</b> l	(degree) of sexu	ual desire or intere	st?	
	Very high	High	Moderate	Low	Very low or

	0	0	0	0	none at all			
41. How <b>often</b> did you feel sexually aroused ("turned on") during sexual activity or intercourse?								
	•	Most times	ea on ) auring sex Sometimes	A few times				
No sexual activity	Almost always or always	(more than half the time)	(about half the time)	(less than half the time)	Almost never or never			
0	0	0	0	0	0			
42. How would y	you rate your <b>leve</b>	of sexual arous	al ("turn on") durin	ig sexual activity c				
activity	Very high	High	Moderate	Low	Very low or none at all			
0	0	0	0	0	0			
	s a feeling that inc of warmth or tinglii weeks;							
43. How <b>confid</b>	ent were you abou	ıt becoming sexu	ually aroused durir	ng sexual activity of Low	or intercourse?			
No sexual activity	Very high confidence	High confidence	Moderate confidence	confidence	Very low or no confidence			
0	0	0	0	0	0			
44. How <b>often</b> h intercourse?	ave you been satis	sfied with your ar	ousal (excitement	) during sexual ac	tivity or			
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never			
0	0	0	0	0	0			
45. How often o	did you become lul	oricated ("wet") d	luring sexual activ	ity or intercourse?				
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never			
0	0	0	O	0	0			
46. How difficu	It was it to become	e lubricated ("we	t") during sexual a	ctivity or intercour	se?			
No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult			
0	0	0	0	0	0			

47. How often did you <b>maintain</b> your lubrication ("wetness") until completion of sexual activity or intercourse?						
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never	
0	0	0	0	0	0	
48. How <b>difficult</b> was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?						
No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult	
0	0	0	0	0	0	
49. When you ha	ad sexual stimulati		<del>-</del>		climax)?	
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never	
0	0	0	0	0	0	
50. When you h (climax)?	nad sexual stimulat	ion or intercourse	e, how <b>difficult</b> w	as it for you to rea	ch orgasm	
No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult	
0	O	0	0	0	0	
O	O	O	O	O	O	
51. How satisfie intercourse?	ed were you with y	our ability to reac	h orgasm (climax	) during sexual ac	tivity or	
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	
0	0	0	0	0	0	
52. How satisfi between you an	ed have you been d your partner?	with the amount	of emotional close	eness during sexu	al activity	
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	
0	0	0	0	0	0	
53. How satisfie	ed have you been	with your sexual	relationship with y	our partner?		
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	
0	0	0	0	0	0	

The WHOQOL-BREF is a shortened version of the WHOQOL-100 that has been validated for use across 15 countries and provides 'insights into the nature of disease by assessing how disease impairs the subjective well being of a person across a whole range of areas (see Figure 5.6). The four domains - physical, psychological, social and environmental can provide useful assessment of an individuals' perception of their overall well-being. The first two questions refer to the respondents' overall perception of their health. Raw scores for each domain are computed and transformed to give a possible score out of 100 for each domain. Domain scores are scaled in a positive direction with higher scores denoting a higher quality of life. The mean score of the items in each domain is used to calculate the domain score. The mean scores for each domain are then multiplied by four to make domain scores comparable with the scores used in WHOQOL-100.

## Figure 5.6 WHOQOL-BREF

Please choose the answer that appears the most appropriate. If you are unsure about which response to give to a question, the first one you give is usually the best one. (*Please circle one answer*)

We ask you to think about your life in the last four weeks.

58. How would you rate your			Neither		
quality of life?	Very Poor	Poor	poor Nor good	Good	Very Good
59. How satisfied are you with your health?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied

The following questions ask about how much you have experienced certain things in the last four weeks.

60. To what extent do you feel that physical pain prevents you from doing what you need to do?	Not at all	A little	A moderate amount	Very much	An extreme amount
61. How much do you need any medical treatment to function in your daily life?	Not at all	A little	A moderate amount	Very much	An extreme amount

62. How much do you enjoy your life?	Not at all	A little	A moderate amount	Very much	An extreme amount
63. To what extent do you feel your life to be meaningful?	Not at all	A little	A moderate amount	Very much	An extreme amount
64. How well are you able to concentrate?	Not at all	A little	A moderate amount	Very much	An extreme amount
65. How safe do you feel in your daily life?	Not at all	A little	A moderate amount	Very much	An extreme amount
66. How healthy is your physical environment?	Not at all	A little	A moderate amount	Very much	An extreme amount

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

67. Do you have enough energy for everyday life?	Not at all	A little	Moderately	Mostly	Completely
68. Are you able to accept your bodily appearance?	Not at all	A little	Moderately	Mostly	Completely
69. Do you have enough money to meet your needs?	Not at all	A little	Moderately	Mostly	Completely
70. How available to you is the information that you need in your day-to-day life?	Not at all	A little	Moderately	Mostly	Completely
71. To what extent do you have the opportunity for leisure activity?	Not at all	A little	Moderately	Mostly	Completely
72. How well are you able to get around?	Not at all	A little	Moderately	Mostly	Completely
73. How satisfied are you with your sleep?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
74. How satisfied are you with your ability to perform your daily living activities?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
75. How satisfied are you with your capacity for work?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
76. How satisfied are you with yourself?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
77. How satisfied are you with	Very	Dissatisfied	Neither	Satisfied	Very

your personal relationships?	dissatisfied		satisfied nor dissatisfied		Satisfied
78. How satisfied are you with your sex life?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
79. How satisfied are you with			Neither		
the support you get from your friends?	Very dissatisfied	Dissatisfied	eatisfied	Satisfied	Very Satisfied
80. How satisfied are you with the conditions of your living place?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
04 11			N1 '41		
81. How satisfied are you with your access to health services?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
82. How satisfied are you with your transport?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied

The following question refers to how often you have felt or experienced certain things in the last four weeks.

Never	Seldom	Quite often	Very often	Always

# 5.7 Data analysis

Analysis was undertaken in two stages - with data from questionnaire one and questionnaire two analysed separately. Non-responder bias was assessed for each questionnaire in terms of where treatment was undertaken, age socioeconomic status and treatment type and is reported in Chapter 6.

### 5.7.1 Analysis questionnaire one (Q1)

Analysis of questionnaire one included calculation of the frequencies of responses to all questions in terms of age, socioeconomic status and treatment type. Chi<sup>2</sup> tests were performed to investigate the relationships between age, socioeconomic status

and treatment type and the physical, emotional and sexual function measures included in the questionnaire. In terms of the questions related to sexual function, a bivariate analysis each factor was investigated individually using the three variables on interest - treatment type, age and socioeconomic status. Following this, a multivariate analysis was undertaken to ascertain, the 'best' if any predictors of reporting problems of a sexual nature.

For the two questions related to problems with social activities and general health, analysis was undertaken by dichotomising the possible responses to. The question related to problems with to social activities grouped 'little of the time' and 'none of the time' responses and compared then with 'some of the time', ''most of the time' and 'all of the time', the later three indicating more pronounced problems, The questions related to best describing general health grouped 'good', 'very good' and 'excellent' and compared this with the responses 'poor' and 'fair'. Again, the later responses indicating poorer patient rated health. Frequencies of responses for the measures relating to social activities, satisfaction with sex life and partner satisfaction were also investigated utilising non-parametric testing (Kruskall-Wallis).

#### 5.7.2 Analysis Questionnaire two (Q2)

Analysis of questionnaire two was undertaken in six stages.

**Stage one** reported the proportion of responses to each question relating to demographic details, lifestyle, health status, partner status, gynaecological and sexual issues.

**Stage two** analysed the association between treatment type and all factors.

**Stage three** reported the scores calculated for the validated measures for each respondent FSD, HADS anxiety, HADS depression and WHOQOL-BREF domain scores.

**Stage four** investigated the presence of FSD and HADS anxiety and HADS depression scores of 'normal' or 'mild and above' in association with the three main potential predictors of interest - treatment type, deprivation and age.

**Stage five** utilised bivariate analyses of the presence of FSD and scores of 'normal' or 'mild or above' for HADS anxiety/depression were undertaken for the three potential predictors of interest.

**Stage six** comprised logistic regression modelling to ascertain the significant predictors of the presence or absence of FSD and scores of 'normal' or 'mild and above' on the anxiety/depression scale. In terms of the WHOQOL-BREF domains, a comparison of means test (ANOVA) was undertaken for the scores from each domain in terms of treatment type, age and deprivation.

## 5.8 Summary of methods

This chapter has outlined the methodology used for the study, providing an overview of the study methodology; justification for the use of questionnaires to collect the

quantitative and qualitative data; an outline of the study population including description and recruitment of the study centres, inclusion and exclusion criteria, and the logistics of how the data was collected. Following this, the sample size was described and justified and the penultimate section focused upon the data collection tools employed (including a description of the validated and non-validated measures used). The final section gave a brief overview of the analysis undertaken for the study.

Chapter 6 will report the recruitment results for both stages of the study and the results from the analysis of the first stage (Q1) of the study.

# **CHAPTER 6: RESULTS - QUESTIONNAIRE ONE (Q1)**

#### **6.1 Introduction**

This chapter reports the analysis and results of the first stage of the study, Questionnaire one (Q1). Section 6.2 will outline details of the study recruitment for both phases. Section 6.3 will report details of responder bias for both phases of the study (Q1 and Q2). Section 6.4 begins with the results from the analysis stage of the study, firstly by outlining the characteristics of responders to Q1 and presenting the factors studied and potential predictors. Section 6.5 presents the frequency of responses to the questions for all respondents before focusing upon the characteristics of responders in terms of level of intervention, socioeconomic status and age and responses to the questions. Section 6.6 presents the summary of the findings from Q1, and Section 6.7 presents a short discussion of the limitations of this stage of the study.

# 6.2 Study recruitment

Women who attended for colposcopy between 1<sup>st</sup> April 2008 and 31<sup>st</sup> March 2009 were invited to participate in the first stage of the study.

Women who had experienced colposcopy during the time period were stratified by level of intervention for both stages of the study (stage one total n=560, stage two total n=279);

#### Questionnaire one:

- Colposcopy only no treatment or investigation (n=251)
- Colposcopy with investigation/diagnosis i.e. punch biopsy (n= 151)
- Colposcopy and treatment i.e. loop excision (n= 158)

#### Questionnaire two:

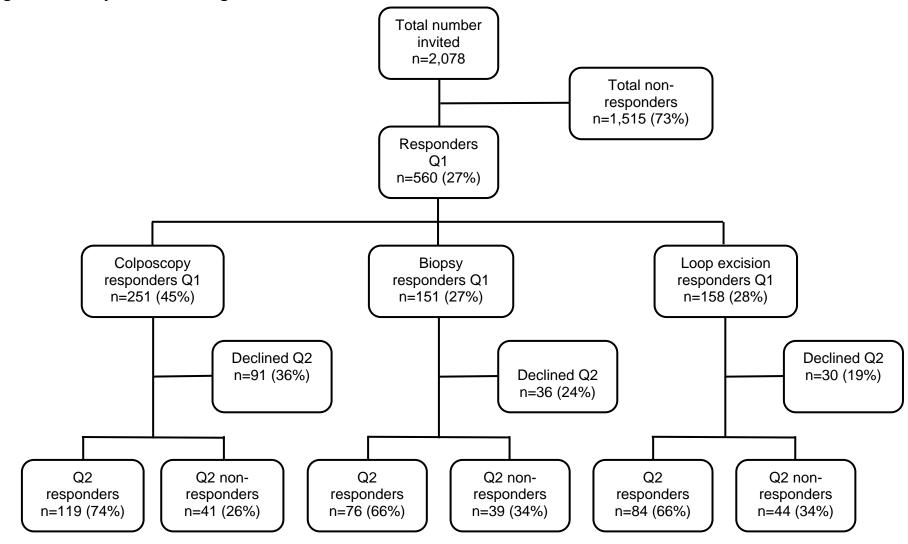
Due to the lower than anticipated response rate for the study, the final sample of responders to Q2 (where presence of FSD is calculated from) was as follows -

- Colposcopy only no treatment or investigation (n=119)
- Colposcopy with investigation/diagnosis i.e. punch biopsy (n= 76)
- Colposcopy and treatment i.e. loop excision (n= 84)

Given these figures, it was estimated that rather than a doubling of risk it was possible to estimate 2.6 times the risk of FSD (from 15-39%) for the cohort (at 90% power and 5% significance).

The overall number of patients recruited to the study are shown in Figure 6.1.

Figure 6.1 Study recruitment figures



# 6.3 Responders/non-responders Q1, Q2

Prior to the presentation of non-responder bias for Q1 and Q2, the proportion of those who responded to the invitation to participate for both stage of the study are presented in tables 6.1 and 6.2.

Table 6.1 Responders Q1

Characteristic	Total number invited	Number of responders (%)	Number of non- responders
Colposcopy unit		( 1)	()
Women's	1023	328 (32.1)	695 (67.9)
City	356	74 (20.7)	282 (79.3)
Solihull	401	87 (22.0)	314 (78.0)
Heartlands	100	19 (19.0)	81 (81.0)
Good Hope	198	52 (26.3)	146 (73.7)
Age range			
19-29	531	122 (30.0)	409 (70.0)
30-39	799	220 (27.5)	579 (72.5)
40-49	488	142 (29.1)	346 (70.9)
50+	248	76 (30.6)	172 (69.4)
		,	,
Deprivation *			
Most Affluent (Q1)	202	34 (17.0)	168 (83.0)
Less Affluent (Q2)	308	125 (40.2)	184 (59.8)
Less Deprived (Q3)	528	170 (32.2)	358 (67.8)
Most Deprived (Q4)	984	984 (23.0)	762 (77.0)
Woot Dopintod (Q 1)		001 (20.0)	102 (11.0)
Treatment type			
Colposcopy only	862	251 (29.1)	611 (69.9)
Biopsy	151	151 (26.0)	439 (74.0)
Loop Excision	158	158 (25.2)	468 (74.8)

<sup>\*</sup> Deprivation quartile derived from 2007 Index of Multiple Deprivation 137

Table 6.2. Responders Q2

Characteristic	Total number invited	Number of responders (%)	Number of non- responders
Colposcopy unit Women's City Solihull Heartlands Good Hope	221	167 (75.6)	54 (24.4)
	57	36 (63.1)	21 (36.9)
	68	38 (56.0)	30 (44.0)
	17	13 (76.5)	4 (23.5)
	40	25 (62.5)	15 (37.5)
<b>Age range</b> 19-29 30-39 40-49 50+	100 161 95 47	80 (80.0) 95 (61.0) 70 (74.0) 31 (66.0)	20 (20.0) 63 (39.0) 25 (26.0) 16 (34.0)
Deprivation * Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	40	28 (70.0)	12 (30.0)
	76	51 (67.0)	25 (33.0)
	107	78 (73.0)	29 (27.0)
	170	114 (67.0)	56 (33.0)
Treatment type Colposcopy only Biopsy Loop Excision	160	119 (74.0)	41 (26.0)
	115	76 (66.0)	39 (34.0)
	128	84 (66.0)	44 (34.0)

<sup>\*</sup> Deprivation quartile derived from 2007 Index of Multiple Deprivation 137

The characteristics of responders and non-responders for Q1 were compared to assess potential responder bias on the basis of where colposcopy was undertaken, patient age, type of treatment, and deprivation quartile of those invited to participate in the study (see Table 6.3). This was also completed for Q2 results shown in Table 6.4.

Table 6.3 Non-responders bias Q1

Characteristic	Responders (%)	Non-responders (%)	Non-responder bias
Colposcopy unit Women's City Solihull Heartlands Good Hope	328 (58.6) 74 (13.2) 87 (15.5) 19 (3.4) 52 (9.3)	695 (45.8) 282 (18.6) 314 (20.7) 81 (5.3) 146 (9.6)	X <sup>2</sup> =29.43; p=<0.0001
<b>Age range</b> 19-29 30-39 40-49 50+	122 (21.8) 220 (39.3) 142 (25.4) 76 (13.6)	409 (27.2) 579 (38.4) 346 (23.0) 172 (11.4)	X <sup>2</sup> =7.21; p=0.0655
Deprivation * Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	34 (6.2) 124 (22.5) 170 (30.9) 222 (40.4)	168 (11.4) 184 (12.5) 358 (24.3) 762 (51.8)	X <sup>2</sup> =54.85; p=<0.0001
Treatment type Colposcopy only Biopsy Loop Excision	251 (44.8) 151 (27.0) 158 (28.2)	611 (40.3) 439 (28.9) 468 (30.8)	X <sup>2</sup> =3.54; p=0.1703

<sup>\*</sup> Deprivation quartile derived from 2007 Index of Multiple Deprivation 137

There was a significant difference between the proportion of responders and non-responders on the basis of the colposcopy units from which patients were invited (X²=29.43; p=<0.0001). There were fewer than expected numbers of responders from Good Hope, Heartlands, City and Solihull, and higher than expected numbers of women responding from the Women's hospital (i.e. the numbers of respondents that would be expected to respond at each unit if responses were equally distributed across groups).

This may be explained by the fact that women attending City and Heartlands hospitals may have been less likely to respond given the ethnic make up of their populations. Both of these hospitals serve areas of ethnic diversity and have some of

the highest number of women from South Asian populations in the West Midlands. Given some of the cultural norms for these groups (women may be less likely to be able to read or write English; the head of the household is male and may open the post; the sensitive nature of questions around satisfaction with sexual life may not be amenable for these women), this may go some way to explaining the lower than expected responses from these hospitals. However, higher than expected numbers of non-responders were found in the hospitals situated in generally more affluent and less ethnically diverse areas (Good Hope and Solihull). It is difficult to draw conclusions about reasons for this; data on the ethnicity of women who either responded or did not respond to Q1 were not available.

Differences between the proportion of responders and non-responders were found in terms of age (X<sup>2</sup>=7.21; p=0.0655), with higher than expected numbers of patients responding from the 30 to 39, 40 to 49 and the 50+ age groups. The lowest proportion of responders was found in the 19 to 29 group. This may be because younger women may feel less inclined to participate in health related research.<sup>151</sup> They may also be less likely to experience poor health outcomes due to their age.

The level of deprivation was found to be significantly associated with the likelihood of responding to Q1 (X<sup>2</sup>=54.85; p=<0.0001) with higher than expected numbers of responders from the less affluent and less deprived groups (quartiles 2 and 3) and higher than expected numbers of non-responders in the most affluent and most deprived groups (quartiles 1 and 4). Although a lower response rate may be expected from women in the most deprived quartile, as these women may have poorer literacy rates; less inclination to participate in research or perceived barriers to

participation, the lower than expected response rate in the most affluent group was somewhat surprising given the perception that more affluent groups are more likely to participate in research.

No significant differences in the proportion of responders and non-responders were found on the basis of treatment type ( $X^2=3.54$ ; p=0.1703).

Table 6.4 Responders/non-responders Q2

Responders	Responders (%)	Non-responders (%)	Non-responder bias
Colposcopy unit			
Women's	167 (59.9)	54 (43.5)	
City	36 (12.9)	21 (16.9)	
Solihull	38 (13.6)	30 (24.2)	X <sup>2</sup> =12.11; p=0.0166
Heartlands	13 (4.7)	4 (3.2)	
Good Hope	25 (9.0)	15 (12.1)	
Age range			
19-29	80 (28.7)	20 (16.1)	
30-39	98 (35.1)	63 (50.8)	
40-49	70 (25.1)	25 (20.2)	X <sup>2</sup> =11.85; p=0.0079
50+	31 (11.1)	16 (12.9)	
Deprivation quartile*			
Most Affluent (Q1)	28 (10.3)	12 (9.8)	
Less Affluent (Q2)	51 (18.8)	25 (20.5)	X <sup>2</sup> =1.2; p=0.753
Less Deprived (Q3)	78 (28.8)	29 (23.8)	
Most Deprived (Q4)	114 (42.1)	56 (45.9)	
Treatment type			
Colposcopy Only	119 (42.7)	41 (33.1)	_
Biopsy	76 (27.2)	39 (31.5)	X <sup>2</sup> =3.3; p=0.0192
Loop Excision	84 (30.1)	44 (35.5)	127

<sup>\*</sup> Deprivation quartile derived from 2007 Index of Multiple Deprivation <sup>137</sup>

The characteristics of responders and non-responders to Q2 were compared to explore potential responder bias on the basis of where colposcopy was undertaken, treatment type, age and deprivation quartile, for those invited to participate in the study. There was a significant difference between the proportion of responders and non-responders on the basis of the colposcopy units from which patients were invited  $(X^2=12.11; p=0.0166)$ . As for Q1, there was a lower than expected number of

responders from Good Hope, City and Solihull. Higher than anticipated numbers of women responded from both the Women's and Heartlands hospitals.

Significant differences between the proportion of responders and non-responders were found with regard to age group ( $X^2$ =11.85; p=0.0079), with higher than expected numbers of patients responding from the 19 to 29 and 40 to 49 groups. Lower than expected numbers of responses were received from women in the 30 to 39 and 50+ age groups.

Significant differences were also found in the proportion of responders and non-responders on the basis of treatment type ( $X^2$ =3.3; p=0.0192) with proportionally larger numbers in the colposcopy group responding to Q2 and significantly lower than expected responses from individuals in the biopsy or loop excision groups.

The level of deprivation was not found to be significantly associated with the likelihood of responding to Q2.

# 6.4 Results of Analysis - Q1

Questionnaire one was designed to ascertain participants' perception of their general health; physical and emotional health; sexual life and partner satisfaction and social life. Responder characteristics are presented in Table 6.5.

Table 6.5 Characteristics of responders Q1

Characteristic	n(%)
Colposcopy unit Women's City Solihull Heartlands Good Hope	328 (58.6) 74 (13.2) 87 (15.5) 19 (3.4) 52 (9.3)
<b>Age range</b> 19-29 30-39 40-49 50+	121 (21.7) 219 (39.3) 141 (25.3) 76 (13.6)
Deprivation quartile * Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	34 (6.2) 124 (22.5) 170 (30.9) 222 (40.4)
Treatment type Colposcopy only Biopsy Loop Excision	251 (44.8) 151 (27.0) 158 (28.2)

<sup>\*</sup> Deprivation quartile derived from 2007 Index of Multiple Deprivation <sup>137</sup>

Nearly two thirds of patients were treated at the Women's hospital (n=328; 58.6%). In terms of age range, the 30 to 39 group accounted for the largest proportion of the sample (n=219; 39.3%). The 40 to 49 group and the 19 to 29 group were similar in their proportion of responders (n=141; 25.3% and n=121; 21.7% respectively). The lowest proportion of the sample were from the 50 group (n=76; 13.6%) The majority of the sample were from the most deprived quartiles (n=328; 58.69%). In terms of treatment type, women undergoing colposcopy accounted for almost half of the sample (n=251; 44.8%); with the remaining patients split fairly evenly between the biopsy and loop groups (n=151; 27.0%, n=158; 28.2% respectively).

The following questions were considered when analysing Q1:

- Is age associated with women experiencing physical, emotional, social or sexual problems?
- Is there a relationship between quality of life scores and levels of deprivation and/or age?
- Is there a relationship between treatment type and physical/emotional/sexual health (e.g. are women who have undergone loop excision more likely to experience sexual problems due to the invasive nature of the procedure when compared with the biopsy/colposcopy only groups)?

The results are presented below - including graphical representation of response frequencies and an investigation of the association between age, deprivation and treatment type and responses to the questions.

Chi<sup>2</sup> tests were performed to investigate the relationships between age stratified by range, deprivation stratified by level of deprivation and treatment type and the outcome measures relating to physical, emotional and sexual function. Frequency tables of responses for problems with social activities, satisfaction with sex life and satisfaction with partner are also presented.

Table 6.6 Factors studied and potential predictors (Q1)

Factor	Potential Predictors
General Health Quality	Level of treatment, deprivation quartile, age
<ul> <li>Physical Health affecting:</li> <li>Ability to carry out normal tasks</li> <li>Kind of work/activities undertaken</li> </ul>	Level of treatment, deprivation quartile, age
<ul> <li>Emotional Health</li> <li>Accomplishing less than would like</li> <li>Not doing work or other activities</li> </ul>	Level of treatment, deprivation quartile, age
<ul> <li>Sexual Health</li> <li>Lacking interest in having sex</li> <li>Anxious about ability to perform</li> <li>Unable to come to climax</li> <li>Climaxing too quickly</li> <li>Pain during intercourse</li> <li>Problems lubricating</li> </ul>	Level of treatment, deprivation quartile, age
Problems with social activities	Level of treatment, deprivation quartile, age
Overall satisfaction with sex life	Level of treatment, deprivation quartile, age
Overall satisfaction with partner	Level of treatment, deprivation quartile, age

## 6.5 Analysis of results - Q1

Analysis of questionnaire one presents the overall frequency of responses for all respondents to the questions relating to physical, emotional and sexual health before presenting analysis of the characteristics of responders in relation to the range of responses given to questions about physical, emotional and sexual health. This analysis was repeated for the questions relating to general health, social activities, satisfaction with sex life and satisfaction with partner. In terms of the six questions related to sexual function, bivariate analysis was undertaken for each question using

the three predictor variables - treatment type, deprivation and age. The purpose of the analysis of responder characteristics was to ascertain if there were any statistically significant relationships between variables, and thus whether clinical or sociodemographic predictors of these factors could be found.

The characteristics considered in the analysis were - level of intervention (colposcopy vs. biopsy vs. loop excision) level of deprivation and patient age. Further analysis was undertaken comparing the colposcopy group (to act as a proxy in the absence of a matched control group – see Section 5.4.6) with those undergoing biopsy or loop excision. It was hypothesised that women undergoing biopsy or loop excision were at greatest risk of experiencing adverse events - such as impaired physical and emotional health or reduced sexual functioning following the procedure, as these procedures could be considered more 'invasive' than colposcopy alone. Similarly, analysis was undertaken by collapsing the four deprivation quartiles into a dichotomous variable representing 'affluent' and 'deprived'. Significant results from this stage of analysis are reported.

## 6.5.1 Physical, emotional and sexual health

This section presents the analysis for the questions relating to physical, emotional and sexual health, presenting the total responses followed by analysis of the characteristics of responders in relation to these questions. Women were asked to consider the last 12 months and respond with 'yes' or 'no' to two questions relating to their physical health and two questions relating to their emotional health. They were

asked to consider the last three months and respond with a 'yes' or 'no' answer to six questions relating to their sexual well-being (Table 6.7).

Table 6.7 Frequency of response (all respondents) to questions on physical, emotional and sexual health

	Yes n	(%)	No n	(%)	Missing n	(%)	Total n	(%)
Physical/Emotional Health		(13)		(7.5)		(73)		(13)
Physical Health 1- less able to carry out normal tasks	111	(19.8)	437	(78.0)	12	(2.1)	560	100
Physical Health 2 - limiting kind of work/activities undertaken	111	(19.8)	433	(77.3)	16	(2.9)	560	100
Emotional Health 1 - accomplished less than would like	166	(29.6)	385	(68.8)	9	(1.6)	560	100
Emotional Health 2 - Didn't do work or other activities	135	(24.1)	408	(72.9)	17	(3.0)	560	100
Sexual Health								
Lacked interest in having sex	199	(35.5)	338	(60.4)	23	(4.1)	560	100
Anxious about ability to perform	127	(22.7)	400	(71.4)	33	(5.9)	560	100
Unable to come to climax	134	(23.9)	389	(69.5)	37	(6.6)	560	100
Come to climax too quickly	37	(6.6)	479	(85.5)	44	(7.9)	560	100
Experienced pain during intercourse	192	(34.3)	334	(59.6)	34	(6.1)	560	100
Experienced problems lubricating	143	(25.5)	381	(68.0)	36	(6.4)	560	100

Just under one fifth of responders reported that their physical health meant that they were less able to carry out normal tasks (n=111; 19.8%), or that it limited work or other activities normally undertaken (n=111; 19.8%). Just under one third of responders found that their emotional health meant that they accomplished less than they would like to (n=166; 29.6%) around a quarter found that their emotional health impacted upon work and other activities (n=135; 24.1%). With regard to sexual health, around one third of respondents reported lacking interest in sex (n=199; 35.3%) and experiencing pain during intercourse (n=192; 34.3%). The least common sexual problem related to coming to a climax too quickly, with 6.6% (n=37) of respondents reporting problems in this area.

Table 6.8 presents the results of the analysis relating to physical, emotional and sexual health in terms of treatment type.

Table 6.8 Physical/emotional/sexual heath - responses categorised by treatment type

	Col	poscopy		Biopsy		Loop Excision				
	Yes	No	Total	Yes	No	Total	Yes	No	Total	
Physical/Emotional Health	n (%)	n (%)		n (%)	n (%)		n (%)	n (%)		
Physical Health 1- less able to carry out normal tasks	59 (23.8)	189 (76.2)	248	27 (18.2)	121 (81.8)	148	25 (16.4)	127 (83.6)	152	$X^2$ =3.65 p=0.1612
Physical Health 2 - limiting kind of work/activities undertaken	58 (23.6)	188 (76.4)	246	29 (19.9)	117 (80.1)	146	24 (15.8)	128 (84.2)	152	X <sup>2</sup> =3.54 p=0.1703
Emotional Health 1 - accomplished less than would like	85 (43.1)	164 (65.9)	249	42 (28.4)	106 (71.6)	148	39 (25.3)	115 (74.7)	154	X <sup>2</sup> =3.8 p=0.1496
Emotional Health 2 - Didn't do work or other activities	68 (27.7)	178 (72.4)	246	37 (25.7)	107 (74.3)	144	30 (19.6)	123 (80.4)	153	$X^2$ =3.33 p=0.1892
Sexual Health										
Lacked interest in having Sex	87 (37.2)	147 62.8)	234	54 (36.0)	96 (64.0)	150	58 (37.9)	95 (62.1)	153	X <sup>2</sup> =0.12 p=0.9418
Anxious about ability to perform	54 (23.3)	178 (76.7)	232	34 (23.6)	110 (76.4)	144	39 (25.8)	112 (74.2)	151	$X^2$ =0.35 p=0.8395
Unable to come to climax	63 (27.4)	167 (72.6)	230	35 (24.1)	110 (75.9)	145	36 (24.3)	112 (75.7)	148	$X^2 = 0.68$
Come to climax too quickly	15 (6.6)	213 (93.4)	228	8 (5.6)	134 (94.4)	142	14 (9.6)	132 (90.4)	146	p=0.7118 X <sup>2</sup> =1.91 p=0.3848
Experienced pain during intercourse	94 (40.5)	138 (59.5)	232	50 (34.5)	95 (65.5)	145	48 (32.2)	101 (67.8)	149	$X^2 = 3.05$ p=0.2176
Experienced problems lubricating	69 (29.6)	164 (70.4)	233	33 (23.1)	110 (76.9)	143	41 (27.7)	107 (72.3)	148	$X^2$ =1.93 p=0.381

No significant differences were found between respondents to questions relating to whether physical health impacted upon ability to carry out normal tasks or limited the kind of work or activities undertaken ( $X^2$ =3.65, p=0.1612;  $X^2$ = 3.54, p=0.1703). Around a quarter of the respondents in the treatment group reported problems with physical health in terms of its impact on carrying out normal tasks and limiting work or activities compared with 18.2% (n=27) and 19.9% (n=29) in the biopsy group and 16.4% (n=25) and 15.8% (n=24) in the loop excision group. Similarly, no significant differences were found in relation to the impact of emotional health upon ability to accomplish what respondents would like to or upon undertaking work or other activities ( $X^2$ =3.8, p=0.1496;  $X^2$ =3.33, p=0.1892).

Treatment type was not significantly associated with an impact upon sexual health-lacking interest in having sex ( $X^2$ =012, p=0.9418); being anxious about ability to perform ( $X^2$ =0.35, p=0.8395); being unable to come to a climax ( $X^2$ =0.68, p=0.7118), coming to climax too quickly ( $X^2$ =1.91, p=0.3848); experiencing pain during intercourse ( $X^2$ =3.05, p=0.2176), or experiencing problems lubricating ( $X^2$ =1.93, p=0.381). A similar proportion of responders across all treatment groups reported 'lacking interest in sex' - colposcopy 37.2% (n=87); biopsy 36.0% (n=54) and loop excision 37.9% (n=58). The least problematic area in terms of sexual health was respondents climaxing too quickly. Similar proportions of responses were observed across treatment types - colposcopy 6.6% (n=15); biopsy 5.6% (n=8) and loop excision 9.6% (n=14).

Table 6.9 presents results relating to physical, emotional and sexual health in terms of treatment type using colposcopy as a proxy for a 'control' group.

Table 6.9 Physical/emotional/sexual health - responses categorised by undergoing colposcopy only, or biopsy/loop excision

	Colp	оссору		Biopsy			
	Yes	No	Total	Yes	No	Total	
Physical/Emotion al Health	n (%)	n (%)		n (%)	n (%)		
Physical Health 1- less able to carry out normal tasks	59 (23.8)	189 (76.2)	248	52 (17.3)	248 (82.7)	300	Pearson X <sup>2</sup> =3.5 p=0.0614
Physical Health 2 - limiting kind of work/activities undertaken	58 (23.6)	188 (76.4)	246	53 (17.8)	245 (82.2)	298	Pearson X <sup>2</sup> =2.78 p=0.0954
Emotional Health 1 - accomplished less than would like	85 (43.1)	164 (65.9)	249	81 (26.8)	221 (73.2)	302	Pearson X <sup>2</sup> =3.47 p=0.0625
Emotional Health 2 - Didn't do work or other activities	68 (27.7)	178 (72.4)	246	67 (22.6)	230 (77.4)	297	Pearson X <sup>2</sup> =1.86 p=0.1726
Sexual Health							
Lacked interest in having sex	87 (37.2)	147 (62.8)	234	112 (37.0)	191 (63.0)	303	Pearson X <sup>2</sup> =0 p=1
Anxious about ability to perform	54 (23.3)	178 (76.7)	232	73 (25.0)	222 (75.0)	295	Pearson X <sup>2</sup> =0.15 p=0.6985
Unable to come to climax	63 (27.4)	167 (72.6)	230	71 (24.2)	222 (75.8)	293	Pearson X <sup>2</sup> =0.67 p=0.4131
Come to climax too quickly	15 (6.6)	213 (93.4)	228	22 (7.7)	266 (92.3)	288	Pearson X <sup>2</sup> =0.21 p=0.6468
Experienced pain during intercourse	94 (40.5)	138 (59.5)	232	98 (33.0)	196 (67.0)	294	Pearson X <sup>2</sup> =2.89 p=0.0891
Experienced problems lubricating	69 (29.6)	164 (70.4)	233	74 (25.0)	217 (75.0)	291	Pearson X <sup>2</sup> =1.14 p=0.2857

The premise of comparing the colposcopy group to a combined biopsy/loop groups is that colposcopy can be considered less 'invasive' than the other treatment types and therefore may be associated with fewer problems. Biopsy and loop excision groups were analysed together and compared with colposcopy patients, and although no

statistically significant differences were found, the degree of difference between factors following Chi<sup>2</sup> analysis was higher than that found during analysis undertaken with the three groups considered separately.

A higher than expected number in the colposcopy group answered 'yes' to questions relating to physical health - being less able to carry out normal tasks and limiting work activities undertaken and a lower than expected number from the biopsy/loop excision group agreed with these statements (X²=3.5, p=0.0614; X²=2.78, p=0.0954). Similarly, higher than expected numbers in the colposcopy group answered 'yes' to questions relating to emotional health - accomplishing less than they would like and noting an effect upon ability to undertaken work or other activities. A lower than expected number from the biopsy or loop excision group responded 'yes' to these statements (X²=3.47, p=0.0625; X²=1.86, p=0.1726). In this analysis, intervention level was not significantly associated with any impact upon sexual health for any of the questions within these 'domains'. These findings show that level of intervention is not a significant indicator of physical, emotional or sexual problems following colposcopy.

The following tables present the analysis of the association between physical, emotional and sexual health and levels of deprivation. Deprivation was analysed in two stages - first with deprivation categorised into four quartiles (most affluent, less affluent, less deprived and most deprived) (Table 6.10) and secondly dichotomised between affluent and deprived, with Q1 and Q2 indicating 'affluence' and Q3 and Q4 indicating 'deprived' individuals. As no significant results were found in this stage of analysis, these results are not reported.

Table 6.10 Physical/emotional/sexual health - responses categorised by deprivation quartile

	Mos Ye	<b>t Affluen</b> s	t No		Total	<b>Less</b> Yes	Affluent	t No		Total	<b>Less</b> Yes	Deprive	d No		Total	Most Yes	Deprive	d No		Total	p value*
	n	(%)	n	(%)		n	(%)	n	(%)		n	(%)	n	(%)		n	(%)	n	(%)		
Physical/Emotional He	alth																				_
Physical Health 1- less able to carry out normal tasks	3	(8.8)	31	(91.2)	34	28	(23.3)	92	(76.7)	120	32	(18.9)	137	(81.1)	169	44	(20.5)	171	(79.5)	215	X <sup>2</sup> =3.65 P=0.3018
Physical Health 2 - limiting kind of work/activities undertaken	5	(15.2)	28	(84.8)	33	27	(22.7)	92	(77.3)	119	30	(18.0)	137	(82.0)	167	46	(21.4)	169	(78.6)	215	X <sup>2</sup> =1.69 P=0.06392
Emotional Health 1 - accomplished less than would like	7	(21.2)	26	(78.2))	33	30	(25.0)	90	(75.0)	120	45	(26.8)	123	(73.2)	168	81	(36.8)	139	(63.2)	220	X <sup>2</sup> =8.31 P=0.04
Emotional Health 2 - Didn't do work or other activities Sexual Health	4	(12.1)	29	(87.9)	33	30	(35.0)	90	(75.0)	120	35	(20.7)	134	(79.3)	169	63	(29.9)	148	(70.1)	211	X <sup>2</sup> =7.26 P=0.0641
Lacked interest in having sex	14	(41.2)	20	(58.8)	34	40	(34.2)	77	(65.8)	117	65	(38.9)	102	(61.1)	167	77	(36.8)	132	(63.2)	209	X <sup>2</sup> =0.91 P=0.823
Anxious about ability to perform	8	(23.5)	26	(76.5)	34	29	(24.8)	88	(75.2)	117	34	(21.0)	124	(79.0)	162	53	(26.0)	151	(74.0)	204	X <sup>2</sup> =1 P=0.8013
Unable to come to climax	8	(23.5)	26	(76.5)	34	29	(25.2)	86	(74.8)	115	35	(21.6)	125	(78.1)	160	61	(29.9)	143	(70.1)	204	X <sup>2</sup> =3.8 P=0.3647
Come to climax too quickly	3	(9.1)	30	(90.9)	33	7	(6.3)	105	(93.8)	112	12	(7.5)	147	(92.5)	159	14	(6.9)	188	(93.1)	202	X <sup>2</sup> =0.38 P=0.9443
Experienced pain during intercourse	9	(26.5)	25	(73.5)	34	45	(38.8)	71	(61.2)	116	66	(41.0)	95	(59.0)	160	67	(32.7)	138	(67.3)	205	X <sup>2</sup> =4.43 P=0.2186
Experienced problems lubricating	9	(26.5)	25	(73.5)	34	35	(30.2)	81	(69.8)	116	48	(30.0)	112	(70.0)	160	49	(24.0)	155	(76.0)	204	X <sup>2</sup> =2.18 P=0.5359

<sup>\*</sup> Statistically significant results are shown in bold text

As shown in Table 6.10, no statistically significant differences were found in the proportion of participants answering 'yes' to questions relating to physical health impact upon carrying out normal tasks ( $X^2=3.65$ , p=0.3018).

