THE PSYCHOSEXUAL IMPACT OF TESTING POSITIVE FOR HIGH-RISK CERVICAL HUMAN PAPILLOMAVIRUS

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A thesis submitted for the degree of Doctor of Philosophy

DECLARATION

I, Kirsty Fiona Bennett, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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ABSTRACT

Human papillomavirus (HPV)-based cervical screening has replaced cytology-based cervical screening in England. Due to its sexually transmitted nature, testing HPV positive may have psychosexual implications. The work presented in this thesis explored the psychosexual impact of testing positive for high-risk cervical HPV.

Three studies were carried out (2017-2021). Study 1 synthesised the existing quantitative and qualitative literature on (a) the psychosexual impact of testing HPV positive (n=25 studies) and (b) concerns about disclosing HPV to a sexual partner (n=13 studies). Study 2 assessed psychosexual distress following routine HPV primary screening among women receiving different HPV and cytology results at three time points over a year (n=1133). Study 3 qualitatively explored the psychosexual impact and disclosure experiences of women who had tested HPV positive in the context of HPV-based cervical screening (n=21).

In Study 1a, the psychosexual impact of testing HPV positive from the existing quantitative literature was mixed. The qualitative literature highlighted concerns including transmitting HPV to a partner and where the infection came from. In Study 1b, women were concerned about disclosing HPV to a sexual partner, partly due to the stigma of having a sexually transmitted infection and how a partner might respond. Study 2 showed that receiving an HPV positive result caused elevated psychosexual distress shortly after women received their screening result, but this declined over time. In Study 3, the extent of psychosexual impact among women testing HPV positive was influenced by how they conceptualised HPV, knowledge of HPV, concerns about transmitting HPV and having a persistent HPV infection.

Testing HPV positive in the context of HPV-based cervical screening can have a psychosexual impact. Providing clear and consistent information in screening materials and results letters may help to minimise the psychosexual consequences of testing HPV positive.

IMPACT STATEMENT

The findings of this thesis suggest that testing positive for HPV can have a psychosexual impact, particularly in the short-term. Millions of women attend cervical screening each year in England, and based on the English HPV primary screening pilot, where 13% tested HPV positive, this would equate to around 450,000 women. Even if a very small percentage of women experience adverse psychosexual consequences following an HPV positive result, this could have a negative impact on a large number of women. An essential criterion for any screening programme is that the benefit gained by individuals should outweigh the harms, therefore it is important to address and minimise any adverse psychosexual consequences of testing HPV positive.

The work in this thesis allowed me to go beyond previous literature and identify factors which influence women's psychosexual response to testing HPV positive. Women's psychosexual response to testing HPV positive was influenced by how they conceptualised HPV, their understanding of key aspects of HPV such as its high prevalence and dormancy, concerns about transmitting HPV and having a persistent HPV infection. Future research will need to explore the influence of these factors further, but my thesis provides a starting point for understanding the variation in psychosexual response among women who test HPV positive. Factors which influence psychosexual response could be targeted in screening materials and results letters in the future to minimise psychosexual impact.

To help mitigate any negative psychosexual consequences of testing HPV positive, providing additional information to women taking part in HPV primary screening is needed. Based on my findings, I have made recommendations regarding what information should be provided, who might need this information the most, how the information should be provided and when the information should be provided. In summary, information highlighting that HPV is very common and that it can clear without any treatment should be provided to women in screening materials and results letters. Addressing concerns about transmitting HPV and where the infection came from is also important. Referring to HPV as an infection that is passed on by skin-to-skin contact during any type of sexual activity rather than a sexually transmitted infection may help to reduce

psychosexual impact triggered by the STI label. Providing additional information online about HPV and training healthcare professionals carrying out cervical screening to give brief information during screening will ensure that women understand their results when they receive them. These recommendations will be beneficial to policymakers involved in the NHS Cervical Screening Programme in England, but also to screening programmes in other countries where HPV primary screening is being introduced.

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LIST OF ABBREVIATIONS

BISF-W	The Brief Index of Sexual Functioning for Women
CAG	Confidentiality Advisory Group
CCG	Clinical Commissioning Group
CFA	Confirmatory factor analysis
CI	Confidence interval
CIN	Cervical intraepithelial neoplasia
COVID-19	Coronavirus disease
CRN	Clinical Research Network
DNA	Deoxyribonucleic acid
DSM	Diagnostic and Statistical Manual of Mental Disorders
EFA	Exploratory factor analysis
GAD	Generalised anxiety disorder
GP	General practice
HDI	Human development index
HIP	HPV Impact Profile
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
HRA	Health Research Authority
HSV	Herpes simplex virus
IMD	Index of Multiple Deprivation
IQR	Interquartile range
KMO	Kaiser-Mayer-Olkin
LEEP	Loop electrical excision procedure
LLETZ	Large loop excision of the transformation zone
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OR	Odds ratio
P-P	Probability-probability
PAIS-SR	Psychosocial Adjustment to Illness Scale-Self-Report

PEAPS-Q	Psychosocial Effects of Abnormal Pap Smears Questionnaire
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
Q-Q	Quantile-quantile
RAC	Research advisory committee
RCT	Randomised controlled trial
REC	Research Ethics Committee
SCSF	Symptom Checklist of Sexual Function
SE	Standard error
SRS	Sexual Rating Scale
STI	Sexually transmitted infection
UCL	University College London
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

LIST OF PUBLICATIONS

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Bennett, K. F., Waller, J., Ryan, M., Bailey, J. V., & Marlow, L. A. V. (2019). The psychosexual impact of testing positive for high-risk cervical human papillomavirus (HPV): a systematic review. *Psycho-oncology, 28*(10), 1959-1970. doi:10.1002/pon.5198

CHAPTER 1: INTRODUCTION

1.1: Overview

Infection with a high-risk type of human papillomavirus (HPV[1]) is the cause of virtually all cervical cancers. HPV is a very common infection which is transmitted through skin-to-skin genital contact during any type of sexual activity. While an HPV infection is the underlying cause of virtually all cervical cancers, being infected with HPV very rarely causes cancer and most infections are cleared by the body's immune system within two years. In England, the roll-out of HPV primary screening was completed in December 2019. Women attending cervical screening will be tested for the presence of HPV in the first instance rather than first detecting cytological abnormalities. HPV primary screening has changed the screening results women receive. Due to the sexually transmitted nature of HPV, there may be psychosexual consequences of testing positive for the virus.

This chapter describes the background to my thesis and presents information on the epidemiology of HPV and cervical cancer, the methods to prevent cervical cancer which have been developed such as HPV testing and HPV vaccination and the potential for cervical cancer to be eliminated in the future. I will then describe the literature on the impact of HPV testing. I will define 'psychosexual' and draw on the literature from other sexually transmitted infections to explore why psychosexual impact might be a particularly relevant consideration for HPV testing. At the end of this chapter, I will outline the aims and objectives of the thesis.

1.2: Burden of cervical cancer

In 2018 there were approximately 570,000 new cases of cervical cancer, and 311,000 deaths worldwide, making it the fourth most frequently diagnosed cancer, and the fourth leading cause of cancer death in women (Arbyn et al., 2020). It is the most commonly diagnosed cancer in women in 28 countries and the leading cause of cancer death in 42 countries, most of which are developing

[1] Throughout my thesis, HPV will be used to denote high-risk HPV, unless stated otherwise.

countries in Sub-Saharan Africa and South-Eastern Asia (Bray et al., 2018). Cervical cancer incidence and mortality are high in developing countries partly because of inequalities in access to adequate cervical screening and treatment (Arbyn et al., 2020; Sahasrabuddhe, Parham, Mwanahamuntu, & Vermund, 2012). Cervical cancer incidence and mortality, in relative terms, are seven to ten times lower in developed countries such as the United States of America (USA), Australia and New Zealand (Bray et al., 2018).

In England in 2017 there were 2,591 new cases and 674 deaths from cervical cancer (Office for National Statistics, 2019). The number of new cases was highest among women aged 25 to 34 years (26%), with women aged 25 to 49 years accounting for nearly 60% of cervical cancers (Office for National Statistics, 2019). Cases of cervical cancer have declined in countries where organised screening programmes are available (Mathew & George, 2009). In England and Wales, prior to the introduction of the NHS Cervical Screening Programme in 1988, the cervical cancer death rate had been steadily increasing among women aged 20 to 34 years from 0.73 per 100,000 women between 1963 and 1967 (163 deaths) to 2.2 per 100,000 women between 1983 and 1987 (605 deaths) (Peto, Gilham, Fletcher, & Matthews, 2004). Following the introduction of cervical screening the death rate decreased to 1.77 per 100,000 women between 1988 and 1992 (516 deaths) and 1.03 per 100,000 women between 1998 and 2002 among women aged 20 to 34 years (278 deaths) (Peto et al., 2004). Decreases in cervical cancer death rates were observed across all other age groups (Peto et al., 2004). Therefore, the low incidence of cervical cancer in England is likely to be due, in part, to the NHS Cervical Screening Programme.

1.3: Human papillomavirus

It is now well-established that virtually all cervical cancers are caused by a persistent infection with an oncogenic or high-risk type of HPV (Bosch, Lorincz, Munoz, Meijer, & Shah, 2002; Bosch et al., 1995; Walboomers et al., 1999). HPV is a very commonly occurring sexually transmitted infection (STI) which affects both men and women, and it has been estimated that 80% of individuals will acquire a genital HPV infection by age 50 (Koutsky, Galloway, & Holmes, 1988; Satterwhite et al., 2013). HPV is transmitted through skin-to-skin genital

contact during any type of sexual activity and many individuals are infected with the virus shortly after becoming sexually active (World Health Organisation, 2016).

Over 100 types of HPV have been identified, some which do not cause cancer but can cause genital warts or verruca's ("low-risk HPV") and some which can develop into cancer ("high-risk HPV"). Fifteen HPV types have been classified as high-risk (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82) (Muñoz et al., 2003). Over 99% of cervical cancers are caused by a persistent HPV infection, with two HPV types (HPV 16 and HPV 18) accounting for around 70% of all cervical cancers (Brown et al., 2018; de Martel, Plummer, Vignat, & Franceschi, 2017; Muñoz et al., 2004; Walboomers et al., 1999). Approximately 4.5% of cancers worldwide can be attributed to an HPV infection, with cervical cancer accounting for 83% of these cases (de Martel et al., 2017). In addition to cervical cancer, HPV is related to other anogenital cancers including anal, vulval, vaginal and penile cancer and some head and neck cancers (de Martel et al., 2017). Similarly to cervical cancer, HPV 16 and HPV 18 account for a large proportion of these cancers (de Martel et al., 2017).

1.3.1: Prevalence of HPV

The prevalence of HPV appears to vary across samples and countries. The estimated prevalence of cervical HPV-DNA in the general population has been found to range from 2 to 44% (Bosch & de Sanjosé, 2003). The range in estimated prevalence could be due to the difference in age of the populations and the sensitivity of the DNA assay used to detect HPV (Baseman & Koutsky, 2005). The third National Survey of Sexual Attitudes and Lifestyles (NATSAL-3) described the prevalence of four STIs in Great Britain (England, Scotland and Wales) among men and women aged 16 to 44 years (Sonnenberg et al., 2013). Among women in this sample, gonorrhoea, HIV and chlamydia were found to be uncommon (prevalence of <0.1, 0.1 and 1.5% respectively). In contrast, 15.9% of women tested positive for HPV, with prevalence highest among those aged 18 to 19 years (29.6%) and 20 to 24 years (26.6%). In a study carried out in the context of the HPV primary screening pilot in England, 12.7% of women received an HPV positive result, with the highest prevalence found among women aged 24 to 29 years (28%) (Rebolj et al., 2019b).

Most studies show that the prevalence of HPV is highest among younger women and declines with increasing age, however some studies show there is also a second 'peak' of HPV prevalence among older women (Brotherton et al., 2015; Chan et al., 2010; Lazcano-Ponce et al., 2001). The age of the second peak differs between studies but generally HPV prevalence appears to increase between 45 and 55 years (Brotherton et al., 2015; Chan et al., 2010; Lazcano-Ponce et al., 2001). It is unknown exactly why some studies show a second peak of HPV prevalence among older women. One explanation is that it could be the reactivation of a latent, previously acquired, HPV infection (Brotherton et al., 2015; Chan et al., 2010).

1.3.2: HPV clearance

While infection with HPV is the underlying cause of almost all cervical cancers, being infected with HPV very rarely causes cancer. Most infections do not cause symptoms and are 'cleared' by the body's immune system (i.e. HPV can no longer be detected) (Stanley, 2006). The duration between infection with HPV and clearance varies between published studies but it appears that this generally occurs within two years (Franco et al., 1999; Giuliano et al., 2002a; Plummer, Schiffman, Castle, Maucort-Boulch, & Wheeler, 2007; Winer et al., 2011).

Some uncertainty exists about whether an HPV infection that is not detected at repeat testing has truly cleared or whether it persists at a low, undetectable level, or is in a latent state (Gravitt & Winer, 2017). A review published in 2012 found that recurrent detection of type-specific HPV following a period of non-detection ranged from 3.7 to 19.4% (Gravitt, 2012). However, it has been acknowledged that this could be due to reasons other than latent virus reactivation, for example a new infection with the same HPV type or result misclassification (i.e. a false positive or false negative result) (Gravitt, 2012).

1.3.3: Steps in cervical carcinogenesis

The major steps in cervical carcinogenesis are shown in Figure 1.1 (Moscicki, Schiffman, Kjaer, & Villa, 2006). If the immune system fails to clear an HPV infection and the infection becomes persistent this can lead to cervical intra-

epithelial neoplasia (CIN)[2] which, if left untreated, can lead to cervical cancer (Schiffman, Castle, Jeronimo, Rodriguez, & Wacholder, 2007). While the duration between infection with HPV and progression to CIN2 or CIN3 can be relatively short, progression to invasive cancer is generally longer and it can take ten to thirty years from infection with HPV to the development of cervical cancer (National Cancer Institute, 2021; Winer et al., 2005). In addition, even when high-grade cell changes are seen on the cervix, not all women will go on to develop cervical cancer. A systematic review and meta-analysis published in 2018 explored the histological outcomes of women with CIN 1-3 during observational management and found that the regression rate of cytological abnormalities ranged from 24.9 to 44.7% (Bekos et al., 2018). Regression rates decreased with increasing age and were highest among women aged less than 25 years and lowest among women aged more than 40 years. (Bekos et al., 2018).

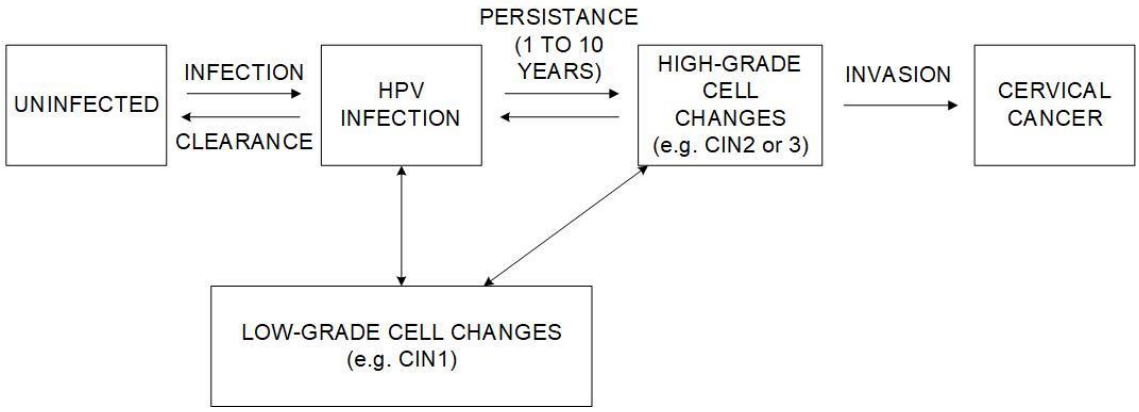

Figure 1.1: Major steps in cervical carcinogenesis

(adapted from Moscicki et al., 2006)

[2] CIN is graded from 1 to 3. CIN1 are low-grade cytological abnormalities (cell changes) on the cervix. It is unlikely that the cell changes will develop into cervical cancer and they normally go back to normal ('regress') without any treatment. Women found to have CIN1 are usually invited for cervical screening 12 months later to see if the cell changes have regressed. CIN2 and CIN3 are high-grade cervical abnormalities on the cervix and there is a higher chance that the cell changes will develop into cervical cancer. The management of CIN2 depends on individual circumstances and the size of the affected area on the cervix. Women may be monitored more frequently or receive treatment to remove the abnormal cells. Women with CIN3 usually receive treatment as it is less likely that the cell changes will regress and if left untreated there is a significant risk that the cell changes will develop into cervical cancer. In England, cell changes are sometimes referred to as low-grade or high-grade dyskaryosis (Jo's Cervical Cancer Trust, 2020a; Whittington Health NHS Trust).

1.3.4: HPV and cervical cancer risk factors

Infection with HPV is the underlying cause of almost all cervical cancers but not all HPV infections progress to CIN or cancer. Therefore, it is likely that other factors influence the risk of transition from an HPV infection to cervical cancer (Castellsagué, Bosch, & Muñoz, 2002). Several risk factors for acquisition of an HPV infection, HPV persistence, CIN2 or CIN3 and invasive cervical cancer have been suggested.

The risk factors associated with acquiring an HPV infection are predominantly behaviours related to sexual activity (Chelimo, Wouldes, Cameron, & Elwood, 2013). Well-established risk factors for women include a higher number of lifetime sexual partners, a new sexual partner in the last twelve months and male partner characteristics such as their number of lifetime sexual partners and whether they are monogamous (Chelimo et al., 2013). Being a current smoker has also been found to be a risk factor for acquiring HPV (Vaccarella et al., 2008).

Risk factors for HPV persistence include age, HPV type and smoking. HPV persistence has been found to increase with age and evidence suggests that some HPV infections (e.g. HPV 16, 31, 33 and 52) are more likely to persist and take longer to clear than others (Castle et al., 2005; Rositch et al., 2013). Compared to women who had never smoked, smokers had a lower probability of clearing an HPV infection (Giuliano et al., 2002b).

High parity, long-term oral contraception use and smoking are associated with an increased risk of developing CIN2, CIN3 and invasive cervical cancer (Appleby et al., 2006; Castellsagué & Muñoz, 2003; Collins, Rollason, Young, & Woodman, 2010; Deacon et al., 2000; Haverkos, Soon, Steckley, & Pickworth, 2003; Luhn et al., 2013; Muñoz et al., 2002).

As virtually all cases of cervical cancer are caused by a persistent HPV infection, methods such as HPV testing and the HPV vaccination have been developed to prevent cervical cancer.

1.4: HPV vaccination

Around 80 countries worldwide offer an HPV vaccination programme (Bruni et al., 2019). There are three HPV vaccines available which protect against two (bivalent vaccine), four (quadrivalent vaccine) or nine (nonavalent vaccine) types of HPV. Since 2008, girls aged 12 to 13 years in England have been offered the HPV vaccine as part of a school-based programme, with boys being offered the vaccine from September 2019 (NHS, 2019b). The vaccination programme in England currently uses a quadrivalent vaccine called Gardasil (Merck), administered in a two-dose schedule, which protects against HPV 6 and 11 (which cause around 90% of genital warts) and HPV 16 and 18 (which cause around 70% of cervical cancers) (NHS, 2019b). Between 2018 and 2019, 83.9% of girls aged 13 to 14 years had completed the two-dose vaccination course (Public Health England, 2019d). As boys have only been offered the vaccine since September 2019 there is not any data available yet for the number completing the two-dose vaccination course.

The introduction of HPV vaccine programmes have resulted in a number of positive outcomes. Since the introduction of the HPV vaccine in England, the prevalence of HPV 16 and HPV 18 has significantly declined among women aged 16 to 24 years (Mesher et al., 2018). A Cochrane review, which included 26 studies worldwide involving 73,000 adolescent girls and young women aged 15 to 26 years, found that the HPV vaccination protects against CIN2+ and CIN3+[3] (Arbyn, Xu, Simoens, & Martin-Hirsch, 2018). A number of studies suggest evidence of herd protection in unvaccinated women (Drolet et al., 2015; Kahn et al., 2012; Tabrizi et al., 2014). Herd protection is when a high percentage of the population is vaccinated and consequently it is difficult for the infection to spread because there are not many people who can be infected (Oxford Vaccine Group, 2018). In addition, research regarding the longer-term impact of the HPV vaccine is now beginning to emerge. A Swedish study which followed over 1.5 million girls and young women for up to eleven years found that the quadrivalent HPV vaccine substantially reduced the risk of invasive cervical cancer (Lei et al., 2020). Compared to girls who had not been

[3] CIN2+ includes CIN2, CIN3 and invasive cancer. CIN3+ includes CIN3 and invasive cancer.

vaccinated, the risk of cervical cancer was 88% lower among girls who had been vaccinated before seventeen years of age (Lei et al., 2020).

In addition to protecting against HPV 16 and HPV 18, which cause around 70% of cervical cancers, a systematic review and meta-analysis of twenty studies found that in countries with female vaccine coverage of at least 50% there were significant reductions in HPV 31, HPV 33 and HPV 45 in girls younger than twenty years of age, suggesting evidence of vaccine cross-protection (Drolet et al., 2015). However, the HPV vaccine does not protect against all types of high-risk HPV, so it is important that girls who receive the vaccine still attend cervical screening when invited. Although cervical screening intervals are currently the same for vaccinated and unvaccinated women, research suggests that women who have been vaccinated against HPV 16 and HPV 18 may require fewer lifetime cervical screens than unvaccinated women to have the same level of protection against cervical cancer (three lifetime screens vs. seven lifetime screens for vaccinated and unvaccinated women respectively) (Landy, Windridge, Gillman, & Sasieni, 2018). Among unvaccinated women (i.e. most women that were born before 1990), cervical screening is the only way to prevent cervical cancer.

1.5: The NHS Cervical Screening Programme

The NHS Cervical Screening Programme aims to reduce the number of women and people with a cervix[4] who develop and die from cervical cancer (NHS, 2020). Cervical screening aims to detect high-risk types of HPV which can cause cytological abnormalities of the cervix (Public Health England, 2019b). The screening programme is free at the point of use and available to women aged 25 to 64 years in England (Public Health England, 2019b). Women who are registered with a GP are routinely invited every three (for those aged 25 to 49 years) or five years (for those aged 50 to 64 years) (Public Health England, 2019b). It has been estimated that screening in England currently prevents 70% of cervical cancer deaths, a figure which would be higher (83%) if all women regularly attended screening (Landy, Pesola, Castanon, & Sasieni, 2016). Research published in 2004 estimated that up to 5,000 cervical cancer deaths a

[4] All individuals with a cervix should attend cervical screening. This includes transgender men and those of non-binary gender.

year have been prevented in England and Wales as a result of the screening programme (Peto et al., 2004). Research published more recently in 2019 estimated a more conservative figure of 65,000 cervical cancers having been prevented by screening between 1988 and 2013 (Pesola & Sasieni, 2019).

1.5.1: Cytology-based screening

Until December 2019, the screening programme used liquid-based cytology as the primary method for detecting cytological abnormalities of the cervix. During cervical screening, a sample of cells from the cervix is collected and this is rinsed or placed in a vial of preservative fluid (Mayor, 2003). This was then examined under a microscope to look for cytological abnormalities (Public Health England, 2019b). Women attending cytology-based cervical screening received one of three cytology results: normal (no abnormal cell changes found), abnormal (women receiving this result were told they either had low-cell changes or high-grade cell changes), or inadequate (where the test had to be repeated because the first one could not be read properly) (Public Health England, 2019e). One of the benefits of using liquid-based preparations is that the sample of cells can also be tested for HPV. In 2013 the NHS Cervical Screening Programme introduced HPV testing as a triage method for women with borderline or low-grade cell changes (women who were HPV positive were referred to colposcopy and women who were HPV negative were returned to routine recall) and as a ‘test of cure’ following treatment for CIN2 or CIN3 (Public Health England, 2016). Figure 1.2 shows the cytology-based screening pathway.

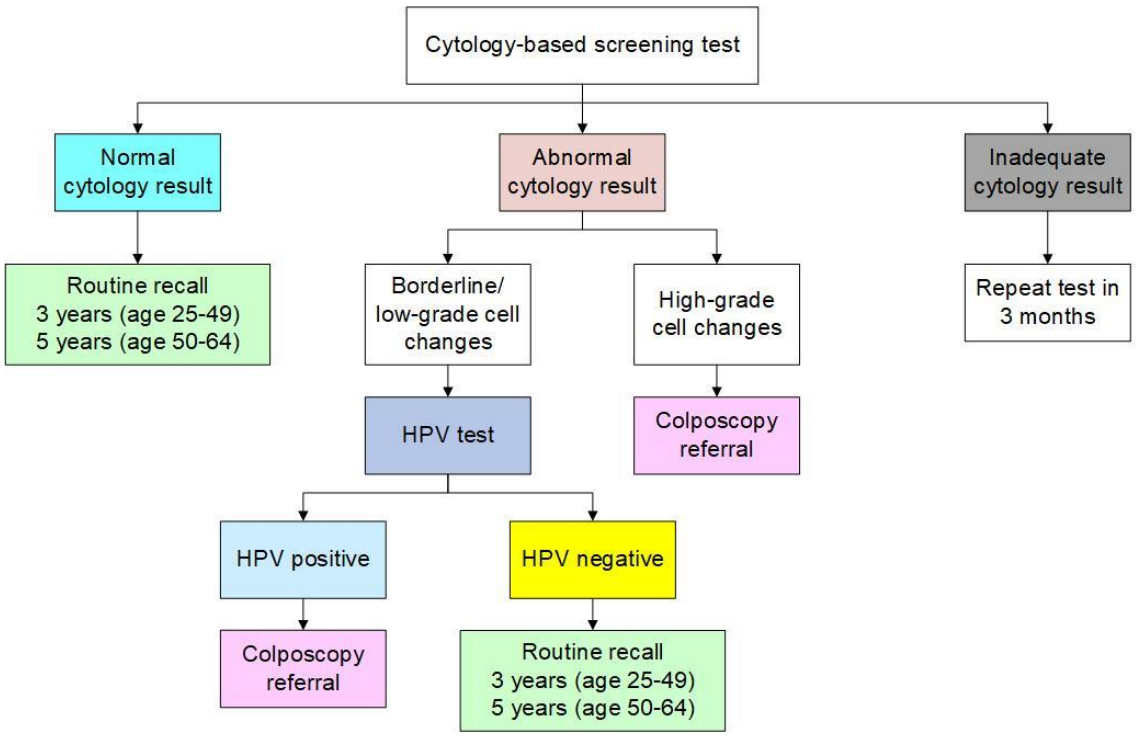

Figure 1.2: Cytology-based screening pathway

A key limitation of cytology-based screening is its relatively low sensitivity for detecting high-grade cell changes (i.e. the ability of the test to correctly identify individuals with high-grade cell changes). A Cochrane review reported that the sensitivity of liquid-based cytology to detect CIN2+ and CIN3+ ranged from 52 to 94% (pooled: 75.5%) and 52 to 98% (pooled: 76%) respectively, suggesting that this method of screening is also inconsistent (Koliopoulos et al., 2017). In addition, it has been suggested that the identification of changes within cells during a cytological examination is subjective and cytology screening is a repetitive process which could lead to a greater number of interpretation errors (Cuzick et al., 2006).

1.5.2: HPV primary screening

Since December 2019[5], the screening programme in England has used HPV primary screening, which tests for presence of HPV in the first instance rather than first detecting cytological abnormalities. Pilot studies of HPV primary

[5] In England, HPV primary screening was introduced in 6 pilot sites between May and August 2013 (Bristol, North West London, Sheffield, Norwich and Norfolk, Liverpool and Manchester). It was rolled out across the rest of England during 2019 (and in some areas prior to 2019) and fully implemented by December 2019.

screening began in 2013 (Public Health England, 2019a). In 2016 the UK National Screening Committee recommended that the NHS Cervical Screening Programme use HPV testing as the primary screening test because evidence suggests that HPV primary screening has higher sensitivity for identifying high-grade cell changes (Cuzick et al., 2006; Ronco et al., 2014; Ronco et al., 2010; UK National Screening Committee (UK NSC), 2018). HPV primary screening has also been fully implemented in Wales (in September 2018) and Scotland (in March 2020) and will be implemented in Northern Ireland in the future (date to be confirmed) (Jo's Cervical Cancer Trust, 2020b; Public Health Scotland, 2021; Public Health Wales, 2018). Several other countries have moved, or plan to move, to HPV primary screening. Mexico began offering HPV primary screening to women over the age of 35 years in 2008, followed by Turkey in 2014 for women aged between 30 and 65 years (Gultekin et al., 2018; Hurtado-Salgado et al., 2018). More recently, HPV primary screening was introduced in the Netherlands in January 2017 and Australia in December 2017 (Aitken et al., 2019; Australian Government - Department of Health National Cervical Screening Program). HPV primary screening is expected to be implemented in Norway, Denmark, Belgium and Germany by 2021 (Maver & Poljak, 2020).

The move to HPV primary screening in England has changed the cervical screening results women receive. Women who attend screening are informed that they are HPV positive or HPV negative. All women testing HPV positive have their sample of cells examined using cytology and are either told they are HPV positive with normal cytology or HPV positive with abnormal cytology (Public Health England, 2019e). Women testing HPV positive with abnormal cytology are referred to colposcopy (Public Health England, 2019e). Testing HPV positive with normal cytology is a new result created by the HPV primary screening pathway. These women are at very low immediate risk of developing CIN3+ or cervical cancer (1-year cumulative risk of CIN3+: 2.1%, 1-year cumulative risk of cervical cancer: 0.8%) (Malagón et al., 2020). However, women testing HPV positive with normal cytology are recalled for screening earlier than those testing HPV negative, 12 months after their HPV positive result, to see whether their HPV infection has cleared. Women testing HPV positive with normal cytology on three successive occasions are referred to colposcopy (Public Health England, 2017). Figure 1.3 shows the HPV primary screening pathway.