Physical health limiting the kind of work or activities undertaken although not statistically significant, was of higher significance (X²=1.69, p=0.06392) than other responses. A lower number of most affluent participants responded 'yes' to this question - 8.8% (n=3), compared to 23.3% (n=28) in the less affluent quartile; 18.9% (n=32) in the less deprived quartile and 20.5% (n=44) in the most deprived quartile. Similar levels of significance were found in relation to the impact of emotional health upon ability to do work and other activities (X²=7.26, p=0.0641) with a lower number of most affluent respondents answering yes to this statement and a higher number of most deprived respondents also answering yes to this statement.

Statistically significant differences were found in responses regarding the effect of emotional health upon ability to accomplish what respondents would like. Respondents in the 'most affluent' group were less likely to answer 'yes' to this statement and responders in the 'most deprived' group were more likely to respond with a "yes" to this statement (X²=8.31, p=0.04). This would appear to support the theory that an individual's level of deprivation can be associated with impairments in some aspects of emotional well-being, but given that analysis categorised by treatment type did not demonstrate any significant associations, and can therefore not be assumed to be due to their clinical treatment these differences are likely to be independent of whether an individual had undergone colposcopy/biopsy or loop excision.

Deprivation levels were not significantly associated with an impact upon sexual health - lacking interest in having sex; being anxious about ability to perform; being unable to come to a climax; coming to climax too quickly; experiencing pain during intercourse and experiencing problems lubricating.

Overall, these results suggest that socioeconomic deprivation does not have a significant association with respondents' perceptions of their physical, emotional or sexual well-being. This is a surprising finding as there is a body of evidence that supports the notion that those living in more deprived areas experience more pronounced health problems. However, these findings should be placed in context. The IMD deprivation quartiles may be considered as a fairly crude instrument in assigning deprivation or affluence to a particular individual.

Table 6.11 presents the analysis of the association between physical, emotional and sexual health and patient age. Responses were categorised into four age groups: 19 to 29, 30 to 39, 40 to 49 and 50+.

Table 6.11 Physical/emotional/sexual health - responses categorised by age group

		19	to 29				30	to 39	•		J	40	to 49	J · J · ·	•	<b>50</b> +					
	Yes		No		Total	Yes		No		Total	Yes		No		Total	Yes		No		Total	
Physical/ Emotional Health	n	(%)	n	(%)		n	(%)	n	(%)		n	(%)	n	(%)		n	(%)	n	(%)		
Physical Health 1- less able to carry out normal tasks	10	(8.3)	110	(91.7)	120	37	(17.1)	180	(82.9)	217	36	(26.5)	100	(73.5)	136	28	(38.9)	44	(61.1)	72	X <sup>2</sup> =30.54 Cramer=0.2367 p=<0.001
Physical Health 2 - limiting work / activities	12	(10.1)	107	(89.9)	119	36	(16.7)	180	(83.3)	216	36	(26.9)	98	(73.1)	134	27	(37.5)	45	(62.5)	72	X <sup>2</sup> =25.95 Cramer=0.219 p=0.001
Emotional Health 1 accomplished less than would like to	31	(25.6)	90	(74.4)	121	57	(26.3)	160	(73.7)	217	45	(33.1)	91	(66.9)	136	33	(44.6)	41	(55.4)	74	X <sup>2</sup> =10.59 Cramer=0.139 p=0.0142
Emotional Health 2 - Didn't do work or other activities	25	(20.8)	95	(79.2)	120	53	(24.4)	164	(75.6)	217	35	(26.1)	99	(73.9)	134	22	(31.9)	47	(68.1)	69	X <sup>2</sup> =2.98 Cramer=0.0743 p=0.3947
Sexual Health																					
Lacked interest in having sex	40	(36.6)	79	(66.4)	119	75	(35.0)	139	(65.0)	214	53	(39.3)	82	(60.7)	135	31	(47.0)	35	(53.0)	66	X <sup>2</sup> =4.02 Cramer=0.0868 p=0.2593
Anxious about ability to perform	32	(27.1)	86	(72.9)	118	48	(22.4)	166	(77.6)	214	30	(23.4)	98	(76.6)	128	17	(26.6)	47	(73.4)	64	X <sup>2</sup> =1.15 Cramer=0.0468 p=0.765
Unable to come to climax	32	(27.4)	85	(72.6)	117	45	(21.2)	167	(78.8)	212	37	(28.7)	92	(71.3)	129	20	(32.3)	42	(67.7)	62	X <sup>2</sup> =4.38 Cramer=0.0918 p=0.2232
Come to climax too quickly	8	(6.8)	109	(93.2)	117	14	(6.7)	194	(93.3)	208	11	(8.6)	117	(91.4)	128	4	(6.7)	56	(93.3)	60	X <sup>2</sup> =0.49 Cramer=0.0309 p=0.9211
Experienced pain during intercourse	54	(45.4)	65	(54.6)	119	78	(36.4)	136	(63.6)	214	42	(33.1)	85	(66.9)	127	17	(27.0)	46	(73.0)	63	X <sup>2</sup> =7.15 Cramer=0.1169 p=0.0673
Experienced problems lubricating	29	(24.6)		(75.4)	118	54	(25.2)	160	(74.8)	214	35	(28.2)	89	(71.8)	124	25	(38.5)	40	(61.5)	65	X <sup>2</sup> =5.01 Cramer=0.0981 p=0.1711

Statistically significant results are shown in bold text

A significant difference between age groups was observed in responses to the question regarding the effect physical health had upon individuals' ability to carry out normal tasks. Participants aged 50 and over were significantly more likely to answer 'yes' to this statement ( $X^2$ =30.54; p=<0.001) and the 19 to 29 age group less likely to answer agree with this statement than those in the other age groups. Similarly, there was a significant difference in responses to the statement regarding the effect of physical health limiting the kind of work or activities undertaken. Again, the older age group were significantly more likely to answer 'yes' and the younger group more likely to answer 'no' ( $X^2$ =25.95, p=<0.001).

A significant difference was also observed in responses to the question regarding the impact of emotional health upon accomplishing what individuals would like to, with the older group more likely to answer 'yes' to this question and the younger group less likely to answer "no" to this statement ( $X^2$ =10.59, p=0.0142).

Age group did not appear to be significantly associated with responses to questions relating to sexual health, lacking interest in having sex; being anxious about ability to perform; being unable to come to a climax; coming to climax too quickly; and experiencing problems lubricating. However, although not statistically significant (X<sup>2</sup>=7.15, p=0.0673), younger women were more likely to report having experienced pain during intercourse than those in the 50+ age group.

## Bivariate analysis of questions related to sexual function

This section will present the results from the bivariate analysis of the questions related to sexual function utilising the three predictors of interest - treatment, deprivation and age. The results are shown in tables 6.12 to table 6.17 All responses relate to problems experienced for three months or longer.

Table 6.12 Bivariate analysis of predictor variables in relation 'lacking interest in having sex'

Lacked interest in having sex			Bivariate OR (95% CI)	p value
naving sex	Yes	No	(93 % CI)	
Treatment type				
Colposcopy Only	87 (37.2)	147 (62.8)	0.97 (0.6 - 1.5)	0.86
Biopsy	54 (36.0)	` ,	0.92 (0.6 - 1.5	0.73
Loop Excision	58 (37.9)		Reference	Reference
Deprivation quartile				
Most Affluent (Q1)	14 (41.2)	20 (58.8)	1.20 (0.5 - 2.5)	0.62
Less Affluent (Q2)	40 (34.2)	77 (65.8)	0.89 (0.5 - 1.4)	0.63
Less Deprived (Q3)	65 (38.9)	102 (61.1)	1.09 (0.7 - 1.6)	0.79
Most Deprived (Q4)	77 (36.8)	132 (63.2)	Reference	
Age group				
19 to 29	40 (36.6)	79 (66.4)	0.57 (0.3 - 1.0)	0.07
30 to 39	75 (35.0)	139 (65.0)	0.60 (0.3 - 1.0)	0.08
40 to 49	53 (39.3)		0.73 (0.4 - 1.3)	0.29
50+	31 (47.0)	36 (53.0)	Reference	

Table 6.13 Bivariate analysis of predictor variables in relation to 'feeling anxious before having sex'

Felt anxious about having sex			Bivariate OR (95% CI)	p value
<b>3</b>	Yes	No	(=====	
Treatment type				
Colposcopy Only	54 (23.3)	178 (76.7	0.87 (0.5 - 1.4)	0.56
Biopsy	34 (23.6)	,	0.88 (0.5 - 1.5) <sup>°</sup>	0.65
Loop Excision	39 (25.8)	112 (74.2)	Reference	
Deprivation quartile				
Most Affluent (Q1)	8 (23.5)	26 (76.5)	0.87 (0.3 - 2.0)	0.76
Less Affluent (Q2)	29 (24.8)	88 (75.2)	0.93 (0.5 - 1.5)	0.81
Less Deprived (Q3)	34 (21.0)	124 (79.0)	0.75 (0.4 - 1.2)	0.26
Most Deprived (Q4)	53 (26.0)	151 (74.0)	Reference	
Age group				
19 to 29	32 (27.1)	86 (72.9)	1.02 (0.5 - 2.0)	0.93
30 to 39	48 (22.4)	166 (77.6)	0.79 (0.4 - 1.5)	0.49
40 to 49	30 (23.4)	98 (76.6)	0.84 )0.4 - 1.6)	0.63
50+	17 (26.6)	47 (73.4)	Reference	

Table 6.14 Bivariate analysis of predictor variables in relation to being 'unable to come to a climax

Unable to come to a climax			Bivariate OR (95% CI)	p value	
	Yes	No	, ,		
Treatment type					
Colposcopy Only	63 (27.4)	167 (72.6	1.17 (0.7 - 1.8)	0.50	
Biopsy	35 (24.1)	110 (75.9)	0.97 (0.5 - 1.6)	0.99	
Loop Excision	36 (24.3)	112 (75.7)	Reference	Reference	
Deprivation quartile					
Most Affluent (Q1)	8 (23.5)	26 (76.5)	0.72 (0.3 - 1.6)	0.45	
Less Affluent (Q2)	29 (25.2)	86 (74.8)	0.79 (0.4 - 1.5)	0.37	
Less Deprived (Q3)	35 (21.6)	125 (78.1)	0.65 (0.4 - 1.0)	0.08	
Most Deprived (Q4)	61 (29.9)	143 (70.1)	Reference		
Age group					
19 to 29	32 (27.4)	85 (72.6)	0.79 (0.4 - 1.5)	0.49	
30 to 39	45 (21.1)	167 (78.8)	0.56 (0.3 - 1.0)	0.07	
40 to 49	37 (28.7)	92 (71.3)	0.84 (0.4 - 1.6)	0.61	
50+	20 (32.3)	42 (67.7)	Reference		

Table 6.15 Bivariate analysis of predictor variables in relation to 'coming to a climax to quickly'

Climax too quickly			Bivariate OR	p value
	Yes	No	(95% CI)	
Treatment type	4 = (0,0)	0.4.0.400.4	0.04 (0.0.4.4)	
Colposcopy Only	15 (6.6)	213 (93.4	0.64 (0.3 - 1.4)	0.29
Biopsy Loop Excision	8 (5.6) 14 (9.6)	134 (94.4) 132 (90.4)	0.56 (0.2 - 1.3) Reference	0.56
Deprivation quartile				
Most Affluent (Q1)	3 (9.1)	30 (90.9)	1.34 (0.3 - 4.9)	0.65
Less Affluent (Q2)	7 (6.3)	105 (93.8)	0.89 (0.3 - 2.2)	0.81
Less Deprived (Q3)	12 (7.5)	147 (92.5)	0.82 (0.4 - 2.4)	1.09
Most Deprived (Q4)	14 (6.9)	188 (93.1)	Reference	
Age group				
19 to 29	8 (6.8)	109 (93.2)	1.02 (0.2 - 3.5)	0.96
30 to 39	14 (6.7)	194 (93.3)	1.01 (0.2 - 3.1)	0.98
40 to 49	11 (8.6)	117 (91.4)	1.31 (0.4 - 4.3)	0.65
50+	4 (6.7)	56 (93.3)	Reference	

Table 6.16 Bivariate analysis of predictor variables in relation to 'experiencing pain during sex'

Pain during sex			Bivariate OR (95% CI)	p value
	Yes	No	(30 % 31)	
Treatment type				
Colposcopy Only	94 (40.5)	138 (59.5)	1.43 (0.9 - 2.2)	0.10
Biopsy	50 (34.5)	95 65.5)	1.10 (0.6 - 1.7)	0.68
Loop Excision	48 (32.2)	101 (67.8)	Reference	
Deprivation quartile				
Most Affluent (Q1)	9 (26.5)	25 (73.5)	0.74 (0.3 - 1.6)	0.47
Less Affluent (Q2)	45 (38.8)	71 (61.2)	1.30 (0.8 - 2.0)	0.27
Less Deprived (Q3)	66 (41.0)	95 (59.0)	1.43 (0.9 - 2.1)	0.10
Most Deprived (Q4)	67 (32.7)	138 (67.3)	Reference	
_				
Age group	E 4 (4E 4)	05 (54.0	0.04 (4.4.4.0)	0.04
19 to 29	54 (45.4)	65 (54.6	2.24 (1.1 - 4.3)	0.01
30 to 39	78 (36.4)	136 (63.6)	1.55 (0.8 - 2.8)	0.16
40 to 49	42 (33.1)	85 (66.9)	1.55 (0.8 - 2.8)	0.39
50+	17 (27.0)	46 (73.0)	Reference	

Table 6.17 Bivariate analysis of predictor variables in relation to 'problems lubricating'

Problems lubricating			Bivariate OR (95% CI)	p value
	Yes	No	(6676 6.1)	
Treatment type				
Colposcopy Only	69 (29.6)	164 (70.4	1.0 (0.6 - 1.7)	0.68
Biopsy	33 (23.1)		0.7 (0.4 - 1.3)	0.36
Loop Excision	41 (27.7)	107 (72.3)	Reference	
Deprivation quartile				
Most Affluent (Q1)	9 (26.5)	25 (73.5)	1.13 (0.4 - 2.6)	0.75
Less Affluent (Q2)	35 (30.2)	81 (69.8)	1.36 (0.8 - 2.2)	0.23
Less Deprived (Q3)	48 (30.0)		1.35 (0.8 - 2.1)	0.20
Most Deprived (Q4)	49 (24.0)	155 (76.0)	Reference	
	,	,		
19 to 29	29 (24.6)	89 (75.4)	0.52 (0.2 - 1.0)	0.05
30 to 39	54 (25.2)	160 (74.8)	0.54 (0.3 - 0.9)	0.04
40 to 49	35 (28.2)	89 (71.8)	0.62 (0.3 - 1.1)	0.15
50+	25 (38.5)	40 (61.5)	Reference	
		•		

Following bivariate analysis of the responses to the six questions relating to sexual function, the only significant predictors of experiencing problems with sexual function were observed in terms of experiencing pain during sexual intercourse and problems with lubrication. Younger women (aged 19-29) were over twice as likely to report experiencing pain during sex compared with women over 50 years of age (OR: 2.24; CI 1.1 to 4.3). Women aged 19-29 were also half as likely to report problems with lubrication (OR: 0.52; 0.2 to 1.0) compared to women over 50.

#### Multivariate analysis of questions related to sexual function

This section will present the results from the multivariate regression undertaken to establish which, if any, of the three factors of interest might be significant predictors

of experiencing problems across the 6 six domain questions, when all other factors are controlled for in the model.

Table 6.18 Multivariate analysis of predictor variables in relation to 'lacking interest in having sex'

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.75 (0.225)	0.73	0.927	(0.5 - 1.4)
Treatment type 2 (biopsy)	0.004 (0.253)	0.98	1.004	(0.6 - 1.6)
IMD				
IMD 1 (Q1)	0.208 (0.388)	0.59	1.231	(0.5 - 2.6)
IMD 2 (Q2)	-0.109 (0.255)	0.67	0.897	(0.5 - 1.4)
IMD 3 (Q3)	0.077 (0.219)	0.72	1.080	(0.7 - 1.6)
Age range				
Age 1 (19-29)	-0.555 (0.317)	0.80	0.564	(0.3 - 1.0)
Age 2 (29-39)	-0.499 (0.289)	0.84	0.607	(0.3 - 1.0)
Age 3 (40-49)	-0.328 (0.307)	0.28	0.720	(0.3 - 1.3)

Note: Model  $X^2$  =4.753 (p=0.784); Hosmer and Lemeshow = 8.871 (p=3.53); Cox & Snell R<sup>2</sup>=0.09; Nagelkerke R<sup>2</sup> = 0.012

Table 6.19 Multivariate analysis of predictor variables in relation to 'feeling anxious before having sex'

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.233 (0.254)	0.35	0.792	(0.4 - 1.3)
Treatment type 2 (biopsy)	-0.143 (0.287)	0.61	0.866	(0.4 - 1.5)
IMD				
IMD 1 (Q1)	-0.123 (0.445)	0.78	0.884	(0.3 - 2.1)
IMD 2 (Q2)	-0.054 (0.281)	0.84	0.948	(0.5 - 1.6)
IMD 3 (Q3)	-0.317 (0.256)	0.21	0.72	(0.4 - 1.2)
Age range				
Age 1 (19-29)	0.015 (0.355)	0.96	1.015	(0.5 - 2.0)
Age 2 (29-39)	-0.242 (0.332)	0.46	0.785	(0.4 - 1.5)
Age 3 (40-49) Note: Model X <sup>2</sup> =3.4	  -0.209 (0.357)   -0.901): Hos	0.55 mer and Len	0.812 neshow = 2.110	(0.4 - 1.6) (p=0.977); Cox & Snell R <sup>2</sup> =0.

Note: Model  $X^2 = 3.481$  (p=0.901); Hosmer and Lemeshow = 2.110 (p=0.977); Cox & Snell  $R^2 = 0.007$ ; Nagelkerke  $R^2 = 0.010$ 

Table 6.20 Multivariate analysis of predictor variables in relation to being 'unable to come to a climax

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	0.069 (0.254)	0.78	1.071	(0.6 - 1.7)
Treatment type 2 (biopsy)	-0.017 (0.290)	0.95	0.983	(0.5 - 1.7)
IMD				
IMD 1 (Q1)	-0.255 (0.442)	0.56	0.775	(0.3 - 1.8)
IMD 2 (Q2)	-0.163 (0.278)	0.55	0.849	(0.4 - 1.4)
IMD 3 (Q3)	-0.394 (0.250)	0.166	0.675	(0.4 - 1.1)
Age range				
Age 1 (19-29)	-0.189 (0.346)	0.58	0.828	(0.4 - 1.6)
Age 2 (29-39)	-0.496 (0.324)	0.21	0.609	(0.3 - 1.1)
Age 3 (40-49) Note: Model X <sup>2</sup> =7.05	   -0.111 (0.339)   -0.531): Hosi	0.073 mer and Lem	0.529 neshow = 5.018	(0.4 - 1.7) (p=0.756); Cox & Snell R <sup>2</sup> =

Note: Model  $X^2$  =7.054 (p=0.531); Hosmer and Lemeshow = 5.018 (p=0.756); Cox & Snell  $R^2$ =0.014; Nagelkerke  $R^2$  = 0.020

Table 6.21 Multivariate analysis of predictor variables in relation to 'coming to a climax to quickly'

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.493 (0.408)	0.22	0.611	(0.2 - 1.3)
Treatment type 2 (biopsy)	-0.557 (0.482)	0.24	0.573	(0.2 - 1.4)
IMD				
IMD 1 (Q1)	0.168 (0.681)	0.80	1.183	(0.3 - 4.4)
IMD 2 (Q2)	-0.052 (0.501)	0.91	0.949	(0.3 - 2.5)
IMD 3 (Q3)	-0.005 (0.419)	0.99	0.995	(0.4 - 2.2)
Age range				
Age 1 (19-29)	-0.013 (0.641)	0.98	0.987	(0.2 - 3.4)
Age 2 (29-39)	-0.014 (0.594)	0.98	0.987	(0.3 - 3.1)
Age 3 (40-49) Note: Model X <sup>2</sup> =2.48	0.173 (0/618) 9 (p=0.962): Hosn	0.77 ner and Lem	1.189 eshow = 4.179	(0.3 - 3.9) (p=0.841): Cox & Snell R <sup>2</sup>

Note: Model  $X^2$  = 2.489 (p=0.962); Hosmer and Lemeshow = 4.179 (p=0.841); Cox & Snell  $R^2$ =0.005; Nagelkerke  $R^2$  = 0.012

Table 6.22 Multivariate analysis of predictor variables in relation to 'experiencing pain during sex'

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	0.503 (0.234)	0.03	1.654	(1.0 - 2.6)
Treatment type 2 (biopsy)	0.027 (0.267)	0.92	1.027	(0.6 - 1.7)
IMD				
IMD 1 (Q1)	-0.84 (0.429)	0.84	0.920	(0.3 - 2.1)
IMD 2 (Q2)	0.419 (0.258)	0.10	1.520	(0.9 - 2.5)
IMD 3 (Q3)	0.480 (0.227)	0.03	1.615	(1.0 - 2.5)
Age range				
Age 1 (19-29)	0.884 (0.346)	0.01	2.421	(1.2 - 4.7)
Age 2 (29-39)	0.500 (0.325)	0.12	1.648	(0.8) - 3.1)
Age 3 (40-49)	0.320 (0.348)	0.35	1.376	(0.6 - 2.7)

Note: Model  $X^2$  =17.414 (p=0.026); Hosmer and Lemeshow = 3.154 (p=0.924); Cox & Snell  $R^2$ =0.033; Nagelkerke  $R^2$  = 0.046

Table 6.23 Multivariate analysis of predictor variables in relation to 'problems lubricating'

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	0.20 (0.245)	0.93	1.021	(0.6 - 1.6)
Treatment type 2 (biopsy)	-0.333 (0.288)	0.248	0.717	(0.4 - 1.2)
IMD				
IMD 1 (Q1)	0.159 (0.433)	0.71	1.172	(0.5 - 2.7)
IMD 2 (Q2)	0.479 (0.276)	0.08	1.614	(0.9 - 2.7)
IMD 3 (Q3)	0.336 (0.245)	0.16	1.400	(0.8 - 2.8)
Age range				
Age 1 (19-29)	-0.620 (0.388)	0.06	0.538	(0.2 - 1.0)
Age 2 (29-39)	-0.623 (0.306)	0.42	0.536	(0.2 - 0.7)
Age 3 (40-49) Note: Model X <sup>2</sup> =9.38	-0.457 (0.329) 34 (p=0.311): Hos	0.16 mer and Len	0.633 neshow = 4 196	(0.3 - 1.2) 5(p=0.839): Cox & Snell R <sup>2</sup> =0.

Note: Model  $X^2$  = 9.384 (p=0.311); Hosmer and Lemeshow = 4.196(p=0.839); Cox & Snell  $R^2$  = 0.018; Nagelkerke  $R^2$  = 0.026

Following multivariate analysis, none of the three potential predictors were found to be significantly associated with experiencing sexual problems except in the response to the question relating to experiencing pain during sex.

After controlling for all factors in the model, three significant predictors of experiencing pain during sex were identified. Women aged between 19 and 29 were almost two and a half times as likely to experience pain during sex compared with women over 50 (p=0.001). Women who had undergone colposcopy were half as likely to experience pain during sex compared with women who had undergone loop

excision (p= 0.03). Finally, women in the less deprived quartile were half as likely to undergo pain during sex compared with women in the most deprived quartile.

Caution is required when interpreting these results as the amount of variation explained by these variables is between 3.0 and 4.6 percent.

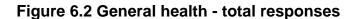
### 6.5.2 General health

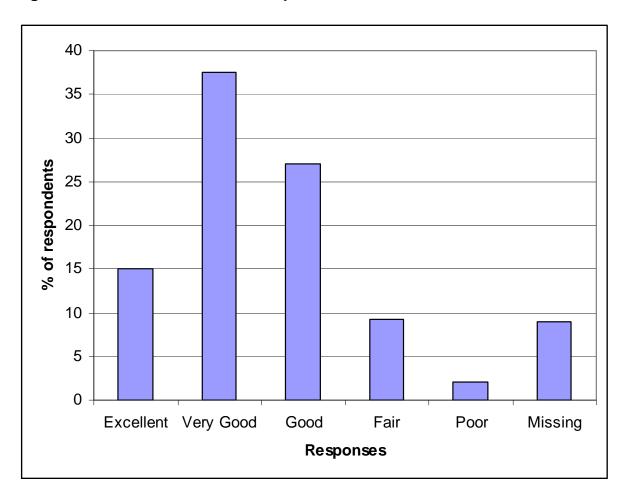
The following section presents the analysis for the question relating to general health, presenting the aggregate responses for all respondents, followed by an analysis of the characteristics of responders in relation to these questions.

Women were asked which response best described their general health from the following options: 'excellent', 'very good', 'good', 'fair' or 'poor.' The total responses for each of the domains of interest are presented in Table 6.24 and illustrated graphically in Figure 6.2.

Table 6.24 General health - total responses

<b>General Health</b>	n	(%)
Excellent	84	(15.0)
Very Good	210	(37.5)
Good	152	(27.1)
Fair	52	(9.3)
Poor	12	(2.1)
Missing	50	(8.9)
Total	560	(100.0)





When all responses were analysed together, the majority of individuals reported having 'excellent', 'very good' or 'good' health (n=446; 79.6%). Only 12 respondents considered their general health to be 'poor' (2.1%). 50 survey participants did not answer the question, thus 8.9% of responses were missing.

Table 6.25 presents the responses to the question relating to general health in terms of treatment undergone. Table 6.26 presents the responses to the general health question dichotomising responses into 'excellent', 'very good' and 'good' and comparing this with 'fair' and 'poor'.

Table 6.25 General health - categorised by treatment type

<b>General Health</b>	Colposcopy		Biops	Biopsy		Excision
	n	(%)	n	(%)	n	(%)
Excellent	37	(16.1)	25	(18.1)	22	(15.5)
Very Good	83	(36.1)	58	(42.0)	69	(48.6)
Good	72	(31.3)	38	(27.5)	42	(29.6)
Fair	28	(12.2)	15	(10.9)	9	(6.3)
Poor	10	(4.3)	2	(1.4)	0	(0.0)
Total	230	(100.0)	138	(100.0)	142	(100.0)

It was not possible to undertake more sophisticated analyses of the responses to the question relating to general health when broken down by treatment type due to presence of zero values in response fields. However, across all treatment groups (colposcopy n=192; 83.5%, biopsy n=121; 87.6%, loop excision n=133; 93.7%), higher proportions of responders stated that their general health was 'good', 'very good' or 'excellent' than those stating that their general health was 'fair' or 'poor'. To undertake more sophisticated analysis of the responses these were dichotomised between 'excellent', 'very good' and 'good' and compared with 'fair' and 'poor'. Table 6.26 presents the dichotomised responses to these questions as outlined above.

Table 6.26 General health dichotomised responses - categorised by treatment type

General Health	Colposcopy	Biopsy	Loop Excision	
	n (%)	n (%)	n (%)	
Group 1 ('excellent', 'very good' or 'good')	192 (83.5)	121 (87.7)	133 (93.7) $X^2 = 8.31$ p=0.0157	
Group 2 ('fair' 'poor')	38 (16.5)	17 (12.3)	9 (6.3)	
Total	230 (100)	138 (100)	142 (100)	

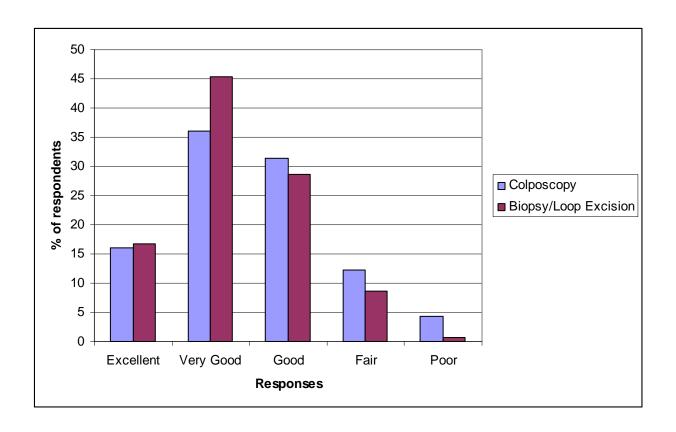
The analysis shown in table 6.26 shows a significant difference in terms of treatment type and dichotomised responses to the question related to general health. Women who underwent colposcopy were more likely to rate their problems as 'poor' or 'fair' and women in the loop excision group were less likely to rate their general heath as 'poor' or 'fair' ( $X^2=8.31$ ; p=0.0157).

Table 6.27 presents the responses to the question relating to general health in terms of treatment undergone, with colposcopy being used as a proxy for a control group.

Table 6.27 General health - responses categorised by undergoing colposcopy only, or biopsy/loop excision

<b>General Health</b>	Colposcopy	•	Biopsy/Lo	ор	
	n	(%)	n	(%)	
Excellent	37	(16.1)	47	(16.8)	
Very Good	83	(36.1)	127	(45.3)	
Good	72	(31.3)	80	(28.6)	
Fair	28	(12.2)	24	(8.6)	
Poor	10	(4.3)	2	(0.70)	
Total	230	(100.0)	280	(100.00)	

Figure 6.3 General health - responses categorised by undergoing colposcopy only, or biopsy/loop excision



It was not possible to undertake formal statistical tests for association between variables to the question relating to general health and treatment type, due to some response fields including zero values. However, across both groups, as shown in Figure 6.3, a high proportion of responders stated that their general health was 'good', 'very good' or 'excellent'. Furthermore, 254 (90.7%) responders in the biopsy and loop excision group reported that their general health as 'excellent', 'very good' or 'good' was compared to the colposcopy group (n=192; 83.5%). Thus, there was very little difference in the responses given regarding general health between the colposcopy group and the combined biopsy/loop excision group.

As per section above, to undertake more sophisticated analysis of the responses these were dichotomised between 'excellent', 'very good' and 'good' and compared with 'fair' and 'poor' and the responses are presented in table 6.28.

Table 6.28 General health dichotomised responses - categorised by treatment type (Colposcopy v biopsy and loop excision)

General Health	Colposcopy	Biopsy/Loop	
пеанн	n (%)	n (%)	
Group 1 ('excellent', 'very good' or 'good')	192 (83.5)	254 (90.8)	Pearson X <sup>2</sup> = 6.02
Group 2 ('fair' 'poor')	38 (16.5)	17 (926)	p=0.0141
Total	230 (100)	280 (100)	

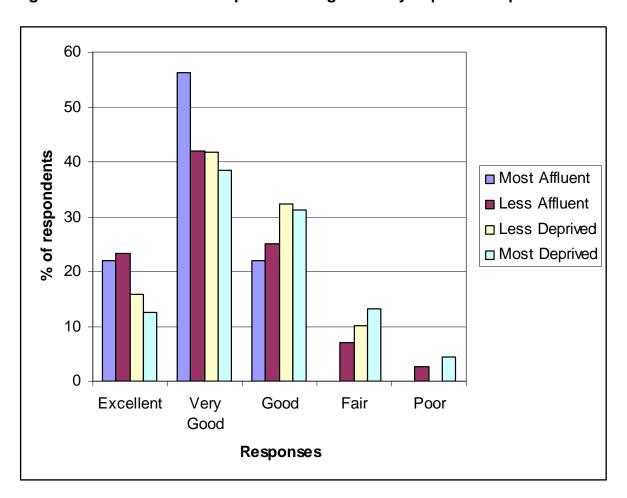
When treatment groups were dichotomised between colposcopy compared with biopsy and loop excision, statistically more women in the colposcopy group likely to report their health as 'poor' or fair' compared to the biopsy/loop excision group (Pearson X2=6.02; p=0.0141).

Table 6.29 presents the responses to the question relating to general health in terms of deprivation quartile.

Table 6.29 General health responses categorised by deprivation quartile

General Health		ost luent	Less	Affluent	Less Deprived		Most Deprived	
	n	(%)	n	(%)	n	(%)	n	(%)
Excellent	7	(21.9)	26	(23.2)	25	(15.8)	25	(12.6)
V. Good	18	(56.3)	47	(42.0)	66	(41.8)	76	(38.4)
Good	7	(21.9)	28	(25.0)	51	(32.3)	62	(31.3)
Fair	0	(0.0)	8	(7.1)	16	(10.1)	26	(13.1)
Poor	0	(0.0)	3	(2.7)	0	(0.0)	9	(4.5)
Total	32	(100.0)	112	(100.0)	158	(100.0)	198	(100.0)

Figure 6.4 General health responses categorised by deprivation quartile



All respondents in the most affluent quartile rated their general health as 'excellent', 'very good' or 'good' (n=32; 100%). Around 90% of respondents in the less affluent and less deprived quartile rated their general health 'excellent', 'very good' or 'good'.

Just over 80% of respondents in the most deprived quartile rated their general health in these terms. There were higher proportions of responders in the most deprived and less deprived groups stating that their general health was 'fair' or 'poor' as demonstrated in Figure 6.4.

Table 6.30 presents the responses to the question relating to general health when deprivation quartiles were dichotomised into two groups representing 'affluent' and 'deprived' (quartiles 1 and 2 combined to form the affluent group, and quartiles 3 and 4 combined to form the deprived group).

Table 6.30 General health responses categorised by 'affluent' or 'deprived'

General Health	Affluent		Dep	rived	
	n	(%)	n	(%)	
Excellent	33	(22.9)	50	(14.0)	
Very Good	65	(45.1)	142	(39.9)	$X^2=11.54$
Good	35	(24.3)	113	(31.7)	p=0.0211
Fair	8	(5.6)	42	(11.8)	
Poor	3	(2.1)	9	(2.5)	
Total	144	(100.0)	356	(100.0)	

Just over 90% of respondents in the 'affluent' group rated their general health as 'excellent', 'very good' or 'good' (n=133) compared with respondents in the 'deprived' group (85.8%; n=305). This difference between groups was statistically significant  $(X^2=11.54; p=0.0211)$ .

As demonstrated in figure 6.5, a higher proportion of respondents from the deprived group rated their heath as 'good' or 'fair' compared with the affluent group, with very similar proportions observed for respondents rating their health as 'poor'.

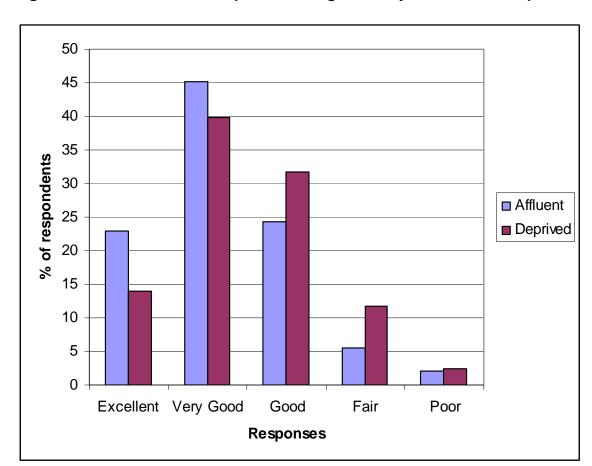


Figure 6.5 General health responses categorised by 'affluent' or 'deprived'

Further analysis was undertaken using the dichotomised groups comparing general health rated as 'excellent', 'very good' or 'good' compared with 'fair' and 'poor'. This was undertaken for the dichotomised quartiles only (presented in Table 6.31). It was not possible to undertaken more formal analysis using the four quartiles due to the presence of zero values.

Table 6.31 General health dichotomised responses - affluent/deprived

General Health	Affluent	Deprived	
	n (%)	n (%)	
Group 1 ('excellent', 'very good' or 'good')	133 (92.4)	305 (85.7)	PearsonX <sup>2</sup> = 4.22
Group 2 ('fair' 'poor')	11 (7.6)	51 (14.3)	p=0.04
Total ´	144 (100.0))	356 (100.0)	

When the general health responses were dichotomised into two groups a significant result was observed with women in the deprived group being more likely to rate their general health as 'fair' or 'poor' compared to the affluent group (Pearson 6.02; p=0.04).

Table 6.32 presents the responses to the question relating to general health in terms of respondent age group.

Table 6.32 General health - responses categorised by age group

General Health	19-2	9	30-39	9	40-4	9	50+		_
	n	(%)	n	(%)	n	(%)	n	(%)	
Excellent	19	(17.0)	34	(16.7)	22	(18.0)	7	(10.0)	
V. Good	59	(52.7)	88	(43.3)	42	(34.4)	20	(28.6)	$X^2 = 37.07$
Good	24	(21.4)	67	(33.0)	38	(31.1)	23	(32.9)	p=0.0002
Fair	9	(8.0)	12	(5.9)	16	(13.1)	15	(21.4)	•
Poor	1	(0.9)	2	(1.0)	4	(3.3)	5	(7.1)	
Total	112	(100.0)	203	(100.0)	122	(100.0)	70	(100.0)	

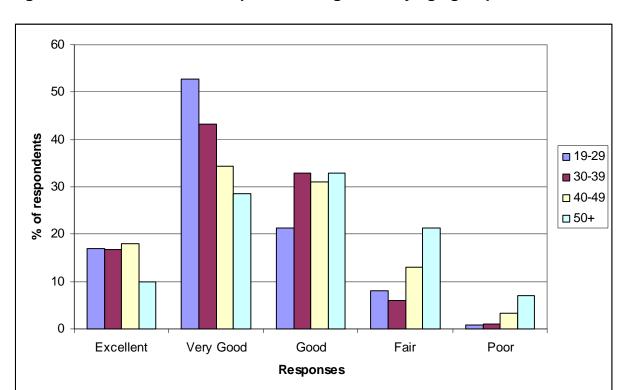


Figure 6.6 General health - responses categorised by age group

Just over 90% of responders in the 19 to 39 and 30 to 39 age groups rated their general health as 'excellent', 'very good' or 'good'. The proportion of respondents rating their health in these terms decreased as the age group increased (40 to 49 n=102; 83.5%, 50+ n= 50; 71.5%), (see Figure 6.6).

Just over 7% (n=5) of respondents from the 50+ age group rated their general health as 'poor' compared to 3.3% (n=4) in the 40 to 49 group; 1% in the 30 to 39 age group (n=2) and just under 1% in the 19-29 group (n=1). A significant difference was observed across the four age groups in terms of responses to the question rating respondents' perception of their general health. Respondents in the age groups 19 to 29, 30-39 and 40 to 49 were significantly more likely to rate their general health as 'excellent' or 'very good' than women in the 50 and over group (X²=37.07; p=0.0002).

### 6.5.3 Problems with social activities

This section presents the analysis for the survey question relating to experiencing problems with social activities due to individuals' physical and emotional health, presenting the total, aggregated responses, followed by analysis of the characteristics of responders in relation to these questions.

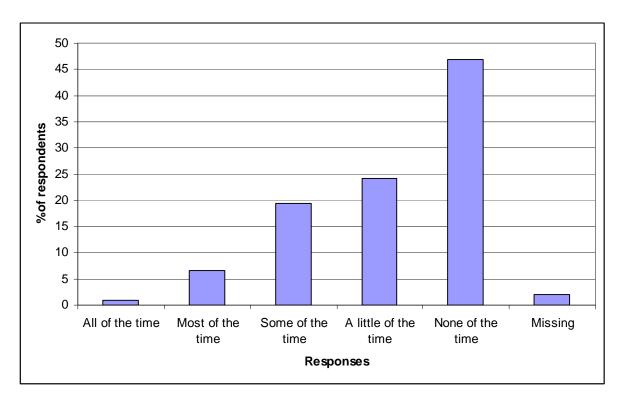
Women were asked to consider the previous 12 months in terms of how much they perceived that their physical and emotional health had interfered with their social activities and choose from the following responses - 'all of the time', 'most of the time', 'some of the time', 'a little of the time' or 'none of the time'.

Table 6.33 presents the total responses to the question relating to problems with social activities.

Table 6.33 Frequency of response (all respondents) to question relating to problems with social activities

Problems with social activities		
	n	%
All the time	5	(0.9)
Most of the time	37	(6.6)
Some of the time	109	(19.5)
A little of the time	135	(24.1)
None of the time	262	(46.8)
Missing	12	(2.1)
Total	560	(100.0)



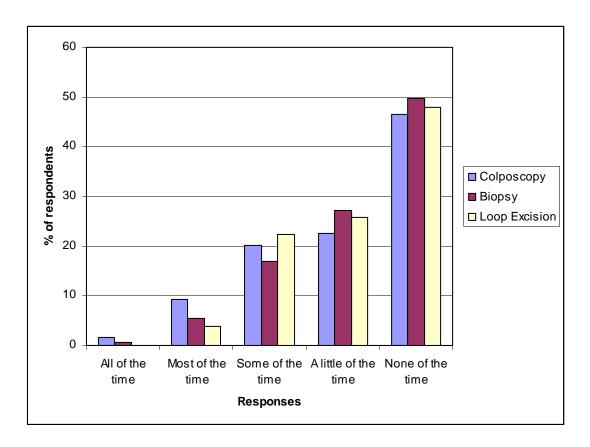


Almost half of the sample reported never experiencing problems with social activities (n=262; 46.8%). Fewer than 10% of the sample reported experiencing problems with social activities 'all of the time' and 'most of the time'. Table 6.34 presents the responses to the question relating to problems with social activities broken down by treatment type.

Table 6.34 Problems with social activities - categorised by treatment type

Problems with Social Activities	Colposcopy		Biop	Biopsy		p ion
	n	(%)	n	(%)	n	(%)
All of the time Most of the time Some of the time A little of the time None of the time Total	4 23 50 56 116 249	(1.6) (9.2) (20.1) (22.5) (46.6) (100.0)	1 8 25 40 73 147	(0.7) (5.4) (17.0) (27.2) (49.7) (100.0)	0 6 34 39 73 152	(0.0) (3.9) (22.4) (25.7) (48.0) (100.0)

Figure 6.8 Problems with social activities - treatment type



Similar proportions of responders across the three treatment types reported never experiencing problems relating to social activities due to their physical or emotional health (colposcopy n=116; 46.6%, biopsy n=73; 49.7%, loop excision n=73; 48.0%). As Figure 6.8 shows, no respondents from the loop excision group reported experiencing problems with social activities 'all of the time'.

To undertake more sophisticated analysis of the responses these were dichotomised between responders reporting problems with social activities 'all of the time', 'most of the time' and 'some of the time' compared with the responses 'a little of the time' and 'none of the time'.

Table 6.35 presents the dichotomised responses to these questions as outlined above.

Table 6.35 Problems with social activities dichotomised responses - categorised by treatment type

Problems with social activities	Colposcopy	Biopsy	Loop Excision	
	n (%)	n (%)	n (%)	
Group 1 ('none of the time, 'a little of the time')	172 (69.1)	113 (76.9)	112 (73.7)	$X^2 = 2.97$ p=0.224
Group 2 ('all of the time', most of the time', 'some of the time	77 (30.9)	34 (23.1)	40 (26.3)	
Total	249 (100.0)	147 (100.0)	152 (100.0)	

When responses were dichotomised between responders reporting problems with social activities 'none of the time', 'a little of the time' compared with responders reporting problems 'all of the time', 'most of the time' and 'some of the time, in terms of treatment type, no statistically significant differences were observed between groups.

Table 6.36 presents the results of the analysis relating to problems with social activities in terms of treatment type using colposcopy as a proxy for a 'control' group, compared to a combined biopsy/loop excision group.

Table 6.36 Problems with social activities - responses categorised by undergoing colposcopy only, or biopsy/loop excision

Problems with Social Activities	Colposcopy	Biopsy/Loop excision	
	n (%)	n (%)	
All of the time	4 (1.6)	1 (0.3)	_
Most of the time	23 (9.2)	14 (4.7)	$X^2 = 7.59$
Some of the time	50 (20.1)	59 (20.0)	p=0.1078
A little of the time	56 (22.5)	79 (26.0)	•
None of the time	116 (46.6)	146 (49.0)	
Total	249 (100.0)	299 (100.0)	

When the colposcopy group was compared with the combined biopsy and loop excision groups with regard to respondents' perceptions of their problems with social activities, higher proportions of respondents in the colposcopy group reported experiencing problems 'all of the time' and 'most of the time', although these findings were not statistically significant ( $X^2=7.59$ ; p=0.1078).

However, as demonstrated by Figure 6.9, the differences between groups were, on the whole, very small. Only 1.6% of respondents in the colposcopy group (n=4) felt that their physical and emotional health impacted upon their social activities 'all of the time' and 0.3% (n=1) of responders in the biopsy and loop excision group noted this impact 'all of the time'.



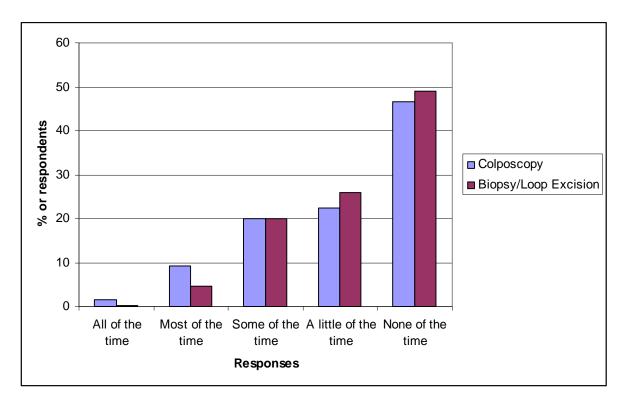


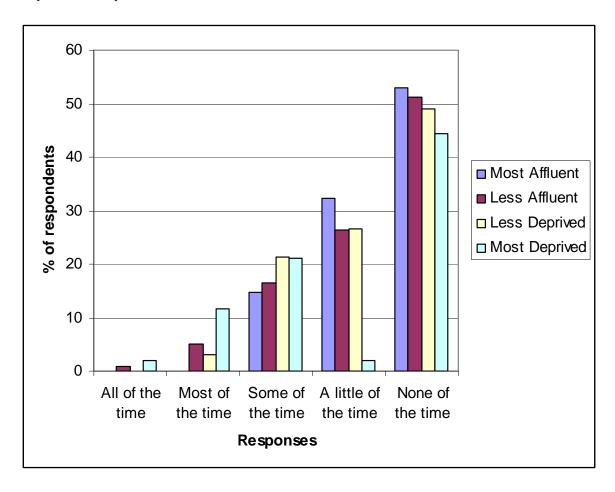
Table 6.37 presents the responses to the question relating to problems with social activities in terms of deprivation quartile.

Table 6.37 Problems with social activities - responses categorised by deprivation quartile

Problems with social activities	Mo: Affl	st luent	Less Afflu		Les Dep	s prived	Mos Dep	t rived
	n	(%)	n	(%)	n	(%)	n	(%)
All the time	0	(0.0)	1	(8.0)	0	(0.0)	4	(1.9)
Most of the time	0	(0.0)	6	(5.0)	5	(3.0)	25	(11.7)
Some of the time	5	(14.7)	20	(16.5)	36	(21.3)	45	(21.0)
A little of the time	11	(32.4)	32	(26.4)	45	(26.6)	45	2(1.0)
None of the time	18	(52.9)	62	(51.2)	83	(49.1)	95	(44.4)
Total	34	(100.0)	121	(100.0)	169	(100.0)	214	(100.0)

Just under half of the sample in the 'most deprived' and 'less deprived' quartiles (44.4% and 49.1% respectively) had no problems with social activities due to their physical and emotional health and just over half the sample in the 'most affluent' and 'less affluent' quartiles (52.9% and 51.2% respectively) also reported no problems in this area. However, higher proportions of respondents in the 'most deprived' quartile reported experiencing problems with social activities 'all of the time' and 'most of the time' (n=4; 1.9% and n= 25; 11.7% respectively), although the absolute numbers of individuals with these issues was low. As Figure 6.10 demonstrates, the majority of responses tended towards the end of the scale, indicating few problems in the area of social activities.

Figure 6.10 Problems with social activities - responses categorised by deprivation quartile



More formal analysis was undertaken dichotomising responses between experiencing problems with social activities 'none of the time', and 'a little of a time' and responses - 'all of the time', most of the time' and 'some of the time'. The results are presented in table 6.38.

Table 6.38 Problems with social activities dichotomised responses - categorised by deprivation quartile

Problems with social activities	Mos	t affluent	Less	affluent	Less depriv	/ed	Most deprived	
	n	(%)	n	(%)	n	(%)		
Group 1 ('none of the time, 'a little of the time')	29 (85	5.3)	94 (77	.7)	128 (7	(5.7)	140 (65.4)	X <sup>2</sup> =10.73
Group 2 ('all of the time', most of the time', 'some of the time	5 (14.	7)	27 (22	.3)	41 (24	3)	74 (34.6)	p=0.0133
Total	34 (10	0.00)	121 (1	00.0)	169 (1	00.0)	214 (100.0)	

Following analysis of the dichotomised responses, a significant result was observed with women in the most deprived quartile more likely to experience problems with social activities compared with all three other quartiles (X<sup>2</sup>=10.73; p=0.0133).

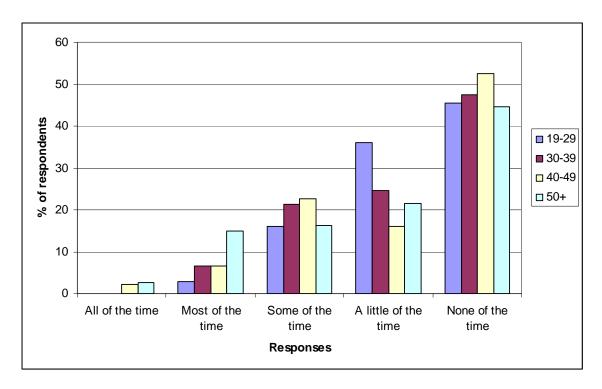
Table 6.39 presents the responses to the question relating to problems related to social activities in terms of respondent age group. Table 6\*\* presents the responses

Table 6.39 Problems with social activities - categorised by age group

Problems with social activities	19-29	30-39	40-49	50+
Social activities	n (%)	n (%)	n (%)	n (%)
All the time	0 (0.0)	0 (0.0)	3 (2.2)	2 (2.7)
Most of the time	3 (2.8)	14 (6.5)	9 (6.6)	11 (14.9)
Some of the time	19 (16.0)	46 (21.4)	31 (22.6)	12 (16.2)
Little of the time	43 (36.1)	53 (24.7)	22 (16.1)	16 (21.6)
None of the time	54 (45.4)	102 (47.4)	72 (52.6)	33 (44.6)
Total	119 (100.0)	215 (100.0)	137 (100.0)	74 (100.0)

Almost half of the responders across all four age groups reported never experiencing problems with social activities. In the 40 to 49 age group, over half of the responders never experienced problems with social activities (52.6%; n=72). As shown in Figure 6.11, in the younger age groups (19 to 29 and 30 to 39) no respondents reported having problems relating to social activities 'all of the time'. In the older age range group (40 to 49 and 50+) less than 3% of the respondents reported having problems 'all of the time' in the relation to social activities.

Figure 6.11 Problems with social activities - responses categorised by age group



To undertake more sophisticated analysis of the responses these were dichotomised between responders reporting problems with social activities 'all of the time', 'most of the time' and 'some of the time' compared with the responses 'a little of the time' and 'none of the time'. The results are presented in table 6.40.

Table 6.40 Problems with social activities - dichotomised responses - categorised by age group

Problems with social activities	19-29	30-39	40-49	50+	
Social activities	n (%)	n (%)	n (%)	n (%)	
Group 1 ('none of the time, 'a little of the time')	97 (81.5)	155 (72.1)	94 (68.6)	49 (66.2)	$X^2 = 7.37$
Group 2 ('all of the time', most of the time', 'some of the time	22 (18.5)	60 (27.9)	43 (31.4)	25 (33.8)	p=0.061
Total	119 (100.0)	215 (100.0)	137 (100.0)	74 (100.0)	

No significant differences were observed between responder age range and responses to the dichotomised question related to problems with social activities.

#### 6.5.4 Satisfaction with sex life

This section presents the analysis for the question relating to respondents' satisfaction with their sex life. It will present a summary of all responses aggregated together, followed by sub-group analyses of the characteristics of responders in relation to these questions. Women were asked to rank their satisfaction with their sex life on a Likert scale with one indicating 'most dissatisfied' and 10 indicating 'most satisfied'. Response five indicated that respondents were neither satisfied or dissatisfied.

Table 6.41 shows the responses for all survey participants, with the data illustrated graphically in Figure 6.12.

Table 6.41 Frequency of responses (all respondents) to question relating to satisfaction with sex life

Satisfaction with sex life

	n	(%)
1 Most dissatisfied	27	(4.8)
2	15	(2.7)
3	21	(3.8)
4	28	(5.0)
5	106	(18.9)
6	34	(6.1)
7	62	(11.1)
8	104	(18.6)
9	49	(8.8)
10 Most satisfied	91	(16.3)
Missing	23	(4.1)
Total	560	(100.0)

Just over 60% of respondents (n=340) rated their satisfaction between six and ten, which would indicate that a larger proportion of the respondents were on the satisfied side of the scale.

Figure 6.12 Satisfaction with sex life - all responses

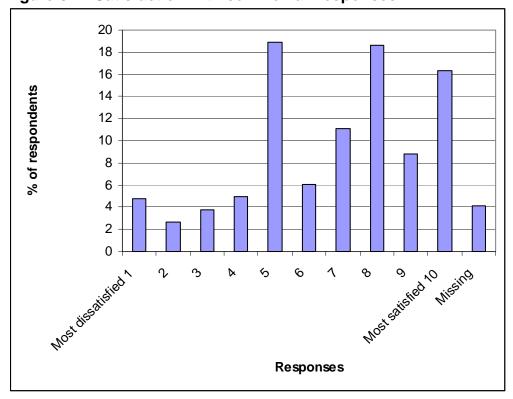


Table 6.42 presents the responses to the question relating to respondents' satisfaction with their sex life in terms of treatment type, and this is graphically illustrated in Figure 6.13.

Table 6.42 Satisfaction with sex life - responses categorised by treatment type

Satisfaction with sex life	Colposcopy	Biopsy	Loop Excision	Total
OOX IIIO	n (%)	n (%)	n (%)	n (%)
1 Most dissatisfied	13 (5.5)	7 (4.8)	7 (4.6)	27 (5.0)
2	8 (3.4)	2 (1.4)	5 (3.3)	15 (2.8)
3	6 (2.5)	7 (6.8)	8 (5.2)	21 (3.9)
4	10 (4.2)	10 (6.8)	8 (5.2)	28 (5.2)
5	43 (18.1)	30 (20.5)	33 (21.6)	106 (18.9)
6	17 (7.1)	6 (4.1)	11 (7.2)	34 (6.3)
7	27 (11.3)	17 (11.6)	18 (11.8)	62 (11.5)
8	49 (20.6)	27 (18.5)	28 (18.3)	104 (19.4)
9	18 (7.6)	20 (13.7)	11 (7.2)	49 (9.1)
10 Most satisfied	47 (19.7)	20 (13.7)	24 (15.7)	91 (16.9)
Total	238(100.0)	146(100.0)	153(100.0)	537(100.0)
Median	7 (IQR* 5 to 9)	7 (IQR 5 to 9)	7(IQR 5 to 8)	<u> </u>

<sup>\*</sup> IQR = Inter quartile range

Median scores for satisfaction with sex life were the same across all treatment groups (colposcopy: IQR = 5 to 9; biopsy: IQR = 5 to 9; loop excision: IQR = 5 to 8), indicating that there is likely to be no association between treatment type and scores on the satisfaction with sex life scale. The proportion of scores between six and 10 (representing the satisfied end of the scale) was similar across all three treatment groups: colposcopy 66.3% (n=158); biopsy 61.6% (n=90); loop excision 60.2% (n=92).

Following non-parametric testing (Kruskall-Wallis) no significant difference was observed across the treatment types ( $X^2$ = 1.75; p=0.40) in response to this question.



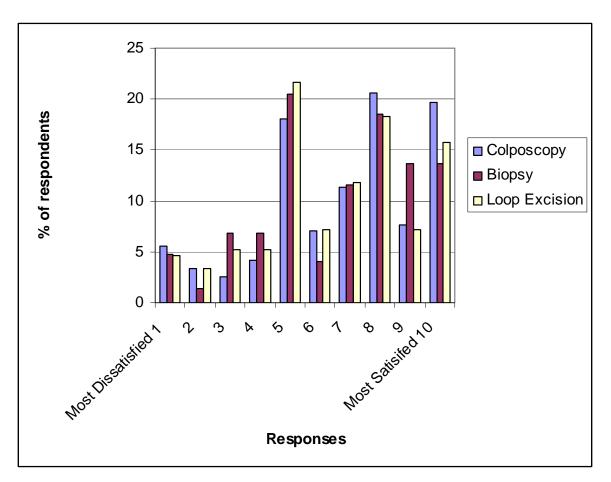


Table 6.43 presents proportion of responses to the question relating to satisfaction with sex life, with colposcopy serving as a 'control' to compare with a combined biopsy and loop excision group. When colposcopy median scores were compared with biopsy and loop excision scores, both groups scored 7 for satisfaction with sex life (colposcopy IQR = 5 to 9; biopsy and loop excision IQR = 5 to 9). This again supports the theory that level of treatment alone is not associated with satisfaction with sex life. As illustrated by Figure 6.14, the majority of responses are on the 'satisfied' section of the scale. 66.3% (n=158) of respondents undergoing colposcopy rated satisfaction with their sex life as between six and 10. 60.9% (n=182) of

respondents undergoing biopsy or loop excision rated satisfaction with their sex life between six and 10.

Table 6.43 Satisfaction with sex life - responses categorised by undergoing colposcopy only, or biopsy/loop excision

Satisfaction with sex life	Colposcopy	Biopsy/Loop	Total
	n(%)	n(%)	n (%)
1 Most dissatisfied	13 (5.5)	14 (4.7)	27 (5.0)
2	8 (3.4)	7 (2.3)	15 (2.8)
3	6 (2.5)	15 (5.0)	21 (3.9)
4	10 (4.2)	18 (6.0)	28 (5.2)
5	43 (18.1)	63 (21.1)	106 (18.9)
6	17 (7.1)	17 (5.7)	34 (6.3)
7	27 (11.3)	35 (11.7)	62 (11.5)
8	49 (20.6)	55 (18.4)	104 (19.4)
9	18 (7.6)	31 (10.4)	49 (9.1)
10 Most satisfied	47 (19.7)	44 (14.7)	91 (16.9)
Total	238 (100.0)	299 (100.0)	537 (100.0)
Median	7 (IQR* 5 to 9)	7 (IQR 5 to 9)	·

<sup>\*</sup> IQR = Inter quartile range

Figure 6.14 Satisfaction with sex life - responses categorised by undergoing colposcopy only, or biopsy/loop excision

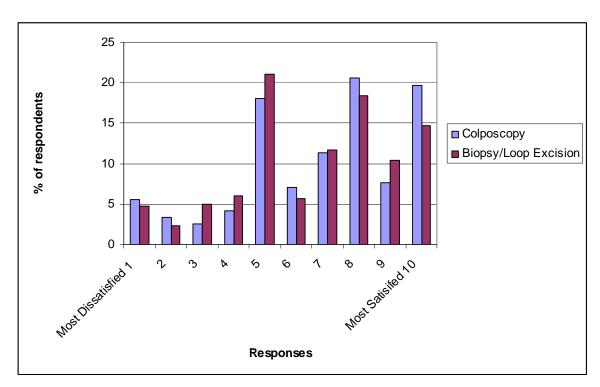


Table 6.44 presents the responses to the question relating to respondents satisfaction with their sex life in terms of deprivation quartile, along with the median scores for satisfaction with sex life in terms of respondents' deprivation quartile.

Table 6.44 Satisfaction with sex life - responses by deprivation quartile

Satisfaction with sex life	Most Affluent	Less Affluent	Less Deprived	Most Deprived	Total
with Sex life	n (%)	n (%)	n (%)	n (%)	
1	2 (6.1)	5 (4.3)	6 (3.6)	13 (6.2)	26
2	1 (3.0)	4 (3.4)	5 (3.0)	5 (2.4)	15
3	2 (6.1)	3 (2.6)	7 (4.2)	8 (3.8)	20
4	0(0.0)	8 (6.8)	9 (5.4)	10 (4.7)	27
5	4 (12.1)	22 (18.8)	30 (18.1)	49 (23.2)	105
6	4 (12.1)	8 (6.8)	16 (9.6)	6 (2.8)	34
7	6 (18.2)	15 (12.8)	16 (9.6)	23 (10.9)	60
8	8 (24.2)	25 (21.4)	34 (20.5)	37 (17.5)	104
9	4 (12.1)	9 (7.7)	17 (10.2)	17 (8.1)	47
10	2 (6.1)	18 (15.4)	26 (15.7)	43 (20.4)	69
Total	33 (100.0)	117 (100.0)	166 (100.0)	211 (100.0)	
Median; IQR*	7 (IQR 5 to 8)	7 (IQR 5 to 8)	7 (IQR 5 to 9)	7 (IQR 5 to 9)	

<sup>\*</sup>IQR = Inter quartile range

These scores were the same across the deprivation quartiles (7) indicating that level of deprivation does not influence scores on this scale (IQR most affluent 5 to 8; IQR less affluent 5 to 8; IQR less deprived 5 to 9; IQR most deprived 5 to 9). Figure 6.15 illustrates the proportion of responses between one and 10 for each quartile.

Following non-parametric testing (Kruskall-Wallis) no significant difference was observed across deprivation quartiles ( $X^2$ = 1.84; p=0.98) in response to this question.

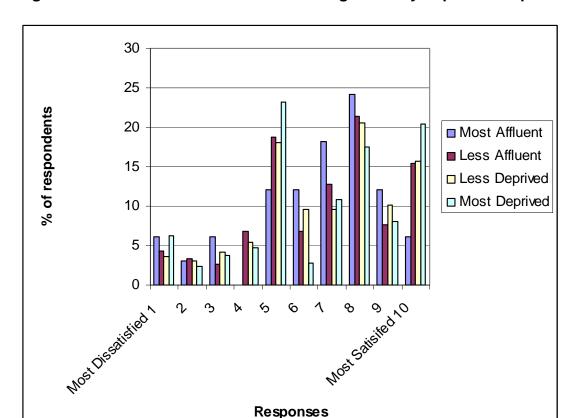


Figure 6.15 Satisfaction with sex life - categorised by deprivation quartile

Although across all quartiles over 50% of the proportion of responders scored between six and 10 on the scale, the proportion for each quartile was as follows: most affluent: 72.7% (n=24); less affluent: 64.1% (n=75); less deprived: 65.6% (n=109) and most deprived: 59.7% (n=126). Respondents in the most affluent group reported the highest degree of satisfaction with their sex life, with those in the most deprived group reporting a lower degree of satisfaction (although this disparity can be explained by the higher proportion of individuals in the most deprived group who reported being neither satisfied or dissatisfied).

Table 6.45 presents the responses to the question relating to respondents satisfaction with their sex life and age group and the median scores for satisfaction with sex life across the age groups.

Table 6.45 Satisfaction with sex life - responses categorised by age group

Satisfaction with sex life	19 to 29	30 to 39	40 to 49	50+	Total
with sex life	n (%)	n (%)	n (%)	n (%)	
1	2 (1.7)	3 (1.4)	12 (9.0)	10 (15.6)	27
2	5 (4.2)	4 (1.9)	5 (3.7)	1 (1.6)	15
3	5 (4.2)	10 (4.6)	3 (2.2)	3 (4.7)	21
4	6 (5.0)	13 (6.0)	8 (6.0)	1 (1.6)	28
5	19 (15.8)	40 (18.5)	27 (20.1)	20 (31.3)	106
6	3 (2.5)	21 (9.7)	9 (6.7)	1 (1.6)	34
7	21 (17.5)	19 (8.8)	12 (9.0)	10 (15.6)	62
8	25 (20.8)	47 (21.8)	26 (19.4)	6 (9.4)	104
9	12 (10.0)	26 (12.0)	9 (6.7)	1 (1.6)	48
10	22 (18.3)	33 (15.3)	23 (17.2)	11 (17.2)	89
Total	120	216	134	64	
Median	7(IQR 5 to 7)	7 (IQR 5 to 9)	7 (IQR 5 to 9)	5 (IQR 5 to 8)	

<sup>\*</sup> IQR = Inter quartile range

These scores were the same for the 19 to 29, 30 to 39 and 40 to 49 groups (7 IQR 19 to 20: 5 to 7; IQR 30 to 39: 5 to 9; IQR 40 to 49: 5 to 9) although the median score for the 50+ group was lower (5) suggesting that older women were more likely to be neither satisfied or dissatisfied with their sex lives.

Following non-parametric testing (Kruskall-Wallis) a significant difference was observed across the age range ( $X^2$ = 10.4; p=0.015) in response to this question, with older women more likely to have a lower mean score on this measure.

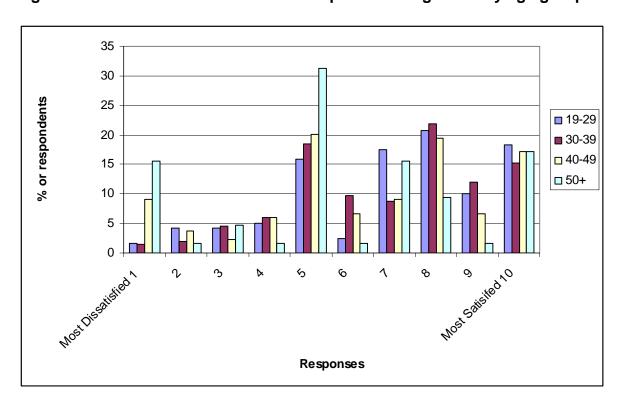


Figure 6.16 Satisfaction with sex life - responses categorised by age group

# 6.5.5 Satisfaction with relationship

This section presents the analysis for the question relating to respondents' satisfaction with their relationships. It will present the total responses followed by analysis of the characteristics of responders in relation to this questions. Women were asked to rank their satisfaction with their relationship on a Likert scale with one indicating 'most dissatisfied' and 10 indicating 'most satisfied'.

Table 6.46 presents the total responses for the question related to satisfaction with relationships.

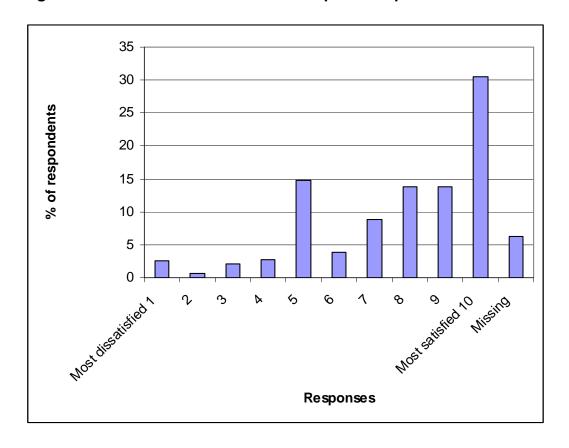
Table 6.46 Frequency of responses (all respondents) to question relating to satisfaction with relationships

# Satisfaction with relationship

	n	(%)
1 Most dissatisfied	14	(2.5)
2	4	(0.7)
3	12	(2.1)
4	15	(2.7)
5	83	(14.8)
6	22	(3.9)
7	50	(8.9)
8	77	(13.8)
9	77	(13.8)
10 Most satisfied	171	(30.5)
Missing	35	(6.3)
Total	560	(100.0)

Figure 6.17 illustrates the proportion of respondents whose response linked to each Likert scale point.

Figure 6.17 Satisfaction with relationship - all respondents



The data show that the greater proportion of the total responders could be categorised at the 'satisfied' part of the scale. Just over 70% of responders (n=397) scored between six and 10 on the scale. Just under a third of responders (30.5%; n=171) were 'most satisfied' with their partner relationships.

Table 6.47 presents the responses to the question relating to satisfaction with relationships in terms of treatment type followed by Figure 6.18 which presents this information graphically.

Table 6.47 Satisfaction with relationship - responses categorised by treatment type

Satisfaction with relationship	Colposcopy	Biopsy	Loop Excision	Total
	n (%)	n (%)	n (%)	n (%)
1 Most dissatisfied	9 (3.9)	2(1.4)	3 (2.0)	14 (2.7)
2	2 (0.9)	0(0.0)	2 (1.3)	4 (0.8)
3	4 (1.7)	6 (4.2)	2 (1.3)	12 (2.3)
4	7 (3.0)	5 (3.5)	3 (2.0)	15 (2.9)
5	44 (19.0)	19 (13.4)	20 (13.2)	83 (15.8)
6	14 (6.1)	2 (1.4)	6 (3.9)	22 (4.2)
7	16 (6.9)	21 (14.8)	13 (8.6)	50 (9.5)
8	26 (1.3)	24 (16.9)	27 (17.8)	77 (14.7)
9	29 (12.6)	21 (14.8)	27 (17.8)	77 (14.7)
10 Most satisfied	80 (34.6)	42 (29.6)	49 (32.2)	171 (32.6)
Total	231 (100.0)	142 (100.0)	152 (100.0)	525 (100.0)
Median	8 (IQR* 5-10)	8 (IQR 7-10)	8.50 (IQR 7-10)	

<sup>\*</sup> IQR = Inter quartile range

The median scores for satisfaction with relationship were the same across the treatment groups although women in the loop excision group scored 8.5 when compared to colposcopy and biopsy (median score 8; IQR colposcopy: 5 to 10; IQR biopsy: 7 to 10; IQR loop excision: 7 to 10). The majority of respondents across all

three treatment groups scored between 6 and 10 on the satisfaction scale, indicating a high level of satisfaction with their relationships.

Following non-parametric testing (Kruskall-Wallis) no significant difference was observed across the treatment types ( $X^2 = 1.75$ ; p=0.40) in response to this question.

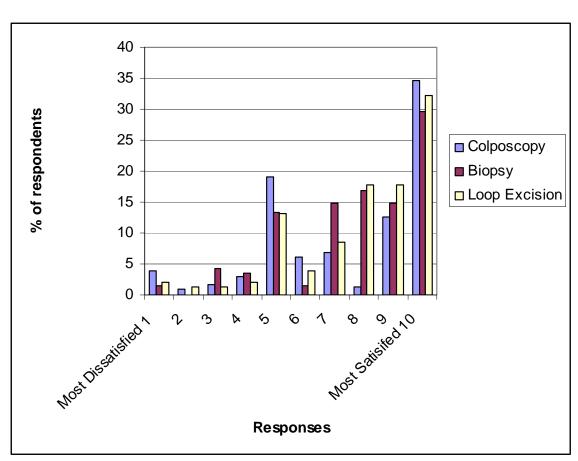


Figure 6.18 Satisfaction with relationship - treatment type

Table 6.48 presents the responses to the question relating to satisfaction with relationships comparing colposcopy only with a combined biopsy and loop excision group.

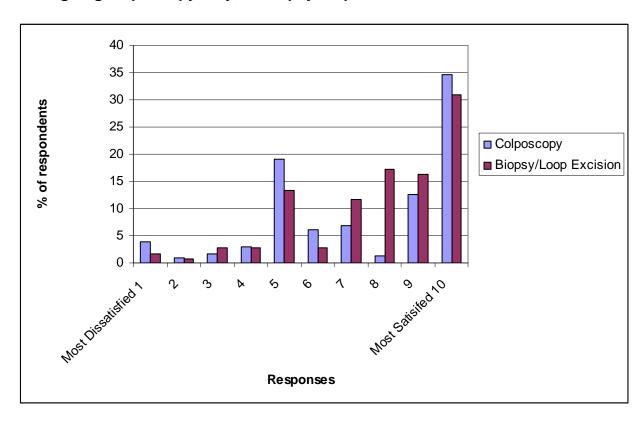
Table 6.48 Satisfaction with relationship - responses categorised by undergoing colposcopy only, or biopsy/loop excision

Satisfaction with relationship	Colposcopy	Biopsy/Loop	Total
	n (%)	n(%)	n (%)
1 Most dissatisfied	9 (3.9)	5(1.7)	14 (2.7)
2	2 (0.9)	2(0.7)	4 (0.8)
3	4 (1.7)	8(2.7)	12 (2.3)
4	7 (3.0)	8(2.7)	15 (2.9)
5	44 (19.0)	39(13.3)	83 (15.8)
6	14 (6.1)	8(2.7)	22 (4.2)
7	16 (6.9)	34(11.6)	50 (9.5)
8	26 (1.3)	51(17.3)	77 (14.7)
9	29 (12.6)	48(16.3)	77 (14.7)
10 Most satisfied	80 (34.6)	91(31.0)	171(32.6)
Total	231 (100.0)	294(100)	525(100.0)
Median	8 (IQR* 5 to 10)	8 (IQR 7 to 10)	

<sup>\*</sup> IQR = Inter quartile range

The median score was the same between both groups (median score 8; colposcopy IQR: 7 to 10; biopsy and loop excision IQR: 7 to 10).

Figure 6.19 Satisfaction with relationship - responses categorised by undergoing colposcopy only, or biopsy/loop excision



Again, as shown in Figure 6.19, the weighting of scores was overwhelmingly towards the 'satisfied' end of the scale. The proportion of respondents scoring between six and 10 for each group were as follows: colposcopy 61.5% (n=165); biopsy and loop excision 78.9% (n=232).

Table 6.49 presents the responses to the question relating to satisfaction with relationships in terms of respondents' deprivation quartile.

Table 6.49 Satisfaction with relationship - categorised by deprivation quartile

Satisfaction with	Most Affluent	Less Affluent	Less Deprived	Most Deprived	Total
relationship	n (%)	n (%)	n (%)	n (%)	
1	0 (0.0)	1 (0.9)	4 (2.5)	8 (3.8)	13
2	0 (0.0)	0 (0.0)	1 (0.6)	3 (1.4)	4
3	1 (2.9)	3 (2.7)	2 (1.2)	5 (2.4)	11
4	1 (3.1)	3 (2.7)	4 (2.5)	7 (3.4)	15
5	4 (12.5)	13 (11.6)	21 (12.9)	44 (21.2)	82
6	1 (3.1)	3 (2.7)	7 (4.2)	11 (5.3)	22
7	2 (6.3)	16 (14.3)	13 (8.0)	18 (8.7)	49
8	7 (20.6)	17 (15.2)	27 (16.6)	24 (11.5)	55
9	7 (20.6)	20 (17.9)	25 (15.3)	24 (11.5)	76
10	9 (28.1)	36 (32.1)	59 (36.2)	64 (30.8)	168
Total	32 (100.0)	112 (100.0)	163 (100.0)	208 (100.0)	
Median	8.50 (IQR* 7 to 10)	8.50 (IQR 7 to 10)	9 (IQR 7 to 10)	8 (IQR 5 to 10)	

<sup>\*</sup> IQR = Inter quartile range

Median scores for satisfaction with relationship were the same across for most affluent and less affluent groups (median 8.5; IQR 7 to 10) although women in the less deprived group scored higher median scores (9; IQR 7 to 10) and the most deprived scored a slightly lower median score (8; IQR 5 to 10). Figure 6.20 illustrates the proportion of scores weighted on the 'satisfied' end of the scale. Over 80% respondents in the less deprived and less affluent quartiles scored between six and 10 on the scale. For the most affluent and

most deprived groups respectively, the proportions were 78.7% (n=26) and 67.8% (n=141).