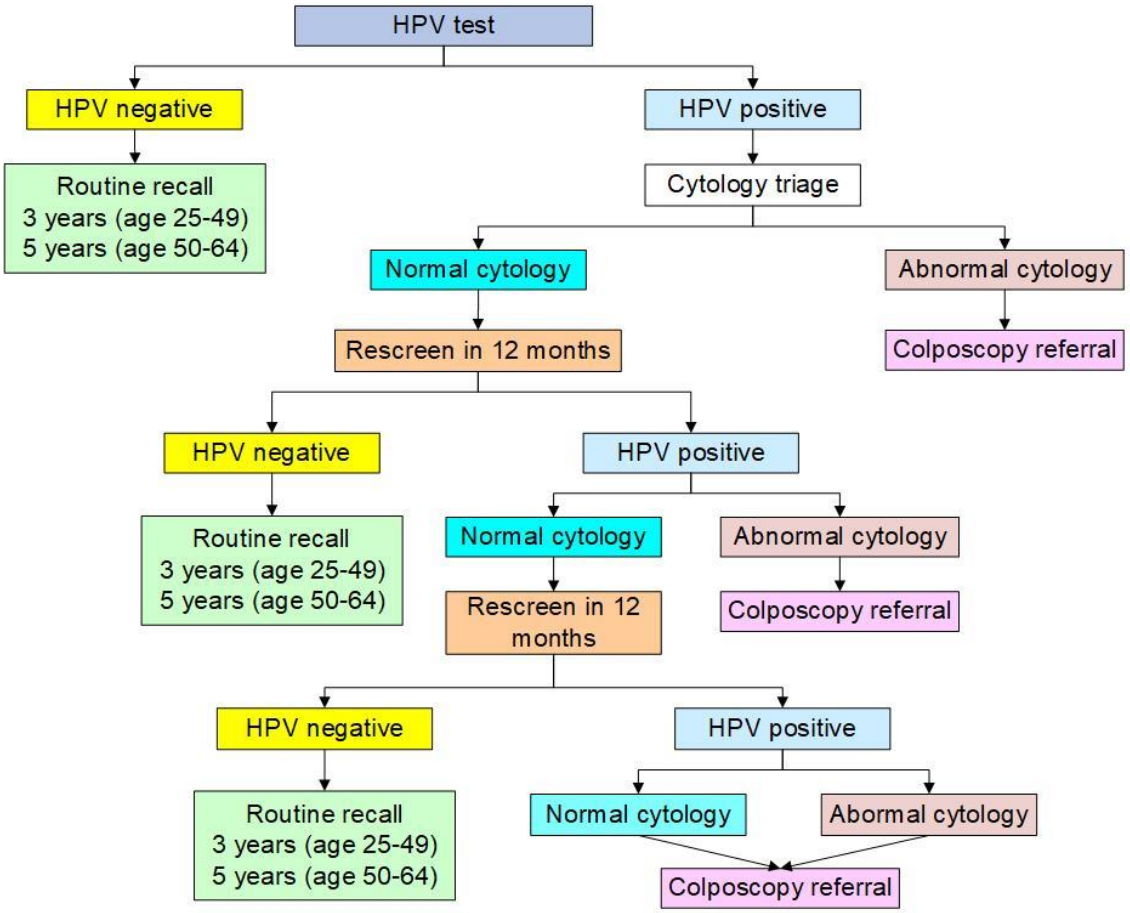

Figure 1.3: The HPV primary screening pathway

(adapted from Public Health England, 2017).

Currently, women aged 25 to 49 years who test HPV negative are routinely recalled every three years, however because of the increased sensitivity of HPV testing, the screening interval can safely be increased. Data from four European randomised controlled trials (RCTs) supported the extension of screening intervals to at least five years and 5-yearly screening using HPV primary screening has already been implemented in Australia and the Netherlands (Ronco et al., 2014). The UK National Screening Committee has recommended changing the screening interval for women aged 25 to 49 years from three to 5-yearly, however the timescales for this change are yet to be announced (Public Health England, 2020; UK National Screening Committee (UK NSC), 2018).

1.5.3: HPV genotyping

In England, the management of women testing HPV positive with normal cytology is the same regardless of the HPV type women test positive for. HPV 16 and HPV 18 account for 70% of all cervical cancers, therefore testing positive for these HPV types confers a greater risk than testing positive for other HPV types (Hashim et al., 2020). Hashim et al. (2020) found that among women with normal cytology, CIN3+ risk was 19.9% for women testing positive for HPV 16, 10.8% for women testing positive for HPV 18 and 5.5% for women testing positive for other HPV types. However, a key limitation of the study by Hashim et al. (2020) was the short follow-up period which ranged from 9 months for women who were HPV positive with abnormal cytology to 21 months for women who were HPV positive with normal cytology.

In some countries such as the USA and Australia, HPV 16 and 18 genotyping is used to identify women at increased risk of CIN, with women testing positive for HPV 16 or 18 immediately referred for colposcopy (Anderson, Saville, Wright, & Cancer Council Australia Cervical Cancer Screening Guidelines Working Party, 2018; Huh et al., 2015). However, in the English pilot of HPV primary screening HPV 16 and 18 genotyping at baseline was not tested out of concern that it would lead to an unsustainable demand for colposcopy and because viral clearance of HPV within 12 months was expected to be high (Rebolj et al., 2019a). Instead, HPV 16 and 18 genotyping was only carried out after two consecutive HPV with normal cytology results (i.e. among women with a persistent HPV infection), in three out of the six sites which were included in the HPV primary screening pilot. In the English pilot of HPV primary screening, HPV 16 and 18 genotyping of persistent HPV infections had little clinical benefit and did not substantially increase CIN2+ detection (Rebolj et al., 2019a).

1.5.4: Cervical screening uptake

In England between 2018 and 2019, 4.41 million woman aged 25 to 64 years were invited for screening, of whom 71.9% were adequately screened (Screening & Immunisations Team (NHS Digital) & PHE Screening (Public Health England), 2019). Uptake among women aged 50 to 64 years was slightly higher (76.2%) than among women aged 25 to 49 years (69.8%). The number

of women being screened has been in decline since 2011 when 76% of women aged 25 to 64 years, 80% of women aged 50 to 64 years and 74% of women aged 25 to 49 years were screened (Screening & Immunisations Team (NHS Digital) & PHE Screening (Public Health England), 2019). Studies exploring screening non-attendance suggest a wide range of barriers, including practical barriers such as difficulties arranging appointments and a lack of time, emotional barriers including embarrassment, fear that screening may be painful and fear of what the test might find, and feeling at low risk of cervical cancer because of current sexual behaviour or absence of symptoms (Ekechi et al., 2014; Marlow, Waller, & Wardle, 2015; Oscarsson, Benzein, & Wijma, 2008; Waller, Bartoszek, Marlow, & Wardle, 2009).

1.6: HPV self-sampling

HPV self-sampling may be one way to overcome some of the barriers to conventional cervical screening and increase uptake. HPV self-sampling allows women to collect a sample from their vagina using a swab or brush, which can then be sent to a laboratory and tested for HPV (Jo's Cervical Cancer Trust, 2021). Research suggests that, depending on the HPV assay used, HPV self-sampling can be as accurate in detecting CIN2+ or CIN3+ as clinician sampling (Arbyn, Smith, Temin, Sultana, & Castle, 2018). A systematic review and meta-analysis found that offering HPV self-sampling increased participation by around 10% among screening non-attenders and several studies have suggested that it is acceptable to women (Dzuba et al., 2002; Huynh, Howard, & Lytwyn, 2010; Igidbashian et al., 2011; Verdoodt et al., 2015; Waller et al., 2006). HPV self-sampling may also be more acceptable to those who find conventional screening invasive or traumatic such as individuals affected by sexual abuse or transgender men (Cadman, Waller, Ashdown-Barr, & Szarewski, 2012; Johnson, Wakefield, & Garthe, 2020; The Eve Appeal, 2019). In the Netherlands, women can request a postal HPV self-sampling kit if they do not wish to have conventional cervical screening (National Institute for Public Health and the Environment. Ministry of Health Welfare and Sport, 2016a, 2016b). Self-sampling is also available in Australia, however, women have to be aged 30 years or over, be overdue for cervical screening by at least two years and the self-sampling must be requested and overseen by a cervical screening

test provider who provides conventional cervical screening (Australian Government - Department of Health, 2020). The YouScreen trial of HPV self-sampling is currently being rolled-out in 166 GP practices in North and East London where screening attendance is low (ISRCTN Registry, 2021; NHS, 2021). Women who are 15 months overdue for screening will be posted a self-sampling test. Women attending a GP appointment who are at least 6 months overdue for screening will also be offered a test. The test can be posted back to the NHS Cervical Screening Programme's laboratory in London where it will be tested for HPV. If a woman tests HPV positive she will be invited to attend cervical screening at her GP practice. Although HPV self-sampling is not currently routinely offered by the NHS Cervical Screening Programme, in the future it may become an option for women who do not wish to participate in conventional screening or are overdue for screening.

1.7: Elimination of cervical cancer

In May 2018, the Director-General of the World Health Organisation (WHO) called for global action to eliminate cervical cancer (World Health Organisation, 2018b). High uptake of both HPV vaccine and HPV testing in cervical screening could control and ultimately eliminate cervical cancer (Bosch, 2011). In December 2019, the WHO proposed a draft global strategy for the elimination of cervical cancer (World Health Organisation, 2020). The strategy stated that to eliminate cervical cancer as a public health problem, all countries must work towards an incidence rate of less than four cases per 100,000 women (World Health Organisation, 2020). The strategy also proposed that the following targets must be met by all countries by 2030: (1) 90% of girls fully vaccinated by age 15, (2) 70% of women screened with a high-performance test by ages 35 and 45 and, (3) 90% of women identified with cervical disease treated (World Health Organisation, 2020).

A modelling study predicted the projected incidence of cervical cancer in 181 countries between 2020 and 2099 (Hall et al., 2019). It estimated that, with high coverage screening and vaccination, cervical cancer incidence could decline to fewer than six new cases per 100,000 individuals by 2045 to 2049 for very high Human Development Index (HDI) countries such as the UK (which would be

considered a rare cancer), and to less than four cases per 100,000 individuals by 2055 to 2059 (Hall et al., 2019).

In another modelling study which predicted cervical cancer in England until 2040 under four scenarios, the predicted reduction was more modest (Castanon, Landy, Pesola, Windridge, & Sasieni, 2018). The study estimated that because women born between 1975 and 1990 are unvaccinated, cervical cancer incidence will only decrease by 10% from 12.8 per 100,000 women in 2011 to 2015 to 11.5 per 100,000 women in 2036 to 2040 (Castanon et al., 2018). The decrease was predicted to be more pronounced among young women aged 25 to 29 years who had been vaccinated against HPV 16 and 18 (9.5 cases per 100,000 women by 2036 to 2040). If the nonavalent vaccination was to be introduced (which protects against nine HPV types which cause around 90% of cervical cancers) incidence would be reduced further (6.1 cases per 100,000 women) (Castanon et al., 2018; Sanofi Pasteur MSD, 2016). Both modelling studies were based on the assumption of at least current levels of vaccination and screening coverage being maintained.

1.8: The impact of HPV testing

There are several positive aspects of HPV testing including its increased sensitivity for detecting high-grade cell changes, the potential for HPV self-sampling and less frequent screening intervals. However, it is important that women understand screening, and the potential risks as well as the benefits, to enable them to make an informed decision as to whether to participate. An essential criterion for any screening programme is that the overall benefits should outweigh the harms, therefore it is important to understand the psychosocial consequences for women participating in this new method of screening to minimise any negative impact (Wilson & Jungner, 1968). The following sections will describe the existing literature on knowledge and attitudes towards, and the psychological impact of, HPV testing.

1.8.1: Knowledge and attitudes towards HPV testing

A review of 17 studies synthesised women’s views about HPV testing in the cervical screening programme prior to its introduction and found a number of

negative consequences and concerns (Hendry et al., 2012). Women reported negative emotions following test results including worry, fear, anger, anxiety, shock and confusion, an impact on their relationships, and worry about the stigma that was associated with having an STI (Hendry et al., 2012). While most participants found HPV testing acceptable, they had a number of questions and misunderstandings (Hendry et al., 2012). A limitation of this review is that in most studies participants had not taken part in HPV testing and were asked their views in the context of a hypothetical scenario. The authors comment that the psychosocial burden of an HPV infection was more prominent in 'real-life' situations than hypothetical scenarios, therefore the findings from hypothetical scenarios may not be generalisable.

More recent research published in 2018 explored women's awareness of, and attitudes towards, HPV primary screening (Patel, Moss, & Sherman, 2018). Qualitative interviews and focus groups were carried out with 46 women recruited from community settings and colposcopy clinics. Some of these women had received an HPV positive result. Many women were unaware that HPV testing was used in the NHS Cervical Screening Programme and lacked knowledge about HPV. Women who had not tested HPV positive felt that they would respond pragmatically to an HPV positive result, however women who had received an HPV positive result described feeling shocked, fearful, and embarrassed. Some women were concerned that they would be judged for participating in HPV primary screening because they were being tested for an STI. Knowing that HPV was sexually transmitted led some women to question whether they would participate in HPV primary screening because they felt they were at low risk of acquiring an STI because they were in a monogamous relationship, had only had one lifetime sexual partner or had been with their partner for a long time. The authors concluded that if HPV primary screening is not acceptable to women, this may have a negative impact on future screening participation.

Research published in 2019 recruited 100 women across Scotland and used individual interviews and focus groups to explore women's understanding of the introduction of HPV testing in the cervical screening programme in Scotland (NHS Health Scotland, 2019). The study included a range of women such as those with additional support needs, lesbian and bisexual women, and women

who had never attended cervical screening as well as those who attended regularly or irregularly. Nearly 40% of participants came from the most deprived areas in Scotland. The study found that many women had not heard of HPV and indicated that they would feel confused if they were told they were HPV positive following cervical screening. Women also reported that they would be worried, anxious or scared, partly because they did not know what HPV was or what could be done about it. Only a small number of women reported that they would not be particularly worried if they were told they had HPV.

Following the announcement of the renewed National Cervical Screening Programme in Australia (which included replacing 2-yearly cytology-based screening with 5-yearly HPV primary screening), a petition objecting to these changes was initiated, generating over 70,000 signatures and 20,000 comments (Obermair, Dodd, Bonner, Jansen, & McCaffery, 2018). In a content analysis of 2,000 randomly selected comments, only a very small proportion of these expressed concern about HPV testing (2.6%). However, 9.9% of commenters believed that the changes to the programme were a ‘cost-cutting exercise’ and 16.7% expressed concerns about the change in the screening interval from 2 to 5-yearly, believing that this was too long between tests to prevent cervical cancer (Obermair et al., 2018). This study highlights the importance of communicating changes to cervical screening programmes, and the reasons for the changes, to the public.

In a study comparing HPV knowledge in the UK, USA and Australia, 39.2% of men and 61.6% of women in the UK had heard of HPV, and of these individuals, most knew that HPV can cause cervical cancer (Marlow, Zimet, McCaffery, Ostini, & Waller, 2013). However, knowledge of other aspects of HPV were low, for example, only around a quarter of UK participants were aware that most sexually active people will acquire HPV at some point in their lives. This study also explored knowledge of HPV testing which, overall, was found to be low (Dodd et al., 2014). Nearly 20% of UK women did not correctly answer the item ‘If a woman tests positive for HPV, she will definitely get cervical cancer’ and only around a quarter of women correctly answered the item ‘If an HPV test shows that a woman does not have HPV, her risk of cervical cancer is low’ (Dodd et al., 2014).