Following non-parametric testing (Kruskall-Wallis) no significant difference was observed across deprivation quartile ( $X^2$ =6.90; p=0.75) in response to this question.

Figure 6.20 Satisfaction with relationship - categorised by deprivation quartile

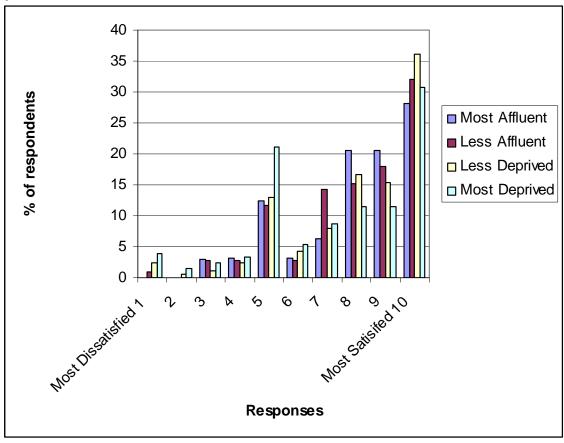


Table 6.50 presents the responses to the question relating to the respondents satisfaction with their relationship in terms of their age group.

Table 6.50 Satisfaction with relationship - responses categorised by age group

Satisfaction with relationship	19-29	30-39	40-49	50+	Tota I
•	n (%)	n (%)	n (%)	n (%)	
1	2 (1.7)	2 (0.9)	7 (5.4)	3 (4.8)	14
2	0 (0.0)	3 (1.4)	0 (0.0)	1 (1.6)	4
3	1 (0.9)	5 (2.3)	4 (3.1)	2 (3.2)	12
4	3 (2.6)	5 (2.3)	5 (3.9)	2 (3.2)	15
5	11 (9.4)	30 (14.1)	22 (17.1)	20 (31.7)	83
6	3 (2.6)	9 (4.2)	8 (6.2)	2 (3.2)	22
7	8 (6.8)	25 (11.7)	13 (10.1)	4 (6.3)	50
8	15 (12.8)	32 (15.0)	21 (16.3)	8 (12.7)	76
9	26 (22.2)	36 (16.9)	11 (8.5)	4 (6.3)	77
10	48 (41.0)	66 (31.0)	38 (29.5)	17 (27.0)	169
Total	117 (100.0)	213 (100.0)	129 (100.0)	63 (100.0)	
Median	9 (IQR* 8 to 10)	8 (IQR 6 to	8 (IQR 5 to	7 (IQR 5 to	
		10)	10)	10)	

<sup>\*</sup> IQR =Inter quartile range

The median scores for satisfaction with relationships ranged from 9 (IQR 8 to 10) in the 19 to 29 group, to 8 in the 30 to 39 (IQR 6 to 10) and 40 to 49 groups (IQR 5 to 10) and 7 in the 50+ group (IQR 5 to 10). This would seem to indicate that younger were women were more satisfied in their partner relationship. Figure 6.21 shows the weighting of scores towards the 'satisfied end of the scale. Whilst 85.4% (n=100) and 78.8% (n=168) of respondents in the 19 to 29 and 30 to 39 age group scored between six and 10 on the scale, the proportions in the 40 to 49 and 50+ age groups were lower (70.6%; and 55.5% respectively).

Following non-parametric testing (Kruskall-Wallis) a significant difference was observed across age ranges ( $X^2$ = 20.09; p=>0.001) in response to this question with younger women scoring significantly higher on this scale.

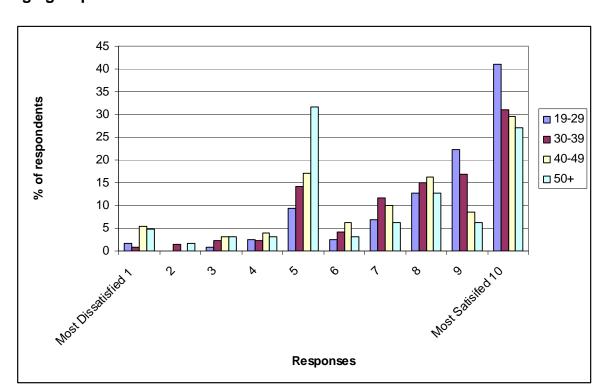


Figure 6.21 Satisfaction with relationship - responses categorised by age group

### 6.6 Summary of findings - questionnaire one (Q1)

This chapter has reported the analysis undertaken and outlined the results of the first stage of the study (questionnaire 1). Before these results were presented, the study recruitment and responder bias for both phases of the study were outlined. The characteristics of responders to Q1 were presented, followed by an outline of the factors studied and potential predictors of the study outcomes. Where possible, Chi² tests were performed to investigate relationships between variables and outcomes. Where it was not possible to undertake more sophisticated analysis, the proportions of responses were reported. Median results and the inter quartile ranges (IQR) were reported for responses measured on a Likert scale.

Section 6.5.1 presented the analysis of responses to survey questions related to physical, emotional and sexual health. The total responses were presented prior to sub-group analyses of the association between the frequency of responses given for each question and potential predictor variables (deprivation quartile, age group and treatment type). This process was repeated for questions relating to general health, problems with social activities, satisfaction with sex life and relationship satisfaction. The question related to general health was further analysed by dichotomising the categories of responses into 'excellent', 'good' or 'very good' compared with 'fair' or 'poor'. The question relating to problems with social activities were analysed after dichotomising responses between 'all of the time', 'most of the time' or 'some of the time' compared with 'a little of the time' and 'none of the time'. This enabled more sophisticated analysis to be undertaken for these questions given the presence of zero responses in the data.

In terms of physical health, less than a fifth of the total sample reported that their physical health impeded their ability to carry out normal tasks or limited the kind of activities normally undertaken. Just under one third of individuals when all responses were analysed together reported that their emotional health meant that they accomplished less than they would like and a quarter reported that their emotional health impacted upon work or other activities. In terms of questions relating to sexual health, around one third of the total sample reported lacking interest in sex, or experiencing pain during intercourse.

When responses to the questions related to physical, emotional and sexual health were analysed after being broken down by treatment type, no significant differences were observed across groups. Where problems were reported, the proportion of responders noting such problems was similar across treatment groups.

As a second stage of analysis of treatment type, the colposcopy group was compared to a combined group comprised of women in the biopsy and loop excision groups. The rationale for this comparison was based on the hypothesis that colposcopy alone may be considered as a less 'invasive' procedure than either biopsy or loop excision, and thus in the absence of a general population control group, the colposcopy only patients could serve as a proxy for controls. This stage of analysis did not show any significant differences between the groups, suggesting that treatment type was not associated in statistical terms with responses to the questions relating to physical, emotional and sexual health.

Responses were then analysed in terms of deprivation quartile. No significant differences were noted for responses to questions relating to physical health, although a lower proportion of responders in the most affluent group reported problems with their physical health impacting upon their ability to carry out normal tasks: 8.8% (n=3), compared with 23.3% (n=28) in the less affluent group; 18.9% (n=32) in the less deprived group and 20.5% (n=44) in the most deprived group. Statistically significant differences were observed between

deprivation quartiles in terms of response to the question relating to the impact of emotional health upon the ability to accomplish what respondents would like ( $X^2$ =8.31; p=0.04).

Deprivation quartiles were not significantly associated with responses to any of the questions relating to sexual health, with similar proportions of responders reporting problems across all questions aside from questions relating to experiencing pain during intercourse. 26.5% (n=9) responders in the most affluent group reported problems in this area compared to 38.8% (n=45) in the less affluent group; 41.0% (n=66) in the less deprived group and 32.7% (n=67) in the most deprived group.

In terms of age, significant differences were observed between responses to questions relating to physical health impacting upon an ability to carry out normal tasks, with responders in the 50+ group more likely to report problems in this area ( $X^2$ =30.54, p=<0.001). Similarly, in responses to the question related to the impact of physical health limiting the kind of work undertaken, the older age group (50+) was significantly more likely to report problems in this area ( $X^2$ =25.95, p=<0.0001). Age was also significantly associated with responses to the question relating to the impact of emotional health upon individuals' ability to perform work or other activities, with the 50+ group more likely to report problems in this area ( $X^2$ =10.59, p=0.0142).

In terms of age and responses to questions related to sexual health, no significant differences were observed between the age groups. In responses

to the question related to 'lacking interest in sex', a higher proportion of responders in the 50+ group reported problems in this area than those in the other age groups (47% compared with 36.6% (n=40) in the 19 to 29 group; 35.0% (n=75) in the 30 to 39 group and 39.3% (n=53) in the 40 to 49 group). Similarly, a higher proportion of responders in the 50+ group reported problems lubricating 38.5% (n=25) compared with 24.6% (n=29) in the 19 to 29 group; 25.2% (n=54) in the 30 to 39 group and 28.2% (n=35) in the 40 to 49 group. In contrast, just under half of responders in the 19 to 29 group reported pain during intercourse, compared with just over a quarter of women in the 50+ group experiencing painful intercourse.

Following bivariate analysis utilising the three predictors on interest, no significant results were observed on any of the questions except in relation to experiencing pain during intercourse and experiencing problems lubricating. Women aged 19-29 were over twice as likely to report experiencing pain during intercourse (OR: 2.24; CI 1.1 to 4.3). Women aged 19-29 were also half as likely to report problems with lubrication (OR: 0.52; 0.2 to 1.0) compared to women over 50. Following multivariate analysis of all domain questions a significant result was observed in relation to experiencing pain during sex. After controlling for all factors the three significant predictors of problems in this domain were age (19-29), treatment type (undergoing loop excision) and socioeconomic status (less deprived quartile). However, the model only explained around 3% of the variance, so caution is advised in interpreting this result.

Section 6.5.2 presented the analysis of the responses to the question relating to general health, including total responses and responses by characteristic. In terms of overall responses, the majority of responders rated their general health to be 'excellent', 'very good' or 'good' (79.6%; n=446).

When results were analysed in terms of treatment type, again, the majority of responders across all the groups rated their general health as 'excellent', 'good' or 'very good'. The highest proportion was observed in the loop excision group (93.7%; n=133). Combining the biopsy and loop excision group with the colposcopy group also demonstrated similar findings. However, once the response categories were dichotomised women in the colposcopy group were significantly more likely to rate their general health as 'poor' or 'fair' when compared with the biopsy or the loop excision group.

In terms of deprivation quartile, no respondents in the 'most affluent' quartile rated their general health as 'poor' or 'fair' compared to the other three quartiles. When the four quartiles were combined and dichotomised into two groups ('affluent' and 'deprived') significantly higher proportions of responders in the affluent group described their general health as 'excellent', 'very good' or 'good' (X²=11.54; p=0.0211).

Analysis of the association between age group and responses to the question relating to general health showed that the proportion of respondents rating their general health as 'excellent', 'very good' or 'good' decreased with age.

Women in the 19 to 29, 30 to 39 and 40 to 49 groups were significantly more likely to rate their general health as 'excellent', 'very good' or 'good, compared with women in the 50+ age group ( $X^2=37.07$ ; p=0.0002).

Section 6.5.3 presented the analysis undertaken on responses to the question exploring whether or not respondents had experienced problems with social activities due to their physical or emotional health. When all responses were analysed together, just under half of the sample reported never experiencing problems in this area and similar proportions were observed when the data was categorised by treatment, deprivation and age.

Analysis of the results in terms of treatment type reported similar findings, with just under half the responders across all treatment groups never experiencing problems with social activities. No responders from the loop excision group experienced problems 'all of the time'.

In terms of deprivation quartile, just under half of respondents from the 'most deprived' and less deprived' quartiles reported no problems with social activities, whilst just over half the respondents in the 'most affluent' and 'less affluent' quartiles reported problems in this area. Overall, the majority of responses across all deprivation quartiles tended towards the positive end of the scale, indicating few problems with social activities. However, following formal analysis dichotomising responses to this question, women in the most deprived quartile reported significantly higher problems with social activities

when compared with the three other quartiles (X2=10.73; p=0.0133). Age was not found to be statistically associated with problems with social activities. Section 6.5.4 presented the analysis for the question related to respondents' satisfaction with their sex life and in terms of total responses, just over 60% of the sample rated their satisfaction levels between six and 10 - i.e. on the more satisfied end of the scale.

The median score for satisfaction with sex life was seven across all treatment groups, with similar proportions of responders from each group scoring between six and 10 on the scale. The same median score was observed on the basis of deprivation quartile, although a higher proportion of respondents in the 'most affluent' quartile scored between six and 10 on the scale 72.7% (n=24) compared with 'less affluent' quartile 64.1% (n=75), the less deprived quartile 65.6% (n=109) and the most deprived quartile 59.7% (n=126).

In terms of age, responders in the 50+ age group had a lower median score (5) compared with responders in the other age groups (median score = 7) and following formal analysis a significant result was observed with older women scoring lower on this scale ( $x^2$ =10.4; p=0.015).

The final section of analysis (Section 6.5) reported the responses to the question relating to respondents' satisfaction with their relationship. Just over 70% of responders scored between six and ten on this scale, indicating that on the whole, they were satisfied with their relationship. With regard to treatment type, the median score for responders in the loop excision group

was slightly higher (8.5) than for the colposcopy and biopsy groups (8) although this difference was not statistically significant. The proportion of responders scoring between six and ten on this scale was higher for those in the loop excision group (80.6%) when compared with colposcopy (61.5%) and biopsy groups (77.5%).

In terms of deprivation, responders in the most deprived quartile had the lowest median score (8), with responders in the most affluent and less affluent groups scoring 8.5. Women in the less deprived quartile had the highest median score (9). Despite this difference, all median scores tended towards the more satisfied end of the scale.

Older women scored the lowest median score on this scale (7) compared to a score of eight in the 30 to 39 and 40 to 49 age groups, and nine in the 19 to 29 age group. Similarly, responders in the 50+ age group had a lower proportion of responders scoring between six and 10 on the relationship satisfaction scale compared with the highest proportion in the 19 to 29 age group with 85.4% of responders scoring between six and 10 on the scale. Following formal analysis, older women were observed to score significantly lower on this measure (X²=20.09; p=>0.005).

Overall, the findings from this stage of the study seem to indicate that treatment had no significant association with any of the responses to the questions posed in questionnaire 1 aside from the question relating to painful

sex, where women in the colposcopy group were half as likely to report problems in the area compared with women in the loop excision group. For the questions relating to general health, a statistically significant difference was observed in terms of age and dichotomised socioeconomic status. In the affluent group, a higher proportion of women described their general health as 'excellent' or 'very good' and a higher proportion of women in the deprived group described their general health as 'fair' or 'poor'. Age was found to have a stronger association with the kinds of responses women gave to questions relating to physical and emotional well-being, although it had little association with responses to questions relating to sexual health. For the question relating to general health, women aged under 50 years were less likely to rate their health as 'excellent' or 'very good'

The results from the responses to the questions relating to sexual health suggest that problems of a sexual nature are not necessarily a facet of being 'younger' or 'older'. Older women may feel more at ease with their sexuality than younger women, despite the fact they may experience more physiological problems related to their sex life (menopause, vaginal dryness). Conversely, younger women may feel greater pressure to 'perform' sexually and feel less sexually confident than older women. Having multiple partners or shorter term relationships may also impact upon sexual well-being. A higher proportion of younger women reported problems related to pain during intercourse when compared with older women and following bivariate and multivariate analysis, this proportion was significantly higher. However, although not statistically significant, the results from the questions relating to

satisfaction with sex life and relationships would appear to indicate that younger women were more satisfied with both these areas of their lives when compared to women in the older age groups. As is shown in the analysis of questionnaire 2 (Chapter 7), it appears that sexual problems increase with age.

Analysis of responses to the question relating to 'general health' and problems with social activities due to physical and emotional health, indicated that overall, respondents to the questionnaire experienced few problems in these areas. However, women in the older age group (50+) were significantly less likely to score 'excellent', 'very good' or 'good' when rating their general health.

# **CHAPTER 7: RESULTS - QUESTIONNAIRE TWO (Q2)**

#### 7.1 Introduction

This chapter reports the analysis and results of the second stage of the study, questionnaire two. Q2 was designed to collect a wider range of demographic data and health and lifestyle related factors, and incorporates three validated measures relating to sexual functioning, depression and anxiety and four other domains pertaining to physical, psychological, social and emotional factors. The demographic data collected were as follows: age, ethnicity, education and socioeconomic status. Other factors were: treatment type; smoking status; alcohol use and number of units drunk per week; problems with drugs or alcohol; partner status; whether respondents were currently sexually active and sexually active prior to the colposcopy (no specified time scale of sexual activity was given); sexual orientation; use of contraception; having children; ever having had a miscarriage premature birth or still birth; having gynaecological problems; having had a sexually transmitted infection; experiencing long term health problems, and the number of visits made to the GP over the previous 12 months.

This chapter will begin by presenting a description of the demographic and health and lifestyle details of the population responding to Q2, including data collected relating to potential predictors of outcomes (Section 7.1). Section 7.2 presents the characteristics of responders to Q2 and Section 7.3 presents the results from the analysis of treatment type and all outcome variables. Section 7.4 presents an introduction to the analyses of the validated measures,

outlining a table of the three potential predictors of interest. Section 7.5 presents the results pertaining to the presence of Female Sexual Dysfunction (FSD) in terms of the results for all respondents and the association between presence of FSD and treatment type, deprivation quartiles and age.

Section 7.5.3 presents the results from bivariate analysis of presence/absence of FSD and the three potential predictor variables of interest. Section 7.5.4 presents the multivariate analysis for predictors of FSD. Section 7.6 presents the results for all respondents in terms of HADS anxiety and depression rating. Section 7.6.1 presents the mean scores for HADS anxiety and depression. Sections 7.7.1 to 7.7.3 include the analysis of the associations between HADS anxiety, treatment, deprivation quartile and age. Section 7.7.4 presents the bivariate analysis for HADS anxiety and predictors of scoring 'normal' or 'mild and above'. Section 7.7.5 presents the multivariate analysis of predictors of scoring 'normal' or 'mild and above' on the anxiety scale. Section 7.8.1 to 7.8.3 includes the analysis of the associations between HADS depression, treatment, deprivation quartile and age. Section 7.8.4 presents the bivariate analysis for HADS depression and predictors of scoring 'normal' or 'mild and above' and Section 7.8.5 presents the multivariate analysis for this measure.

Section 7.9.1 presents the scores from all respondents on the WHOQOL-BREF physical, psychological, social and environmental domains and section 7.9.2 presents the median scores for all four domains. Section 7.9.3 presents

the mean scores of these four domains. The overall results from this Chapter are summarised in section 7\*.

# 7.2 Characteristics of responders Q2

Table 7.1 presents the sociodemographic and health and lifestyle characteristics of responders to Q2.

Table 7.1 Characteristics of all responders to Q2

Respondent Characteristic		n (%)*
Colposcopy unit	Women's Hospital	167 (59.9)
	City Hospital	36 (12.9)
	Solihull Hospital	38 (13.6)
	Heartlands Hospital	13 (4.7)
	Good Hope Hospital	25 (9.0)
	Total	279 (100.0)
Treatment type	Colposcopy	119 (42.7)
	Biopsy	76 (27.2)
	Loop excision	84 (30.1)
	Total	279 (100.0)
Deprivation quartile	Most Affluent (Q1)	28 (10.0)
	Less Affluent (Q2)	51 (18.3)
	Less Deprived (Q3)	78 (28.0)
	Most Deprived (Q4)	114 (40.9)
	Total	271 (97.1)
Age group	19 to 29	80 (28.7)
	30 to 39	98 (35.1)
	40 to 49	70 (25.1)
	50+	31 (11.1)
	Total	279 (100.0)
Ethnicity	White British	219 (78.5)
	Other	60 (21.5)
	Total	279 (100.0)
Education	Up to GCSE	99 (35.5)
	Post GCSE	179 (64.2)
	Total	278 (99.6)
Smoking status	Non-smoker	131 (47.0)
	Smoker	79 (28.3)
	Ex-smoker	69 (24.7)
	Total	279 (100.0)
Alcohol use	Do not drink alcohol	49 (17.6)
	Drinks alcohol	224 (80.3)
	Total	273 (97.8)
Alcohol units per week	1-7	145 (52.0)
	8-13	40 (14.3)

Respondent Characteristic		n (%)*
	14+	36 (12.9)
	Total	221 (79.2)
Problems with	Yes	10 (3.6)
drugs/alcohol		,
	No	261 (93.5)
	Total	271 (97.1)
Partner	Yes	227 (81.4)
	No	48 (17.2)
	Total	275 (98.6)
Sexually active	Yes	227 (81.4)
	No	45 (16.1)
	Total	272 (97.5)
Sexually active before	Yes	253 (90.7)
colposcopy	No	16 (5.7)
	Total	269 (96.4)
Sexual orientation	Straight	268 (96.1)
	Gay	4 (1.4)
	Bi-sexual	2 (0.7)
	Total	274 (98.2)
Contraception use	Yes	156 (55.9)
	No	114 (40.9)
	Total	270 (96.8)
Children	Yes	183 (65.6)
	No	94 (33.7)
	Total	277 (99.3)
Miscarriage	Yes	52 (18.6)
	No	215 (77.1)
Duomostumo hinth	Total	267 (95.7)
Premature birth	Yes No	26 (9.3)
	Total	234 (83.9) 260 (93.2)
Still birth	Yes	5 (1.8)
Suir birtii	No	253 (90.7)
	Total	258 (90.7) 258 (92.5)
Gynaecological problems	Yes	141 (50.5)
Synaecological problems	No	129 (46.2)
	Total	270 (96.8)
Sexually transmitted	Yes	79 (28.3)
infection		70 (20.0)
	No	198 (71.0)
	Total	277 (99.3)
Long term health problems	Yes	73 (26.2)
	No	200 (71.7)
	Total	273 (97.8)
Visits to GP in last 12	0	14 (5.0)
months		. ,
	1-5	190 (68.1)
	6-9	34 (12.2)
	10+	24 (8.6)
	Total	262 (93.9)

<sup>\*</sup> Percentages may not total 100 due to missing data

Responders from the Women's hospital accounted for 59.9% (n=167) of the sample, with participants from Solihull hospital comprising 13.6% (n=38) of the sample. City hospital accounted for 12.9% (n=36); Good Hope hospital 9.0% (n= 25), and Heartlands accounted for 4.7% (n=13) of the sample. In terms of age group, 35.1% of the sample (n=98) were in the 30 to 39 age group. The smallest number of responses was obtained from the 50+ age group, with women over 50 accounting for 11.1% of the sample (n=31). With regard to deprivation, the largest group of respondents came from the most deprived quartile (Q4), accounting for 40.9% (n=114) of the sample. The most affluent deprivation quartile (Q1) was the smallest group (10.0%; n=28). Index of Multiple Deprivation (IMD) quartile could not be assigned to 8 individuals within the sample (2.9%). In terms of treatment type, just under half of the sample was comprised of women who had undergone colposcopy only (42.7%; n=119), with similar proportions of women having had loop excision or biopsy (30.1%, n=84 vs. 27.2%, n=76 respectively).

Data on ethnicity was collected, but due to the small sub-group sizes for ethnicity, and given that 78.5% of the sample were white British, ethnicity was dichotomised into 'white' vs. 'non-white' for the purposes of analysis. Non-white British ethnicities were comprised of 20.0% Asian/Asian British (n=12); 7.2% Black/Black British (n=20); 5.0% White non-British; 2.5% Mixed race (n=2.5); 2.2% other ethnicities (n=2.2) and 1% Chinese/Chinese British (n=1).

Data related to level of education were also collected, and again, due to small sub-group sizes, the seven categories for which data were collected were

dichotomised for the purposes of analyses (up to GCSE and post GCSE). The original categories were as follows: 26.2% of the sample had GCSE or equivalent qualifications (n=73); 19.7% had non-degree qualifications (n=55); 19.0% had a degree (n=53); 16.1% had post graduate qualifications (n=45); 9.3% had been trained through work with formal qualifications; 8.6% had no formal qualifications (n=24); and 0.7% had never attended school (n=2). There was missing data for one respondent.

For those responding to the question relating to smoking status, smokers accounted for under a third of the sample (n= 79; 28.3%) and almost half the sample were non-smokers (n= 131; 47.0%).

Although 80.3% of responders to the question relating to alcohol reported drinking alcohol, only 12.9% (n=36) reported drinking 14 or more units per week. 14 units per week is the recommended 'safe' limit for women. For the purposes of analysis (, weekly alcohol intake was dichotomised into zero to 14 and 14 and over. The majority of the responders to the question relating to problem alcohol/drug use (n= 261; 93.5%) reported having no substance misuse related problems.

A high proportion of the responders to question regarding partnership status had a partner (n= 227; 81.4%), compared with 17.2 % (n=48) who did not. A large proportion of the responders to questions relating to current sexual activity were sexually active (n= 227; 81.4%), compared with 16.1% (n=45) who were not. Ninety nine point seven percent (n= 253) of the responders

reported being sexually active prior to colposcopy, although it is not possible to infer that any observed difference between current sexual activity and reported activity prior to colposcopy was due to the colposcopy itself.

Ninety six point one percent (n= 268) of the responders to the question relating to sexual orientation identified themselves as straight, with only small proportions identifying as gay (1.4%) or bi-sexual (0.7%).

Over half the responders to the question relating to contraception use used contraception (n=156; 55.9%) compared to 40.9% (n=114) who did not. 65.6% (n=183) of responders had children. Just under one fifth of responders had had a miscarriage (n=52; 18.6%). Lower proportions of responders had had a premature birth (n=26; 9.3%) and a yet smaller proportion of responders to the question relating to still birth had experienced a stillbirth (n=5; 1.8%). Around half of the responders reported having had gynaecological problems (n=141; 50.5%) and 28.3% (n=79) of responders had had a sexually transmitted disease.

Just over a quarter of responders reported having long-term health problems (n=73; 26.2%). The highest proportion of responders to the question relating to visits to the GP in the last 12 months attended their GP between one and five times (n=190; 68.1%).

Section 7.3 will outline the results for analysis of treatment type as a predictor variable. Table 7.2 presents the factors and potential predictors of interest,

and Table 7.3 presents the validated measure outcomes investigated along with the potential predictors of these outcomes.

Table 7.2 Factors studied and potential predictors in terms of treatment type (Q2)

Factor	Potential Predictors
Demographic/health/lifestyle factors Deprivation Age Ethnicity Education Smoking status Alcohol use Alcohol units per week Problems with drugs/alcohol Partner status Sexual activity Sexual activity prior to colposcopy Sexual orientation Contraception use Having children Miscarriage Premature birth Still birth	Treatment type
Gynaecological problems	
Sexually transmitted infection	
Long term health problem	
Number of visits to GP in last 12 months	

Table 7.3 Validated outcome measures and potential predictors (Q2)

Validated measure outcomes	Potential predictors
Presence/absence of FSD	
Variation in FSFI score	
HADS anxiety score 'normal' or 'mild and above'	
Variation in HADS anxiety score	
HADS depression score 'normal' or 'mild and above'	
Variation in HADS depression score	
WHO-QOL BREF physical domain median score	
Variation in WHO-QOL BREF physical domain score	Treatment type Deprivation
WHO-QOL BREF psychological domain median score	Age
Variation in WHO-QOL BREF psychological domain score	
WHO-QOL BREF social domain median score	
Variation in WHO-QOL BREF social domain score	
WHO-QOL BREF environmental domain median score	
Variation in WHO-QOL BREF environmental domain score	

# 7.3 Analysis of treatment type and all outcome variables

This section will present the findings from analysis of treatment type as a potential predictor of all outcome variables. One of the aims of the study was

to ascertain if treatment type in particular was significantly associated with any of the outcomes investigated.

Table 7.4 presents the analysis of treatment type and its association with socioeconomic deprivation. Treatment type is included in two forms – with the three treatment groups considered separately, and secondly with colposcopy used as a proxy for a control group by being compared to the biopsy and loop excision groups combined.

Table 7.4 Treatment type and deprivation

	Colposcopy	Biopsy	Loop Excision	Biopsy/Loop Excision	Colposcopy vs. biopsy	Colpscopy vs. biopsy
	n (%)	n (%)	n %)	n (%)	vs. loop	& loop
Deprivation quartile						
Q1 Most affluent	6 (5.2)	9 (12.2)	13 (16.0)	22 (14.2)		
Q2 Less affluent	19 (16.4)	19 (25.7)	13 (16.0)	32 (20.6)	X <sup>2</sup> =13.76 p=0.0324	X <sup>2</sup> =7.61 p=0.0548
Q3 Less deprived	38 (32.8)	23 (31.1)	17 (21.0)	40 (25.8)		
Q4 Most deprived	53 (45.7)	23 (31.1)	38 (46.9)	61 (39.4)		
Affluent/ deprived						
Affluent	25 (21.6)	28 (37.8)	26 (32.1)	54 (34.8)	$X^2=6.29$	Pearson X <sup>2</sup> =5.67
Deprived	91 (78.4)	46 (62.2)	55 (67.9)	101 (65.2)	p=0.0431	p=0.0173

In the colposcopy and loop excision groups, the largest proportion of responders was concentrated within the most deprived quartile (Q4) (45.7%; n=53 and 46.9%; n=38 respectively). In the biopsy group, the same proportion

of responders was found in the most deprived (Q4) and less deprived quartiles (Q3) (31.1%; n=23).

Significant differences were found with regard to level of deprivation across the three treatment groups when divided into the four IMD quartiles  $(X^2=13.76; p=0.0324)$ ; although this significant result disappeared when colposcopy was compared with a combined biopsy/loop excision group  $(X^2=7.61; p=0.0548)$ . A higher than expected proportion of women had undergone colposcopy in the most (Q4) deprived and less deprived (Q3) quartile and a lower proportion in the biopsy and loop excision group.

When the deprivation quartiles were combined into dichotomous variables (Q1+Q2 denoting 'affluent' patients; Q3+Q4 denoting 'deprived' patients), significant differences were found when comparing proportions across the three treatment groups  $(X^2=6.29; p=0.0431)$ . Higher than expected numbers of colposcopy patients were found in the deprived group and fewer than expected in the affluent group. Higher than expected numbers of women from the affluent group were found in the biopsy and loop excision group and lower than expected numbers of deprived women were found in both these treatment groups. Similar patterns were found when comparing colposcopy with biopsy and loop excision combined  $(X^2=5.67; p=0.0173)$ .

Table 7.5 presents the findings from analysis in terms of age group vs. treatment type.

Table 7.5 Treatment type and age group

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Age group						
19 to 29	30 (25.2)	24 (31.6)	26 (31.0)	50 (31.3)		
30 to 39	39 (32.8)	27 (35.5)	32 (38.1)	59 (36.9)	$X^2=7.18$	$X^2 = 5.67$
40 to 49	31 (26.1)	17 (22.4)	(26.2)	39 (24.2)	p=0.3045	p=0.1288
50 +	19 (16.0)	8 (10.5)	4 (4.8)	12 (7.5)		

A similar proportion of responders were observed across all age ranges and all treatment groups, except in the 50+ group. For example, only 4.8% (n=4) of responders from the 50+ age group had undergone loop excision compared with 26.2% (n=22) in the 40 to 49 group; 38.1% (n=32) in the 30 to 39 group and 31.0% (n=26) in the 19 to 29 group. No statistically significant differences were observed across the age groups in terms of treatment undergone.

Table 7.6 presents the findings of analyses relating to ethnicity and treatment type.

Table 7.6 Treatment type and ethnicity

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Ethnicity						
White British	89 (74.8)	64 (84.2)	66 (78.6)	130 (81.3)	$X^2=2.44$	Pearson X <sup>2</sup> =1.69
Other	30 (25.2)	12 (15.8)	18 (21.4)	30 (18.8)	p=0.2952	p=0.1936

The majority of respondents across all groups were white British (colposcopy 74.8%; n=89, biopsy 84.2%; n=68, loop excision 81.3%; n=66). No significant differences were observed between white British and other ethnicities across treatment groups.

Table 7.7 outlines the findings regarding an analysis of treatment type vs. education attainment for respondents to Q2.

Table 7.7 Treatment type and educational attainment

	Colposcop y n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/L oop Excision n (%)	Colposcop y vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Education						
To GCSE or	40 (33.6)	25 (33.3)	34 (40.50)	59 (37.1)	X <sup>2</sup> =1.24	Pearson X <sup>2</sup> =0.36
equivalent Post GCSE	79 (66.4)	50 (66.7)	50 (59.5)	100 (62.9)	p=0.5379	p=0.5485

No significant differences were observed between the treatment groups in terms of educational attainment. A larger proportion of responders across all treatment groups were educated to a post GCSE level (colposcopy 66.4%; n=79, biopsy 66.7%; n=50; loop excision 59.5%; n=50).

Table 7.8 Treatment type and smoking status

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Smoking status						
Smoker	29 (24.2)	23 (30.3)	27 (32.1)	50 (31.3)		
Non smoker	65 (54.6)	29 (38.2)	37 (44.0)	66 (41.3)	$X^2$ =6.22 p=0.1833	$X^2$ =4.9 p=0.0863
Ex-smoker	25 (21.0)	24 (31.6)	20 (23.8)	44 (27.5)		•

As shown in Table 7.8, over half of the responders in the colposcopy group were non-smokers (54.6%; n=65). In the biopsy and loop excision group, the proportion of non-smokers was lower (38.2%; n=29 and 44.0%; n=37 respectively). No significant differences were observed between treatment type and smoking status.

Table 7.9 presents the results in terms of whether respondents used alcohol, and if so, at what level (Table 7.10).

Table 7.9 Treatment type and alcohol use

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Alcohol use						
Yes	91 (79.8)	65 (85.5)	68 (81.9)	133 (83.6)	X <sup>2</sup> =1.01	Pearson X <sup>2</sup> =0.66
No	23 (20.2)	11 (14.5)	15 (18.1)	26 (16.4)	p=0.6035	p=0.4166

Table 7.10 Treatment type and alcohol units (2 categories)

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Alcohol units per week						
1-13 14+	75 (81.5) 17 (18.5)	54 (83.1) 11 (16.9)	56 (87.5) 8 (12.5)	110 (85.3) 19 (14.7)	X <sup>2</sup> =1.02 p=0.6005	Pearson X <sup>2</sup> =0.55 p=0.4583

Around 80% of responders across all treatment groups drank alcohol (colposcopy n=91; 79.8, biopsy n=65; 85.5 and loop excision n=68; 81.9%). In terms of alcohol use and units consumed per week, no significant differences were observed between treatment groups. Higher numbers of responders in the colposcopy group drank alcohol (79.8%; n= 91) compared to the biopsy and loop excision groups (85.5%; n=65, 81.9%; n=68 respectively), although this was not statistically significant. In terms of number of units consumed per week, relatively small proportions of responders drank 14+ units per week (colposcopy 18.5%; biopsy 16.9% and loop excision 14.7%).

Table 7.11 presents the proportion of responders across all treatment groups reporting having problems with drugs or alcohol.

Table 7.11 Treatment type and problems with drugs or alcohol

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Problems with alcohol						
Yes No	5 (4.1) 108 (95.6)	4 (5.3) 72 (94.7)	1 (1.2) 81 (98.8)	5 (3.2) 153 (96.8)	Fisher exact p=0.3952	Two tail p=0.7460

These proportions were small (colposcopy 4.1%, n=5; biopsy 5.3%, n=4; and loop excision 1.2%, n=1). There were no significant differences between groups in terms of problem drug or alcohol use.

Table 7.12 shows the relationship between treatment type and respondents' partner status.

**Table 7.12 Treatment type and partner status** 

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Partner						
Yes	89 (76.6)	65 (85.5)	73 (88.0)	138 (86.8)	X <sup>2</sup> =4.88	Pearson X <sup>2</sup> =4.7
No	27 (23.3)	11 (14.5)	10 (12.0)	21 (13.2)	p=0.0872	p=0.0298

The proportion of responders who reported having a partner were relatively high, with the highest proportion found in the loop excision group (n=73; 88.0%). 85.5% (n=65) in the biopsy group had a partner, and the lowest

proportion was found in the colposcopy group (n=89; 76.6%). As shown in Table 7.12, no significant differences were found between the three groups in terms of their partnership status, although a significant difference was observed when biopsy and loop excision groups were combined and compared with colposcopy patients (Pearson X²=4.7; p=0.0298). Here, larger than anticipated numbers in the colposcopy group did not have a partner and larger than anticipated number in the combined biopsy and loop excision group had a partner.

In terms of sexual orientation, 97.4% (n=113) of responders in the colposcopy group identified as straight. In the biopsy and loop excision groups, 98.7% (n=74) and 97.6% (n=81) of responders respectively identified as straight. Due to small numbers of responders identifying as gay or bi-sexual, subgroup analysis was not possible across all the variables studied.

Table 7.13 presents the data on the association between treatment type and current reported sexual activity.

Table 7.13 Treatment type and sexual activity

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Sexually active						
Yes	93 (82.3)	63 (82.9)	71 (85.5)	134 (84.3)	X <sup>2</sup> =0.39	Pearson X <sup>2</sup> =0.14
No	20 (17.7)	13 (17.1)	12 (14.5)	25 (15.7)	p=0.822	p=0.6629

82.3% (n=93) of women in the colposcopy group reported being sexually active compared with 82.9% (n=63) and 85.5% (n=71) in the biopsy and loop excision groups respectively. No significant differences were observed in terms of treatment type and sexual activity. Table 7.14 shows the proportion of women across the treatment groups who were sexually active prior to colposcopy.

Table 7.14 Treatment type and sexual activity prior to colposcopy

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Sexually activity prior to colposcopy						
Yes	107 (95.5)	71 (95.9)	71 (85.5)	134 (83.3)	X <sup>2</sup> =8.61	Pearson X <sup>2</sup> =8.46
No	5 (4.5)	3 (4.1)	12 (14.5)	25 (15.7)	p=0.0135	p=0.0036

Almost all women in the colposcopy and biopsy groups were sexually active prior to colposcopy (n=107; 95.5% and n=107; 95.9%) with slightly fewer women observed in the loop excision group (n=71; 85.5). There were significant differences observed across the groups in terms of sexual activity prior to colposcopy and type of treatment. Higher than anticipated numbers of women in the colposcopy and biopsy group were sexually active prior to colposcopy compared to the loop excision group. (X²=8.61; p=0.0135). When biopsy and loop excision groups were combined and compared with colposcopy, significantly higher proportions of women in the colposcopy group

indicated that they were sexually active prior to colposcopy (Pearson  $X^2$ =8.46; p=0.0036).

Table 7.15 Treatment type and contraception use

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Contraception use						
Yes	60 (53.1)	45 (60.0)	51 (62.2)	96 (61.1)	X <sup>2</sup> =1.82	Pearson X <sup>2</sup> =1.75
No	53 (46.9)	30 (40.0)	31 (37.8)	61 (38.9)	p=0.0821	p=0.1859

As shown in Table 7.15, just over half of responders in the colposcopy group used contraception (53.1%; n=60) and 60.0% (n=45) and 62.2% (n=51) of responders in the biopsy and loop excision groups respectively used contraception. There were no statistically significant differences between groups in terms of contraception use.

Table 7.16 Treatment type and children

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Children						
Yes	79 (66.4)	50 (66.7)	54 (65.1)	104 (65.8)	$X^2=0.05$	Pearson X <sup>2</sup> =0.01
No	40 (33.6)	25 (33.3)	29 (34.9)	54 (34.2)	p=0.9753	p=0.9205

In the colposcopy group, 66.4% (n=79) of responders had children. In the biopsy and loop excision groups 66.7% (n=50) and 65.1% (n=54) of respondents, respectively, had children. As shown in Table 7.16, no significant differences were observed between treatment groups and the number of responders with children.

Table 7.17 Treatment type and miscarriage

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Ever had Miscarriage						
Yes	25 (21.9)	15 (20.8)	12 (14.8)	27 (17.6)	X <sup>2</sup> =1.64	Pearson X <sup>2</sup> =0.76
No	89 (78.1)	57 (79.2)	69 (85.2)	126 (82.4)	p=0.4404	p=0.3833

Table 7.17 shows the proportion of women who had had a miscarriage, broken down by treatment type. In the colposcopy group, 21.9% (n=25) of responders had a miscarriage. In the biopsy and loop excision groups 20.8% (n=15) and 14.8% (n=12) of responders respectively, had had a miscarriage. No statistically significant differences in these proportions were observed between treatment groups.

Table 7.18 compares the proportions of respondents to Q2 who had given birth prematurely across treatment groups.

Table 7.18 Treatment type and premature birth

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Premature birth						
Yes	15 (13.4)	6 (8.5)	5 (6.5)	11 (7.4)	X <sup>2</sup> =1.64	Pearson X <sup>2</sup> =0.76
No	97 (86.6)	65 (91.5)	72 (93.5)	137 (92.6)	p=0.4404	p=0.3833

Just under a quarter of women in the colposcopy group had had a premature birth (n=15). In the biopsy and loop excision groups 8.5% (n=6) and 6.5% (n=5) of responders respectively had had a premature birth. No statistically significant differences were observed between treatment groups. In terms of women having had a still birth, due to small numbers of responders experiencing this (colposcopy 1.8%, n=2; biopsy 2.8%, n=2; loop excision 1.3%, n=1), sub-group analysis was not possible.

Table 7.19 Treatment type and gynaecological problems

	Colposcop y n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loo p Excision n (%)	Colposcop y vs. biopsy vs. loop	Colposcop y vs. biopsy & loop
Ever had gynaecologica I problems						
Yes	64 (56.1)	42 (56.0)	35 (43.2)	77 (49.4)	$X^2=3.77$	Pearson X <sup>2</sup> =1.21
No	50 (43.9)	33 (44.0)	46 (56.8)	79 (50.6)	p=0.1182	p=0.2713

The proportion of women across treatment groups experiencing gynaecological problems is shown in Table 7.19. Just over half of women in the colposcopy and biopsy groups reported having had gynaecological

problems (colposcopy 56.1%; n=64, biopsy 56.0%; n=42). Lower proportions of women in the loop excision group had experienced gynaecological problems. However, no significant differences were observed between treatment groups.

Table 7.20 compares treatment groups with respondents reporting a history of sexually transmitted infections.

Table 7.20 Treatment type and history of sexually transmitted infections (STIs)

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Ever had an STI						
Yes	30 (25.4)	25 (32.9)	24 (28.9)	49 (30.8)	X <sup>2</sup> =1.27	Pearson X <sup>2</sup> =0.97
No	88 (74.6)	51 (67.1)	59 (71.1)	110 (69.2)	p=0.5299	p=0.3247

Around a quarter of responders from the colposcopy group had a history of STI's (n= 30; 25.4%). Slightly higher proportions were observed in the biopsy and loop excision groups, where 32.9% (n=25) and 28.9% (n=24) of respondents respectively had a history of STIs. However, there were no significant differences in these proportions across treatment groups.

Table 7.21 shows the proportions of women who reported having long term health problems.

Table 7.21 Treatment type and long term health problems

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Long term health problems						
Yes	42 (35.6)	61 (21.3)	15 (18.8)	31 (20.0)	X <sup>2</sup> =21.36	Pearson X <sup>2</sup> =8.32
No	76 (64.4)	59 (78.7)	65 (81.3)	124 (80.0)	p=<0.001	p=0.0039

The highest proportion of responders with long term health conditions was observed in the colposcopy group with around a third of responders reporting such problems (n=42). This was compared with 21.3% (n=61) in the biopsy group and 18.8% (n=15) in the loop excision group and this result was statistically significant. When biopsy and loop excision groups were combined and compared with colposcopy patients, higher than expected numbers in the colposcopy group had long term health problems with lower numbers in the biopsy/loop excision group (Pearson X²=8.32; p=0.0039).

Table 7.22 Treatment type and number of visits to the GP in last 12 months

	Colposcopy n (%)	Biopsy n (%)	Loop Excision n (%)	Biopsy/Loop Excision n (%)	Colposcopy vs. biopsy vs. loop	Colposcopy vs. biopsy & loop
Number of visits to GP						
0 1 to 5	1 (0.9) 84 (74.3)	6 (8.8) 46 (67.6)	7 (8.6) 60 (74.1)	13 (8.7) 106 (71.1)	X <sup>2</sup> =12.34	X <sup>2</sup> =9.33
6 to 9	16 (14.2)	7 (10.3)	11 (13.6)	18 (12.1)	p=0.0548	p=0.0252
10+	12 (10.1)	9 (13.2)	3 (3.7)	12 (8.1)		

With regard to the number of times respondents had visited their GP in the 12 months prior to receiving the questionnaire (Table 7.22), 74.3% (n=84) of responders in the colposcopy group reported having visited their GP on between one and five occasions. In the biopsy and loop excision groups 67.6% (n=46) and 74.1% (n=60) of responders respectively visited their GP on between one and five occasions in the previous 12 months. In the colposcopy group, 10.1% (n=12) of respondents visited their GP on ten or more occasions, compared with 13.2% (n=9) in the biopsy group and 3.7% (n=3) in the loop excision group. When the colposcopy group was compared with the combined biopsy and loop excision group, a higher proportion of responders from the biopsy and loop excision group had not visited their GP at all when compared with the same proportion in the colposcopy group. Similarly, a higher proportion of responders in the colposcopy group visited their GP on 10 or more occasions when compared with the biopsy and loop excision group combined (X²=9.33; p=0.0252).

### 7.4 Analysis of responses to validated measures

The following sections will present the analyses for the responses to the validated measures included in Q2: the Female Sexual Function Index (FSFI), HADS depression and HADS anxiety measures, and the WHOQOL-BREF scale.

The results for each validated measure will be presented in a separate section.

Section 7.5 - pertaining to female sexual dysfunction - will present the results for the presence or absence of FSD for in terms of the three potential predictors of interest (treatment type, deprivation quartile and age). It will assess if there are any statistically significant associations between the presence of FSD and these predictors using Chi² tests for association.

Following this, odds ratios derived from binary logistic regression modelling will be presented, in order to demonstrate which of the factors investigated in Q2 (see Table 7.3) may be considered predictors of FSD for responders to Q2. The same process will then be undertaken for the HADS anxiety and HADS depression measures, looking at responders in the 'normal' range compared to the 'mild and above range of depression and anxiety scores. Finally, results will presented for the four WHOQOL-BREF domains (psychological, social, environmental and physical), including the median and mean scores for each domain.

### 7.5 Female Sexual Dysfunction

This section will present the results for the presence or absence of FSD for the potential predictor - treatment type, deprivation quartile and age. It will assess if there are any statistically significant associations between the presence of FSD and these predictors using Chi² tests for association. As discussed in chapter five, a sensitivity analysis will be performed removing women who had reported not being 'sexually active' as a response across all the FSFI domains. Following this, odds ratios derived from binary logistic regression modelling will be presented, in order to demonstrate which of the

factors investigated in Q2 may be considered predictors of FSD in responders to Q2.

### 7.5.1 Female Sexual Dysfunction results for all respondents

To ascertain the presence or absence of female sexual dysfunction for study participants, the Female Sexual Function Index (FSFI) was administered.

More detail about how scores were derived is presented in Chapter 5 (Section 5.6.2). The results for all respondents are presented in Table 7.23.

Table 7.23 Proportion of respondents to Q2 calculated as having female sexual dysfunction

Presence of FSD	n (%)
Yes	153 (54.8) 126 (45.2)
No	126 (45.2)
Total	279 (100.0)

In the sample responding to Q2, over 50% of respondents were found to have FSD, with 153 (54.7%) of responders scoring  $\leq$  26.55 on the FSFI scale. Similar proportions were observed after removal of women who were not sexually active (table 7.24).

Table 7.24 Proportion of respondents to Q2 calculated as having female sexual dysfunction (removing non-sexually active from analysis)

Presence of FSD	n (%)
Yes No	136(52.0) 126 (48.0)
Total	262 (100.0)

# 7.5.2 FSFI - Female Sexual Dysfunction proportion of responses by treatment type, deprivation and age group

Table 7.25 presents the proportion of women with FSD by treatment type, age and deprivation quartile. For all potential predictors, more than half of the women responding had FSD and in the 50+ age group, close to three quarters of women who responded had FSD (71.0%), although the absolute numbers were quite small (n=22). In terms of treatment, the highest proportion of women with FSD was observed in the loop excision group (n=49; 58.3%) and lowest in the biopsy group (n=36; 47.4%). Similar proportions of responders with FSD were observed in the less affluent and most deprived groups (n=26; 51.0% and n=59; 51.8% respectively).

Table 7.25 Presence of FSD - proportion of responses by treatment type, deprivation and age

Predictors	Participants with FSD (n)	Proportion with FSD %
Treatment type		
Colposcopy	68	57.1
Biopsy	36	47.4
Loop Excision	49	58.3
Total	153	
Biopsy/Loop Excision	85	53.1
Deprivation Quartile		
Most Affluent (Q1)	16	57.1
Less Affluent (Q2)	26	51.0
Less Deprived (Q3)	48	61.5
Most Deprived (Q4)	59	51.8
Total	149	
Affluent/Deprived		
Affluent	42	53.2
Deprived	107	55.7
Total	149	
_		
Age		
19-29	43	53.8
30-39	50	51.0
40-49	38	54.3
50+	22	71.0
Total	153	

The next three sections present the results for the associations between treatment type, deprivation quartile and age group and the presence of FSD using Chi<sup>2</sup> tests.

### Association between treatment type and FSD

Table 7.26 presents a comparison of the proportion of responders who had FSD between treatment groups. The highest proportion of responders with FSD was observed in the loop excision group (n=49; 58.3%) closely followed by the colposcopy group (n=68; 57.1%). No significant differences were observed in terms of the presence of FSD and level of treatment. This was the case both when the three treatment groups were compared to each other separately, and when the colposcopy group was compared to a combined biopsy/loop excision group.

Following sensitivity analysis (table 7.27), removing women who had recorded no sexual activity from the analysis, no significant differences were observed in terms of treatment type and presence of FSD.

Table 7.26 Association between treatment type and FSD - all responses

	FSD Yes n (%)	FSD No n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type				
Colposcopy Biopsy Loop Excision Biopsy/Loop	68 (57.1) 36 (47.4) 49 (58.3) 85 (53.1)	51 (42.9) 40 (52.6) 35 (41.7) 75 (46.9)	X <sup>2</sup> =2.8 p=0.30	Pearson X <sup>2</sup> =0.44 p=0.50

Table 7.27 Association between treatment type and FSD - sensitivity analysis

	FSD Yes n (%)	FSD No n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type				
Colposcopy Biopsy Loop Excision Biopsy/Loop	64 (56.6) 33 (47.9) 45 (57.7) 70 (47.0)	49 (43.4) 37 (52.1) 33 (42.3) 79 (53.0)	X <sup>2</sup> =1.78 p=0.41	Pearson X <sup>2</sup> =0.34 p=0.55

Association between deprivation quartile and FSD

The highest proportion of responders with FSD was observed in the less deprived quartile (Q3) (n=48; 61.5%) with the lowest proportion observed in the less affluent (Q2) and most deprived quartile (Q4). Here, around 50% of responders had FSD (n=26 and n=59 respectively). As shown in Table 7.28, no statistically significant differences were observed in terms of the presence of FSD and level of deprivation across the four deprivation quartiles. Following sensitivity analysis, presented in table 7.29 no significant differences were observed between in terms of presence of FSD and deprivation quartile.

Table 7.28 Association between deprivation quartile and FSD

	FSD Yes n (%)	FSD No n %)	p value
Deprivation quartile			
Q1 (Most Affluent) Q2 (Less Affluent) Q3 (Less Deprived) Q4 (Most Deprived)	16 (57.1) 26 (51.0) 48 (61.5) 59 (51.8)	12 (42.9) 25 (49.0) 30 (38.5) 55 (48.2)	X <sup>2</sup> =2.22 p=0.528

Table 7.29 Association between deprivation quartile and FSD - sensitivity analysis

	FSD Yes n (%)	FSD No n %)	p value
Deprivation quartile			
Q1 (Most Affluent) Q2 (Less Affluent) Q3 (Less Deprived) Q4 (Most Deprived)	16 (57.1) 26 (51.0) 42 (60.0) 55 (50.9)	12 (42.9) 25 (49.0) 28 (40.0) 53 (49.1)	X <sup>2</sup> =1.49 p=0.68

### Association between age group and FSD

Table 7.30 shows the proportion of women with FSD between age groups. The highest proportion of FSD was observed in the 50+ group (n=22; 71.0%) compared with proportions of around 50% for the other three age groups. Despite these differences in proportions, there was no statistically significant difference observed across age groups with regard to the prevalence of FSD in the sample. Similarly, no significant differences were noted following sensitivity analysis.

Table 7.30 Association between age group and FSD

	FSD Yes n(%)	FSD No n(%)	Significance
Age range			
19 to 29	43 (53.8)	37 (46.3)	
30 to 39	50 (51.0)	48 (49.0)	$X^2 = 3.84$
40 to 49	38 (54.3)	32 (45.7)	p=0.27
50+	22 (71.0)	9 (29.9)	

Table 7.31 Association between age group and FSD - sensitivity analysis

	FSD Yes n(%)	FSD No n(%)	Significance
Age range			
19 to 29	41 (53.9)	35 (46.1)	
30 to 39	50 (50.5)	48 (49.5)	$X^2 = 3.85$
40 to 49	35 (53.8)	30 (46.2)	p=0.27
50+	20 (71.4)	8 (28.6)	

### 7.5.3 Predictors of FSD - bivariate analysis

The next section will outline the results from the bivariate analysis of FSD incidence across the three potential predictor variables of interest i.e. the Odds Ratios (OR) derived from a binary logistic regression analysis, to determine the predictors of the presence of FSD derived from responses to the FSFI measure.

Table 7.32 presents the results from the analysis for presence of FSD for the three potential predictor variables of interest.

Table 7.32 Results FSD bivariate analysis for potential predictors of interest

Characteristic	Presence of FSD n ( %)		Bivariate OR (95% CI)	p value *
	Yes	No		
Treatment type				
Colposcopy Only	68 (57.1)	51 (42.9)	0.9 (0.5 -1.7)	0.90
Biopsy	36 (47.4)	40 (52.6)	0.6 (0.3 - 1.2)	0.16
Loop Excision	49 (58.3)	35 (41.7)	Reference	Reference
Deprivation quartile				
Most Affluent (Q1)	16 (57.1)	12 (42.9)	1.2 (0.5 - 2.9)	0.60
Less Affluent (Q2)	26 (51.0)		0.9 (0.5 - 1.8)	0.92
Less Deprived (Q3)	48 (61.5)	30 (38.5)	1.5 (0.8 - 2.6)	0.18
Most Deprived (Q4)	59 (51.8)	55 (48.2)	Reference	Reference
Age group				
19 to 29	43 (53.8)	37 (46.3)	0.5 (0.2 - 1.1)	0.10
30 to 39	50 (51.0)	` '	0.4 (0.2 - 1.0)	0.06
40 to 49	38 (54.3)	32 (45.7)	0.5 (0.2 - 1.2)	0.12
50+	22 (71.0)	9 (29.9)	Reference	Reference

None of the potential predictor variables was found to be significantly associated with presence/absence of FSD in the bivariate analysis.

### 7.5.4 Predictors of FSD - multivariate analysis

This section will present the results from the multivariate regression where the effects of each variable were controlled for by all other variables within the model. Thus, the remaining variables which are retained in the model can be considered independent predictors of the presence of FSD when the effect of all other variables are accounted for. A logistic regression (using the Enter method) was performed using all three variables and each of the dichotomous outcome variables in order to ascertain potentially significant predictors of FSD. The results are presented in Table 7.33.

Table 7.33 Results of FSD multivariate analysis for predictors of interest

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.061 (0.303)	0.84	0.941	(0.5 - 1.7)
Treatment type 2 (biopsy)	-0.410 (0.331)	0.21	0.216	(0.3 - 1.2)
IMD				
IMD 1 (Q1)	0.289 (0.440)	0.51	1.335	(0.5 - 3.1)
IMD 2 (Q2)	0.041 (0.344)	0.90	1.042	(0.5 - 2.0)
IMD 3 (Q3)	0.420 (0.305)	0.16	1.522	(0.8 - 2.7)
Age range				
Age 1 (19-29)	-0.700 (0.464)	0.13	0.496	(0.2 - 1.2)
Age 2 (29-39)	-0.863 (0.453)	0.06	0.422	(0.7 - 1.2)
Age 3 (40-49)	-0.699 (0.197)	0.13	0.497	(0.9 - 1.2)

Following multivariate analysis, no significant results were observed in terms of predictors for the presence of FSD.

# 7.6 Anxiety and Depression Scale (HADS) results for all respondents

HADS is a short measure of anxiety and depression that is appropriate for use in a general population. It is a fourteen item scale, with seven questions relating to anxiety and seven relating to depression. The outcomes indicate anxiety/depression levels with a range of 'normal', 'mild', 'moderate' and 'severe.' The results for all responses considered together are presented in Table 7.34. In the main results section, the results are presented for the four ranges of anxiety levels as well as scores dichotomised between 'normal' and 'mild and above'. Chapter 5 (Section 5.6.2) provides more detail for how the scores on this scale were calculated.

Table 7.34 HADS Anxiety/Depression results for all respondents

HADS anxiety score	n (%)	HADS Depression Score (%)
Normal	58 (20.8)	126 (45.2)
Mild	67 (24.0)	59 (21.1)
Moderate	96 (34.4)	77 (27.6)
Severe	56 (20.1)	15 (5.4)
Missing	2 (0.7)	2 (0.7)
Total	279 (100.0)	279 (100.0)

Just under half of the sample (n=126; 45.2%) scored within the 'normal' range on the depression scale. 66.3% (n=185) of the sample scored either 'normal'

or 'mild' on the depression scale. 33% of respondents (n=92) scored within the 'moderate' or 'severe' range of the depression scale. In terms of anxiety, one fifth of the sample (n=58; 20.8%) scored within the 'normal' range of the scale and just under half scored either 'normal' or 'mild' on the anxiety scale (n=125; 44.8%). Over half of the sample scored within the 'moderate' or 'severe' end of the scale (n=153; 54.4%). Data were missing for 0.7% of the sample (n=2).

### 7.6.1 HADS Anxiety/Depression mean scores

Table 7.35 presents the mean scores for anxiety and depression across the three primary predictor variables (treatment type, deprivation and age).

Table 7.35 Mean Scores - HADS Anxiety/Depression

Predictor variable	Anxiety Mean Score (SD)*	Depression Mean Score (SD)
Treatment type		
Colposcopy	10.88 (4.421)	8.44 (4.515)
Biopsy	11.75 (4.262)	8.70 (4.262)
Loop Excision	10.99 (4.110)	8.22 (3.829)
Biopsy/Loop Excision	11.35 (4.187)	8.45 (3.926)
Biopsy/Loop Excision	11.55 (4.167)	0.43 (0.320)
Deprivation quartile		
Most Affluent (Q1)	10.96 (4.678)	7.36 (4.556)
Less Affluent (Q2)	11.04 (4.463)	7.53 (4.258)
Less Deprived (Q3)	11.47 (4.394)	8.49 (3.889)
Most Deprived (Q4)	11.08 (4.113)	9.00 (4.158)
• • • •	, ,	, ,
Affluent/Deprived		
Affluent (Q1+Q2)	11.01 (4.511)	7.49 (4.338)
Deprived (Q3+Q4)	11.24 (4.222)	8.79 (4.048)
Age group		
19 to 29	11.90 (4.224)	8.40 (4.301)
30 to 39	10.59 (4.375)	7.88 (4.116)
40 to 49	11.04 (4.364)	8.62 (4.336)
50+	11.23 (3.888)	9.94 (3.425)

<sup>\*</sup> SD = Standard Deviation

Overall, mean depression scores on the HADS scale were lower than the anxiety scores. Women in the biopsy treatment group scored marginally higher on the anxiety and depression scale (11.75; SD = 8.70) than respondents in the colposcopy and loop excision groups. In terms of deprivation quartile, responders in the less deprived group (quartile 3) scored highest on the anxiety scale (11.47) and the most affluent group (quartile 1) scored the lowest on this scale (10.96). The most deprived group scored highest on the depression scale (9.00) and the most affluent group scored lowest on this scale (7.36). In terms of age, the 19 to 29 group scored highest on the anxiety scale (11.90) and lowest on the depression scale (8.40). The 50+ group scored highest on the depression scale (9.94).

Section 7.7 presents the proportion of participants with anxiety levels rated as either 'normal', 'mild', 'moderate' or 'severe' and tests for association between anxiety level and treatment type, deprivation and age. Further analysis was undertaken dichotomising anxiety levels into 'normal' or 'mild and above'.

### 7.7 HADS anxiety results

#### 7.7.1 Association between treatment type and HADS anxiety level

Table 7.36 presents the proportion of responders rated on each level of the anxiety scale in terms of treatment type; both taken separately, and with colposcopy compared to a combined biopsy/loop excision group. Around a quarter of responders in the loop excision group had anxiety levels rated as

'normal' (n=20). This group had the highest proportion of responders in the normal range. 23.7% (n=18) of responders in the biopsy group were rated as having 'severe' anxiety. The lowest proportion of responders rated as having 'severe' anxiety were observed in the loop excision group (n=15; 18.1%). As shown in Table 7.37, similar proportions were observed when the HADS scale was dichotomised into 'normal' or 'mild and above'. However, no statistically significant differences were observed in term of anxiety levels and treatment type using the four levels of anxiety or when scores were dichotomised into two groups.

Table 7.36 Association between treatment type and HADS anxiety level

HADS Anxiety	Normal n (%)	Mild n (%)	Moderate n ( %)	Severe n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type						
Colposcopy	27 (22.9)	31 (26.3)	37 (31.4)	23 (19.5)		
Biopsy	11 (14.5)	17 (22.4)	30 (39.5)	18 (23.7)	$X^2 = 4.05$	$X^2 = 1.44$
Loop Excision	20 (24.1)	19 (22.9)	29 (34.9)	15 (18.1)	p=0.6699	p=0.6962
Biopsy/Loop	31 (19.5)	36 (22.6)	59 (37.1)	33 (20.8)	•	•

Table 7.37 Association between treatment type and HADS anxiety level (normal vs. mild and above)

HADS Anxiety	Normal n (%)	Mild and above n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type				
Colposcopy Biopsy	27 (22.9) 11 (14.5)	91 (77.1) 65 (85.5)	X <sup>2</sup> =2.69	Pearson X <sup>2</sup> =0.47 p=0.493
Loop Excision	20 (24.1)	63 (75.9)	p=0.2605	
Biopsy/Loop	31 (19.5)	128 (80.5)		

## 7.7.2 Association between deprivation quartile and HADS anxiety level

Table 7.38 presents the proportions of responders rated as 'normal', 'mild', 'moderate' and 'severe' on the anxiety scale when responses are categorised by deprivation quartile. The highest proportion of responders rated as 'normal' on the scale were from the less affluent quartile (Q2) (n=13; 25.5%). The lowest proportion of responders on the 'normal' range were in the most affluent quartile (Q1) (n=5; 17.9%). The less affluent group (Q2) had the highest proportion of responders with anxiety rated as 'severe' (n=13; 25.5%). The most deprived group (Q4) had the lowest proportion of responders rated as 'severe' (n=17; 15%). There were no statistically significant differences observed in terms of anxiety levels and deprivation level using the four levels of anxiety scores on the HADS scale.

As shown in Table 7.39, when anxiety scores were dichotomised into 'normal' and 'mild and above', a significant difference was observed (X²=60.87; p=0.001) with lower than anticipated numbers of patients rated as 'normal' in the 'most affluent' (Q1) and 'less affluent' (Q2) groups and higher than anticipated numbers rated as 'normal' in the 'less deprived' (Q3) and 'most deprived' (Q4) groups. These findings suggest that more affluent participants were more likely to experience more pronounced levels of anxiety when compared with more socioeconomically deprived respondents.

Table 7.38 Association between deprivation quartile and HADS anxiety level

HADS Anxiety	Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	p value
Deprivation quartile Q1 (Most Affluent) Q2 (Less Affluent) Q3 (Less Deprived) Q4 (Most Deprived)	5 (17.9) 13 (25.5) 15 (19.5) 23 (20.4)	10 (35.7) 11 (21.6) 18 (23.4) 27 (23.9)	7 (25.0) 14 (27.5) 25 (32.5) 46 (40.7)	6 (21.4) 13 (25.5) 19 (24.7) 17 (15.0)	X <sup>2</sup> =8.17 p=0.5171

Table 7.39 Association age group and HADS anxiety level (normal v mild and above)

HADS Anxiety	Normal n (%)	Mild and above n (%)	p value
Deprivation quartile			
Q1 (Most Affluent) Q2 (Less Affluent) Q3 (Less Deprived) Q4 (Most Deprived)	5 (17.9) 13 (25.5) 56 (74.7) 78 (74.3)	23 (82.1) 38 (74.5) 19 (25.3) 27 (25.7)	X <sup>2</sup> =60.87 p=<0.001

### 7.7.3 Association between age group and HADS anxiety level

Table 7.40 presents the proportion of responders rated on the anxiety scale in terms of age. The lowest proportion of responders rated in the 'normal' range were from the 50+ age group (n=3; 9.7%). The 30 to 39 and 40 to 49 age groups both had around a quarter of respondents rated as having 'normal' anxiety levels (n=26; n=17 respectively). In terms of 'severe' anxiety, the group with the highest proportion of responders was from the 19 to 29 age group (n=19; 23.8%). As shown in Table 7.41, when the anxiety scores were dichotomised into 'normal' or 'mild and above', the highest proportion of

responders scoring 'mild or above' on the HADS anxiety scale was in the 50+ age group. No statistically significant differences were observed between levels of anxiety and age group.

Table 7.40 Association between age group and HADS anxiety level

HADS Anxiety	Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	p value
Age group 19 to 29 30 to 39 40 to 49 50+	12 (15.0) 26 (26.8) 17 (24.6) 3 (9.7)	18 (22.5) 24 (24.7) 13 (18.8) 12 (38.7)	31 (38.8) 27 (27.8) 27 (39.1) 11 (35.5)	19 (23.8) 20 (20.6) 12 (17.4) 5 (16.1)	X <sup>2</sup> =12.02 p=0.2122

Table 7.41 Association between age group and HADS anxiety level (normal vs. mild and above)

HADS Anxiety	Normal n (%)	Mild or above n (%)	p value
Age group 19 to 29 30 to 39 40 to 49 50+	12 (15.0) 26 (26.8) 17 (24.6) 3 (9.7)	68 (85.0) 71 (73.2) 52 (75.4) 28 (90.3)	X <sup>2</sup> =6.67 p=0.0832

## 7.7.4 Predictors of scoring 'normal' or 'mild and above' on the HADS anxiety scale - bivariate analyses

Section 7.7.4 will outline the results from the bivariate analysis i.e. the Odds Ratios (OR) derived from a binary logistic regression analysis, to determine the predictors of respondents rating either 'normal' or 'mild and above' on the HADS anxiety scale. Table 7.42 presents the results from this analysis for the three potential predictor variables of interest.

Table 7.42 Predictors of scoring 'normal' or 'mild and above' on the HADS anxiety scale - Bivariate analyses for all predictors

Characteristic	HADS Anxiety Score n (%)		Bivariate OR (95% CI)	p value*
	Normal	Mild or above		
Treatment type				
Colposcopy only	27 (22.9)	91 (77.1)	1.0 (0.5 - 2.0)	0.84
Biopsy	11 (14.5)	65 (85.5)	1.9 (0.8 - 4.2)	0.12
Loop excision	20 (24.1)	63 (75.9)	Reference	Reference
Deprivation quartile				
Most Affluent (Q1)	5 (17.9)	23 (82.1)	1.1 (0.4 - 3.4)	0.76
Less Affluent (Q2)	13 (25.5)	38 (74.5)	0.7 (0.3 - 1.6)	0.43
Less Deprived (Q3)	56 (74.7)	19 (25.3)	0.9 (0.5 - 2.1)	0.88
Most Deprived (Q4)	78 (74.3)	27 (25.7)	Reference	Reference
<b>A</b>				
<b>Age group</b> 19 to 29	12 (15 0)	GO (OF O)	0.6 (0.4 0.2)	0.46
	12 (15.0)	68 (85.0)	0.6 (0.1 - 2.3)	0.46
30 to 39	26 (26.8)	71 (73.2)	0.3 (0.8 - 1.0)	0.58
40 to 49	17 (24.6)	52 (75.4)	0.3 (0.8 - 1.2)	0.95
50+	3 (9.7)	28 (90.3)	Reference	Reference

Following bivariate analysis, none of the potential predictors of interest were significantly associated with scoring 'normal' or mild and above' on the HADS anxiety scale.

# 7.7.5 Predictors of scoring 'normal' or 'mild and above' on the HADS scale - multivariate analysis

This section will present the results from the multivariate regression undertaken to establish which factors might be significant predictors of anxiety on the HADS scale when all other factors are controlled for in the model. A logistic regression (using the enter method) was performed using all variables. The results are presented in Table 7.43.

Table 7.43 Results scoring 'normal' or 'mild and above' on the HADS anxiety scale - multivariate analysis for all predictors

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.038 (0.356)	0.91	0.963	(0.4 - 1.9)
Treatment type 2 (biopsy)	0.700 (0.438)	0.11	2.014	(0.8 - 4.7)
IMD				
IMD 1 (Q1)	0.218 (0.564)	0.69	1.243	(0.4 - 3.7)
IMD 2 (Q2)	-0.392 (0.410)	0.33	0.676	(0.3 - 1.5)
IMD 3 (Q3)	-0.047 (0.379)	0.90	0.954	(0.4 - 2.0)
Age range				
Age 1 (19-29)	-0.528 (0.693)	0.44	0.590	(0.1 - 2.2)
Age 2 (29-39)	-1.263 (0.661)	0.06	0.283	(0.7-1.0)
Age 3 (40-49)	-1.125 (0.679)	0.09	0.325	(0.8 - 1.2)

Note: Model  $X^2$  =11.716 (p=0.164); Hosmer and Lemeshow = 4.160 (p=0.761); Cox & Snell  $R^2$ =0.043; Nagelkerke  $R^2$  = 0.067

Following multivariate regression, none of the potential predictors entered into the model were significant predictors of scoring 'normal' or 'mild and above' on the HADS anxiety scale.

### 7.8 HADS Depression results

#### 7.8.1 Association between treatment type and HADS depression level

Table 7.44 presents the responses on the HADS depression scale disaggregated by treatment type. It shows the proportions of responders scoring 'normal', 'mild', 'moderate' or 'severe' on the HADS depression scale.

Similar proportions of responders across all treatment groups were rated as having 'normal' scores on the depression scale (colposcopy n=56; 47.1%, biopsy n=17; 44.7% and loop excision n=36; 43.4%). Relatively small proportions of women were rated as having 'severe' depression' between all groups, although the loop excision group had the lowest proportion (n=3; 4.4%). As shown in Table 7.45, similar proportions were observed across treatment groups when the depression scale was dichotomised into 'normal' and 'mild and above'. Just over half of the sample were rated as having 'mild or above' depression. However, no statistically significant differences were observed in terms of depression levels and treatment type using the four levels of depression or when scores were dichotomised into 'normal' or 'mild and above', nor was there a difference when considering the three treatment types separately or comparing the colposcopy group to a combined biopsy/loop excision group.

Table 7.44 Association between treatment type and HADS depression level

HADS Depression	Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type						
Colposcopy Biopsy Loop Excision Biopsy/Loop	56 (47.1) 34 (44.7) 36 (43.4) 70 (44.0)	17 (14.4) 18 (23.7) 24 (28.9) 42 (26.4)	37 (31.4) 20 (26.3) 20 (24.1) 40 (25.2)	8 (6.8) 4 (5.3) 3 (3.6) 7 (4.4)	X <sup>2</sup> =7.2 p=0.3027	X <sup>2</sup> =6.4 p=0.0937

Table 7.45 Association between treatment type and HADS anxiety depression (normal vs. mild and above)

HADS Depression	Normal n (%)	Mild and above n (%)	Colposcopy vs. biopsy vs. loop excision	Colposcopy vs. biopsy & loop excision
Treatment type				
Colposcopy Biopsy Loop Excision Biopsy/Loop	56 (47.5) 34 (44.7) 36 (43.4) 70 (44.0)	62 (52.5) 42 (55.3) 47 (56.6) 89 (56.0)	X <sup>2</sup> =0.35 p=0.8395	Pearson X <sup>2</sup> =0.32 p=0.5716

# 7.8.2 Association between deprivation quartile and HADS depression level

Table 7.46 presents the proportion of responders rated as having 'normal', 'mild', 'moderate' or 'severe' depression when responses were considered on the basis of deprivation quartile.

A higher proportion of women in the less affluent quartile (Q2) scored 'normal' on the depression scale (n=29; 56.9%), compared with 50.0% (n=14) in the most affluent quartile (n=14; 50.0%), 42.9% (n=33) in the less deprived quartile (Q3). The lowest proportion of responders scoring 'normal' on this scale was observed in the most deprived quartile (Q4) (n=47; 41.6%). Similar proportions of respondents scoring 'severe' on the depression scale were observed in the most affluent (Q1), less affluent (Q2), and less deprived quartiles (Q3) with the highest proportion observed in the most deprived quartile (n=8; 7.1%). When scores were dichotomised into 'normal' or 'mild and above', higher proportions of responders scored 'mild or above' in the less deprived (Q3) and most deprived quartile (Q4) (n=44; 57.1% and n=66;

58.4% respectively). However, no statistically significant differences were observed between depression scores and the four deprivation quartiles.

Table 7.46 Association between deprivation and HADS depression level

HADS Depression	Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	p value
Deprivation quartile					
Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	14 (50.0) 29 (56.9) 33 (42.9) 47 (41.6)	7 (25.0) 10 (19.6) 18 (23.4) 23 (20.4)	6 (21.4) 10 (19.6) 23 (29.9) 35 (31.0)	1 (3.6) 2 (3.9) 3 (3.9) 8 (7.1)	X <sup>2</sup> =6 p=0.7399

Table 7.47 Association between deprivation quartile and HADS depression (normal vs. mild and above)

HADS Depression	Normal n (%)	Mild and above n (%)	p value
Deprivation quartile			
Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	14 (50.0) 29 (56.9) 33 (42.9) 47 (41.6)	14 (50.0) 22 (43.1) 44 (57.1) 66 (58.4)	X <sup>2</sup> =3.79 p= 0.2851

### 7.8.3 Association between age group and HADS depression level

Table 7.48 shows the proportion of responders scoring 'normal', 'mild', 'moderate' or 'severe' in terms of age group. Around half of responders in the 30 to 39 and 40 to 49 age group were observed in the 'normal range', with the lowest proportion in the 'normal' range observed in the 50+ range (n=7; 22.6%). Due to insufficient numbers of responses, it was not possible to

perform more sophisticated statistical analysis and tests for association across age groups and the four levels of depression responses for the HADS measure.

When depression scores were dichotomised into two groups representing 'normal' and 'mild and above', (Table 7.49) a significant difference was observed with lower proportions of patients from the 19 to 29 and 50+ groups in the 'normal' range and higher proportions of patients from the 30 to 39 and 40 to 49 groups in the normal range ( $X^2$ =8.41; p=0.0383).