More recent research carried out with 246 women in the UK aged 25 years or older suggests that some aspects of knowledge about HPV and HPV testing appear to have increased since the studies by Marlow et al. (2013) and Dodd et al. (2014) (Kola-Palmer & Dhingra, 2020). However, knowledge of some aspects, particularly around HPV testing, remain low. For example, although 82% of women were aware that an HPV positive result does not necessarily mean that an individual will get cervical cancer, only 31% were aware that if an HPV test shows that a women does not have HPV, her risk of cervical cancer is low (Kola-Palmer & Dhingra, 2020). To my knowledge, no research has explored knowledge of HPV and HPV testing since the introduction of HPV primary screening in England. This should be explored. Knowledge of the key aspects of HPV testing is important to make an informed decision about whether to attend screening. It has also been found that increased HPV and HPV test knowledge is associated with higher HPV test acceptability (Tatar et al., 2018). Knowledge of HPV may also help women deal more effectively with an HPV positive result.

1.8.2: The psychological impact of HPV testing

A recent systematic review and meta-analysis explored women's emotional responses to testing HPV positive (McBride et al., 2020c). Eight emotional responses were experienced by women: anxiety, psychological distress (sexual, test-specific and general), fear, surprise and confusion, shame and disgust, sadness, positive affect (relief and acceptance) and apathy. Meta-analyses revealed that, compared to the control group (women who were HPV negative and/or had a normal cytology result), short-term anxiety was higher among women who were HPV positive with normal or abnormal cytology, but this did not persist in the longer term (more than two months after women received their results). Higher psychological distress was observed for women testing HPV positive with abnormal cytology both in the short and long-term. While the authors advise that the results of the meta-analyses should be interpreted with caution due to the high levels of statistical heterogeneity, this review highlights several emotional responses to testing HPV positive.

A small number of studies have explored psychological outcomes in the context of routine HPV primary screening. A study in Australia found that anxiety,

distress, concern and distress about test result and cancer worry were higher among women who reported testing HPV positive compared to women who reported testing HPV negative (Dodd, Mac, Brotherton, Cvejic, & McCaffery, 2020). A second study, carried out in the context of the English HPV primary screening pilot, explored anxiety and distress among six groups of women with a combination of HPV and cytology results (including a control group who were not tested for HPV and received a normal cytology result) two weeks after they received their screening results (McBride et al., 2020b). Anxiety was significantly higher among women testing HPV positive with either normal or abnormal cytology compared to the control group. Distress was also found to be significantly higher but only among women testing HPV positive with abnormal cytology. Increased anxiety or distress were not observed among women with a persistent HPV infection (woman who had tested HPV positive two years consecutively), suggesting that that the adverse psychological impact of testing HPV positive may normalise or reduce over time (McBride et al., 2020b). A recent qualitative study with women testing HPV positive with normal cytology at routine HPV primary screening found that several HPV-related responses differed between women who were categorised as having low-to-normal anxiety and women with high anxiety, suggesting that messaging targeting the concerns of highly anxious women may be warranted (McBride, Marlow, Bennett, Stearns, & Waller, 2020a).

1.8.3: The psychosexual impact of HPV testing

Due to the sexually transmitted nature of HPV, there may also be psychosexual consequences of testing positive for the virus. In the following sections I will first describe how psychosexual impact is defined. Secondly, research exploring the psychosexual impact of receiving an abnormal cytology result will be outlined. Finally, literature from other sexually transmitted infections will be drawn upon to explore how psychosexual impact might be a particularly relevant consideration for HPV testing.

1.8.3.1: Defining psychosexual impact

‘Psychosexual Disorders’ first appeared in the Diagnostic and Statistical Manual of Mental Disorders third edition (DSM-III), published in 1980 (American

Psychiatric Association, 1980). The DSM is published by the American Psychiatric Association and provides descriptions and criteria of a range of mental disorders. With regards to 'Psychosexual Disorders', the DSM-III states that "…psychological factors are assumed to be of major etiological significance of the disorders…" and "…are characterised by inhibitions in sexual desire or the psychophysiological changes that characterise the sexual response cycle" (American Psychiatric Association, 1980). According to the DSM-III, the sexual response cycle consists of four phases: (1) Appetite (sexual fantasies and sexual desire), (2) Excitement (sexual pleasure), (3) Orgasm and 4) Resolution (general relaxation and well-being) (American Psychiatric Association, 1980). Psychosexual dysfunctions listed in the DSM-III include inhibited sexual desire, inhibited sexual excitement, inhibited orgasm and dyspareunia (persistent genital pain) (American Psychiatric Association, 1980). The current edition of the DSM (DSM-V) refers to psychosexual issues as 'Sexual Dysfunctions', and while the names of the disorders are slightly different to those used in the DSM-III, it continues to include issues with sexual interest, arousal, orgasm and genital pain (American Psychiatric Association, 2013).

To my knowledge, no previous literature has formally defined the term 'psychosexual'. Mindel and Marks (2005), in a review of the psychological impact of a genital herpes infection, state that "Psychosexual difficulties include the effects of being diagnosed with an STI on relationships and the challenges that arise when trying to develop and achieve intimacy. Sexual dysfunctions, such as a change in libido, pain with sex and erectile difficulties, may also develop". Flynn, Kew and Kisely (2009), in a review of interventions for psychosexual dysfunction in women treated for gynaecological cancer, refer to psychosexual dysfunction as "sexual difficulties not directly due to physical factors". In two papers explicitly exploring the psychosexual impact of an abnormal cervical screening result or HPV, psychosexual is not defined, however, the studies measure interest in and frequency of sex, sexual arousal, sexual satisfaction and negative feelings towards sex, relationships or sexual partners (Campion et al., 1988; Reed, Ruffin, Gorenflo, & Zazove, 1999).

Based on the DSM-III and DSM-V, and from papers that have described and measured psychosexual impact, I define psychosexual as "Feelings, worries and concerns that relate to, or impact on, sexual behaviour or sexual

relationships. This can include the impact on sexual behaviour or sexual functioning (e.g. sexual interest, arousal and pleasure) caused primarily by psychological factors, feelings about sexual partners and sexual relationships, and feelings about one's own sexual self-image" (American Psychiatric Association, 1980, 2013; Campion et al., 1988; Flynn et al., 2009; Mindel & Marks, 2005; Reed et al., 1999).

1.8.3.2: Psychosexual impact of an abnormal cervical screening result

As described previously in this chapter, testing HPV positive can result in elevated anxiety and distress. Research carried out prior to the introduction of HPV primary screening suggests that an abnormal cytology result may also result in increased anxiety (Bell et al., 1995; Drolet et al., 2012; Wilkinson, Jones, & McBride, 1990). Fewer studies have explored psychosexual outcomes following an abnormal cytology result, however those that have suggest that there is a negative impact on frequency of sex, interest in sex and satisfaction with sex among women with an abnormal cytology result compared to women with a normal cytology result or no cervical disease (Campion et al., 1988; Drolet et al., 2012; Lerman et al., 1991; Wardle, Pernet, & Stephens, 1995). Research has also suggested that an abnormal cytology result can have an impact on a women's relationship with their partner (Thangarajah et al., 2016). While receiving an abnormal cytology result appears to have a psychosexual impact, to my knowledge, there is no evidence to suggest that cervical screening itself has a psychosexual impact.

If cytological abnormalities are found during cervical screening, women are invited to have a colposcopy. If cytological abnormalities are found during a colposcopy, treatment to remove them may be recommended. This can be done during the colposcopy. Common treatments to remove cytological abnormalities from the cervix include large loop excision of the transformation zone (LLETZ, also known as LEEP – loop electrical excision procedure), cone biopsy, cryotherapy, laser treatment and cold coagulation (NHS, 2019a).

A systematic review which explored psychosexual outcomes following colposcopy and other related procedures found that psychosexual impact varied across studies with no consistent pattern of impact being demonstrated (O'Connor et al., 2016). The context in which psychosexual impact was

measured in the studies differed. Two studies measured psychosexual impact after a LEEP. Treatments to remove cytological abnormalities such as LLETZ or LEEP can have a physiological impact and cause side effects such as pain and bleeding (Jo's Cervical Cancer Trust, 2020d). These physiological side effects may affect how someone feels about having sex. It is therefore possible that having treatment has an additional psychosexual impact compared to colposcopy alone, which could explain why the review found no consistent pattern of psychosexual impact.

A study by Bonevski, Sanson-Fisher, Girgis and Perkins (1998) not included in the systematic review by O'Connor et al. (2016) found that, of the 38% of women who reported diminished interest in sex prior to colposcopy, 13% were improved, 25% were worse and 62% did not report any change post-colposcopy. However, women in this study were asked to think back to the time between receiving their cervical screening result and colposcopy when completing the questionnaire, therefore the results may be prone to recall bias.

A review of a small number of studies published in 2015 suggests that treatment for CIN appears to have a psychosexual impact, with sexual desire, interest, frequency and satisfaction all reduced following treatment for CIN (Cendejas, Smith-McCune, & Khan, 2015). Sparić et al. (2019) explored long-term psychosexual outcomes among women who had undergone cervical excisional treatment (LLETZ or cone biopsy) at least two years previously and found that 27.4% of women reported being less interested in sex post-treatment compared to pre-treatment. However, this study did not include a comparison group and it is possible that interest in sex may have decreased over time, regardless of the cervical excisional treatment.

In summary, previous research suggests that receiving an abnormal cytology result and having a colposcopy or treatment for CIN can have a negative psychosexual impact. However, as previously described in this chapter, knowledge of HPV is relatively low, and it is likely that most of these women would have been unaware that their abnormal cervical screening result was caused by an STI. Informing woman that they are HPV positive makes the STI aspect much more explicit. The psychosexual impact of being informed about an STI diagnosis will be explored in the next section.

1.8.3.3: Psychosexual impact of an STI

The diagnosis of an STI can have a negative impact on quality of life and psychological well-being (Carney, Ross, Bunker, Ikkos, & Mindel, 1994; Drolet et al., 2011; Mark, Gilbert, & Nanda, 2009; Mortensen, 2010; Raj, Sreenivas, Mehta, & Gupta, 2011; Stronks et al., 1993; Woodhall et al., 2008). This may be a consequence of the stigma and shame that is associated with having an STI (Bickford, Barton, & Mandalia, 2007; Jeynes, Chung, & Challenor, 2009; Melville et al., 2003; Nack, 2000). The diagnosis of an STI can also have a psychosexual impact. The psychosexual impact of testing positive for HIV, genital warts, genital herpes and chlamydia will be discussed in the following sections.

1.8.3.3.1: HIV

The psychosexual impact of HIV has been well-documented. Carlsson-Lalloo, Rusner, Mellgren and Berg (2016) carried out a meta-synthesis to describe the sexual and reproductive wellbeing of HIV positive women. The meta-synthesis included 18 qualitative studies, 17 of which were from high-income countries (USA; n=11, Canada; n=2, UK; n=2, Australia; n=1 and Ireland; n=1). The remaining study was carried out in Brazil. In total, 588 HIV positive women were included. The meta-synthesis found that an HIV positive diagnosis resulted in women feeling as though they had ‘lost’ a normal sex life. Changes in sexual activity and intimate partner relations, such as reduced sexual function and desire were described. Women felt less sexually spontaneous, partly because they felt obligated to use condoms to prevent transmission of HIV. They also felt ‘contaminated’, ‘disgusting’ and less sexually attractive.

1.8.3.3.2: Genital warts

Research suggests that having genital warts (“low-risk” HPV) can have a psychosexual impact. A study by Conaglen, Hughes, Conaglen and Morgan (2001) compared women with genital warts, women with a condition other than genital warts (which was not specified in the article) and women with no STI. Women in the genital warts group had a lower overall sexual function score than the other two groups and reported lower sexual arousal, initiation of sexual

activity and sexual satisfaction, however the difference between groups was not statistically significant. A small qualitative study with men and women with genital warts found that the disease affected participants' sex and love lives, with participants reporting a loss of sexual desire and feeling sexually unattractive (Mortensen & Larsen, 2010). Qi et al. (2014) explored psychosocial burden among men and women with genital warts. Psychosocial burden was measured using the HPV Impact Profile (HIP) which consists of seven domains: (1) Worries and concerns, (2) Emotional impact, (3) Sexual impact, (4) Self-image, (5) Partner issues and transmission, (6) Interactions with physicians and, (7) Life/control impact. Self-image and sexual impact were the domains that were affected the most by having genital warts. Drolet et al. (2011) used the same measure as Qi et al. (2014) and found that self-image, sexual impact and partner issues and transmission were the domains that were most affected. While the psychosocial burden of having genital warts decreased over a six-month period, it remained higher among men and woman whose genital warts persisted, in comparison to those whose genital warts had cleared (Drolet et al., 2011). This suggests that having visible symptoms can particularly impact psychosexual functioning.

1.8.3.3.3: Genital herpes

The psychosexual impact of testing positive for genital herpes appears to be more mixed. Foster and Byers (2013) found that men and women with genital herpes and/or HPV were less sexually satisfied, had lower sexual self-esteem and were more likely to report a sexual problem than participants with no STI. However, participants with herpes and/or HPV reported engaging in sexual activity more frequently than participants with no STI. As this was a cross-sectional study, it is not possible to make causal inferences between having an STI and frequency of sex and it is possible that frequency of sex may have predicted having an STI, rather than having an STI predicting frequency of sex. In addition, this study included participants with genital herpes and/or HPV and some participants also had other STI diagnoses (predominantly chlamydia, pubic lice or gonorrhoea), so it is difficult to determine the psychosexual impact of solely having genital herpes from this study. Another study found that, in comparison to individuals with no STI, participants with genital herpes reported

higher levels of sexual anxiety, fear of sex and sexual depression and lower levels of sexual satisfaction (Newton & McCabe, 2008a).

A systematic review by Ross, Johnston and Wald (2011) which included five qualitative studies measuring sexual satisfaction found that only one study reported a negative impact for participants who tested positive for the genital herpes virus, compared to participants who tested negative, when measured a week after diagnosis. However, the difference no longer remained at the three-month follow-up. A qualitative study by Melville et al. (2003) which was included in the review by Ross et al. (2011) reported that participants diagnosed with the genital herpes virus (none of whom had a clinical history of genital herpes) felt sexually undesirable and avoided having sex to prevent passing the infection on to their partner. Although none of the participants in this study had a clinical history of genital herpes, they may have received guidance advising them to avoid sexual activity while symptomatic which may have influenced their feelings about sex. Since the review by Ross et al. (2011) was published, a qualitative study of 25 women with genital herpes (10 of whom were symptomatic) found that 80% of women abstained from sex immediately after being diagnosed, however, most reported that they had begun having sex again six months later (Davis, Roth, Brand, Zimet, & Van Der Pol, 2016).

1.8.3.3.4: Chlamydia

Testing positive for chlamydia appears to have a psychosexual impact, although it has only been explored in a limited number of studies. A systematic review of a small number of studies measuring the impact on quality of life among women undergoing chlamydia testing reported that, while there were no differences in sexual functioning, women testing positive for chlamydia were more anxious about sexual aspects of their life than those testing negative (Jackson & Roberts, 2016). In addition, the review reported that women who tested positive felt less sexually attractive and were more likely to report breaking up with a partner. A study exploring the sexual impact of a chlamydia infection compared three groups of women: those with chlamydia, those with a common genital bacteria or yeast infection, and those without either infection, and found that women with chlamydia reported feeling less sexually desirable and sexually satisfied than women in the other two groups (Cai et al., 2011).