Table 7.48 Association between age group and HADS depression level

HADS	Normal	Mild	Moderate	Severe	p value
Depression	n (%)	n (%)	n (%)	n (%)	
Age group					
19 to 29	35 (43.8)	17 (21.3)	24 (30.0)	4 (5.0)	Cannot calculate
30 to 39	49 (50.5)	20 (20.6)	24 (24.7)	4 (4.1)	
40 to 49	35 (50.7)	14 (20.3)	13 (18.8)	7 (10.1)	
50+	7 (22.6)	8 (25.8)	16 (51.6)	0 (0.0)	

Table 7.49 Association between age quartile and HADS depression (normal v mild and above)

HADS Depression	Normal n (%)	Mild or above n (%)	p value
Age group			
19 to 29 30 to 39 40 to 49 50+	35 (43.8) 49 (50.5) 35 (50.7) 7 (22.6)	45 (56.3) 48 (49.5) 34 (49.3) 24 (77.4)	X <sup>2</sup> =8.41 p=0.0383

# 7.8.4 Predictors of scoring 'normal' or 'mild and above' on the HADS depression scale - bivariate analyses

Section 7.8.4 will outline the results from the bivariate analysis undertaken to determine the predictors of rating either 'normal' or 'mild and above' on the HADS depression scale. Table 7.50 presents the results from this analysis for the three potential predictor variables of interest.

Table 7.50 Predictors of scoring 'normal' or 'mild and above' on the HADS depression scale - bivariate analyses for potential predictors of interest

Characteristic	HADS Depression Score n (%)		Bivariate OR (95% CI)	p value
	Normal	Mild or above		
Treatment type				
Colposcopy Only	56 (52.5)	62 (52.5)	0.8 (0.5 - 1.5)	0.56
Biopsy	34 (44.7)	42 (55.3)	0.9 (0.5 - 1.8)	0.86
Loop Excision	36 (43.4)	47 (56.6)	Reference	Reference
Deprivation quartile				
Most Affluent (Q1)	14 (50.0)	14 (50.0)	0.7 (0.3 - 1.6)	0.42
Less Affluent (Q2)	29 (56.9)	22 (43.1)	0.5 (0.3 - 1.0)	0.07
Less Deprived (Q3)	33 (42.9)	44 (57.1)	0.9 (0.5 - 1.7)	0.86
Most Deprived (Q4)	47 (41.6)	66 (58.4)	Reference	Reference
Age group				
19-29	35 (43.8)	45 (56.3)	0.4 (0.1 - 0.9)	0.04
30-39	49 (50.5)	48 (49.5)	0.3 (0.1 - 0.7)	0.008
40-49	35 (50.7)	34 (49.3)	0.3 (0.1 - 0.7)	0.01
50+	7 (22.6)	24 (77.4)	Reference	Reference

In terms of HADS depression scores, age was the most prominent predictor of higher depression scores. Women aged 50+ were significantly more likely to score mild or above on the depression scale than those in the 19-29, 30-39 and 40-49 groups (OR: 0.4; CI 0.1 to 0.9 vs. OR: 0.3; CI 0.3 to 1.0 and OR: 0.3; CI 0.1 to 0.7 respectively).

# 7.8.5 Predictors of scoring 'normal' or 'mild and above' on the HADS scale - multivariate analysis

As outlined in Section 7.6, a logistic regression (forward LR) was performed using all variables (whether significant or not) and each of the dichotomous outcome variables in order to ascertain potentially significant predictors of scoring mild or above on the depression scale. The results are outlined in Table 7.51.

Table 7.51 Results scoring 'normal' or 'mild and above' on the HADS depression scale - multivariate analysis for predictors of interest

Included Variables	B(SE)	p value	Exp b	CI for Exp b (95% CI)
Model				
Treatment type				
Treatment type 1 (colposcopy)	-0.265 (0.307)	0.37	0.767	(0.4 - 1.3)
Treatment type 2 (biopsy)	0.069 (0.336)	0.83	1.071	(0.5 - 2.0)
IMD				
IMD 1 (Q1)	-0.369 (0.441)	0.40	0.692	(0.2 - 1.6)
IMD 2 (Q2)	-0.671 (0.352)	0.06	0.511	(0.2 - 1.0)
IMD 3 (Q3)	-0.116 (0.307)	0.70	0.891	(0.4 - 1.6)
Age range				
Age 1 (19-29)	-1.026 (0.495)	0.03	0.359	(0.1 - 0.9)
Age 2 (29-39)	-1.326 (0.486)	0.006	0.266	(0.1 - 0.6)
Age 3 (40-49)	-1.375 (0.503)	0.006	0.253	(0.1 - 0.6)

Note: Model  $X^2$  =14.500 (p=0.070); Hosmer and Lemeshow = 4.099 (p=0.848); Cox & Snell  $R^2$ =0.052; Nagelkerke  $R^2$  = 0.070

Addition of all the potential predictor variables for whether women scored normal or mild and above on the HADS scale score indicated that a woman's age was the only significant predictor of scoring mild or above on the depression scale. Women aged 19-29, 30-39 and 40-49 were significantly less likely to score mild or above on the HADS depression scale (OR: 0.359, 95% CI: 0.1 to 0.9; OR: 0.266, 95% CI: 0.1 to 0.6 and OR: 0.253, 95% CI: 0.1 - 0.6 respectively).

However, the proportion of variability explained by the multivariate model was low (5-7%).

#### 7.9 Results - WHOQOL-BREF

The following sections will present the results from the responses to the WHOQOL-BREF measure. Section 7.9.1 presents the total scores for each of the four domains that comprise the WHOQOL-BREF measure for all respondents. This is followed by presentation of the median scores for each domain in terms of treatment type, deprivation quartile and age. The mean scores are then presented for each domain in terms of the main predictors of interest.

### 7.9.1 WHOQOL-BREF scores for all respondents

The WHOQOL-BREF assesses quality of life across four domains - physical health, psychological health, social relationships and environmental factors.

The detail of how the scores were calculated is provided in Chapter 5, Section 5.6.2.

Table 7.52 presents the distribution of scores for the WHOQOL-BREF physical domain, for all respondents to questionnaire 2.

Table 7.52 WHOQOL-BREF - all respondents' physical domain distribution of scores

Total physical score	n (%)
3.57	1 (0.4)
17.86	2 (0.7)
21.43	1 (0.4)
28.57	1 (0.4)
32.14	4 (1.1)
35.71	3 (1.1)
39.29	2 (0.7)
42.86	5 (1.8)
46.43	1 (0.4)
50.00	7 (2.5)
53.57	7 (2.5)
57.14	7 (2.5)
60.71	14 (5.0)
64.29	12 (4.3)
67.86	15 (5.4)
71.43	18 (6.8)
75.00	25 (9.4)
78.57	26 (9.8)
82.14	18 (6.8)
85.71	27 (10.2)
89.29	28 (10.5)
92.86	20 (7.5)
96.43	13 (4.9)
100.0	9 (3.4)
Missing	13 (4.7)
Total	279 (100.0)

In the WHOQOL-BREF measure, higher scores indicate better physical health. Around 10% of the sample scored between 3.57 and 50.00 (n=20). The remaining 85.8% of the sample scored greater than 50, indicating good physical health. 4.7% (n=13) of data items were missing.

Table 7.53 presents the distribution of scores for the WHOQOL-BREF psychological domain, when all respondents were taken together.

Table 7.53 WHOQOL-BREF all respondents psychological domain total

Total psychological score	n (%)
4.17	1 (0.4)
8.33	3 (1.1)
20.83	1 (0.4)
25.00	2 (0.7)
29.17	11 (3.9)
33.33	6 (2.2)
37.50	7 (2.5)
41.67	11 (3.9)
45.83	10 (3.6)
50.00	11 (3.9)
54.17	18 (6.5)
58.33	22 (7.9)
62.50	22 (7.9)
66.67	17 (6.1)
70.83	39 (14.0)
75.00	27 (9.7)
79.17	19 (6.8)
83.33	18 (6.5)
87.50	2 (0.7)
91.67	7 (2.5)
95.83	9 (3.2)
Missing	16 (5.7)
Total	279 (100.0)

As with the physical domain, higher scores in the psychological domain indicate better psychological health. Around one fifth of the sample scored between 4.17 and 50.00 (n=63). The remaining 71.7% of the sample scored

greater than 50 (n=200). 5.7% (n=16) of data were missing, thus psychological domain scores could not be calculated for these individuals.

Table 7.54 presents the total response scores for the WHOQOL-BREF social domain. Again, higher scores indicate better wellbeing within this domain.

Table 7.54 WHOQOL-BREF all respondents social domain total

Total social domain score	n (%)
0.00	2 (0.7)
8.33	1 (0.4)
16.67	3 (1.1)
25.00	4 (1.4)
33.33	10 (3.6)
41.67	14 (5.0)
50.00	26 (9.3)
58.33	30 (10.8)
66.67	53 (19.0)
75.00	48 (17.2)
83.33	28 (10.0)
91.67	25 (9.0)
100.00	25 (9.0)
Missing	10 (3.6)
Total	279 (100.0)

Around one fifth of the sample scored between 0.00 and 50.00 (n=60; 12.2%). The remaining 74.9% of the sample scored higher than 50 for the social domain score (n=209). Data for 10 individuals (3.6%) were missing.

Finally, Table 7.55 presents the distribution of scores on the WHOQOL-BREF environmental domain for all respondents combined. Just under one fifth of

the sample scored between 12.50 and 50.00 (n=50). The remaining 78.7% of the sample scored greater than 50 (n=220). 3.2% (n=9) of data were missing.

Table 7.55 WHOQOL-BREF all respondents environmental domain total

Total environmental score	n (%)
12.50	1 (0.4)
15.63	1 (0.4)
21.88	2 (0.7)
25.00	1 (0.4)
28.13	1 (0.4)
31.25	2 (0.7)
34.38	2 (0.7)
37.50	6 (2.2)
40.63	5 (1.8)
43.75	8 (2.9)
46.88	14 (5.0)
50.00	7 (2.5)
53.13	4 (1.4)
56.25	15 (5.4)
59.38	15 (5.4)
62.50	18 (6.5)
65.63	15 (5.4)
68.75	20 (7.2)
71.88	31 (11.1)
75.00	21 (7.5)
78.13	17 (6.1)
81.25	16 (5.7)
84.38	19 (6.8)
87.50	10 (3.6)
90.63	6 (2.2)
93.75	5 (1.8)
96.88	7 (2.5)
100	1 (0.4)
Missing	9 (3.2)
Total	279 (100.0)

#### 7.9.2 WHOQOL-BREF median scores

There are no currently available UK normative data for this measure.

Comparisons were drawn between the groups studied in this cohort.

WHOQOL-BREF domain scores were not normally distributed across any of the comparison groups therefore all analyses undertaken with these data utilised non-parametric tests (Kruskal Wallis). The median scores and interquartile range (IQR) for each domain are presented in the following three tables categorised by treatment type (Table 7.56), deprivation quartile (Table 7.57), and age group (Table 7.58).

Table 7.56 WHOQOL-BREF median scores categorised by treatment type

Treatment Type	Physical domain	Psychological domain	Social domain	Environmental domain
Colposcopy	78.6	66.7	66.7	68.8
	(IQR 60.7-	(IQR 54.2-75.0)	(IQR 56.3-85.3)	(IQR 59.4-78.1)
	85.7)			
Biopsy	78.6	66.7	66.7	68.8
	(IQR 64.3-	(IQR 50.0-75.0)	(IQR 58.3-83.3)	(IQR 59.4-78.1)
	89.3)			
Loop Excision	78.6	62.5	66.7	68.8
	(IQR 67.9-	(IQR 54.2-75.0)	(IQR 58.3-83.3)	(IQR 53.9-81.3)
	89.3)			
Biopsy/Loop	78.6	64.6	66.7	68.8
Excision	(IQR 67.9-	(IQR 50.0-75.0)	(IQR 58.3-83.3)	(IQR 56.3-79.7)
	89.3)	,	,	,

Table 7.57 WHOQOL-BREF median scores categorised by deprivation quartile

Deprivation quartile	Physical domain	Psychological domain	Social domain	Environmental domain
Most Affluent (Q1)	82.1	66.7	75.0	73.4
	(IQR 75.9-92.9)	(IQR 58.3-79.2)	(IQR 60.4-	(IQR 63.3-81.3)
			83.3)	
Less Affluent (Q2)	82.1	70.8	75.0 <sup>°</sup>	75.0
, ,	(IQR 66.1-89.3)	(IQR 56.3-79.2)	(IQR 66.7-	(IQR 67.2-84.4)
		,	91.7)	,
Less Deprived	78.6	66.7	66.7 <sup>°</sup>	68.8
(Q3)	(IQR 67.9-89.3)	(IQR 51.0-75.0)	(IQR 58.3-	(IQR 59.4-81.3)
,	,	,	83.3)	,
Most Deprived	75.0	62.50	66.7 <sup>′</sup>	65.6
(Q4)	(IQR 60.7-85.7)	(IQR 50.0-75.0)	(IQR 50.0- 83.3)	(IQR 52.3-75.0)

Table 7.58 WHOQOL-BREF median scores categorised by age group

Age group	Physical domain	Psychological domain	Social domain	Environmental domain
19-29	78.6	62.5	66.7	65.6
	(IQR 71.4-89.3)	(IQR 50.0-70.8)	(IQR 58.3-83.3)	(IQR 50.0-77.3)
30-39	80.4	66.7	66.7	71.9
	(IQR 67.9-89.3)	(IQR 58.3-79.2)	(IQR 58.3-83.3)	(IQR 52.5-78.1)
40-49	75.0	66.7	66.7	71.9
	(IQR 62.5-89.3)	(IQR 50.0-79.2)	(IQR 58.3-83.3)	(IQR 56.2-82.8)
50+	66.0	60.4	66.7	68.8
	(IQR 54.5-78.6)	(IQR 46.9-74.0)	(IQR 41.7-81.3)	(IQR 56.3-79.7)

Non-parametric tests (Kruskall-Wallis) were performed to investigate whether there were any statistically significant differences in WHOQOL-BREF scores across variables. The findings of these tests are summarised below:

### Treatment type

The distribution of the physical, psychological, social and environmental domain scores were the same across treatment groups (physical p=0.480; psychological, p=0.663; social, p=0.899; environmental p=0.923).

#### Deprivation quartile

The distribution of the psychological and social domain scores was the same across deprivation quartiles (psychological, p=0.445; social p=0.122).

However, the distribution of physical and environmental domain scores were not the same across deprivation quartiles, with women from the most deprived group (Q4) scoring comparatively lower than those in the more affluent deprivation quartiles, indicating the presence of more pronounced physical health and environmental related problems in the more deprived group

(physical score=75.0; p=0.039; environmental score=65.6; p=0.001 respectively).

When the four IMD quartiles were amalgamated and dichotomised into two 'affluent' and 'deprived' groups, the distribution of scores differed across the physical, social and environmental domains (physical, p=0.026; social, p=0.0026; environmental, p=<0.001), with the deprived group scoring comparatively lower in these three domains, indicating more pronounced problems in these areas than their more affluent counterparts. The distribution of psychological domain scores was the same across both deprived and affluent groups (psychological, p=0.151).

#### Age group

The distribution of the psychological, social and environmental domain scores was the same across age groups (psychological, p=0.142; social, p=0.408, environmental, p=0.074). However, the distribution of physical domain scores was not the same across all age groups, with women in the 50+ group scoring comparatively lower than those in other groups, indicating the presence of more pronounced physical health related problems amongst these respondents (physical, p=0.031).

These results would be expected as social, physical and environmental factors may all be influenced by age and level of deprivation. The lack of difference in the distribution of psychological scores across all variables is supported by the results of the HADS measure where no differences were

found between groups on the basis of treatment type or deprivation quartile, except when the scale scores were amalgamated into larger groups. When HADS depression scores were dichotomised into 'normal' and 'mild and above' some differences were shown in terms of age.

#### 7.9.3 WHOQOL-BREF mean scores for all domains

This section presents the analyses undertaken of the comparison of mean scores for each of the four WHOQOL-BREF domains using ANOVA one-way and post-hoc analyses (using Tukey's HSD test) for each of the groups of interest. Tables 7.59 and 7.60 summarise the WHOQOL-BREF mean scores for each domain, categorised by treatment type, and present the findings of ANOVA tests undertaken on these data.

Table 7.59 WHOQOL - BREF mean scores for responses categorised by treatment type

Treatment Type	Physical domain	Psychological domain	Social domain	Environmental domain
Colposcopy	73.81	64.34	67.84	67.98
Biopsy	73.92	61.50	69.10	66.34
Loop Excision	77.39	62.71	68.37	67.19
Biopsy/Loop excision	75.76	62.14	68.71	66.82

Table 7.60 Anova (one way) WHOQOL-BREF treatment type

	Sum of squares	df	Mean square	F	p value
Physical Total Between Groups Within Groups Total	711.653 79542.682 80254.335	2 263 265	355.826 302.444	1.177	0.310
Psychological Total Between Groups Within Groups Total	364.077 86425.372 86789.449	2 260 262	182.038 332.405	0.548	0.579

Social Total Between Groups Within Groups Total	70.305 109593.573 109663.879	2 266 268	35.153 412.006	0.085	0.918
Environmental Total Between Groups Within Groups Total	112.364 73687.730 73800.094	2 267 269	56.182 275.984	0.204	0.816

No significant differences were observed across any of the four WHOQOL-BREF domains with regard to treatment type.

These analyses were repeated for deprivation quartile (Tables 7.61 and 7.62).

Table 7.61 WHOQOL - BREF mean scores for responses categorised by deprivation quartile

Deprivation quartile	Physical domain	Psychological domain	Social domain	Environmental domain
Most Affluent (Q1)	79.97	64.51	72.92	71.87
Less Affluent (Q2)	76.68	65.65	72.83	74.55
Less Deprived (Q3)	76.37	63.83	68.51	67.33
Most Deprived (Q4)	72.18	61.56	65.49	63.52

Table 7.62 ANOVA (one way) WHOQOL-BREF deprivation quartile

	Sum of squares	df	Mean square	F	p value*
Physical Total	1832.251	3	610.750	2.082	0.103
Between Groups Within Groups Total	74799.614 76631.865	255 258	293.332	2.062	0.103
<b>Psychological Total</b>					
Between Groups	651.263	3	217.088	0.668	0.573
Within Groups Total	81598.465 82249.728	251 254	325.093		
Social Total					
Between Groups Within Groups Total	2445.332 99374.591 101819.923	3 257 260	815.111 386.672	2.108	0.100
<b>Environmental Total</b>					
Between Groups Within Groups Total	4714.714 65222.704 69937.418	3 258 261	1571.571 252.801	6.217	<0.001

Following ANOVA testing, a significant difference was observed in terms of the median score for the WHOQOL-BREF environmental domain in relation to deprivation quartile (F=6.217; p=<0.001). However, although two homogenous sub-sets of responses were identified in post-hoc analysis (Table 7.63); with women from the more deprived quartiles and those from more affluent quartiles tending to give similar responses on this domain, there were no statistically significant differences between these subsets.

Table 7.63 Tukey HSD for environmental domain total score

Deprivation quartile	n	1	2
Most deprived (Q4)	110	63.5227	
Less deprived (Q3)	75	67.3333	67.333
Most affluent (Q1)	28		71.8750
Less affluent (Q2)	49		74.5539
Significance		0.621	0.103

Table 7.64 presents the WHOQOL-BREF mean scores for responses broken down by deprivation quartile dichotomised between 'affluent' and 'deprived' groups, followed by Table 7.65 showing the results of the ANOVA tests for these responses.

Table 7.64 WHOQOL-BREF mean scores for responses categorised by deprivation when dichotomised between 'affluent' and 'deprived'

Deprivation	Physical domain	Psychological domain	Social domain	Environmental domain
Affluent	77.88	65.24	72.86	73.58
Deprived	73.87	62.48	66.76	65.07

Table 7.65 ANOVA (one way) WHOQOL-BREF 'affluent' and 'deprived'

	Sum of squares	df	Mean square	F	p value*
Physical Total					
Between Groups	871.732	1	871.732	2.957	0.87
Within Groups	75760.133	257	294.787		
Total	76631.865	258			
Psychological Total					
Between Groups	407.719	1	407.719	1.260	0.263
Within Groups	81842.008	253	323.486		
Total	82249.728	254			
Social Total					
Between Groups	2038.678	1	2038.678	5.292	0.022
Within Groups	99781.246	259	385.256		
Total	101819.923	260			
Environmental Total					
Between Groups	3939.328	1	3939.328	15.519	<0.001
Within Groups	65998.090	260	253.839	10.010	<b>~0.001</b>
Total	69937.418	261	200.000		
*Ctatiatically significant	1	_	-4		

<sup>\*</sup>Statistically significant results are indicated in bold text

These results indicate that significant differences were observed between affluent and deprived groups in terms of the WHOQOL-BREF social and environmental domain median scores (F=5.292; p=0.022; F=15.519; p=<0.001 respectively). Post-hoc analysis to investigate homogeneous subsets of responses was not required as there were only two groups in the analysis.

Finally, Table 7.66 shows the results of the mean scores for responses broken down by respondent age group, followed by Table 7.67 which presents the ANOVA analysis undertaken for this group.

Table 7.66 WHOQOL-BREF mean scores for responses categorised by age group

Age Group	Physical domain	Psychological domain	Social domain	Environmental domain
19-29	77.21	60.77	69.23	63.55
30-39	77.24	66.53	70.61	70.40
40-49	72.80	62.25	66.42	68.02
50+	65.82	60.12	62.80	65.96

Table 7.67 ANOVA (one way) WHOQOL-BREF age group

	Sum of squares	df	Mean square	F	p value
Physical Total Between Groups Within Groups Total	3534.725 76719.610 80254.335	3 262 265	1178.242 292.823	4.024	0.008
Psychological Total Between Groups Within Groups Total	1785.616 85003.832 86789.449	3 259 262	595.205 328.200	1.814	0.145
Social Total Between Groups Within Groups Total	1663.527 108000.351 109663.879	3 265 268	554.509 407.548	1.361	0.255
Environmental Total Between Groups Within Groups Total	2100.497 71699.597 73800.094	3 266 269	700.166 269.547	2.598	0.053

The ANOVA tests indicated a statistically significant difference in the mean score for the WHOQOL-BREF physical domain in terms of age group (F= 4.024; p=0.008). Post hoc testing was undertaken to investigate whether there were statistically significant homogeneous subsets of responses within the physical domain (Table 7.68). This table shows that although two homogeneous subsets were identified, with the 19 to 29 and 50+ age groups responding in a similar fashion, and the 19 to 29, 30 to 39 and 40 to 49 year age groups also being similar to each other, there were no statistically significant differences between these groups.

Table 7.68 Tukey HSD for physical domain total score

Deprivation quartile	n	1	2
		05.0400	
50+	28	65.8163	
19 to 29	65	72.8022	72.8022
40 to 49	79		77.2152
30-39	94		77.2416
Significance		0.150	0.535

### 7.10 Summary of findings - Q2

This Chapter has reported the findings from questionnaire two (Q2). It described the demographic characteristics of the population responding to Q2 and reported the proportion of responses to each question relating to demographic details, lifestyle, health status, partner status, gynaecological and sexual issues. Analysis of the influence of treatment type upon all responses was also presented.

The proportion of responses to the validated measures relating to FSD, HADS anxiety, HADS depression and WHOQOL-BREF domains were presented. The predictors of each measure were investigated separately. The results from the findings for the presence or absence of FSD were reported. Presence of FSD was explored in terms of the three main predictors of interest - treatment type, deprivation and age. Bivariate analysis of the presence of FSD was undertaken for all potential predictors. A logistic regression was performed to ascertain the significant predictors of the presence or absence of FSD. This process was undertaken for HADS anxiety and HADS depression dichotomising responses into 'normal' and 'mild and above'. Comparison of means was undertaken for the results from WHOQOL-BREF (physical, psychological, social and environmental domains).

### Characteristics of responders

The largest proportion of responders were from the Women's hospital (around 60%) and the lowest proportion were from Heartlands hospital (just under

5%). In terms of treatment, a greater proportion of women had undergone colposcopy (n=119; 42.7%) and the lowest proportion was found in the biopsy group (n=76; 27.2%). The most deprived quartile (Q4) had the highest number of responders (n=114; 40.9%) and the lowest proportion was observed in the most affluent quartile (Q1) (n=28; 10.0%). The age groups of responders were fairly evenly spread between the 19 to 29, 30 to 39 and 40 to 49 groups, although women in the 50+ group only accounted for around 10% of the sample.

Associations between treatment type and other variables

All variables were explored against treatment type to investigate associations between treatment type undergone and all variables of interest. In terms of demographic data, significant differences were observed in terms of deprivation quartile with higher than expected responders from the colposcopy group in the most deprived and less deprived quartiles. Higher than expected numbers of responders from the biopsy group were observed in the most affluent and less affluent quartiles, and higher than expected proportions of respondents from the most affluent and most deprived group were observed in the loop excision group (p=0.0324). No significant differences were observed in terms of ethnicity and level of education and treatment type.

In terms of variables relating to lifestyle factors, no significant differences were observed in terms of smoking status, alcohol use, or problems with drugs or alcohol.

In terms of the variables relating to partner and sexual status, no significant differences were observed in terms of partnership status when comparing between the three groups. When the colposcopy group was compared with the biopsy and loop excision combined, a significant difference was observed with larger than anticipated numbers in the biopsy and loop excision group having a partner (p=0.0298). A significantly higher proportion of women reported not being currently sexually active in the loop excision group (p=0.0379). Similarly, significantly higher than anticipated numbers of women from the loop excision group were not sexually active prior to colposcopy (p=0.0135).

No significant differences were observed in terms of treatment type and having children; having a miscarriage, premature birth or still birth; gynaecological problems or history of STIs. In terms of long term health problems, significant differences were observed, with greater proportions of women in the biopsy group reporting long term health problems when compared with colposcopy or loop excision (p=<0.001). No significant differences were observed in terms of treatment type and number of visits to the GP in the last 12 months. Presented below are the results from all analyses for each of the validated measures utilised in questionnaire 2.

### FSD presence/absence

Analysis of the associations between the variables studied and presence of FSD found that there were no significant differences between the type of

treatment undergone and the presence/absence of FSD. There were also no significant differences observed in terms of presence/absence of FSD and levels of deprivation or age. Following multivariate analysis of the presence or absence of FSD, no significant results were observed after the three outcomes of interest were added into the model.

HADS anxiety 'normal' and 'mild or above' and HADS anxiety total score

No differences were observed in terms of associations between treatment
type or age group and whether respondents scored 'normal' or 'mild and
above' on the HADS anxiety scale. However, a significant association was
observed between deprivation quartile and scoring 'normal' or 'mild or above'
on this scale (p=<0.0001) with higher than anticipated numbers of
respondents scoring 'mild or above' in the more affluent groups (Q1 and Q2).
No significant results were observed following multivariate analysis of the
potential predictors of scoring 'normal' or 'mild and above' on the anxiety
scale

HADS depression 'normal' and 'mild or above' and HADS depression total score

No differences were observed in terms of treatment type or deprivation quartile and scoring 'normal' or 'mild and above' on the HADS depression scale. However, a significant difference was noted between age and whether women scored 'normal' or 'mild or above' on the HADS depression scale.

Older women were significantly more likely to score 'mild or above' on this

measure, suggesting that older respondents were more likely to experience depressive problems (p=0.0383).

These finding was replicated following multivariate analysis with older women significantly more likely to score 'mild or above' on the scale compared with younger women in the cohort. However the model R<sup>2</sup> was low.

WHOQOL-BREF physical/psychological/social/environmental domains

There were no significant differences observed in terms of the distribution of scores across the four WHOQOL-BREF domains and treatment type.

However, women in the most deprived quartiles had lower scores on the WHOQOL-BREF physical and environmental domains suggesting that deprivation levels impact negatively upon both these factors. In terms of age, on the WHOQOL-BREF physical domain, older women had lower scores indicating that increasing age is negatively correlated with physical health and well-being.

Following comparison of means tests (ANOVA), no significant differences were observed for any of the four WHOQOL-BREF domains on the basis of treatment type. In terms of deprivation, a significant difference was observed between mean scores on the environmental domain. However, following post hoc analysis, no significant differences were observed between the two homogenous sub-sets. Similarly, significant differences were observed between the mean score on the physical domain and age group. Again

following post hoc analysis, there were no significant differences observed between the two homogeneous groups.

## **CHAPTER 8: ANALYSIS - QUALITATIVE DATA**

# 8.1 Introduction

Qualitative data are most commonly gathered via face to face interviews with participants, having the advantage of being able to elicit in-depth data on participants views and experiences. As the opportunity to interview participants about their experiences was outside the scope of the study, questionnaire one provided participants with an A4 sized space to note any specific comments relating to their colposcopy experience.

The advantages of using an open text option in a survey are well described. They can be used to corroborate responses to closed questions and there is evidence that they can increase response rates. There are inherent limitations in using this method, for example, there is no avenue for checking the status of the responses. In the context of a quantitative study, it is possible that those who choose to respond to an open question are not necessarily representative of the sample.

Despite these limitations, it was deemed important that participants were given the opportunity to elaborate and add context to issues raised in the questionnaire.

The aim of adding this qualitative aspect to questionnaire one was to present the breadth of experience and opinion to complement the findings from the quantitative data.

#### 8.2 Methods

Participant responses were analysed using a conventional content analysis approach which essentially assigns codes to the data, enabling further categorisation and development of broader themes as they emerge. This approach is often referred to as the constant comparative method. This approach is widely utilised in qualitative data analysis, as it enables the researcher to fully immerse themselves in the data.

The full text was copied verbatim from each of the completed sections to facilitate familiarity with the scripts and to aid thematic analysis. Reading through the scripts enabled greater immersion in the data and codes were applied manually to the scripts and were refined following discussions with study supervisors. The over arching themes were established and quotations were chosen that best represented the themes. The seven main themes are described in the results section using illustrative quotations and the discussion brings together the main findings in the light of the wider literature.

#### 8.3 Results

Of the 560 women who completed Q1, 198 completed the open text section - a response rate of 35%. Table 8.1 shows the demographic details, treatment type and where attended for treatment for responders and non-responders.

The differences between responders/non-responders almost reached

significance in the treatment group ( $X^2$ =5.9; p=0.0523), with a higher than expected number of responders in the loop excision group and lower than expected number of responders in the colposcopy and biopsy groups. Although not statistically significant, there were higher than anticipated number of responders in the first three deprivation quartiles (most affluent, less affluent, less deprived) than in the most deprived quartile (Q4) ( $X^2$ =7.2; p=0.065).

Table 8.1 Characteristic of responders/non-responders to open text

Characteristic	Responders (%)	Non- responders	Significance
Colposcopy unit Women's City Solihull Heartlands Good Hope	113 (57.1) 26 (13.1) 36 (18.2) 7 (3.5) 16 (8.1)	215 (59.4) 48 (13.3) 51 (14.1) 12 (3.3) 36 (9.9)	X <sup>2</sup> =2; p=0.738
<b>Age group</b> 19-29 30-39 40-49 50+	46 (23.2) 68 (34.3) 55 (27.8) 29 (14.6)	76 (21.0) 152 (42.0) 87 (24.0) 47 (13.0)	X <sup>2</sup> =3.17; p=0.36
Deprivation quartile * Most Affluent (Q1) Less Affluent (Q2) Less Deprived (Q3) Most Deprived (Q4)	14 (7.1) 48 (24.5) 68 (34.7) 64 (32.7)	20 (5.5) 76 (21.0) 101 (27.9) 159 (43.9)	X <sup>2</sup> =7.2; p=0.006
Treatment type Colposcopy only Biopsy Loop Excision	79 (39.9) 51 (25.8) 68 (34.3)	172 (47.5) 100 (27.6) 90 (24.9)	X <sup>2</sup> =5.9; p=0.052

<sup>\*</sup> IMD derived from 2007 Index of Multiple Deprivation

The seven broad themes identified and the range of codes applied across the data are shown in Table 8.2.

**Table 8.2 Themes and codes** 

Themes	Codes
Fear	Fear of cancer Fear about future fertility Fear about recurrence Fear of effect upon sex life Procedure allayed fears Fear of looking stupid
Physical effects	Pain - at time of the procedure and post procedure. Bleeding Post operative effects Tiredness Soreness Stenosis Effect upon menstrual cycle Physical effects not attributable to procedure
Psychological effects	Fearfulness Low mood Depression Worry about the results Stress Embarrassment Trauma Feeling sick and exposed Feeling 'out of control' of own body Stigmatised Seeing procedure on monitor Insomnia
Sex life and relationships	Fear that won't be able to have sex again Partner not understanding Partner very understanding Reduced sexual desire/interest No effect upon desire/interest Pain during intercourse Feeling unattractive Loss of woman-hood
Experiences with health professionals	Fear of looking stupid Positive experiences with staff - understanding, caring, good bedside manner, short waiting time to get results Negative experiences - Inexperienced staff, poor bedside manner, seeing someone different at each appointment, need for counselling

Knowledge deficit

Needing more information

Being worried about asking for more information

Positive experiences

Procedure allayed fears Colposcopy as a 'life saver'

Reassurance

Seeing procedure on monitor Partner understanding

There is a certain degree of linkage between themes - fear and psychological outcomes; physical side effects and sexuality; sexuality and psychological effects. Although themes are not distinct, they are presented separately.

Fear is a psychological reaction and one of the 'fears' identified by respondents was the possibility of having cervical cancer, and linked to this, the fear that abnormalities may recur and lead to further investigation. Due to the prominence of 'fear' as a theme in the data, it has been discussed as a standalone theme, despite its psychological basis. 'Fear' of cancer was alluded to on a number of occasions - not merely the fear in relation to the possible outcome of the treatment - 'do I have cancer?', and 'will I get cancer?', but also fear of the procedure itself. Fear of the procedure, rather than the procedure itself was on occasions the more prominent source of anxiety.

The spectre of cervical cancer has become more prominent on the public radar in the last three years, partly due to the relatively recent and high profile death from cervical cancer of a young celebrity - Jade Goody. Furthermore, the 'pressure' put upon women to attend for regular cervical screening, it could be argued, may elevate disproportionately the worries that women have

about getting cervical cancer. There are national screening targets for cervical screening targets and the QOF arrangements in place reward general practitioners for screening eligible patients.<sup>157</sup>

The fear and preoccupation with the recurrence of abnormalities or cells changes was mentioned by a number of participants. One woman stated (110005) that due to her fears of cancer, she felt she needed reassurance that any infections had cleared. The colposcopy would be seen to represent on the one hand the 'spectre' of cancer, whilst also being the very procedure that could also help to allay or dispel any fears:

'I have become worried and anxious about getting cancer, I worry that one day I will develop cancer, not just cervical, but elsewhere... I understand that some procedures have to be done for prevention and this is a good thing.' (Respondent 210339)

This sentiment was echoed by another respondent who stated:

'You worry in case you get cancer of the cervix so I think it is a great idea having check ups' (Respondent 320089)

One respondent seemed to have a more fatalistic approach, worrying that rereferrals and regular follow-ups may eventually lead to a diagnosis of cancer:

'It is quite stressful to know that someday, I may develop cervical cancer'. There is a sense of the inevitability that once any abnormalities are found then it is just a 'matter of time'. (Respondent 110055)

'I felt shocked that there could potentially be something life threatening when I felt so well. It was constantly on my mind and I kept asking myself - what if?. It made me re-evaluate relationships and life generally despite being told on the day that it was unlikely to be anything sinister.' (Respondent 110677)

The sense of feeling 'well' whilst being 'ill' is a theme that Hounsgaard et al<sup>98</sup> identified in the qualitative study discussed in chapter three. The notion of 'body betrayal' would seem to be a particular characteristic for patients diagnosed with cervical cancer, which to a large extent is asymptomatic in its early stages:

'I feel that the more times you attend the colposcopy clinic the greater the effect of the issues mentioned. On my first visit, although a little nervous about the procedure it did not affect my emotional well being or sexual health. However each time I attend I seem to get more concerned and nervous for longer periods of time. I spent over a week in the lead up to my most recent appt becoming very stressed, anxious and nervous about the results and therefore disinterested in sex because I worry about the result. After the appointment, whilst waiting for results I am also same. As the more prolonged the period of monitoring is the more you convince yourself that the term 'precancerous cells' will turn into 'cancerous cell'. (Respondent 110740)

This respondent's concerns seem to reflect those found more widely in the literature - the sense that it is the process of waiting for results rather than the procedure itself that can cause distress. Some respondents also explained that they had worries and fears about how the procedure would affect their current or future fertility and obstetric health. This is particularly prescient in light of the fact that women under the age of 35 are the group most likely to get cancer of the cervix and these women may be more likely to be considering having children. Respondent 110419 who was pregnant at the time of completing the survey reported that she was worried about the effect

of the loop excision upon her cervical health and the effect it may have upon the pregnancy. She stated:

'I think all women who have the procedure worry about the effect on their ability to carry a pregnancy to term.' (Respondent 110419)

Another respondent (330035) said that as she was getting ready to start a family she was worried about the long term effects of the colposcopy upon her ability to conceive and carry a child. Conception worries were mentioned again (respondent 210027) as the respondent felt that women's health usually relates to older women, but felt that younger women needed support as well especially in terms of any potential side-effects that the treatment may have had. Conceptions of self-identity and femininity will be discussed later in this chapter but it would seem that concerns about fertility are inextricably linked to the idea of woman-hood and perceptions that an inability to conceive is somehow a deficit of femininity. One respondent stated:

'I have been advised that I cannot conceive naturally, so as a sexual women I feel redundant and useless.' (Respondent 110376)

latrogenic effects - physical and psychological

Some women's responses indicated the breadth of physical and emotional experience of undergoing a colposcopy, with many finding it an extremely uncomfortable, painful and distressing ordeal. One respondent had experienced heavy bleeding and pain following the procedure and was later diagnosed with a post-operative infection, meaning she had to take time off work:

'it seems unfair that a small procedure can cause such an infection.' (Respondent 110137)

'A colposcopy is very embarrassing, uncomfortable and it stings. It was very frightening at the time.' (Respondent 110168)

One respondent described the 'stress and nerves' associated with colposcopy and cervical screening tests. Both made her feel 'sick and exposed' and she found the experience mentally traumatic. She described feeling 'out of control' of her own body.' (Respondent 110172)

One respondent felt she would feel more comfortable if she could have medication, or even be 'put out', so she was unaware of what was going on during treatment. (110339).