Overall, studies from the STI literature suggest that even in the absence of symptoms, having an STI can have a psychosexual impact.

1.8.3.4: The psychological impact of disclosing an STI to a sexual partner

From the literature on the psychosocial impact of having an STI, a key concern among infected individuals is disclosing the infection to a sexual partner. In studies with participants with genital herpes and chlamydia, disclosure is described as something that is difficult, fear-inducing and a considerable source of worry (Duncan, Hart, Scoular, & Bigrigg, 2001; Mills, Daker-White, Graham, & Campbell, 2006). Concerns about disclosure include a negative reaction from a partner, being rejected or a partner ending a relationship, and a partner telling others about the STI (Duncan et al., 2001; Green et al., 2003; Melville et al., 2003; Myers, Buhi, Marhefka, Daley, & Dedrick, 2016; Scrivener, Green, Hetherton, & Brook, 2008). HPV is very common and most men and women will be infected with it at some point during their life (Koutsky et al., 1988; Satterwhite et al., 2013). However, because it is an STI, women may feel obliged to disclose the infection to a sexual partner and doing so may have a psychological impact like that of disclosing other STIs.

1.8.3.5: The psychosexual impact of testing HPV positive

In addition to the psychological impact of testing HPV positive described previously in this chapter, a small number of studies carried out in England have explored the psychosexual impact of testing HPV positive. These studies have all been carried out in the context of co-testing (where HPV and cytology testing are carried out concurrently) rather than HPV primary screening. A quantitative study found that women who tested HPV positive were more likely to report feeling worse about their current, past and future sexual relationships a week after receiving their result than HPV negative women, irrespective of their cytology result (McCaffery et al., 2004). A second quantitative study included three groups of women who had all received an abnormal cytology result but had different HPV results (HPV positive, HPV negative and a group who were not tested for HPV). Six months after receiving their results, sexual worries were significantly higher among women who had tested HPV positive than the other two groups (Maissi et al., 2005). In a qualitative study of 74 women, women

who tested HPV positive reported feeling concerned about their sexual relationships and worried about disclosing their HPV positive result to others (McCaffery, Waller, Nazroo, & Wardle, 2006).

1.9: Summary

It is now well-established that virtually all cervical cancers are caused by infection with a high-risk type of HPV (Bosch et al., 2002; Bosch et al., 1995; Walboomers et al., 1999). Evidence suggests that HPV testing has higher sensitivity for identifying high-grade cell changes than cytology (Cuzick et al., 2006; Ronco et al., 2014; Ronco et al., 2010). However, the introduction of HPV primary screening has changed the screening results women receive. In the English HPV primary screening pilot, 12.7% of women received an HPV positive result, compared to 3.8% of women who received an abnormal cytology result (Rebolj et al., 2019b). Women who receive an HPV positive result may not have heard of HPV or understand what their result means, which may cause anxiety and distress. In addition, because of the sexually transmitted nature of HPV, there may also be psychosexual consequences of testing positive for the virus. Evidence from the STI literature suggests that receiving an HPV positive result could have a negative impact on psychosexual outcomes and this warrants further exploration. With the introduction of HPV primary screening in the NHS Cervical Screening Programme in England, and other countries, it is important to explore the psychosexual impact of testing positive for HPV to determine whether additional information and support may be required for women receiving an HPV positive result. This is particularly important given that a greater number of women will receive an HPV positive result following HPV primary screening than the number who previously received an abnormal screening result following cytology-based screening.

1.10: Aims and objectives of the thesis

Aim

The aim of this thesis is to explore the psychosexual impact of testing positive for high-risk cervical HPV.

Objectives

1. Review the existing qualitative and quantitative literature exploring:

    a. The psychosexual impact of testing positive for high-risk cervical HPV and;
    b. Concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

2. Assess psychosexual distress following routine HPV primary screening in the context of the English Cervical Screening Programme.

3. Explore the psychosexual impact and disclosure experiences of women who have tested HPV positive in the context of HPV-based cervical screening.

To address these objectives, I have carried out three studies using different methodologies.

Study 1

Study 1 addressed Objectives 1a and 1b. To provide context and background to my thesis and explore what is currently known, a systematic review synthesised existing qualitative and quantitative literature exploring the psychosexual impact of testing positive for high-risk cervical HPV (Study 1a) and concerns about disclosing a high-risk cervical HPV infection to a sexual partner (Study 1b). The database search, which included search terms related to both research questions, was initially run in October 2017 and re-run in January 2019. This study was carried out between September 2017 and September 2019.

Study 2

Study 2 addressed Objective 2. This study used a between-groups design to assess psychosexual distress following HPV primary screening among women receiving different HPV and cytology results, at three time points over a year: shortly after they received their results and 6 and 12 months later. The study

also assessed changes in psychosexual distress by screening result group between baseline and 6 months and baseline and 12 months. Baseline data were collected as part of the Psychological Impact of Primary Screening for HPV (PIPS) study between November 2016 and October 2017. This study was carried out between January 2018 and July 2020.

Study 3

Study 3 addressed Objective 3. This study used qualitative methodology to explore the psychosexual questions and concerns women taking part in HPV-based cervical screening have, and their experiences, questions and concerns about disclosing HPV. The study also aimed to explore whether there were any differences in responses between women who were in a relationship and women who were not in a relationship. This study was carried out between June 2020 and February 2021.

CHAPTER 2: THE PSYCHOSEXUAL IMPACT OF TESTING POSITIVE FOR HIGH-RISK CERVICAL HPV: A SYSTEMATIC REVIEW OF THE LITERATURE (STUDY 1A)

2.1: Roles and contributions

I conceived the study with Dr Laura Marlow and Dr Jo Waller. I developed the search strategy with assistance from Dr Laura Marlow, Dr Jo Waller and a librarian at University College London with expertise in systematic review searching. I ran the searches and screened all article titles. Mairead Ryan and I independently screened the abstracts and full-text papers of the remaining articles. I extracted data and carried out a quality assessment for each article. Mairead Ryan checked the extracted information and quality assessments for 20% of articles (n=6/30). I developed a coding frame and coded all the qualitative data from included articles. Mairead Ryan second coded 41% of the included articles (n=7/17). I interpreted the data with assistance from Dr Laura Marlow. A version of this chapter has been published in *Psycho-oncology* (see Appendix 2.1).

2.2: Introduction

As discussed in Chapter 1, the move to HPV primary screening changes the cervical screening results women receive. Women will either be told they are HPV negative or HPV positive. In the HPV primary screening pilot in England, approximately 13% of the screened population received an HPV positive result (Rebolj et al., 2019b).

Due to the sexually transmitted nature of HPV, there may be psychosexual consequences of testing positive for the virus. As outlined in Chapter 1, previous research suggests a diagnosis of an STI such as genital warts, genital herpes and chlamydia can have a psychosexual impact with consequences including reduced sexual desire, reduced sexual satisfaction, and feeling sexually unattractive, sexually anxious or depressed (Cai et al., 2011; Mortensen & Larsen, 2010; Newton & McCabe, 2008a). An early qualitative

study of HPV testing (in the context of co-testing) suggested that similar concerns might apply to women who are told they are HPV positive (McCaffery et al., 2006). One criterion of screening is that the overall benefits should outweigh the harms, therefore it is important to understand and address any psychosexual consequences of testing positive for HPV, particularly as there will be a sizeable proportion of women receiving an HPV positive result (Rebolj et al., 2019b; Wilson & Jungner, 1968).

Two previous reviews have explored the psychosexual impact of testing positive for HPV (Fleurence, Dixon, Milanova, & Beusterien, 2007; Graziottin & Serafini, 2009). One review focused on the economic burden and health-related quality-of-life impact of cervical HPV-related conditions (HPV infection, abnormal cytology result and invasive cervical cancer) (Fleurence et al., 2007). In total the review included 33 studies, 9 studies assessing economic burden and 24 studies assessing health-related quality-of-life, of which five studies assessed the impact of an HPV infection. Of these five studies, four reported psychosexual outcomes (relationship with partner, sexual contact and sexual interest). The review does not provide a summary of study characteristics or findings but reports that most studies found that there was a negative impact on women's sexual functioning following an HPV positive result. While the review reported psychosexual outcomes such as relationship with a partner, sexual contact and sexual interest, it did not include psychosexual outcomes in the search strategy so there may be additional papers which focus on these specific outcomes.

A second review explored the impact of genital warts and HPV-related genital, oral and anal precancerous lesions[6] on women's sexual function (Graziottin & Serafini, 2009). The authors concluded that evidence regarding the psychosexual impact of HPV is limited and more research in this area is needed. The two existing reviews were published in 2007 and 2009 and with the increasing use of HPV testing in cervical screening (e.g. for triage and test of cure), combined with the introduction of HPV primary screening, it is likely that additional studies have since been published.

[6] Cytological abnormalities are referred to as precancerous cells or precancerous lesions in some countries.

I therefore aimed to review the existing qualitative and quantitative literature exploring the psychosexual impact of testing positive for high-risk cervical HPV.

2.3: Methods

This review was registered with PROSPERO (CRD42018083969) and followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009). The review aimed to explore:

1. The psychosexual impact of testing positive for high-risk cervical HPV and;
2. Concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

Findings are reported separately. Findings exploring the psychosexual impact of testing positive for high-risk cervical HPV are reported in this chapter. Findings exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner are reported in Chapter 3.

2.3.1: Search strategy for identifying papers

Search terms were developed by identifying key terms used in previous relevant reviews and primary research and with the assistance of a librarian at University College London (UCL) with expertise in systematic review searching. The search included terms relating to (1) high-risk cervical HPV and, (2) a psychosexual or disclosure-related outcome (e.g. sexual behaviour, sexual function, the disclosure of an HPV result to a sexual partner) and were linked using Boolean operators. The full search strategy for each database can be found in Appendix 2.2. The search was conducted in MEDLINE, PsycINFO, CINAHL Plus, Web of Science and EMBASE on 09/01/2019. There were no study design, date or language limits applied to the initial search and both qualitative and quantitative articles were included. Additional articles were identified by searching the grey literature using OpenGrey (www.opengrey.eu), PsycEXTRA, the reference lists of included articles and forward reference searching. Results from the searches were exported to EndNote and duplicate papers were removed.

2.3.2: Selection process

Studies were included if they mentioned 1) HPV and, 2) a psychosexual or disclosure-related outcome. Reviews, conference abstracts, dissertation abstracts, letters, commentaries, case studies, opinion pieces and editorials were excluded. Studies were also excluded if they were not written in English, explicitly focused only on low-risk HPV (i.e. types of HPV that cannot cause cancer, e.g. genital warts) focused on the psychosexual impact of cervical cancer, treatment for cervical cancer or colposcopy or focused on non-cervical related HPV. I decided not to include articles that focused exclusively on low-risk types of HPV (i.e. genital warts) because 1) HPV primary screening will only test for high-risk types of HPV, and 2) the psychosexual impact of testing positive for, and feelings about disclosing low-risk HPV, were expected to be distinct because of its symptomatic, visible nature.

I screened all article titles and excluded any that were not written in English or clearly met the exclusion criteria of the review. Another researcher (MR[7]) and I independently screened the abstracts of the remaining articles. I obtained full-text papers for articles that met the inclusion criteria based on the title and abstract. Where an article could not be assessed for relevance based on the title and abstract, the full-text paper was obtained to determine eligibility. Any disagreements regarding whether an article should be included in the review were resolved by discussion.

2.3.3: Data extraction

Using a standardised data extraction form, I extracted information from each article, recording this in Microsoft Excel. The data extracted included relevant demographics of participants, methods (e.g. study design, recruitment method and setting, outcomes measured and method(s) of analysis) and a summary of psychosexual and disclosure-related outcomes. MR checked the extracted information for 20% of studies (n=6/30). This included an equal mix of studies reporting psychosexual-related outcomes only, disclosure-related outcomes only and studies reporting both psychosexual and disclosure-related outcomes.

[7] Mairead Ryan, Research Assistant, Department of Behavioural Science and Health, UCL.

Any disagreements regarding the information that was extracted were resolved by discussion. The data extraction form used can be found in Appendix 2.3.

2.3.4: Quality assessment

The quality of studies was assessed using modified versions of the National Institute for Health and Care Excellence (NICE) quality appraisal checklists for quantitative and qualitative studies. Quantitative studies were given separate overall quality grades for internal and external validity. Qualitative studies were given an overall quality grade. I carried out a quality assessment for each article and MR checked 20% of the assessments (n=6/30). This included an equal mix of studies reporting psychosexual-related outcomes only, disclosure-related outcomes only and studies reporting both psychosexual and disclosure-related outcomes. Disagreements about study quality were resolved by discussion. The quality appraisal checklists used can be found in Appendices 2.4 (quantitative studies) and 2.5 (qualitative studies).

2.3.5: Analysis

The results from articles measuring the psychosexual impact of high-risk cervical HPV are reported. Quantitative and qualitative findings were analysed separately.

For quantitative studies, a narrative synthesis was conducted, and the results described descriptively. I utilised Popay et al.'s (2006) framework for narrative synthesis and followed three of the suggested elements: (1) Develop a preliminary synthesis of findings across the included studies – this involved summarising and organising findings so patterns across studies could be described, (2) Explore relationships in the data – as patterns began to emerge during the preliminary synthesis, relationships between and within studies were explored to identify similarities and differences across included studies and, (3) Assessing the robustness of the synthesis – this involved assessing the quality of the studies included in the review to determine the trustworthiness of the synthesis itself. Popay et al. (2006) suggest that if studies of poor methodological quality are included in a review in an uncritical manner then this

may affect the trustworthiness and the conclusions that can be drawn from the review.

For qualitative studies I conducted a thematic synthesis, following the three stages outlined by Thomas and Harden (2008): (1) Line-by-line coding – this involved coding each relevant line of text in the results and discussion sections of included papers according to its meaning and content, (2) The development of 'descriptive themes' – this involved looking for similarities and differences between codes and beginning to group them together into a hierarchy and, (3) The generation of 'analytic themes' – using the judgement and insights of the reviewers this involved 'going beyond' the content of the studies included in the review to generate new interpretive constructs, explanations or hypotheses appropriate to the aims of the review.

I developed a coding frame and applied it to the data. I coded all the data and MR second coded 41% (n=7/17) of the included qualitative articles. This included a mix of studies reporting psychosexual-related outcomes only, disclosure-related outcomes only and studies reporting both psychosexual and disclosure-related outcomes. Uncertainties regarding coding were resolved through discussion.

2.4: Results

2.4.1: Search results

The initial search returned 7,336 articles, which was reduced to 4,801 after the removal of duplicates. Of these, 4,465 were excluded based on their title, leaving 336 abstracts to be reviewed. After title and abstract screening, 41 articles were obtained for full-text review. Thirteen articles were excluded during the full-text review. The reference lists and forward citation searches of all included articles identified an additional two articles, leaving 30 articles in the final analysis: 17 qualitative articles and 13 quantitative articles. Of the 30 articles, 17 reported psychosexual outcomes only, 5 reported disclosure-related outcomes only and 8 articles included both disclosure and psychosexual-related outcomes. Disclosure-related outcomes are reported in Chapter 3. Twenty-five studies assessed the psychosexual impact of testing positive for high-risk

cervical HPV and are included in the analysis in this Chapter. Figure 2.1 shows the study selection process.

Studies were conducted in England (n=7), the USA (n=5), Taiwan (n=4), Australia (n=2), Hong Kong, Italy, China, Belgium, Brazil, Sweden and Greece (all n=1). Studies were quantitative (n=12) or qualitative (n=13). Of the quantitative studies, two were RCTs (Kitchener et al., 2008; Youngkin, Henry, & Gracely-Kilgore, 1999). Two studies were descriptive studies and only included HPV positive participants (Ferenidou et al., 2012; Hsu, Wang, Fetzer, Cheng, & Hsu, 2018). One of these studies followed-up women longitudinally (Hsu et al., 2018). The remaining quantitative studies were observational (n=8) (Campion et al., 1988; Kwan et al., 2011; Maggino et al., 2007; Maissi et al., 2005; McCaffery et al., 2004; Reed et al., 1999; Wang et al., 2010; Wang, Shi, Kang, Song, & Qiao, 2011). Seven studies were cross-sectional, and one was a prospective observational study. Most qualitative studies (n=12) used individual interviews (Jeng, Lin, & Wang, 2010; Kosenko, Harvey-Knowles, & Hurley, 2014; Kosenko, Hurley, & Harvey, 2012; Lin, Jeng, & Wang, 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Patel et al., 2018; Rask, Swahnberg, Lindell, & Oscarsson, 2017; Waller, McCaffery, Kitchener, Nazroo, & Wardle, 2007b). One study used qualitative methodology to explore questions about HPV that were submitted to a website (Verhoeven et al., 2010). The included articles were published between 1988 and 2018.

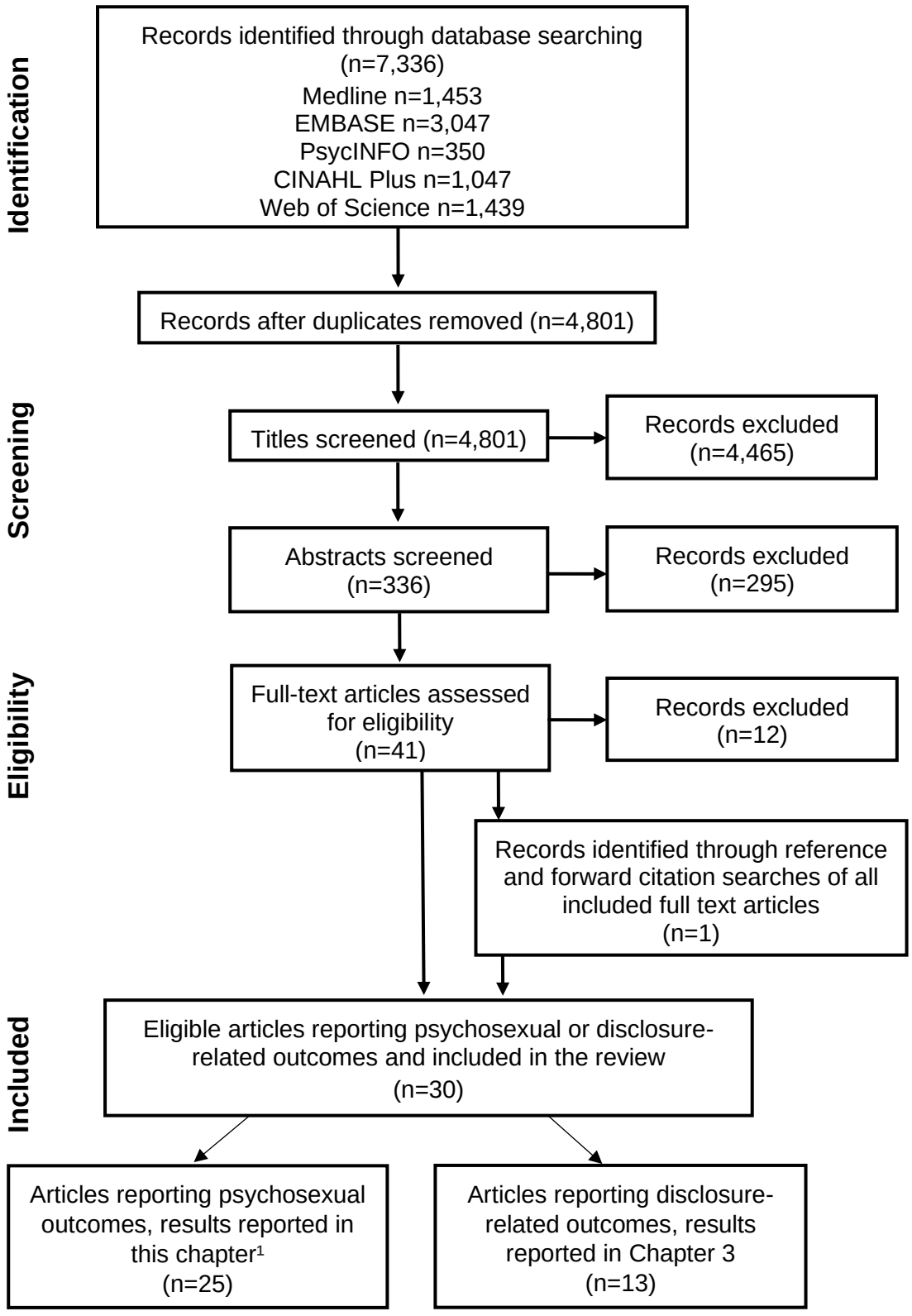

Figure 2.1: Flow diagram of study selection

(Adapted from Moher et al., 2009)

[1] Of the 25 articles included in this review, 8 articles included both psychosexual and disclosure-related outcomes and are reported in this chapter and Chapter 3.

2.4.2: Quality assessment

Based on the NICE quality appraisal checklist for quantitative studies, most quantitative studies were judged to have been designed or conducted in such a way as to minimise the risk of bias (n=7) and had good internal validity. The remaining studies (n=5) were partly designed or conducted to minimise bias, or aspects of the study design were unclear. In terms of external validity, most quantitative studies were judged to have been partly designed or conducted to minimise bias, or aspects of the study design were unclear (n=7). The remaining studies were judged to have been designed or conducted in such a way as to minimise the risk of bias (n=5).

Based on the NICE quality appraisal checklists for qualitative studies, most studies (n=8) were well conducted with most of the checklist criteria fulfilled. A further four studies fulfilled some of the checklist criteria. Only one study fulfilled few of the checklist criteria. Due to the limited number of studies, none were excluded based on their quality assessment score. See Table 2.1 for quality assessment scores.

Table 2.1: Quality assessment rating for studies exploring the psychosexual impact of testing HPV positive in the review

Study	Internal validity[1]	External validity[1]	Overall assessment score[2]
Campion et al. (1988)	++	+	
Ferenidou et al. (2012)	+	+	
Kwan et al. (2011)	+	+	
Kitchener et al. (2008)	++	++	
Hsu et al. (2018)	+	+	
Maggino et al. (2007)	+	+	
Maissi et al. (2005)	++	++	
McCaffery et al. (2004)	++	++	
Reed et al. (1999)	++	+	
Wang et al. (2010)	+	++	
Wang et al. (2011)	++	++	
Youngkin et al. (1998)	++	+	
Jeng et al. (2010)			-
Kosenko et al. (2012)			++
Kosenko et al. (2014)			++
Lin et al. (2011)			+
McCaffery and Irwig (2005)			++
McCaffery et al. (2006)			++
McCurdy et al. (2011)			++
Newton and McCabe (2008b)			+
Parente Sa Barreto et al. (2016)			+
Patel et al. (2018)			+
Rask et al. (2017)			++
Waller et al. (2007b)			++
Verhoeven et al. (2010)			++

[1] For quantitative studies

[2] For qualitative studies

Internal and external validity (quantitative studies)

++ Indicates that the study was designed or conducted in such a way as to minimise the risk of bias.

+ Indicates that the study was partly designed to minimise bias, may not have addressed all potential sources of bias, or it was not clear from the way the study was reported.

− Indicates that the study had significant sources of bias across all aspects of the study design.

Overall assessment score (qualitative studies)

++ Indicates that all or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.

+ Indicates that some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.

– Indicates that few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

2.4.3: Quantitative studies

2.4.3.1: Participants

All quantitative studies assessing the psychosexual impact of testing positive for HPV included female participants only (n=12) (Campion et al., 1988; Ferenidou et al., 2012; Hsu et al., 2018; Kitchener et al., 2008; Kwan et al., 2011; Maggino et al., 2007; Maissi et al., 2005; McCaffery et al., 2004; Reed et al., 1999; Wang et al., 2010; Wang et al., 2011; Youngkin et al., 1999). The number of participants across studies ranged from 51 to 2,508. In the eight studies where the full age range was provided, women ranged from 17 to 65 years of age (Campion et al., 1988; Hsu et al., 2018; Kitchener et al., 2008; Maggino et al., 2007; McCaffery et al., 2004; Reed et al., 1999; Wang et al., 2010; Wang et al., 2011). Participant and study characteristics of quantitative studies reporting psychosexual-related outcomes are shown in Table 2.2.

2.4.3.2: Recruitment

Most participants were recruited from gynaecology outpatient clinics (n=5) (Ferenidou et al., 2012; Hsu et al., 2018; Maggino et al., 2007; Wang et al., 2010; Wang et al., 2011) or routine cervical screening (n=4) (Kitchener et al., 2008; Kwan et al., 2011; Maissi et al., 2005; McCaffery et al., 2004). Participants in the remaining studies were recruited from primary care (Reed et al., 1999), a university student health service and family planning clinic

(Youngkin et al., 1999) and colposcopy and genitourinary clinics (Campion et al., 1988).

2.4.3.3: Comparison groups

Most studies (n=7) compared outcomes among HPV positive women with HPV negative women (Kitchener et al., 2008; Kwan et al., 2011; Maggino et al., 2007; Maissi et al., 2005; McCaffery et al., 2004; Reed et al., 1999; Wang et al., 2011). Some of these studies (n=5) compared outcomes among HPV positive and HPV negative women and also provided women's cytology result (Kitchener et al., 2008; Kwan et al., 2011; Maissi et al., 2005; McCaffery et al., 2004; Wang et al., 2011). Two studies compared outcomes among HPV positive women with women with other HPV-related diagnoses such as genital warts and CIN (Wang et al., 2010; Wang et al., 2011). In one study, some women who were HPV positive also had CIN and/or genital warts (Campion et al., 1988). Two studies included HPV positive women only (Ferenidou et al., 2012; Hsu et al., 2018).

Two studies were RCTs (Kitchener et al., 2008; Youngkin et al., 1999). In one RCT women underwent routine cervical screening and were tested for HPV and were randomised to either have their HPV result revealed to them or concealed from them (both groups were informed of their cytology result) (Kitchener et al., 2008). In the second RCT, women with genital herpes or HPV infections were randomly assigned to receive either routine counselling (control group) or a self-help module plus routine counselling (intervention group) (Youngkin et al., 1999).

2.4.3.4: Time of data collection

The time from receipt of HPV test results to when data were collected varied between studies. Several studies collected data shortly after women received their screening results (n=5) (Ferenidou et al., 2012; Hsu et al., 2018; Kitchener et al., 2008; Kwan et al., 2011; McCaffery et al., 2004). Some of these studies collected data at multiple time points (n=2); one study collected data shortly after women received their results and 6 months later (Kwan et al., 2011) and another collected data shortly after women received their results and 1, 6 and

12 months later (Hsu et al., 2018). Two studies collected data within 3 months of an HPV-related test result (Wang et al., 2010; Wang et al., 2011). One study collected data 6 months after women received their test result (Maissi et al., 2005) and another collected data from participants who had been enrolled in a study primarily about vaginitis for at least 6 months (Reed et al., 1999). The time from receipt of HPV test results to data collection in one study varied from shortly after women received their result to more than a year after they received their result (Maggino et al., 2007). In one of the RCTs, participants were followed up four weeks after completing a baseline questionnaire and being randomised, but it is unclear when participants received their HPV test result (Youngkin et al., 1999).

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Campion et al. (1988) England Not reported	Median age (interquartile range in brackets) Group 1: 24 (19-26) Group 2a: 23 (19-25) Group 2b: 24 (18-26) Group 3: 22 (17-25)	High-risk	105	Questionnaire administered during an interview	Baseline: participants were asked to complete the baseline questionnaire based on their sexual behaviour 6 months before attending colposcopy or the genitourinary clinic. Follow-up: approximately 5-6 months later	Women attending a colposcopy or a genitourinary clinic	1) Women who had an abnormal cytology result and CIN who were HPV positive. 2) Women traced as the regular sexual partner of a man with genital warts who: a) were HPV positive or HPV positive with CIN or, b) had no cervical disease 3) Women referred as the regular sexual partner of a man diagnosed as having non-specific urethritis who had no evidence of cervical disease

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Ferenidou et al. (2011) Greece 2008-2009	20-50+	Not reported	51	Questionnaire	Participants were asked to complete the questionnaire after a gynaecology examination, having been told they were HPV positive at a previous visit	Women attending a gynaecology clinic	HPV positive participants only
Hsu et al. (2018) Taiwan 2011-2013	20-61	High-risk and low-risk	70	Questionnaire	Baseline: at the first follow-up appointment after testing HPV positive. Follow-up: 1, 6 and 12 months after testing HPV positive	Women attending a gynaecology clinic	HPV positive participants only

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Kitchener et al. (2008) England 2001-2003	20-64	High-risk	2,508 (analysis only includes 2,003 participants who had a current sexual partner)	Questionnaire data was initially collected in face-to-face interviews (n=106) and was subsequently collected by postal questionnaire	2 weeks after receiving screening test results	Women eligible for routine cervical screening as part of the NHS Cervical Screening Programme in Greater Manchester, England	Revealed arm: 1. HPV negative, normal cytology 2. HPV positive, normal cytology 3. HPV negative, mild or borderline cytology 4. HPV positive, mild or borderline cytology Concealed arm: 1. HPV negative, normal cytology 2. HPV positive, normal cytology 3. HPV negative, mild or borderline cytology 4. HPV positive, mild or borderline cytology

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Kwan et al. (2011) Hong Kong 2008-2009	36.8 (mean)	High-risk	299	Questionnaire	Baseline: after being informed of their screening test results. Follow-up: 6 months later	Women attending routine cervical screening who had an abnormal cytology result	1. HPV positive with abnormal cytology 2. HPV negative with abnormal cytology

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Maggino et al. (2007) Italy 2006-2007	20-45	Not reported	72	Questionnaire	The time between receipt of screening test results and distribution of the questionnaire varied: 50% received the questionnaire 0 to 6 months later, 39% between 6 and 12 months later and 11% more than one year after receiving their screening test results	Women attending a gynaecology clinic	1. HPV positive 2. HPV negative

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Maissi et al. (2005) England 2002-2003	Mean age by group: HPV positive, abnormal cytology: 32.7 HPV negative, abnormal cytology: 41.6 Abnormal cytology, not tested for HPV: 36.6	High-risk	1,011	Postal questionnaire	6 months after women received their screening test result	Women undergoing routine cervical screening at one of the two centres taking part in the English pilot study of liquid-based cytology and HPV testing who received a normal or a borderline/ mildly abnormal test result	1. HPV positive, abnormal cytology 2. HPV negative, abnormal cytology 3. Abnormal cytology, not tested for HPV