For some women, changes in menstruation and associated pain had had a negative impact upon their sex life:

'Since having a colposcopy, intercourse has been much worse. I have pain in the stomach three to four times per month and suffer with sleeplessness and menstrual pain.' (Respondent 110449)

'The blood loss was quite thick and brown and lasted a few weeks. I felt very put off from having intercourse even after the bleeding had stopped.' (Respondent 330110)

Prolonged menstruation was also problematic for one respondent:

'My periods have definitely changed since the procedure - they are longer. I 'show' for a few days before the usual heavy couple of days then the period lasts for nine rather than 5 days.' (Respondent 330131)

It seemed that for some women the opportunity to observe the procedure was in itself, a source of trauma:

'I found the initial exploration of the cervix rather traumatic as I didn't know what to expect and wasn't prepared for what I saw on the monitor as it looked horribly diseased. It kept haunting me for weeks afterwards.' (Respondent 110465)

Respondent 110508 found that although the doctor was keen to show her what was happening on the screen, she didn't want to look.

Another respondent describes the fact that 'there was a me before colposcopy and a me after colposcopy.' (310002) She noted that following colposcopy she suffered heavy and painful periods and felt unwell during menstruation, and this was very unlike her. She clearly experienced some radical physiological changes that she felt could only be attributed to the colposcopy.

However, some respondents did not find the experience too onerous and welcomed the chance to observe how the procedure went:

'I was anxious about the initial test but was fascinated by the photos on the screen of my cervix - which the doctor talked me through - I'm not squeamish at all! The whole process was a little worse than a smear test, but the staff were very reassuring and comforting.' (Respondent 330285)

Effect upon sex life and relationships

As the questionnaire and patient information literature was explicit about the fact that this study was designed to investigate any potential sexual

dysfunction, it is maybe unsurprising that effects upon participants' sex life feature prominently within the open-text responses.

Several respondents discussed the fear of resuming sexual activity following the procedure; concerns that partners would not understand, or feel somehow different towards their partners; physiological sexual problems - painful intercourse, problems lubricating; loss of desire and interest in sex were all part of the narrative for a number of the participants. There was a sense for some women that they felt 'less womanly' either because of the nature of the procedure or because they felt that the procedure has led to reduced sexual desire.

Respondent 110005 stated that she felt tentative about resuming her sex life with her husband despite having a supportive husband. One respondent (110134) alluded to the fact that the effect of the procedure upon her sex life had been a cause of anguish. She had felt 'unable to perform' for the last two years. This had left her tearful, but had not affected her relationship with her 'wonderful husband', it had led to both her and her husband feeling 'anxious and depressed' about their sex life. She mentioned that she felt confused about the situation as she was still attracted to her husband and this had led her to feel 'bad about myself.' Respondent 110168 reported that although her sexual desire was undiminished, her lack of confidence had led to her avoid sexual situations.

Two respondents felt unable to answer questions related to sex due to their religious beliefs or said that they felt they were too personal. This was to be expected, given the intimate nature of some of the questions asked.

A number of respondents raised the particular issue of the effect of the procedure upon their sexual life. It is plausible that this was prompted by the nature of the questions in questionnaire one (alluding to sexual function) and that without it, women may not have made reference to their sexual life. However, it was clear that for some women, given the nature of their descriptions, the impact upon their sex life was acute:

The colposcopy caused 'fears and anxieties before during and after sex' (Respondent 110168)

'I felt unable to have sex despite wanting to' (Respondent 110172)

This response demonstrates the apparent disjuncture between the presence of sexual desire, but feelings that the colposcopy procedure had impeded the physical ability to engage in sexual activity:

'Before I went for a colposcopy, I was worried for myself and partner as I didn't know what to expect from the procedure or result. This affected our sex life more before than after the colposcopy' (Respondent 110499)

Respondent 110662 was referred for colposcopy at a young age and the doctor's expression of surprise at seeing a woman 20 years of age magnified her worries. She felt there was something wrong given her young age and although she had a boyfriend of three years who was supportive, she couldn't

help worrying about the impact upon their sex life. She felt 'unattractive' and 'unwomanly.'

Similarly, one respondent attributed her 'sexual hang-ups' and lack of sexual interest to the sense of guilt she felt about starting to have sex from a relatively young age:

'I feel that this has somehow contributed to my abnormal cells.' (Respondent 330072)

Although there is evidence that women who have their first experience of intercourse at a young age or who have had multiple partners are at increased risk of contracting HPV,<sup>158</sup> the sense that getting cervical cancer is a punishment for promiscuity had a major impact upon respondent 330072. Certainly, early health promotion materials from the 1960's used to encourage attendance for cervical screening did have a moralistic and potentially stigmatising tone that may have attributed to feelings of guilt for women diagnosed with cervical abnormalities.

'After when I was all healed I didn't feel like sex for month. When I did, it hurt a lot. I still don't have much of a sex drive anymore and it still hurts during foreplay and sometimes during sex.' (Respondent 330301)

'I have no desire for a partner because I no longer feel very sexual. I would have considered myself highly sexed before. It's depressed me and left me feeling low.' (Respondent 110738)

'Since having last colposcopy, I have neither had sex or want sex. I do not know why this problem of not wanting or having sex has come about. I do know that I find having sex a very painful ordeal. The same as when I have a colposcopy I do find it very painful. Every time I have one this is one of the reasons I do not attend my appointments and deep down I know that I should because it is for my own good. If I could have the choice to have everything taken away, I would. Then perhaps I would feel better about having sex. Perhaps it worries me in

case having sex could cause me harm. I do not really know.' (Respondent 111026)

These excepts reflect the complex nature of female sexuality and how different women with different histories and experiences can all tell a powerful story - Feelings of guilt, worries about attractiveness, despair at the loss of libido and concerns about how a partner may react to the situation. There is also a sense of bewilderment voiced in the last excerpt as the respondent is unable to understand her response to the colposcopy and it's effect upon her.

A number of respondents believed that there were other factors that explained their lack of sexual interest, emotional well-being or physical symptoms - sex drive diminishing with age and associated physical health problems (undergoing hysterectomy, being on HRT, being menopausal, weight gain); relationship breakdown; bereavement or becoming a parent.

'I do not feel the colposcopy has anything to do with my current sex life (or lack of). It is more to do with the fact that I am post menopausal and suffer with vaginal dryness... Anyway at 65 years of age I'm not that interested.' (Respondent 110849)

'I have had abnormal smears for many years on and off and do not relate this to sexual experiences (not consciously). I think the dissatisfaction with my sex life is mostly related to lack of emotional satisfaction in my relationship.' (Respondent 330311)

These quotations capture the sense that female sexuality has emotional as well as physical attributes. Not feeling settled or content with a partner is just as likely to influence the perceived quality of sexual life as is physiological

'functionality.' The Natsal<sup>140</sup> study found that the most common predictor of FSD was partner dissatisfaction and these excerpts give a sense of this.

Conversely, there are also respondents who felt that the procedure had no effect upon their sex life, or others who felt that sex isn't really an issue as they either don't have a partner, or they have a low libido pre-dating the procedure. A number of respondents pointed out that there were other explanations as to why their sexual desire had diminished - going through the menopause; being on HRT; having recently had children or being currently pregnant; or just being too busy. One respondent offers an explanation that seems to crystallise some of these points:

'I think my lack of interest in sex is due to being tired due to having two boys and working full-time. I don't think it is do with the procedure. I don't have an issue with sex... just lost interest. I do enjoy it when we have sex. My relationship with my husband is very strong and we joke about sex a lot - anyway, how often should you have sex to be normal? Sometimes I feel all these emotions in this survey, but they are short lived and usually depend on the week I've had - there are a lot of pressures upon women these days!' (Respondent 310180)

A number of respondents indicated that the procedure had had minimal or no effect upon their sex life:

'I do not feel the colposcopy has anything to do with my current sex life (or lack of) - more to do with the fact I am post menopausal and suffer from vaginal dryness.' (Respondent 110849)

A number noted that abstinence for a period of 6-8 weeks had been advised by the health professional and following this period they had resumed normal sexual activity without any problems.

One respondent was nothing but positive about the experience as it meant that her quality of (sex) life improved following the procedure:

'I have a positive attitude to any of the medical treatments I have received and to sex in general. The colposcopy helped to clear up a long standing problem, which made me more confident.' (Respondent 330365)

One respondent also felt the colposcopy had a minimal impact upon her sex life:

'I was advised to wait six weeks before sex. I tried again after five and it did bleed, but thereafter, everything was fine.' (Respondent 110463)

A number of respondents made the point that their responses to the questions had been influenced by a number of factors unrelated to the colposcopy, or at least they did not feel they could be directly related to the colposcopy itself.

There is a sense that it is difficult to disentangle the possible effects of undergoing a colposcopy from the other physical/psychological/social/sexual/environmental factors that influence health status (self-perceived or otherwise). This difficulty may be compounded by the fact that women contacted to participate would have undergone colposcopy some time ago and therefore, attributing any possible adverse effects to the procedure could be misleading.

Given the nature of the intimate questions being asked, the level of disclosure and openness of many of the participants who completed the open text section was somewhat surprising. It could plausibly be argued that the responders to the survey were the kind of women who felt more comfortable in revealing aspects of their sexual, psychological and physical health. As there were more non-responders than responders to both surveys, it is also plausible that the nature of the questions asked dissuaded women from responding to the questionnaire, although the level of non-responses could also be explained by other factors - disinterest in the subject matter, lack of time or literacy problems.

Responder bias results for this part of the study indicated that a higher proportion of women who underwent loop excision (the most invasive treatment group) responded to the open text invitation (p=0.0523). It is possible that as loop excision is the more invasive treatment, women experienced more pronounced effects and felt more inclined to share their experiences. Although not statistically significant, there was also a lower than expected number of responder in the most deprived quartile.

Experiences with health professionals and patient knowledge deficit

There was a breadth of opinion in terms of how women felt they were treated by medical staff, ranging from total satisfaction to anger about the way they had been treated. Lack of information provision was also raised as a factor that contributed to the overall quality of the experience.

A number of respondents praised the staff at the colposcopy units in terms of how they felt they were treated: 'the staff were sensitive and treated me with respect' (Respondent 110055)

'Staff were warm and positive.' (Respondent 110477)

'Staff were very good and used lay language. This was very helpful as it allayed my fears' (Respondent 110168)

One respondent appeared aggrieved as she felt her GP had referred her inappropriately, as no abnormalities were found:

'If GPs paid more attention, it may lead to less unnecessary referrals for colposcopy.' (Respondent 110099)

Some women felt that their experience would have been improved had they had more information:

'the staff were friendly and professional although I feel that more reassurance and information would improve the experience.' (Respondent 110094)

'I did not receive enough information about the link between HPV and abnormalities, despite trying to broach the subject. My lack of knowledge led to increased worries about having an STI. It was an extremely concerning time.' (Respondent 110121)

'feelings of uncertainty and worry may have been eased with more information and statistics' (Respondent 110188)

Interestingly, these views are in contrast to the findings from Brooks et al<sup>91</sup>, who found an association between pre-colposcopy knowledge and increased anxiety at their first visit. The women who responded to this part of the study all felt that better information would have made the procedure less traumatic.

In this study, some women were dissatisfied with how they had been treated by staff, in terms of the lack of rapport with the doctors and for one woman, the lack of continuity in terms of who they were seen by at their visits:

'Some of the doctors are great, but others less so. It requires sensitivity. Even when the outcome is good, it always affects you emotionally due to how intrusive it is. I never relished seeing the screen.' (Respondent 210270)

One participant felt dissatisfied with her treatment at the colposcopy unit, describing it as 'very poor... both aftercare and support.' (Respondent 110191)

'I found it distressing as each time I was seen by a different person. You can't build up a trusting relationship if you don't see the same doctor or nurse.' (Respondent 110227)

'I felt it took too long to get the results of the treatment - there should be shorter waiting time.' (Respondent 110254)

'I was advised that there were no problems, but I had no explanation, even though I had initially been told I did have problems... no one explained the results.' (Respondent 110376)

One respondent stated that although staff were very supportive, lack of information made the visit particularly traumatic:

'I was totally unaware and unprepared when I turned up at the hospital. I had been given no information about what they were going to do or why they were doing it or how I might feel physically or emotionally afterwards. Although staff were lovely and even held my hand during the procedure and made me a cup of tea afterwards. I would have bought a friend if I had known as I had to drive home crying and shaking in pain. I was given a small leaflet to take home, but would have liked more information about what they did, why they did it and what might be the next step.' (Respondent 330350)

One respondent explained that she was unaware that HPV can lead to cell abnormalities -

'I feel colposcopy, abnormal smears and especially the HPV virus are not very well understood in my age group (18-25 and above). I have made my friends aware about it because of my experiences.' (Respondent 110985)

Positive effects of undergoing colposcopy

As has been shown earlier in this section, a number of respondents reported various difficulties and problems following colposcopy, but a number expressed ambivalence or seem pleased that they had undergone the procedure which they attribute to improving their health status:

'Colposcopy has had no impact upon my life whatsoever. It was something that had to be done to protect my health' (Respondent 330262)

Respondent 110503 found the experience of colposcopy on the whole to be positive as it 'put paid to any greater anxieties' and the care was 'timely and efficient.' Another respondent was quite strident in her view:

'colposcopy doesn't have any medium or long term effect on emotional or physical health.' (Respondent 110411)

'The test saved my health, because my cervical screening showed abnormal cells and as a result, I followed the right treatment... It can save lives.' (Respondent 110695)

At the other extreme end of this spectrum, one respondent stated:

'I feel no different than I did before the colposcopy. As far as I know, my health is fine and I am able to do all the things I used to do before. I have started going the gym.' (Respondent 110779)

Such sentiments were rarely found in the participant responses, but it is entirely plausible that those women who chose not to leave any further comments did so because they felt they had had no problems relating to the procedure.

Effect on participants of receiving the questionnaire

One respondent apologised for the late return of her questionnaire, but explained that she had 'wanted to forget all about the procedure' (330006). At the inception of the study, it had been considered that this could have arisen due to the fact that women were being contacted some time after colposcopy. There is of course a potential that reminding someone of something that occurred in the past may cause distress, as we identified in our ethical approval application, although this is the only returned questionnaire that raised this issue.

Another respondent indicated that although she had experienced sexual problems following the procedure, she had never considered the colposcopy to be the reason for this. Although the patient information sheet is clear that we are unsure of the potential adverse effects of undergoing colposcopy, the questions asked do relate to sexual well-being and this respondent had, not unsurprisingly, attributed her problems to the colposcopy. That said, she appeared to find this reassuring:

'I am happy to know why this is...' (Respondent 110767)

One respondent appeared quite affronted by the nature of the questions being asked:

'It seems odd to me that Cancer Research UK is funding what seems to be a sex survey and I hope your findings justify the cost of all this. I just wish your brains were being put to better use finding cures for cancer. Oh, and in passing, why do you assume all women have sex lives anyway.' (110909)

#### 8.4 Discussion

The range of responses presented provided a diverse picture of how women undergoing colposcopy experience the procedure. The data generated provided an important perspective that will be considered in the light of the qualitative literature and the results from the quantitative data collection from this study.

The quantitative findings from this study appeared to indicate that the treatment type undergone had little effect upon any adverse outcome experienced. Similarly, age and deprivation provided little to support the hypothesis that the age of women undergoing treatment or the level of deprivation experienced will influence the extent of any adverse outcome experienced.

However, the aim of the qualitative data collection was to enable a more nuanced interpretation of women's experience of the procedure. It was not concerned with how many women had good or bad experiences, rather the nature of these experiences and what kind of impact these had had upon their

emotional and physical health, relationship, social interactions and environment.

The main broad themes arising from the analysis were feelings of fear, effects upon identity and femininity, partner relationships and sexual life, psychological and physical effects of the procedure, influence on their experience of how they felt treated by staff, influence of knowledge deficit and positive outcomes following the procedure. The influence of particular coping styles of the participants will also be considered as it adds a further dimension to the discussion.

For women reporting a negative experience of undergoing colposcopy, the feelings of fear were pervasive. Beresford et al<sup>59</sup> identified fear as a major emotion facing women having undergone colposcopy and the four main areas of concern were fear of cancer<sup>60</sup>, fear of reproductive loss and sexual function, fear of the procedure itself and fear of being betrayed by ones own body. As we have seen above, our findings here support the notion that fertility, sexuality, identity and threat to life are experienced by some women undergoing colposcopy. Hounsgaard et al<sup>98</sup> also raised the issue of 'body betrayal' for some women. The experience of feeling 'well' and relatively healthy whilst being diagnosed with a potentially life threatening disease can lead women to feel an unease and lead them to question the integrity of their own relationship with their body.

Furthermore, the authors raised the issue of the disjuncture between a patient or 'lay' interpretation of disease and that of the medical professional. The nature of the progression of CIN as well as the fact that such abnormalities can recede and cause no further harm may be a concept that patients find difficult to interpret in the context of their own disease status. For many women, as our data suggest, being diagnosed with abnormalities sets them upon the seemingly inevitable road to cancer.

Juraskova et al<sup>103</sup> again provided data that demonstrates the 'pathway' experienced by women undergoing investigation and treatment. The fear of the unknown and the shock and anxiety that may accompany a diagnosis of an abnormality can to some degree be more distressing than the treatment itself. Their findings explore the reactions that women have after treatment as their fears are replaced with a sense of relief. Following treatment there is a sense of empowerment and a feeling of reassurance that they are no longer ill. The authors also allude to the sense of loss of trust in their bodies that some women felt, which are also apparent in Beresford et al and Hounsgaard's studies.

The role of health beliefs - attributions - locus of control

One aspect of health psychology - attribution theory<sup>159</sup> could go some way towards explaining the responses of participating women. This theory looks at the ways that individuals explain the causes of certain events (e.g. of

becoming ill; or recovering from an illness). It can also be applied to the way individuals explain behaviours, whether their own or of others.

Although attribution theory may be criticised for being too 'reductionist', compartmentalising people into specific 'types', it does offer a useful framework to understand participants' responses to treatment:

'there seemed to be some confusion about the choice of treatment, whereas I would rather be 'told' by someone who knows, or at least strongly advised. I think this may come under 'patient choice' however if we knew what needed to be done... we'd be doing it - or we'd be doctors! (330164)

This raised an interesting perspective on the perceived patient/professional role. 'Patient choice' is much lauded in the design and delivery of medical services and a priority for recent government intiatives. <sup>160,161</sup> Many patients may perceive the role of medical science to direct and treat them as they see fit, viewing doctors in a rather paternalistic role. <sup>162</sup> For this patient, relinquishing control over what should be the best treatment regimen was entirely appropriate, given that the doctor should know what is the 'best' course of action.

In contrast, one respondent described her treatment by medical staff as 'very professional' for the reason that they accepted her right to 'insist on no intervention' following the result of her second colposcopy. Her belief in 'the power of the body to heal itself' was clearly very important to her and she appreciated the fact that this was respected. From a locus of control perspective 163, it could be argued that the former respondent was demonstrating an 'external locus of control' and the latter an 'internal locus of

control'. An 'internal' locus of control would imply that a person feels that events that may occur in their life are primarily due to the personal choices they make, as opposed to outside influences.

As mentioned at the outset, it is important to be mindful of the psychological profile of the patient when considering the nature of their responses to colposcopy. No one woman will experience colposcopy in the same way that another does. It is the nature of being human to have a unique response to any event. It could be argued that events that threaten to undermine the notion of the self as a 'healthy' human being are likely to produce acute, existential doubts and lead to questioning many of the fundamental beliefs about the 'self.'

Chapter 9 will discuss of the findings from the systematic review and the quantitative and qualitative results of the study.

# **CHAPTER 9: DISCUSSION OF FINDINGS**

### 9.1 Main findings

This chapter will discuss the principal findings from the study as a whole.

Furthermore, the study limitations will be outlined, as will the implications for future services and future work.

The primary aim of this study was to determine whether undergoing colposcopy and treatment for CIN has any long term adverse psychological or sexual impacts.

The objectives of the study were as follows:

- To undertake a systematic review of the available evidence of the psycho-sexual consequences of colposcopy and treatment for CIN
- To investigate the long-term effects of colposcopy upon women's quality of life
- To establish whether there are any long-term effects of colposcopy upon sexual function in particular.
- To characterise adverse sexual function by level of colposcopic intervention.
- To determine the potential sociodemographic and/or clinical predictors
  of adverse outcomes following colposcopy (treatment type,
  socioeconomic status and age).

This study sought to stratify women undergoing colposcopy in terms of level of intervention. It was hypothesised that women undergoing more extensive

and invasive treatment (biopsy and loop excision) would be more likely to experience an excess risk of adverse outcomes when compared with women undergoing colposcopy only. None of the findings from the quantitative stage of this study support this hypothesis. There were no significant differences observed between women undergoing colposcopy, biopsy or loop excision for any of the outcome measures across both stages of the study (questionnaire 1 and questionnaire 2), aside from in terms of the response to the question (Q1) relating to experiencing pain during sex and problems with lubrication. Younger women were significantly more likely to report problems with painful sex, but less likely to report problems with lubrication.

There appears to be a relationship between age and physical and emotional well-being, with older responders to Q1 experiencing more pronounced problems in these areas than their younger counterparts. These findings are supported by data from Q2 that demonstrated that older women had more pronounced problems with depression, physical health, social problems and psychological problems and sexual problems.

One of the main outcomes of interest at the inception of the study was whether undergoing colposcopy would have an impact upon female sexual function. Although this study has established with some degree of confidence that level of treatment does not influence sexual outcomes, it would appear that women in this study cohort had higher levels of sexual dysfunction when compared with currently available data from the general population. As outlined previously, there is a paucity of data relating to female sexual

dysfunction in the UK population. It would have been useful if access to age and deprivation matched controls for this study had been possible, to increase the robustness of the study and its generalisability to the wider population. As described previously, this was not possible, and given the lack of robust normative data, caution is advised in drawing any firm conclusions about the levels of FSD found in the cohort recruited for this study. Normative data indicated that 15% of the general population experienced sexual dysfunction. In our cohort the figure is 55%, which would indicate a tripling of dysfunction. To put this in context, in this study, women were asked to report problems experienced in the previous four weeks. Mercer and colleagues, from whom the normative data cited were derived, asked participants to consider sexual problems experienced in the previous six months. Given the shorter time frame employed in the current study, it is plausible that participants reported short-term, transient problems. The figure of 15% for the general population is more likely to capture persistent sexual problems. As indicated previously, the higher figure in this cohort may be a product of responder bias, with those women with 'more problems' feeling more inclined to respond than those without problems, or with problems considered too minor to warrant reporting.

The study findings indicate that sexual dysfunction increases with age, but these findings were not statistically significant, so we cannot be certain that age can definitely be attributed to this finding. Moreover, as discussed in Chapter 4, caution is needed when trying to 'measure' such nebulous and multi-factorial human characteristics like sexuality, or indeed assigning a label

such as 'dysfunction' to such a cluster of psycho-social and physiological factors relating to sexuality.

Overall, it would appear that the factors influencing whether or not adverse outcomes are experienced can be attributed to factors other than undergoing colposcopy or colposcopically directed treatment. The possibility that colposcopy does have adverse consequences cannot be ruled out completely, but as the evidence from the systematic review demonstrates, many of the adverse outcomes experienced are relatively short-lived and transitory. The women in this cohort underwent colposcopy up to two years previously, so this may explain the fact that adverse outcomes did not seem to be directly linked to the procedure itself. However, as the nature of case identification meant that it was not possible to ascertain from patient data whether women have been subsequently recalled for colposcopy outside of the time period of interest (March 2008 - April 2009), this is a limitation to the findings.

Despite the equivocal findings from the systematic review regarding the psycho-sexual outcomes of undergoing colposcopy, there are a number of indications from the findings of this study that would seem to partly support this. As we have seen where adverse outcomes had been experienced, these were very unlikely to be directly associated with the type of procedure undergone. The psychological profile of a patient is likely to influence how they experience the procedure. The findings from the review indicate that

sexual and psychological problems following colposcopy or treatment for CIN are transient in nature.

This study found higher rates of FSD when compared with the Natsal data. However, as the FSFI asks women to rate any problems they have had in the last four weeks, this measure may pick up a range of transitory problems that do not persist in the long term. Furthermore, findings from the current study indicate that the 'best' predictor of experiencing FSD was whether a woman had gynaecological problems. It is plausible that the higher level of reported FSD compared with normative data can be explained by the presence of comorbid gynaecological problems rather than colposcopically directed treatment. This study was designed to follow women up after a relatively long period following colposcopy, and it is impossible to be able to attribute, with any certainty, that the colposcopy led to the outcomes observed. As discussed, in the context of the findings from Chapter 4, it is important to be mindful that there are inherent difficulties in trying to measure, or ascribe a label of 'dysfunction' to the complex, multi-faceted notion of human sexuality.

The qualitative findings from this study appear to be supported by the qualitative findings from the systematic review. Fear of cancer and fear of the procedure feature prominently, as do the worries associated with feeling well, whilst simultaneously, being 'ill.' In this study, some respondents attribute colposcopy directly to their subsequent sexual and relationship problems and feelings of loss of womanhood and femininity. Of course it is entirely plausible

that these women did experience prolonged adverse outcomes in terms of their sexual life following colposcopy. However, as with any investigation of the adverse outcomes of an invasive procedure, there will always be some women who experience problems to a greater extent than others. Although not generalisable, the qualitative methodology employed generated data that was able to provide an important narrative account of how undergoing a colposcopy can impact adversely upon women. Using a mixed method approach enabled the study to capture both the epidemiological data relating to the prevalence of adverse outcomes as well as the essence of individual experiences which epidemiology alone cannot provide.

## 9.2 Study limitations and strengths

#### Limitations

In the context of the study findings, this section will outline the limitations and strengths of the study.

#### Study power

The study was initially powered to detect a doubling of FSD from 15% to 30% (i.e. the difference between the prevalence of FSD assumed in the general population on the basis of NATSAL data, compared with the hypothesised prevalence of FSD in the study cohort who had undergone colposcopy). Despite mailing over and above the proposed numbers of potential participants required to detect a doubling of FSD, the response rate achieved in this study was lower than anticipated. In light of this, the study was only

powered to estimate a 2.6 fold risk of FSD after treatment for CIN. The lower than anticipated sample size meant that the study was not powered to detect small differences between the groups. Although the study did not find any differences on the basis of treatment type for any of the outcome measures assessed, it is plausible that there may be small differences between groups that this study was not powered to detect.

#### Questionnaire design

The findings from Q1 are limited by the fact that the measures used are adapted and therefore not validated for use with the particular population included in this study (i.e. women who had undergone colposcopy). Along with treatment type, only limited sociodemographic data for responders and non-responders were obtained (deprivation level and age) as potential predictors of problems with physical, emotional and sexual health, general health, problems with social activities and scores on the two satisfaction scales.

#### Use of questionnaire as data collection tool

The use of a questionnaire as the chosen methodology to answer the primary research question regarding adverse outcomes after colposcopy may have led to non-participation and therefore under-representation of people who are less well-educated or who do not read or write in English. There was a significant difference between the proportion of responders and non-responders on the basis of the colposcopy units from which patients were invited (X²=29.43; p=<0.0001), with a higher than expected number of non-responders from Good Hope, Heartlands, City and Solihull hospitals. Similar responder bias was found in the sample invited to participate in Q2. The level

of deprivation was found to be significantly associated with the likelihood of responding to Q1 ( $X^2$ =54.85; p=<0.0001) with higher than expected numbers of responders from the less affluent and less deprived groups (deprivation quartiles 2 and 3), and higher than expected numbers of non-responders in the most affluent and most deprived groups (quartiles 1 and 4).

Significant differences were observed in the proportion of women responding to Q2 in terms of age group, with higher than expected numbers of patients responding from the 19 to 29 and 40 to 49 groups ( $X^2=11.85$ ; p=0.0079). Lower than expected numbers of responses were received from women in the 30 to 39 and 50+ groups. Significant differences between responders and non-responders were also found in the proportion of responders according to treatment type ( $X^2=3.3$ ; p=0.0192) with proportionally larger numbers in the colposcopy group responding to Q2 and significantly lower than expected responses from individuals in the biopsy or loop excision groups.

Those who did take part, as noted above, were more likely to be better educated, and may have been more likely to take a particular interest in their own health and perceive greater value in participating in research projects in general. As no reimbursement for participation was available due to financial constraints, those who did participate would have largely done so for altruistic reasons.

More extensive data were gathered for participants responding to Q2. The decision was made that the initial questionnaire should be short, to encourage

those who invested time in completing Q1 to agree to participate in the second stage of the research, for which the survey was longer and collected data on a wider range of validated measures and other participant characteristics.

#### Piloting issues

Issues related to questionnaire design, and in particular, aspects of specific wording used in both questionnaires may have had an impact on response rates. It was expected that piloting of both questionnaires would have resulted in any inconsistencies or omissions being noted, allowing them to be rectified before questionnaires were sent to potential study participants. Unfortunately, the process of piloting did not identify all of these inconsistencies, which have become clear in hindsight. For example, it would have been useful if Q1 had included a question relating to women's sexual activity status (i.e. whether they were sexually active or not) given the inclusion of six questions related to specific aspects of sexual activity on this questionnaire. Unfortunately, despite piloting Q1 with colleagues and acquaintances, this omission was not noted by any of the individuals with whom Q1 was piloted. Although an explanation of what constituted 'sexual activity' was provided within Q2, it may have benefited participants if such an explanation was also included in Q1. Providing a wider definition of 'sexual activity' may have ensured that participants who described themselves as sexually active, although they were not, for example, engaged in intercourse, may have felt more able respond to these questions.

Furthermore, the question posed on questionnaire two relating to sexual activity prior to colposcopy omitted to define its terms of reference regarding the specific period of time before colposcopy that was of interest for the study. However, this question, along with a number of other health and demography-related questions were excluded from formal analysis, thus any misinterpretation of the meaning of these questions on the part of participants (and thus any inconsistencies in their responses) would not have had any negative impact on the robustness of analyses presented.

#### Lack of a control dataset

At inception, the study proposed to recruit age and deprivation matched controls, to establish prevalence estimates for FSD and quality of life outcomes. This was not possible in light of the logistical issues outlined in Chapter 4 (Section 4.3.3).

Chapter 5 (study methodology) outlines the problems encountered recruiting a practice whose patient list could provide study control participants. The practice approached felt that given other pressures, it would not be possible for practice staff to perform the thorough level of patient list checking perceived as necessary prior to mailing to ensure that questionnaires were not sent to women who had been the victim of sexual abuse. It is, of course, entirely plausible that in some cases, regardless of how thoroughly premailing screening checks were conducted, the practice would not have been aware that a specific patient may have been a victim of sexual abuse. Thus, having 'extra' checks in place would have been unlikely to have completely removed this potential problem.

The concern raised by this particular practice, in hindsight, may have been overcome had the patient information sheet contained a more explicit reference to the fact that the questionnaire contained questions of a sexual nature. It would have given women for whom such questions may have raised concern or worries the opportunity to discard the questionnaire.

However, it is important to be mindful of the fact that because someone has experienced sexual abuse in the past does not mean that they would necessarily been unhappy to receive a questionnaire containing questions of a sexual nature.

Having an age and deprivation matched control group would have enabled a more precise estimate of the prevalence of FSD in the case group. In the light of this, normative data were presented as a proxy for healthy control patients recruited from general practice. However, the limited range of normative data available for the validated measures utilised made interpretation of results in the wider context problematic. Consideration was given to accessing control patients via other means, such as recruiting control participants from the university student population. However, recruiting participants from this population would have made age-matching very difficult given the typical age profile of university students. It is unlikely that sufficient numbers of control participants could have been recruited via this method. Furthermore, the majority of university students live in a relatively small geographical area, so would not have provided the range of deprivation scores required for case-control deprivation matching. Interestingly, the residential postcodes (and therefore the assigned IMD quartile for each student) would not necessarily

have been representative of their 'true' socioecomonic status given the typical location of student accommodation in relatively 'deprived' areas.

#### Outcome measures

The decision to use the FSFI, HADS anxiety and depression scale and WHOQOL-BREF predated commencement of the PhD. The HADS anxiety and depression scale, despite being a well validated and relatively brief measure that is easily understood by research participants is not without limitations. The HADS measure assesses the current anxiety and depression levels of a respondent. As this study was designed to investigate the long-term impacts of colposcopy, it seems plausible that responses to the HADS questions primarily provide a measure of how the respondent felt at the time of receiving the questionnaire, which would have occurred at least 12 months after their procedure. This also assumes that participants had not undergone any further colposcopy related procedures subsequent to their 'index' procedure in the interim, which cannot be ruled out.

Zigmond and Snaith<sup>133</sup> (HADS) cite scores of 8-10 or above indicating mild depression, 11-15 for moderate cases and 16 and above for severe cases, although they recommend that using a threshold of 11 would include all *probable* cases and 8-10 all *possible* cases. This supports the notion that anxiety and depression should be regarded as 'dimensional rather than categorical constructs'.<sup>149</sup> Categorical tests use a 'cut off' score to indicate presence or absence of a problem, thus separating what is defined as 'normal' from was could be considered 'pathological'. This would suggest that

it is less efficacious to use HADS as a tool for 'diagnosing' anxiety and depression, rather than in demonstrating the extent or degree of an existing problem.

Furthermore, one of the limitations in terms of the analysis of the categorical data collected from Q2 where HADS anxiety and depression were dichotomised into 'normal' or 'mild and above' was that the 'mild and above' category encompassed a wide range of scores, many of them at the 'mild' end of the spectrum, thus it is rather blunt instrument to use. It can be argued that dichotomising the scores did not provide a nuanced picture of the mental health of the respondents.

Had the measures to be used in the doctoral research not been pre-specified as part of the study protocol and as a condition of PhD funding, the use of a measure that provided an overall picture of a participant's anxiety and depression that did not require them to complete it in terms of how they were feeling on the day of receiving the questionnaire may have provided a more robust assessment of their general mental health rather than a 'snap shot' of how they were feeling on that day. The use of the State-Trait Anxiety Inventory 168 may have yielded a more rounded picture of responders' anxiety levels, as it asks that they consider their current state, but also poses statements that relate to their overall sense of self in terms of their anxiety. For example, questions such as 'I am content. I am a steady person' should elicit responses that pertain to overall mental well being. However, the majority of validated measures that are used to ascertain psychological well being ask respondents to report their current mental health. However, the focus of the STAI measure is upon anxiety rather than depressive symptoms.

In terms of use of the FSFI, chapter 4 outlines the 'dysfunction' bias that is inherent in the measure. <sup>169</sup> The measure includes a response related to sexual activity in the past 4 weeks, whereby if the respondent has not been sexually active during this time, a zero score is assigned. When calculating the FSFI score (≤ 26.55 indicating presence of sexual dysfunction), the measure implies that women who are not sexually active are sexually dysfunctional, and thus it is possible that analyses based on this scoring convention may result in an over-estimation of the prevalence of FSD in a given population. To assess the extent to which such over-estimation may have been a feature of analyses performed in this study, a sensitivity analysis was undertaken in which all women who did not report being currently sexually active were removed from the dataset. Removal of these cases was shown to have no impact upon the overall prevalence rate of FSD in the cohort.

#### Responder bias

Responders may have been more inclined to participate in the study if either they had had a very positive experience, or a very negative experience of undergoing colposcopy which may have influenced the nature of the data obtained. Negative experiences may be partly ameliorated for a participant if they are able to report the kind of problems they experienced. It can provide an avenue to un-burden themselves of negative feelings. Similarly, having a positive experience may encourage participation as people see it as an opportunity to praise the particular unit they attended. Those who are more

ambivalent about the experience may see little value in participating in the study. It could be argued that the results will over-represent the good and the bad at the expense of the perfectly 'normal' or unremarkable experiences.

Given the more pronounced levels of FSD in the study cohort compared with normative data, it is possible that responders experiencing problems were more inclined to participate.

Older women may feel less compelled to answer questions of a sexual nature when compared with younger, arguably more sexually liberated women. In an increasingly libertarian and non-secular society there have been notable shifts in the ease with which sexuality is discussed in the media. Women today are more likely to engage in a variety of sexual relationships - multiple partners, fewer monogamous relationships, and more same-sex relationships. Younger women in particular may feel more sexually empowered, therefore there may be less stigma for them in answering questions that focus upon sexuality. Women in long-standing relationships may differ in how they view sex and its place within their relationships. They may place less emphasis upon the importance of sex in an otherwise contented and fulfilled relationship.

Women who have had children may be comparatively less affected by the colposcopy procedure as they will have already have undergone the potentially traumatic and intimate experience of giving birth. For women who have never had children, they may be more likely to experience increased anxiety around any adverse effects upon their obstetric health and fertility.

The nature of the kinds of questions asked and the measures used to quantify psychological, physical or sexual health outcomes in the context of having undergone a colposcopy may, for some women, lead them to erroneously assume that any problems they may have are attributable to the procedure. The kinds of experiences of undergoing colposcopy are also likely to depend upon the health locus of control for the individual.

The length of time elapsing between undergoing treatment and receiving the questionnaire makes it difficult to attribute, with certainty, that any adverse outcomes experienced were due to undergoing a colposcopy or colposcopically directed treatment. Furthermore, it is entirely plausible that women who had been recorded as undergoing colposcopy only during the study period (April 2008-March 2009), had subsequently undergone further, more invasive investigation or treatment. Without accessing the full medical records for each patient, which was unfeasible due to the resources available to support the study, this limitation was difficult to overcome.

#### Multiple testing

As this study's main aim was to ascertain whether treatment type, age or deprivation were associated with, or could be considered 'predictors' of experiencing adverse impacts after colposcopy, analysis was undertaken assessing the association between these three predictors and all of the outcomes of interest. The greater the number of statistical comparisons performed on the same set of data, the greater the likelihood that spurious statistical associations between variables (type I errors) may be found simply by chance rather than as the result of 'true' statistical significance. To reduce

the likelihood of such spurious statistical significance being found, a number of statistical techniques have been developed (such as Bonferroni correction), which reduce the p value needed to denote a statistically significant result according to the number of tests being performed on the data. This reduction in the threshold for statistical significance thus compensates for the effects of multiple comparisons in requiring a stronger 'level of evidence' to be observed before statistical significance can be asserted.

Multiple tests were performed on the data as part of this study, and there is a chance that spurious statistical significance may have been detected.

However, while Bonferroni correction was considered as a means of guarding against the spurious assertion of statistical significance, the lack of statistically significant findings in the study data analysis suggested that the likelihood of type I error was extremely low, and that the effect of multiple testing is not likely to have had a significant impact on the study findings.