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
McCaffery et al. (2004) England Not reported	20-64	High-risk	271	Postal questionnaire	One week after receiving screening test results	Women attending an NHS well-woman clinic for routine cervical screening	1. HPV positive, normal cytology 2. HPV negative, normal cytology 3. HPV positive, abnormal/ unsatisfactory cytology 4. HPV negative, abnormal/ unsatisfactory cytology

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Reed et al. (1999) USA 1990-1992	18-50	Not reported	169 (analysis only includes 155 participants who had a current sexual partner)	Postal questionnaire	Participants who had been enrolled in the University of Michigan Vaginitis study for at least 6 months were asked to assess current psychosexual activities and changes in these activities since enrolment, without specific reference to HPV infection	Sexually active women who were enrolled in the University of Michigan Vaginitis study	1. HPV positive 2. HPV negative

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Wang et al. (2010) Taiwan 2006	18-65	High-risk	249	Face-to-face interview	Within 3 months of an HPV-related diagnosis	Women were recruited from outpatient clinics at three hospitals during routine gynaecology visits	1. Normal cytology 2. Abnormal cytology 3. CIN 1/2/3 4. Genital warts 5. HPV positive, abnormal cytology
Wang et al. (2011) China 2007-2008	18-65	High-risk	2,605	Questionnaire completed in the presence of a trained interviewer	Within 3 months of an HPV-related diagnosis	Women attending routine clinical hospital visits	1. Normal cytology 2. Abnormal cytology, no HPV test 3. Genital warts 4. CIN 5. HPV positive, abnormal cytology 6. HPV negative, abnormal cytology

Table 2.2: Characteristics of quantitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference, country and years of study conduct	Age (years)	HPV type	Number of participants	Survey instrument	Time of data collection	Study population	Comparison groups
Youngkin et al. (1998) USA Not reported	17-29+	Not reported	58	Questionnaire given during a clinic visit and returned by post	Baseline: when participants were randomised. Follow-up: 4 weeks after baseline questionnaire	Women from a university student health service and a family planning clinic	1. HPV positive, self-help module plus routine counselling (intervention group) 2. HPV positive, routine counselling (control group)

2.4.3.5: Measures

All studies (n=12) used survey-based methods. Questionnaires were completed during or after clinical appointments (n=7) (Campion et al., 1988; Ferenidou et al., 2012; Hsu et al., 2018; Kwan et al., 2011; Maggino et al., 2007; Wang et al., 2010; Wang et al., 2011) or returned by post (n=5) (Kitchener et al., 2008; Maissi et al., 2005; McCaffery et al., 2004; Reed et al., 1999; Youngkin et al., 1999).

Studies reported various aspects of psychosexual functioning including sexual satisfaction and pleasure (n=5) (Campion et al., 1988; Ferenidou et al., 2012; Maggino et al., 2007; Reed et al., 1999; Youngkin et al., 1999), frequency of sex (n=4) (Campion et al., 1988; Ferenidou et al., 2012; Maggino et al., 2007; Reed et al., 1999), interest in sex, thoughts about sex and sexual arousal (n=4) (Campion et al., 1988; Ferenidou et al., 2012; Maggino et al., 2007; Reed et al., 1999) and feelings about sexual partners and sexual relationships (n=4) (Campion et al., 1988; Ferenidou et al., 2012; McCaffery et al., 2004; Reed et al., 1999). Table 2.3 shows the psychosexual outcomes measured in each study. In six studies an overall mean for all psychosexual outcomes was reported rather than the mean value for each specific aspect of psychosexual functioning (Hsu et al., 2018; Kitchener et al., 2008; Kwan et al., 2011; Maissi et al., 2005; Wang et al., 2010; Wang et al., 2011).

Five studies used measures specific to HPV or an abnormal cytology result (Hsu et al., 2018; Kwan et al., 2011; Maissi et al., 2005; Wang et al., 2010; Wang et al., 2011). Three used the HPV Impact Profile (HIP) questionnaire (Kwan et al., 2011; Wang et al., 2010; Wang et al., 2011) and two used the Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q) (Hsu et al., 2018; Maissi et al., 2005). One study used the PEAPS-Q and the Psychosocial Adjustment to Illness Scale-Self-Report (PAIS-SR) (Hsu et al., 2018). Four studies used a different generic psychosexual measure; the Sexual Rating Scale (SRS) (Kitchener et al., 2008), the Brief Index of Sexual Functioning for Women (BISF-W) (Maggino et al., 2007), the Self-Concept and Satisfaction with Intimate Relationships Scale (Youngkin et al., 1999) and the Symptom Checklist of Sexual Function (SCSF) (Ferenidou et al., 2012). A brief description of each of the measures used is shown in Table 2.4.

Table 2.3: Psychosexual outcomes measured in quantitative studies included in the review

	Sexual satisfaction and pleasure	Frequency of sex	Interest in sex, thoughts about sex and sexual arousal	Concerns about infectivity and transmission	Feelings about sexual partners and sexual relationships
Campion et al. (1988)	x	x	x		x
Ferenidou et al. (2012)	x	x	x		x
Hsu et al. (2018)[1]	x	x	x	x	x
Kitchener et al. (2008)[1]	x	x	x		
Kwan et al. (2011)[1]	x	x		x	x
Maggino et al. (2007)	x	x	x		
Maissi et al. (2005)[1]				x	x
McCaffery et al. (2004)					x
Reed et al. (1999)	x	x	x		x
Wang et al. (2011)[1]	x	x		x	
Wang et al. (2010)[1]	x	x		x	
Youngkin et al. (1999)	x				

[1]Results for some individual items not reported (overall mean reported).

Table 2.4: A description of the quantitative measures assessing the psychosexual impact of testing HPV positive used by studies included in the review

Measure	Description of Measure	Psychosexual outcomes measured	Measure used by
Brief Index of Sexual Functioning for Women (BISF-W) Taylor, Rosen & Leiblum (1994)	A 22-item questionnaire designed to assess current female sexual function and satisfaction.	Frequency of sexual thoughts, frequency of desire to engage in sexual activities, frequency of arousal during sexual activity, frequency of anxiety and inhibitions during sexual activity, frequency of sexual activities, receptivity to, and initiation of, sexual activity, pleasure during sexual activity, frequency of orgasm, sexual satisfaction, importance of sex.	Maggino et al. (2007)
HPV Impact Profile (HIP) Mast et al. (2009)	A 29-item questionnaire designed to assess the psychosocial impact of HPV-related health conditions, covering 7 domains: worries and concerns, emotional impact, sexual impact, self-image, partner and transmission, interactions with physicians and control/life impact.	Frequency of sex, satisfaction with sex life, concerns about transmitting the infection to/from a partner.	Wang et al. (2010) Wang et al. (2011) Kwan et al. (2011)

Table 2.4: A description of the quantitative measures assessing the psychosexual impact of testing HPV positive used by studies included in the review (continued)

Measure	Description of Measure	Psychosexual outcomes measured	Measure used by
Psychosocial Adjustment to Illness Scale-Self-Report (PAIS-SR) Derogatis (1986)	A 46-item questionnaire designed to assess the psychological and social adjustment to a medical illness, covering 7 domains: health care orientation, vocational environment, domestic environment, sexual relationships, extended family relationships, social environment and psychological distress.	Interest in sex, frequency of sex, quality of sex and sexual satisfaction.	Hsu et al. (2018)
Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q) Bennetts et al. (1995)	A 14-item questionnaire designed to measure distress experienced by women undergoing follow-up investigation after an abnormal Pap smear result, covering 4 domains: experience of medical procedures, beliefs/feelings and changes in perception of self, worry about infectivity and effect on sexual relationships.	Worry about infectivity, concerns about continuing to have sex, concerns about whether having sex will make the problem worse and concerns that others will view number of previous sexual partners negatively.	Maissi et al. (2005) Hsu et al. (2018)

Table 2.4: A description of the quantitative measures assessing the psychosexual impact of testing HPV positive used by studies included in the review (continued)

Measure	Description of Measure	Psychosexual outcomes measured	Measure used by
Self-Concept and Satisfaction with Intimate Relationships Scale	The questionnaire used in Youngkin et al. (1999) was based on the edited Berscheid, Walster and Bohrnstedt Body Image Scale used in Polivy (1977). Relevant items from the edited questionnaire were selected and additional items relevant to the aims of the study were added. The edited Body Image Scale used in Polivy's study was a 49-item questionnaire designed to assess body image, self-concept and satisfaction with intimate relationships.	The exact psychosexual outcomes measured in Youngkin et al. (1999) is unclear. The edited Berscheid, Walster and Bohrnstedt Body Image Scale used in Polivy (1977) measures satisfaction with marriage/relationships and the importance of sexual problems in a woman's current relationship.	Youngkin et al. (1999)
Sexual Rating Scale (SRS) Garratt, Torgerson, Wyness, Hall & Reid (1995)	A 12-item questionnaire designed to measure sexual function in premenopausal women.	Interest in sex, frequency of sexual activity, satisfaction with sex life, pleasure from sex, ability to reach orgasm, importance of sex.	Kitchener et al. (2008)
Symptom Checklist of Sexual Function (SCSF) Hatzichristou et al. (2004)	A 4-item questionnaire designed to assess women's perception of, and satisfaction with, sexual function.	Satisfaction with sexual function, interest in sex, problems with reduced genital sensation, problems with reduced or loss of vaginal lubrication, orgasmic disorders, pain during intercourse, other sexual problems.	Ferenidou et al. (2012)

2.4.3.6: Overall psychosexual impact

Six studies reported an overall psychosexual impact score (Hsu et al., 2018; Kitchener et al., 2008; Kwan et al., 2011; Maissi et al., 2005; Wang et al., 2010; Wang et al., 2011). Study designs (including measures used, comparison groups and time of data collection) were diverse making it challenging to summarise the overall psychosexual impact of testing HPV positive.

In a study of 299 Chinese women living in Hong Kong, all of whom had abnormal cytology, the HIP was used to assess psychosocial impact among HPV positive and HPV negative women shortly after they received their HPV test result (baseline) and six months later (Kwan et al., 2011). At baseline, women who were HPV positive had significantly higher psychosocial impact scores than women who were HPV negative. Scores decreased six months later in both groups but remained significantly higher among women who were HPV positive. As the study reported overall psychosocial impact scores rather than the scores of each of the seven HIP domains, it is not possible to report psychosexual outcome differences between groups.

Two further studies used the HIP to assess psychosexual impact, both administering the questionnaire within three months of women receiving an HPV-related diagnosis (Wang et al., 2010; Wang et al., 2011). A study of 248 women in Taiwan found that women with an abnormal cytology result who were also HPV positive had similar scores to women with abnormal cytology who were not tested for HPV in both the sexual impact and partner issues and transmission domains (Wang et al., 2010). While these groups were not directly compared, both groups had significantly higher scores than women with normal cytology who were not tested for HPV. Similar findings were found in a study of 2,605 women in China (Wang et al., 2011). This study also included a group of women who were HPV negative with abnormal cytology and these women were found to have similar sexual impact profiles to those who were HPV positive with abnormal cytology, but again, these groups were not directly compared.

Two studies used the PEAPS-Q to explore the psychosexual impact of receiving an HPV positive result. In a study conducted in the English cervical screening programme which included 723 women with abnormal cytology, women who were HPV positive had significantly more sexual health worries six

months after receiving their results compared to those who were HPV negative or not tested for HPV (Maissi et al., 2005). A second study of 70 HPV positive women in Taiwan, around 65% of whom also had abnormal cytology, found that shortly after receiving their results, 14% of women had mean scores on the sexual relations subscale indicating 'significant distress' (Hsu et al., 2018). Women were followed up 1, 6 and 12 months later using the PAIS-SR. Mean scores at all three time points were low (1 month: 0.69, 6 months: 0.47, 12 months: 0.51, range 0-3).

In a study of 2,508 women carried out in the context of the English cervical screening programme, women were randomised to either have their HPV result revealed to them or concealed from them (both groups were informed of their cytology result) (Kitchener et al., 2008). Psychosexual functioning was assessed among women with a current sexual partner using the SRS approximately two weeks after they received their test results. In the group who had their HPV result revealed to them, women with normal cytology had a similar level of psychosexual functioning regardless of whether they were HPV positive or HPV negative. However, among women with mild/borderline abnormal cytology, women who were HPV positive had better psychosexual functioning than women who were HPV negative.

2.4.3.7: Sexual satisfaction and pleasure

Six studies assessed sexual satisfaction or sexual pleasure (Campion et al., 1988; Ferenidou et al., 2012; Kwan et al., 2011; Maggino et al., 2007; Reed et al., 1999; Youngkin et al., 1999), with three reporting no impact of testing HPV positive (Kwan et al., 2011; Maggino et al., 2007; Reed et al., 1999). One study, conducted in Italy, recruited 72 women from a gynaecology clinic and asked them to complete a questionnaire assessing sexual function (Maggino et al., 2007). Completion of the questionnaire ranged from shortly after women were told about their screening test result, to more than a year later. The study found no significant differences in sexual pleasure/orgasm or sexual satisfaction between women who were HPV positive and women who were HPV negative. A second study, conducted in the USA, recruited 155 sexually active women aged 18 to 60 years who had attended primary care with symptoms of vaginitis or for a routine pelvic examination (Reed et al., 1999). Participants were tested

for HPV and informed if they tested HPV positive. Participants who had been enrolled in the study for at least six months were mailed a questionnaire to assess current psychosexual activities and changes in these activities since enrollment, without reference to HPV. There were no significant differences in sexual satisfaction between women who were HPV positive and HPV negative. A third study recruited 299 Chinese women, all of whom had abnormal cytology, from community women's health clinics in Hong Kong (Kwan et al., 2011). Women completed a questionnaire shortly after receiving their HPV test result and a structured telephone interview six months later. There was no difference in sexual satisfaction between HPV positive and HPV negative women shortly after women received their HPV test result or six months later.

An RCT conducted in the USA recruited 58 women who were HPV positive and 40 women who tested positive for the herpes simplex virus (HSV) from a university student health service and a family planning group (Youngkin et al., 1999). The study aimed to explore the impact of a self-help module on satisfaction with intimate relationships. Women were randomised to the intervention (self-help module which provided information on HPV or HSV plus routine counselling) or control group (routine counselling only). Overall, compared to women who were HSV positive, women who were HPV positive had slightly greater satisfaction with intimate relationships. However, following the intervention, women in the intervention group who were HSV positive had a greater increase in satisfaction with intimate relationships compared to women who were HPV positive. In this study, pre- and post-intervention scores were compared for the HPV and HSV groups separately however differences between the HPV and HSV groups were not compared statistically. In addition, the range of potential scores was not reported.

A study conducted in Greece recruited 51 women from a gynaecology clinic who had recently been told that they were HPV positive (Ferenidou et al., 2012). Women were asked to complete a questionnaire assessing aspects of their sexual health and function. In this descriptive study, three-quarters of women reported being satisfied with their sexual function, however 22% reported feeling dissatisfied with their sex life and 22% reported that they had experienced problems reaching orgasm following their HPV positive result.