#### Strengths

Undertaking a large-scale systematic review of the current evidence base in terms of the adverse psycho-sexual outcomes of undergoing colposcopy provided an important context within which to place the findings from this study. It is also the first review to explore the psycho-sexual outcomes of undergoing colposcopy or CIN directed treatment, and to include both quantitative and qualitative research.

The questionnaire element of the study had a large sample size when viewed in the context of the studies included in the systematic review. Furthermore, in order to ascertain if there was any difference in outcome observed between treatment groups, the study stratified the cohort in terms of what kind of treatment respondents had undergone. It is the first larger scale study to do so.

The mixed methodology approach employed enabled prevalence data in terms of the outcomes measured to be collected as well as data relating to individual experiences of undergoing colposcopy or treatment for CIN.

Exploring psycho-sexual outcomes lends itself to this approach as, to some extent, issues of this nature can be more difficult to assess using purely quantitative methods.

The sample is taken from a large urban, ethnically diverse population and so could be seen to be generalisable to the general population. Although a poorer responses rate may have been expected from black and minority ethnic (BME) groups, some of whom may have felt less comfortable answering questions related to their sexual life, in this study 21.5% of responders to Q2 were from BME groups which is largely representative of the UK population. 167

Sampling across five hospitals within the West Midlands minimised any potential bias in terms of the sample representing the experiences of undergoing colposcopy at one unit only. It would have been difficult to

extrapolate the findings from such a study and conclude that they were representative of the experiences of women undergoing colposcopy.

Finally, the use of validated measures in Questionnaire 2 provided a robust measure of the outcomes of interest - sexual function; anxiety and depression; physical, psychological, social and environmental domains.

## 9.3 Service Improvement

Overall, it would appear that problems observed in this cohort in terms of psycho-sexual functioning are attributable to factors other than the colposcopy itself. This should provide some reassurance that there are unlikely to be long-term adverse consequences for women undergoing treatment and for the health care professionals providing treatment.

However, it is worth noting that from the data generated by the qualitative stage of the research that there are some areas for service improvement that may benefit women undergoing colposcopy. Women's poor experiences are accounted for, in part, by how they felt they were treated by staff at the units. Feeling that they had little information, or impersonal treatment impacted negatively upon some women's experiences. It may also be useful to discuss with women the range of potential adverse consequences they may experience. However, this needs to be balanced with information about the effectiveness of treatment. That said, many women found that they were treated very well by all healthcare professional involved. As with any medical

intervention, especially treatment of an invasive and intimate nature, some after effects are unavoidable. Ensuring that women are informed and empowered to understand what is happening to them and that potential side effects are explained in language that is coherent to a lay person are important in minimising undue distress and trauma.

The diversity of experiences women undergo during and after the colposcopy procedure may be as much a facet of the particular psychological profile of the individual as it is of the way the procedure is performed. It is accepted that undergoing colposcopy is an effective way to manage and treat CIN<sup>41,42</sup> and is therefore a necessity for women who have cervical abnormalities. However, many women may benefit from being better informed by their GP as to what CIN is, what causes it, what they can expect when they attend for colposcopic investigation, along with the potential side-effects of undergoing treatment. Poor communication skills amongst some clinicians may contribute to the poor experience for some women undergoing treatment. Regular assessment of the ability of health care professionals to communicate with patients in a sensitive and appropriate manner may increase the satisfaction levels for women undergoing treatment.

## **CHAPTER 10: CONCLUSIONS**

What can be concluded about the impacts of undergoing colposcopy and treatment for CIN?

This Chapter outlines the conclusions of this study, and will reflect upon the original aims and objectives of the study. It will recap the findings from each stage of the study and will conclude with a summary of the project and suggestions for future research to develop the field of research further.

#### **10.1 Main conclusions**

This study aimed to determine whether undergoing colposcopy and treatment for CIN had any long terms adverse psycho-sexual impacts. After outlining the aims and objectives, the background to the study was outlined including the prevalence and aetiology of cervical cancer and an overview of the National Health Service Cervical Screening Programme (NHSCSP). Current colposcopy service provision was detailed including the current treatments available for CIN. A literature review was undertaken of the current evidence base relating to the more general adverse outcomes after colposcopy including the physical and obstetric consequences of undergoing treatment. A systematic review of the current evidence relating, more specifically, to the adverse psycho-sexual consequences of colposcopy and treatment for CIN was presented. The overarching conclusions from the review suggest that although women may experience adverse psycho-sexual sequelae following colposcopy, these are generally short lived. The higher quality studies in the review, focusing upon long term consequences indicated that any problems

tend to be transitory in nature. The heterogeneity of studies included in terms of design, setting, population, follow-up timescales and quality provided further justification for undertaking this study.

Prior to reporting the analysis and results of the empirical stage of the study, a discussion was presented of the notion of female sexual dysfunction. As an investigation of the prevalence of FSD in women undergoing colposcopy was a main objective of this study, highlighting the debates around the efficacy of using FSD as a diagnostic label for sexual problems in women was deemed an important element in the study. The discussion highlights the fact that there remains a lack of consensus in terms of how best to 'measure' sexuality. These findings informed the discussion of the results from this study.

The study methodology was outlined along with a justification for the methods employed to answer the research questions. The presentation of the results of the analysis also included the details of recruitment and non-responder bias. The main results of the analysis of both stages of the study were presented along with a summary of these findings in the context of the study aims.

The original hypothesis that treatment type would influence the prevalence of FSD was rejected. The three potential predictors of interest in terms of sexual dysfunction, depression, anxiety, physical, psychological, social and environmental factors were studied to ascertain both the prevalence of problems in these areas in the context of normative data, as well as the 'best' predictors of experiencing problems in this cohort. Analysis of the qualitative

stage of the study was also presented and the findings from empirical work were discussed in the context of the conclusions from the systematic review.

The presence of FSD in this cohort was greater than rates observed in the normative data. However, the problems inherent in using normative data as a proxy for age and deprivation matches controls were outlined. Furthermore, the FSFI asks women to rate their sexual 'function' in the previous four weeks. The normative data used to compare prevalence rates (NATSAL) uses a six month time frame, and therefore is more likely to pick up persistent sexual problems. It is plausible that the FSFI, with its shorter time-frame, will pick up sexual problems that are transitory in nature and our findings may be interpreted as an over-estimation of FSD in this cohort.

Findings from the HADS anxiety and depression scale indicated higher levels of these problems compared to normative data. Again, there is a lack of robust normative data available for these measures, so caution is advised when interpreting these findings. Furthermore this scale asks responders to rate the responses on the day of completing the measure. There is a possibility that the rates observed include more transient problems. The lack of normative data available for the WHOQOL-BREF makes if difficult to draw any firm conclusions about the findings for this study in the light of population norms.

Examining the associations between the variables for all measures concluded the following:

#### **FSD**

No significant differences were observed between type of treatment, age or deprivation in terms of the presence of FSD.

### HADS anxiety

Treatment type, deprivation or age were not significantly associated with scoring 'normal' or 'mild and above' on the anxiety scale.

#### HADS depression

Treatment and deprivation were not significantly associated with scoring 'normal' or 'mild and above' on the depression scale. Age, however, showed a significant association with older women more likely to score 'mild and above'.

WHOQOL-BREF (physical, psychological, social, environmental domains)

Across all four domains, treatment type was not associated with any
differences in the score distribution. Associations were observed in terms of
age and physical health outcomes, with older women reporting more
problems in this area. Deprivation was also found to be associated with
experiencing physical and environmental problems. Women in the most
deprived quartile reported more problems in these areas.

In conjunction with the epidemiological data generated, the qualitative data collected provided a more individualised account of women's experiences of undergoing colposcopy. The findings from this stage of the study support the findings from the systematic review of the qualitative data pertaining to women's experiences, especially the fear associated with the procedure and impact of the procedure upon some of the respondents' sense of femininity and sexuality.

Overall, from the findings from the study, it is possible to assert with some certainty that the type of colposcopically directed intervention undergone was not associated with, nor a predictor of any problems observed in terms of sexual function or anxiety and depression levels. Similarly, treatment type was not associated with the variance observed in terms of the physical, psychological, social or environmental domains scores observed. The findings from the systematic review, whilst acknowledging that colposcopy can have an impact upon psycho-sexual function that maybe more pronounced in some women more than others, would appear to indicate that in general these impacts are likely to transitory in nature. This study concludes that other factors unrelated to treatment were likely to best explain any problems observed.

Older women may be more likely to experience problems associated with sexual function. However, these problems cannot necessarily be attributed to colposcopy. Similarly, the higher levels of depression and physical health problems experienced by older women are just as likely to be a facet of

problems relating to getting older. Women living in areas of higher deprivation were more likely to experience environmental problems than women in more affluent areas. Again, this is likely to be due to the kind of problems these women have in terms of poorer housing and access to services, than colposcopy itself.

## 10.2 Summary and suggestions for future research

This study initially sought to compare colposcopy 'cases' with age and deprivation matched 'controls'. This would have provided more robust comparative data, and the problems inherent in comparing outcomes with normative data would have been minimised. It would be useful to attempt to undertake this as a secondary part of this study. However, the problems encountered in attempting to recruit general practitioners willing for their patients to be sent questionnaires asking questions of a sexual nature would need to be overcome. Understandably, many general practitioners feel 'protective' of their patients and may be concerned that receiving such a questionnaire may have a negative impact upon some patients who had experienced sexual trauma. Different approaches to recruitment of control patients when seeking responses about sensitive issues needs exploration.

# **Appendix 1 - Systematic Review Search Strategy**

- 1. CIN
- 2. cervical intraepithelial neoplasia
- 3. cervical dysplasia
- 4. cervix uteri surgery.
- 5. uterine cervical dysplasia.
- 6. colposcopy
- 7. cone biopsy
- 8. coni?ation
- 9. laser coni?ation
- 10. LLETZ
- 11. loop electrosurgical excisional procedure
- 12. LEEP
- 13. large loop excision
- 14. punch biopsy
- 15. cone biopsy
- 16. sexual dysfunction
- 17. sexual function
- 18. sexual well-being
- 19. female sexual dysfunction
- 20. libido
- 21. desire
- 22. dyspareunia
- 23. vaginal dryness
- 24. vaginal lubrication
- 25. body image
- 26. orgasm
- 27. painful intercourse
- 28. psycho-sexual
- 29. psychological
- 30. anxiety
- 31. depression
- 32. emotional
- 33. fear of cancer
- 34. libido
- 35. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 36.
- 37. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
- 38.
- 39. 36 and 38
- 40.

# **Appendix 2 - Data Extraction Form**

#### **General Information**

## Date of data extraction Identification features of the study

Author

Article title

Source (eg Journal, Conference) Year/Volume/Pages/Country of origin Institutional Affiliation (first author) and/or contact address

# Identification of the reviewer Notes

#### **Specific Information**

### Study characteristics Verification of study eligibility

Correct population, interventions, outcomes, and study design

## Population characteristics and care setting

- 1. Target population (describe/size of population)
- 2. Inclusion/exclusion criteria
- 3. Recruitment procedures used (if available)
- 4. Demographic characteristics of women undergoing colposcopy if available
- 5. Is there a comparator population?

#### Methodological quality of the study

- 1. Design of study
- a.) RCT
- b.) Cohort study
- c.) Systematic review
- d.) Qualitative study
- e.) Case study
- 2. Quality assessment

#### Intervention

1. Focus of intervention (describe) Colposcopy

#### **Outcomes, outcome measures**

- 1. What outcomes (adverse or otherwise) were measured?
- 2. Who carried out the measurement?
- 3. What was the measurement tool?
- 4. How many experienced adverse or otherwise outcomes?
- 5. Was/were the tool(s) validated?

## **Analysis**

- 1. Statistical techniques used (if quantitative study)
- 2. Does technique adjust for confounding?
- 3. Unit of analysis

#### Results

- 1. Quantitative results (estimate of effect size)
- 2. Effect of intervention upon outcome measures
- 3. Qualitative results

[Adapted from NHS CRD Report 4 (2<sup>nd</sup> Edition), University of York, March 2001]

# **Appendix 4 Quality Assessment Scores For Systematic Review Studies**

## Studies comparing two or more treatment modalities

	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Balasubramani 2007 <sup>86</sup>	1	1	1	1	1	1	1	0	1	1	9
Baldaro 2003 87	1	1	1	0	0	0	0	0	1	1	5
Ferris 2003 93	1	1	1	0	1	0	0	1	1	1	7
Freeman-Wang	1	1	1	0	0	0	0	0	0	0	3
Hellsten 2008 95	1	1	1	0.5	1	0	0.5	1	1	1	8
Hellsten 2008 96	1	1	1	0.5	1	0	0.5	1	1	1	8
Hellsten et al 2009 97	1	1	1	0.5	1	0	0.5	1	1	1	8
Jones 1996 <sup>102</sup>	1	1	1	0	0	0	0	0	0	0	3
Kitchener 2004 <sup>105</sup>	1	1	1	1	1	0	0	1	1	1	8
Kola 2009 <sup>106</sup>	1	1	0	0	1	0	0	1	1	1	6

Le 2006 <sup>109</sup>	1	1	1	0	1	0	0	1	1	1	7
	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Little (Tombola Group) 2009 111	1	1	1	1	1	1	1	1	1	1	10
Naik 2001 114	1	1	1	0	0	0	0	0	1	1	5
Orbell 2004 115	1	1	1	1	1	0	1	1	0	1	8
Sharp 2010 119	1	1	1	1	1	1	1	1	1	1	10
Tamburini 1991	1	1	1	0	0	0	0	0	0	0	3

## One cohort

	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Boneveski 1998	1	1	0	0	1	0	0	1	0	0	4
Brooks 2002 91	1	1	1	0	0	0	0	0	1	1	5
Gath et al 1995 <sup>61</sup>	1	1	1	0	1	0	0	0	1	1	6
Howells 1999 99	1	1	1	0	0	0	0	1	1	1	6
Idestrom 2003	0	1	0	0	1	1	0	0	1	1	5

	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Inna 2010 <sup>101</sup>	1	1	1	1	1	0	0	1	1	0	7
Kilkku 1982 <sup>104</sup>	0	1	0	0	0	0	0	0	0	0	1
Lauver 1999 <sup>107</sup>	1	0	0	1	1	0	0	0	0	1	4
Lauver 1999 <sup>108</sup>	0	1	1	1	0	0	0	1	1	1	6
Marteau 1990 112	0	1	0	0	0	0	0	0	0	0	1
McDonald 1989	1	1	1	0	0	0	0	0	1	1	5
Richardson 1996 <sup>116</sup>	1	0.5	0.5	0	1	1	0	1	0	1	6
Rubin 2010 <sup>117</sup>	0.5	0.5	1	0	0	0	0	1	1	1	5
Serati 2010 <sup>118</sup>	1	1	1	0	1	0	0	0	1	1	6
Tahseen 2008	1	0	1	0	0	0	1	0	0	1	4
Valdini 2004 <sup>122</sup>	0	1	1	0	0	0	0	0	0	1	3
Zeisler 1997 123	1	1	0	0	0	0	0	0	0	1	

## Disease status

	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Bell et al <sup>33</sup>	1	1	1	0	1	0	0	0	1	1	6
Cairns 2008 92	1	1	0	1	1	0	1	0	1	1	7
Campion et al 1988 <sup>57</sup>	0	1	0	0	1	0	0	0	1	1	4
Lerman 1991 110	1	1	1	0	0	0	0	1	1	0	5
Palmer et al 1993 <sup>54</sup>	0	1	1	1	1	0	1	0	1	1	6

# **Questionnaire development**

	Clear research aims	Quantitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Bennetts 1995 89	1	1	1	1	0	1	0	1	1	1	8
Doherty 1991 58	0	1	0	0	0	0	0	0	1	1	3

## **Qualitative studies**

	Clear research aims	Qualitative Appropriate method	Design appropriate	Recruitment strategy appropriate	Appropriate/ clear data collection	Researcher/participant Appropriate relationship	Ethical issues considered	Data analysis rigourous	Results explicit	Contribution to knowledge base	Total
Beresford 1986	0	1	1	0	0	0	0	0	0	0	2
Hounsgaard 2007 <sup>98</sup>	1	1	1	0	1	0	1	0	1	1	6
Juraskova 2007	1	1	1	0	1	0	0	0	1	1	6
Mortensen 2010	1	1	1	1	1	0	0	1	1	1	8
Posner & Vesey	1	0	0	1	0	1	1	0	0	1	5

# **Appendix 5 Glossary Of Acronyms**

ST - See and Treat
DT - Defer and Treat
DD - Diagnose and Defer
CS - Cytological Surveillance

LLETZ - Large Loop Excision of the Transformation Zone
LEEP - Loop Electrical Excisional Procedure

CC - Cervical Cancer

STI - Sexually Transmitted Infection
CIN - Cervical Intraepithelial Neoplasia

SF - Sexual Function

SQ - Symptom Questionnaire CES-D - Centre for Epidemiological Studies MBSS - Miller Behavioural Style Score

STAI - Spielberger State Trait Inventory

MADRS-S - Montgomery-Asbery Depression Rating Scale

QOL - Quality Of Life

GHQ - General Health Questionnaire HADS - Hospital Anxiety and Depression Scale

IES - Impact of Event Scale
POSM - Process Outcome Specific Measure

MMPI - Minnesota Multiphasic Personality Inventory

ASQ - Abnormal Smear Questionnaire

POMS - Profile Of Mood Status

PSE - Present State Examiniation FSFI - Female Sexual Function Index

PEAPS - Q - Psychological Effects of having an Abnormal Pap Smear Questionnaire

FG - Focus Group

# **Appendix 6 Excel Proforma For Patient Identification**

Uni ID	Postcode	Date	Level of	Referral	Appt	Referral	Treatment	Any	When	When
		of	intervention	date	date	source	method (if	comments	pack	reminder
		birth					applicable)		sent	sent
110001										
110002										
110003										
110004										
110005										

# **Appendix 7 - Participant Invitation Letter**

INSERT TRUST

Title First Name Last Name

Address line 1 Address line 2 Address line 3 Address line 4 Postcode

Date

Dear (personalised)

### **Understanding Women's Experiences of Colposcopy**

I am writing to you to ask if you can help us find out more about women's experiences of having a colposcopy.

Women are usually referred for a colposcopy when they have had an abnormal smear test.

As you may know, colposcopy is an examination of the cervix (neck of the womb) and is performed by a doctor or nurse in a hospital outpatient clinic. Although it is a common procedure, we know very little about whether this has an effect upon women's sex life, or other aspects of their health.

To look at the long term effects we will compare how women who have never had a colposcopy feel, with women who have had a colposcopy.

If you have received this letter, you have been selected from records at a colposcopy unit.

We have enclosed with this letter, an information sheet about this research and a short questionnaire. This questionnaire should take no more that 10 minutes to complete and we would be grateful if you could take the time to fill it in. Your response will be treated in strict confidence.

Many thanks

Yours sincerely

INSERT CONSULTANT ELECTRONIC SIGNATURE



# **Appendix 8 - Participant Information Sheet**

UNIVERSITY<sup>OF</sup> BIRMINGHAM

Participant Information Sheet

# Understanding Women's Experiences of Colposcopy

#### Information about the research

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. The study is to find out what kind of experiences women have had following colposcopy and to see if it has had any effects upon their sex life, health and well-being.

## Why is this study needed?

Colposcopy is a detailed examination of the cervix (neck of the womb) and is performed by a doctor or nurse colposcopist. Although a lot of women have experienced colposcopy, not much is known about what it is like for them and if it has any effects upon their health and well-being. In order to find out more about this we are asking women to complete a questionnaire.

We will compare the experiences of women who have, and have not, had a colposcopy.

# Why have I been invited to take part?

You're being asked to take part in the study because you had a colposcopy.

# Do I have to take part?

It is entirely up to you whether to take part or not. You are free to withdraw or change your mind at any time without giving a reason. Even if you don't want to take part, we would be grateful if you could return the reply slip in the FREEPOST envelope provided.

# What happens if I take part?

At the end of this questionnaire we have left a space for you to add any further comments or raise any other issues that you think may be relevant. It also asks if you would be happy to complete a follow-up questionnaire. If you agree to do so, we will send you a second, more detailed questionnaire. This will take a little longer to complete.

# What are the possible disadvantages and risks of taking part?

This study doesn't involve any treatment or tests, so there is no physical risk involved. Some of the questions relate to psychological and sexual issues which are personal but we would appreciate your honesty when answering these questions.

# What are the possible benefits of taking part?

You'll have the satisfaction of knowing that others may be helped by this research in the future.

### What happens when the research study stops?

When all the questionnaires have been returned and analysed, a report will be prepared and the findings will be published in medical journals and at conferences. It will be several months before this happens. Once published, a summary report will be published on the University of Birmingham's website. All reports and publications will use the information collected in a way that makes sure you cannot be identified.

If you would like to receive a summary of the results, you can tick a box at the end of the second questionnaire and we will send you a copy of this summary.

# What if there's a problem?

If you have any complaint about the way you are dealt with during the study, please contact Professor Sue Wilson at the University of Birmingham on 0121 414 7397. If you remain unhappy and wish to complain formally, you can do this by contacting Birmingham and Black Country Comprehensive Local Research Network (Tel 0121 627 2160).

# What will happen if you don't want to carry on with this study?

You can decide to leave the study at any time without giving a reason.

### Will my taking part in this study be kept confidential?

All information you provide will be kept **strictly confidential** by the research team. This means that **we will never pass on any information about you, your involvement in the study, or the answers you give to anyone, for any reason.** When we publish our results, these will be summaries of what a number of people have told us – you will not be able to be identified. All information will be kept in accordance with the Data Protection Act.

# Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by Black Country Research Ethics Committee.

#### How can I find out more?

If you'd like more information about the study before you make up your mind, you can contact

# Who is organising and funding the research?

The research is being carried out by a team from the Department of Primary Care Clinical Sciences at the University of Birmingham (contact details can be found above). The study is funded by a national cancer charity, Cancer Research UK.



# UNIVERSITY<sup>OF</sup> BIRMINGHAM

	<b>Appendix</b>	9 -	Questionnai	re One
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# **Colposcopy Follow-up Study**

# We are interested in hearing from you, even if you haven't had a colposcopy

#### Please fill in all sections.

Some women find that having a colposcopy or a smear test affects their sex life and other aspects of their life. These possible effects have not been fully explored and we believe it is important that we know more about them, so that the services that are provided take women's experiences into account.

All information you provide will be kept strictly confidential by the research team. This means that we will never pass on any information about you, your involvement in the study, or the answers you give to anyone, for any reason.

#### SECTION 1:

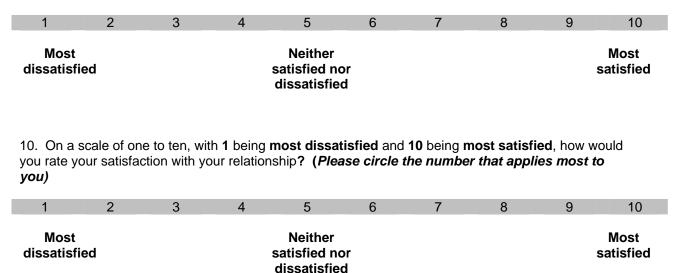
THIS SECTION ASKS YOU GENERAL QUESTIONS ABOUT YOUR HEALTH.

1. In general, would you say that your health is (Please circle one option)

Excellent	Very Good	Good	Fair	Poor					
2. In the <u>past 12 months</u> , have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u> ? ( <i>Please tick one box</i> )									
Felt less able to car	ry out normal tasks		Yes	No 🗌					
Were limited in the <b>kind</b> of work or other activities you have undertaken				No 🗌					
	l <b>2 months</b> , have you h	-	0.	•					
as a result of any e	motional problems (s	uch as feeling depre	essed or anxious)? (	(Please tick one					
Accomplished less to	han you would like		Yes	No 🗌					
Didn't do work or oth	ner activities as vou usu	ally would do	Yes □	No □					

4. During the past 12 interfered with your s							
All of the time	Most of the time	Some of th	e time	A little of	the time	None	of the time
SECTION 2: SEXUA	L HEALTH						
We want to find out to You may find some of you can. 'Sex' an intercourse.		tions a little	personal	but please	e try to ans		
5. Have you ever ha	d a colposcopy?		Yes 8		No	ease go	to question
6. When did you firs	t go for a colposcopy	?	Month/	Year			
7. How many times l colposcopy?	have you been for a						
8. In the past year ha		•	ollowing	for three r	nonths or	longei	?
	. i				Yes		No
Lacked interest in ha	-						
Felt anxious just before having sex about your ability sexually?			to perforr	m			
Were unable to come to a climax (experience an orgasm)?			ısm)?				
Have come to a clima	ax (experienced an c	orgasm) too	quickly?				
Experienced physica	I pain during intercou	urse or sexu	al activity	<b>'</b> ?			
Have had trouble lub	ricating?						

9. On a scale of one to ten, with 1 being most dissatisfied and 10 being most satisfied, how would you rate your satisfaction with your sexual life? (Please circle the number that applies most to you)



#### **SECTION 3**

The space below has been left blank as we are interested in knowing if there are any other experiences or comments you would like to tell us about related to the issues discussed in the questionnaire.					
	1				

SECTION 4
We'd be grateful if you would consider taking part in a follow-up. If you agree we will send you a questionnaire which will ask you some more questions related to your general and sexual health. We hope it will tell us more about the things that are important to women who experience colposcopy.
I wish to participate in the next stage of the study
I do not wish to participate in the next stage of the study
Name:
Address:
Date of birth://
Thank you for your time.  We greatly appreciate your participation. Study results will help us to better understand women's experiences of colposcopy. Please return your completed survey in the enclosed FREEPOST envelope.

Please note: All information provided will be held in accordance with the Data Protection Act

If you have any concerns or questions about the study, please contact:

# **Appendix 10 - Questionnaire Two**

UNIVERSITYO
<b>BIRMINGHAM</b>



ID:

# **Colposcopy Follow-up Study - Part Two**

# We are interested in hearing from you, even if you haven't had a colposcopy

### Please fill in all sections

You have already helped us complete the initial part of our research study and agreed to participate in this second stage. There are some areas that we have already asked you about that we would like to explore in more detail and we would be grateful if you could complete the following questionnaire.

All information you provide will be kept **strictly confidential** by the research team. This means that we will never pass on any information about you, your involvement in the study, or the answers you give to anyone, for any reason.

SECTION 1: THIS SECTION ASKS YOU FOR GENERAL BACKGROUND INFORMATION

(Please answer every question by filling one circle or writing in an answer)

1. What is your age?	Yrs		
2. How would you describe yo	our ethnicity? (Pleas	e fill one circle)	
White – British	0	Mixed	0
White – non-British	0	Chinese/Chinese British	0
Asian/Asian British	0	Other ethnicity (please specify below)	0
Black/Black British	0		

3. At what stage did you finish your full-time education? (Please fill one circle)

Never attended school	0	Qualification other than a degree from college/university	0
No formal qualifications	0	Degree	0
GCSE or 'O' level equivalent	0	Post- Graduate qualification	0
Training through work with formal gualification	0		

4a. Do you smoke cigarettes at all nowadays hand rolled cigarettes)	? (including	Yes Ex-smo	Coker C	) No	)	0	
4b. How many do/did you smoke per day?							
4c. If you are an ex-smoker, when did you give	ve up?	Year					
5a. Do you drink alcohol?		Yes	0	No	0		
5b. If you drink alcohol, how many units per v	week?						
							Units
1 unit 1 unit 1 unit 1 unit	1 unit						
	Y						
	人						
	single						
	asure of peritifs						
6a. In the last 12 months have you used drug		Yes	0	No	0		
in a way that has caused you problems in life?	your daily						
6b. <b>IF YES</b> , please can you describe these p	rohlems in						
the space below?	TODICITIS III						
<b>7 D</b>			$\circ$		$\circ$		
7. Do you have a partner?		Yes	0	No	O		
			_		_		
8. Are you sexually active?		Yes	0	No	0		
		Ctraink	0	0-	, O	D: 0	ovusl
9. Do you identify as	0	Straight		Ga	уО	DI-S	exual

10a. Have you had a colposcopy?	Yes	0	No O	
10b. If so, were you sexually active prior to colposcopy?	Yes	0	No O	
11a. Do you use contraception?	Yes	s O	No O	
11b. If so, which method do you use?				

#### SECTION 2:

THIS SECTION WILL ASK YOU FOR SOME MORE DETAIL ABOUT YOUR MEDICAL HISTORY:

# (Please answer every question by filling one circle or writing in an answer)

12a. Have you ever had any children?		0	No	0
12b. If yes, how many children do you have?				
Have you ever had any of the following?  13. A miscarriage?  14. A baby born early (premature)?  15. A still birth?	Yes Yes Yes	0 0	No No No	O O
16. Have you ever had any gynaecological problems (e.g. women's problems such as bad period pains, or problems requiring treatment or surgery)?  IF YES, please describe these problems in the space below?	Yes	0	No	0
17. Have you ever had a sexually transmitted infections (for example Chlamydia, Herpes, Genital warts, HPV, HIV/AIDS, Hepatitis B, Gonorrhoea)? <b>IF YES</b> , can you describe these problems in the space below?	Yes	0	No	0
18. Have you got any serious long term health problems which require ongoing medical advice (for example asthma, diabetes, heart disease)?  IF YES, can you please describe these problems in the space below?	Yes	0	No	0

19. How many times have you seen your GP in the last 12 months?	

#### **SECTION 3:**

#### THIS SECTION WILL ASK YOU ABOUT YOUR EMOTIONS AND FEELINGS:

Please consider the following statements and fill in the circle which most applies to you. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which best describes your present feeling. (*Please fill one circle only for each question*)

	All of the time	Most of the time	Some of the time	Hardly ever	Never
20. I feel tense and wound up	0	0	0	0	0
21. I still enjoy the things I used to enjoy	0	0	0	0	0
22. I get a sort of frightened feeling as if something awful is about to happen	0	0	0	0	0
23. I can laugh and see the funny side of things	0	0	0	0	0
24. Worrying thoughts go through my mind	0	0	0	0	0
25. I feel cheerful	0	0	0	0	0
26. I can sit at ease and feel relaxed	0	0	0	0	0
27. I feel as if I am slowed down	0	0	0	0	0
28. I get a sort of frightened feeling like butterflies in the stomach	0	0	0	0	0
29. I have lost interest in my appearance	0	0	0	0	0
30. I feel restless as if I have to be on the move	0	0	0	0	0
31. I look forward with enjoyment to things	0	0	0	0	0
32. I get sudden feelings of panic	0	0	0	0	0

33. I can enjoy a g programme	good book or radio	0	0 0					
SECTION 4:								
In the first questionnaire we asked you some questions relating to your sexual feelings and responses during the last 3 months. We would like to ask some more questions that are a little more detailed. We realise that this is a particularly sensitive and private matter. Your responses will be treated in the strictest confidence.								
In answering these questions the following definitions apply:  Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.  Sexual intercourse is defined as penile penetration (entry) of the vagina.  Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.  Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.  Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.  Over the past 4 weeks, (Please fill one circle for each question)								
34. How <b>often</b> did	d you feel sexual d	esire or inte	rest?					
	Almost always or always	Most tim (more than the time	ies S n half (al	Sometimes bout half the time)	A few time (less than h the time)	nalf Almost never or		
	$\circ$	$\circ$		$\circ$	0	$\circ$		
	0	O		0	O	O		
35. How would you rate your <b>level</b> (degree) of sexual desire or interest?  Very high High Moderate Low Very low or none at all								
	O	O		0	0	0		
36. How often di	d you feel sexually			=	-			
No sexual activity	Almost always or always	Most tim (more than the time	n half (al	Sometimes bout half the time)	A few time (less than h the time)	nalf Almost never or		
0	0	0		0	0	0		
	ou rate your <b>level</b>	of sexual ar	ousal ("turi	n on") during	sexual activity			
No sexual activity	Very high	High		Moderate	Low	Very low or none at all		
0	0	0		0	0	0		
	-	_			_	_		
38. How confide	nt were you about	becoming	sexually are	oused during	sexual activity	or intercourse?		
No sexual activity	Very high confidence	High confiden		derate nfidence	Low confide	nce Very low or no confidence		
0	0	0		0	0	0		

	,	39. How <b>often</b> have you been satisfied with your arousal (excitement) during sexual activity or intercourse?					
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never		
0	0	0	0	0	0		
	_	_		_	_		
40. How often d	id you become lub	ricated ("wet") duri	ng sexual activity	or intercourse?			
No sexual Activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never		
0	O	O	O	O	0		
41. How difficul	t was it to become	lubricated ("wet")	during sexual activ	vity or intercourse?	)		
No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult		
0	0	0	0	0	0		
J	<u> </u>	· ·	J	<b>O</b>	J		
12 How often die	d vou <b>maintain</b> voi	ur lubrication ("wet	nece") until comple	ation of covual acti	vity or		
intercourse?	a you mamtam you	ar labrication ( wet	iess / until comple	elion of Sexual acti	vity Oi		
No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never		
_			,	,			
$\cap$	$\cap$	$\circ$	$\cap$	$\circ$	$\cap$		
0	0	0	0	0	0		
	· ·	On your lubrication ("	J	Ü			
43. How difficul	· ·	On your lubrication ("	J	Ü			
43. How difficul intercourse?	t was it to maintain  Extremely  difficult or  impossible	·	wetness") until co	mpletion of sexual	activity or		
43. How difficul intercourse?  No sexual activity	t was it to maintair  Extremely  difficult or	·	wetness") until co	mpletion of sexual	activity or		
43. How difficul intercourse?  No sexual activity	t was it to maintain  Extremely  difficult or  impossible	·	wetness") until col Difficult	mpletion of sexual Slightly difficult	activity or  Not difficult		
43. How difficul intercourse?  No sexual activity	t was it to maintain  Extremely  difficult or  impossible	Very difficult  O  on or intercourse, h  Most times (more than half	wetness") until con Difficult O ow often did your Sometimes (about half the	mpletion of sexual Slightly difficult O reach orgasm (clin A few times (less than half	activity or  Not difficult		
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0	0	0	dissatisfied O	0	0				
	47. How <b>satisfied</b> have you been with the amount of emotional closeness during sexual activity between you and your partner?								
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied				
0	0	0	0	0	0				
48. How satisfied	d have you been wi	th your sexual rela	ationship with you	r partner?					
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied				
0	0	0	0	0	0				
48. How satisfie	d have you been w	ith your overall se	exual life?						
No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied				
0	0	0	0	0	0				
50. How <b>often</b> did	d you experience d	iscomfort or pain o	during vaginal per	netration?					
Did not attempt intercourse	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never				
0	0	0	O	0	0				
51 How often di	id you experience o	liscomfort or pain	following vaginal	nenetration?					
Did not attempt	Almost always	Most times	Sometimes	A few times	Almost never or				
intercourse	or always	(more than half the time)	(about half the time)	(less than half the time)	never				
0	0	0	0	0	0				
52. How would y	ou rate your <b>level</b> (	degree) of discom	nfort or pain during	g or following vagin	nal penetration?				
Did not attempt intercourse	Very high	High	Moderate	Low	Very low or none at all				
0	0	0	0	0	0				

#### SECTION 5:

THESE QUESTIONS ASK YOU HOW YOU FEEL ABOUT YOUR QUALITY OF LIFE, HEALTH AND OTHER AREAS OF YOUR LIFE.

Please choose the answer that appears the most appropriate. If you are unsure about which response to give to a question, the first one you give is usually the best one. (*Please fill one circle for each question*)

We ask you to think about your life in the last four weeks.

53. How would you rate your quality of life?	Very Poor	Poor	Neither poor nor	Good	Very Good
	0	0	good O	0	0
54. How satisfied are you with your health?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
	0	0	0	0	0

The following questions ask about how much you have experienced certain things in the last four weeks.

	Not at all	A little	A moderate amount	Very much	An extreme amount
55. To what extent do you feel that physical pain prevents you from doing what you need to do?	0	0	0	0	0
56. How much do you need any medical treatment to function in your daily life?	0	0	0	0	0
57. How much do you enjoy your life?	0	0	0	0	0
58. To what extent do you feel your life to be meaningful?	0	0	0	0	0
59. How well are you able to concentrate?	0	0	0	0	0
60. How safe do you feel in your daily life?	0	0	0	0	0
61. How healthy is your physical environment?	0	0	0	0	0

The following questions ask about how completely you experienced or were able to do certain things in the last four weeks.

	Not at all	A little	Moderately	Mostly	Completely
62. Do you have enough energy for everyday life?	0	0	0	0	0
63. Are you able to accept your bodily appearance?	0	0	0	0	0

64. Do you have enough money to meet your needs?	0	0	0	0	0
65. How available to you is the information that you need in your day-to-day life?	0	0	0	0	0
66. To what extent do you have the opportunity for leisure activity?	0	0	0	0	0
67. How well are you able to get around?	0	0	0	0	0
	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
68. How satisfied are you with your sleep?	0	0	0	0	0
	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
69. How satisfied are you with your ability to perform your daily living activities?	0	0	0	0	0
70. How satisfied are you with your capacity for work?	0	0	0	0	0
71. How satisfied are you with yourself?	0	0	0	0	0
72. How satisfied are you with your personal relationships?	0	0	0	0	0
73. How satisfied are you with your sex life?	0	0	0	0	0
74. How satisfied are you with the support you get from your friends?	0	0	0	0	0
75. How satisfied are you with the conditions of your living place?	0	0	0	0	0
76. How satisfied are you with your access to health services?	0	0	0	0	0
77. How satisfied are you with your transport?	0	0	0	0	0

The following question refers to hweeks.	ow often you h	nave felt or ex	perienced cert	ain things <b>in th</b>	e last four	
78. How often do you have negative feelings such as low mood, despair, anxiety,	Never	Seldom	Quite often	Very often	Always	
depression?	0	0	0	0	0	
Please fill in the tick box to results of this study, once	•		e to receive	a summary	of the	
I would like to receive a summary	of the study	Yes	O No	0		
Thank you for your time.  We greatly appreciate your participation. Study results will help us to better understand women's experiences of colposcopy. Please return your completed survey in the enclosed FREEPOST envelope.						
Please note: All information provided will be held in accordance with the Data Protection Act						

If you have any concerns or questions about the study, please contact:

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