In a study conducted in England of 105 women attending a colposcopy or genitourinary clinic, women were asked to complete a questionnaire assessing six aspects of sexual behaviour six months prior to diagnosis (baseline) and six months post-treatment (follow-up) (Campion et al., 1988). Four groups were compared: 1) Women who had an abnormal cytology result and CIN who were HPV positive 2) Women traced as the regular sexual partner of a man with genital warts who a) were HPV positive or HPV positive with CIN or b) had no cervical disease and 3) Women referred as the regular sexual partner of a man diagnosed as having non-specific urethritis who had no evidence of cervical disease. Frequency of orgasm decreased between baseline and follow-up among women who were HPV positive (with or without CIN). There was no change in frequency of orgasm among women without HPV.

2.4.3.8: Frequency of sex

Four studies assessed frequency of sex following an HPV positive result (Campion et al., 1988; Ferenidou et al., 2012; Maggino et al., 2007; Reed et al., 1999). Two studies reported no difference in frequency of sex between women who were HPV positive and women who were HPV negative (Maggino et al., 2007; Reed et al., 1999). In an Italian study of 72 women attending a gynaecology clinic, where completion of a questionnaire assessing sexual function ranged from shortly after women were told about their HPV test result to more than a year later, there were no significant differences in frequency of sex between women who were HPV positive and women who were HPV negative (Maggino et al., 2007). A second study, conducted in the USA, recruited 155 sexually active women aged 18 to 60 years who had attended primary care with symptoms of vaginitis or for a routine pelvic examination (Reed et al., 1999). Participants were tested for HPV and informed if they tested HPV positive. Participants who had been enrolled in the study for at least six months were mailed a questionnaire to assess current psychosexual activities and changes in these activities since enrollment, without reference to HPV. There were no significant differences in frequency of sex between women who were HPV positive and HPV negative.

A study conducted in Greece recruited 51 women from a gynaecology clinic who had recently been told that they were HPV positive and asked them to

complete a questionnaire assessing their sexual health and function (Ferenidou et al., 2012). In this descriptive study, 43% reported that their frequency of sex had decreased following their HPV positive result. In a study conducted in England of 105 women attending a colposcopy or genitourinary clinic, women were asked to complete a questionnaire assessing six aspects of sexual behaviour six months prior to diagnosis (baseline) and six months post-treatment (follow-up) (Campion et al., 1988). Women who were HPV positive (with or without CIN) reported a decrease in frequency of sex between baseline and follow-up. Among women without HPV, there was no change in frequency of sex.

2.4.3.9: Interest in sex, thoughts about sex and sexual arousal

Four studies assessed interest in sex, thoughts about sex and sexual arousal following an HPV positive result (Campion et al., 1988; Ferenidou et al., 2012; Maggino et al., 2007; Reed et al., 1999). One study, conducted in Greece, recruited 51 women from a gynaecology clinic who had recently been told that they were HPV positive and asked them to complete a questionnaire (Ferenidou et al., 2012). In this descriptive study, 33% reported feeling less 'sexual', 41% reported decreased sexual desire and 35% reported problems with little or no interest in sex following their HPV positive result. In a second study conducted in England of 105 women attending a colposcopy or genitourinary clinic, women were asked to complete a questionnaire assessing six aspects of sexual behaviour six months prior to diagnosis (baseline) and six months post-treatment (follow-up) (Campion et al., 1988). Women who were HPV positive (with or without CIN) reported decreased spontaneous interest in sex and sexual arousal between baseline and follow-up. Among women without HPV, there was no change in spontaneous interest in sex or sexual arousal.

In contrast, in an Italian study of 72 women attending a gynaecology clinic, where completion of a questionnaire assessing sexual function ranged from shortly after women were told about their HPV test result to more than a year later, there were no significant differences in interest in sex, sexual arousal or sexual thoughts between women who were HPV positive and women who were HPV negative (Maggino et al., 2007). A second study, conducted in the USA, recruited 155 sexually active women aged 18 to 60 years who had attended

primary care with symptoms of vaginitis or for a routine pelvic examination (Reed et al., 1999). Participants were tested for HPV and informed if they tested HPV positive. Participants who had been enrolled in the study for at least six months were mailed a questionnaire to assess current psychosexual activities and changes in these activities since enrollment, without reference to HPV. There were no significant differences in sexual arousal or thinking about sex between women who were HPV positive and HPV negative.

2.4.3.10: Feelings about partners and relationships

Five studies assessed feelings about partners and relationships (Campion et al., 1988; Ferenidou et al., 2012; Kwan et al., 2011; McCaffery et al., 2004; Reed et al., 1999). One study, conducted in Greece, recruited 51 women from a gynaecology clinic who had recently been told that they were HPV positive and asked them to complete a questionnaire (Ferenidou et al., 2012). In this descriptive study, 12% reported that their relationship had been negatively affected following their HPV positive result. In a second study conducted in England, 271 women were recruited from routine cervical screening and asked to complete a questionnaire prior to screening and one week after they had received their HPV and cytology screening results (McCaffery et al., 2004). Women who were HPV positive, regardless of whether they had normal or abnormal cytology, were more likely to report feeling worse than usual about their current, previous and future sexual partners than women who were HPV negative (around a third of HPV positive women compared to less than 2% of HPV negative women). In a third study, also conducted in England, of 105 women attending a colposcopy or genitourinary clinic, women were asked to complete a questionnaire assessing six aspects of sexual behaviour six months prior to diagnosis (baseline) and six months post-treatment (follow-up) (Campion et al., 1988). Women who were HPV positive (with or without CIN) reported an increase in negative feelings about sex with their current partner. Among women without HPV, there was no change in negative feelings about sex, which were low at both baseline and follow-up.

Two studies found no evidence that an HPV positive result affected feelings about partners or relationships (Kwan et al., 2011; Reed et al., 1999). One study recruited 299 Chinese women, all of whom had abnormal cytology, from

community women's health clinics in Hong Kong (Kwan et al., 2011). Women completed a questionnaire shortly after receiving their HPV test result and a structured telephone interview six months later. There was no difference in relationship satisfaction between HPV positive and HPV negative women shortly after women received their HPV test result or six months later. A second study, conducted in the USA, recruited 155 sexually active women aged 18 to 60 years who had attended primary care with symptoms of vaginitis or for a routine pelvic examination. Participants were tested for HPV and informed if they tested HPV positive. Participants who had been enrolled in the study for at least six months were mailed a questionnaire to assess current psychosexual activities and changes in these activities since enrollment, without reference to HPV. There were no significant differences in frequency of negative feelings about relationships, or anger at current or previous partners between women who were HPV positive and HPV negative (Reed et al., 1999).

2.4.4: Qualitative studies

2.4.4.1: Participants

Qualitative studies assessing the psychosexual impact of testing positive for HPV included female participants only (n=11) (Jeng et al., 2010; Kosenko et al., 2014; Kosenko et al., 2012; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Parente Sa Barreto et al., 2016; Patel et al., 2018; Rask et al., 2017; Waller et al., 2007b) and male and female participants (n=2) (Newton & McCabe, 2008b; Verhoeven et al., 2010). In the ten studies where the age range was provided, women ranged from 19 to 64 years (Jeng et al., 2010; Kosenko et al., 2014; Kosenko et al., 2012; Lin et al., 2011; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Patel et al., 2018; Rask et al., 2017; Waller et al., 2007b). The number of participants across studies ranged from 14 to 74. One study analysed questions about HPV from 527 email messages, 432 of which were from women (Verhoeven et al., 2010). Participant and study characteristics for qualitative studies reporting psychosexual-related outcomes are shown in Table 2.5.

2.4.4.2: Recruitment

Most studies recruited participants from clinical settings (e.g. general practice, family planning and sexual health services, gynaecology outpatient clinics) (n=8) (Jeng et al., 2010; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Parente Sa Barreto et al., 2016; Patel et al., 2018; Rask et al., 2017). Participants were also recruited from clinical trials of HPV testing (n=2) (McCaffery et al., 2006; Waller et al., 2007b) and by advertising the study in a variety of community settings and/or online (n=3) (Kosenko et al., 2014; Kosenko et al., 2012; Newton & McCabe, 2008b). One study analysed questions asked by visitors to an HPV website that were sent by email (Verhoeven et al., 2010).

2.4.4.3: Time of data collection

In most studies, the time from receipt of HPV test results to when data were collected was not described (n=10) (Jeng et al., 2010; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Patel et al., 2018; Verhoeven et al., 2010; Waller et al., 2007b). In two studies the time from HPV diagnosis to data collection ranged from 1 to 17 years (Kosenko et al., 2014; Kosenko et al., 2012) and in one study, data were collected two weeks after women received an abnormal cytology result (Rask et al., 2017).

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
Jeng et al. (2010) Taiwan	2008	27-52	Female	High-risk	20	Semi-structured interviews	Not reported	Women who had tested HPV positive who were attending a gynaecology outpatient clinic of a university-based hospital in Taipei, Taiwan
Kosenko et al. (2012) USA	Not reported	19-56	Female	Not reported	25	Semi-structured interviews	Time since receipt of HPV positive result ranged from 1 to 17 years	Women who had been diagnosed with any form of genital HPV who answered an advertisement posted online (on social media websites and online support groups) and in community centres, libraries, restaurants, coffee shops, supermarkets and buildings in college campuses in cities in the southeastern USA

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
Kosenko et al. (2014) USA	Not reported	19-56	Female	Not reported	25	Semi-structured interviews	Time since receipt of HPV positive result ranged from 1 to 17 years	Women who had been diagnosed with any form of genital HPV who answered an advertisement posted on online forums and in college campuses, community centres, libraries, supermarkets, coffee shops and women's health facilities in five cities in the southern USA
Lin et al. (2011) Taiwan	2008	27-56	Female	High-risk	20	Semi-structured interviews	Not reported	Women who had tested HPV positive who were attending a gynaecology outpatient clinic of a university-based hospital in Taipei, Taiwan

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
McCaffery & Irwig (2005) Australia	2002	Range unknown, 53% were <35 years, 47% were >35 years	Female	High-risk	19	In-depth, unstructured interviews	Not reported	Women who had tested HPV positive following routine cervical screening were recruited from family planning clinics, general practice and specialist gynaecologist practices in Sydney, Australia, and the surrounding area
McCaffery et al. (2006) England	2001-2003	20-64	Female	High-risk	74	In-depth interviews	Not reported	Women taking part in clinical trials of HPV testing or attending colposcopy clinics where HPV testing was carried out

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
McCurdy et al. (2011) USA	2003-2004	21-45	Female	High-risk	18	In-depth interviews	Not reported	Women attending three private primary care clinics who were found to have abnormal cytology and a high-risk HPV type
Newton & McCabe (2008b) Australia	Not reported	19-59	Male (n=30) and female (n=30)	Not reported	60 (30 with genital herpes, 30 with HPV)	Semi-structured interviews	Not reported	Men and women responding to an advertisement about the study posted on STI websites, support groups and online STI communities

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
Parente Sa Barreto et al. (2016) Brazil	2012	20-42	Female	Not reported	14	Semi-structured interviews	Not reported	Women attending a Specialised Medical Carer Service unit (a public service supporting sexual and reproductive care) who had HPV. Women were excluded from the study if they were attending the unit for the first time
Patel et al. (2018) England	2015-2016	25-63	Female	High-risk	46	Semi-structured interviews and a focus group	Not reported	Women recruited from colposcopy clinics and community settings, some of whom had received an abnormal cytology and/or HPV positive result
Rask et al. (2017) Sweden	2014-2015	29-53	Female	High-risk	10	Individual interviews	Within 2 weeks of screening	Women attending a women's health clinic who had been diagnosed with CIN 1/2/3

Table 2.5: Characteristics of qualitative studies assessing the psychosexual impact of testing HPV positive included in the review (continued)

Reference and country	Years of study conduct	Age (years)	Gender	HPV type	Number of participants	Study design	Time of data collection	Study population
Verhoeven et al. (2010) Belgium	2005-2009	Not reported	Male (n=95) and Female (n=432).	Not reported	527 email messages (n=432 from women), which included 713 questions about HPV	Qualitative analysis of questions asked by visitors to an HPV website	Not reported	Individuals who emailed questions about HPV to a website of HPV information
Waller at al. (2007b) England	2003	21-64	Female	High-risk	30	In-depth, semi-structured interviews	Not reported	Women taking part in the ARTISTIC trial of HPV testing (a randomised trial of HPV testing in cervical screening)

2.4.4.4: Themes

A thematic synthesis of thirteen studies identified three major themes relating to the psychosexual impact of testing positive for high-risk cervical HPV: (1) Source of HPV infection, (2) Transmission of HPV and (3) Impact of HPV on sex and relationships. Each theme and subtheme are described, along with example quotes with (P) denoting a participant comment and (A) denoting an author comment. Table 2.6 gives a brief description of each theme and shows the studies associated with it.

Table 2.6: A brief description of themes related to the psychosexual impact of testing positive for HPV and the studies associated with them.

Theme	Sub-theme	Studies	Explanation
Source of HPV infection	Where did the infection come from?	Kosenko et al. (2012) Kosenko et al. (2014) Lin et al. (2011) McCaffery and Irwig (2005) McCaffery et al. (2006) McCurdy et al. (2011) Patel et al. (2018) Verhoeven et al. (2010) Waller at al. (2007b)	Women questioned whom they had got their HPV infection from
	Infidelity concerns	Jeng et al. (2010) Lin et al. (2011) McCaffery et al. (2006) McCurdy et al. (2011) Parente Sa Barreto et al. (2016) Verhoeven et al. (2010) Waller et al. (2007b)	Women wondered whether their partner had been unfaithful and whether that was how they had acquired their HPV infection
Transmission of HPV	Transmitting HPV to a partner	Lin et al. (2011) McCaffery and Irwig (2005) McCaffery et al. (2006) McCurdy et al. (2011) Rask et al. (2017) Verhoeven et al. (2010)	Women were concerned about transmitting their HPV infection to their partner
	Being re-infected with HPV	Jeng et al. (2010) McCaffery and Irwig (2005) Verhoeven et al. (2010) Waller et al. (2007b)	Women with a current partner were concerned that they and their partner would keep re-infecting one another, not allowing their HPV infection to clear. Women not in a relationship were concerned that they might be infected with HPV again by a future partner

Table 2.6: A brief description of themes related to the psychosexual impact of testing HPV positive and the studies associated with them (continued)

Theme	Sub-theme	Studies	Explanation
Impact of HPV on sex and relationships	Impact of HPV on relationships	Jeng et al. (2010) Lin et al. (2011) McCurdy et al. (2011) Newton & McCabe (2008b) Rask et al. (2017) Parente Sa Barreto et al. (2016) Patel et al. (2018)	General comments, positive or negative, about the impact on HPV on relationships
	Frequency and interest in sex	Jeng et al. (201) Lin et al. (2011) McCurdy et al. (2011) Newton & McCabe (2008b) Verhoeven et al. (2010)	Women reported that their interest in and frequency of sex decreased after testing HPV positive
	Negative sexual self-image	McCaffery et al. (2006) Newton and McCabe (2008b) Rask et al. (2017) Waller et al. (2007b)	Women reported negative personal feelings after testing HPV positive
	Concerns about risks associated with oral sex	Kosenko et al. (2012) McCaffery and Irwig (2005)	Women were concerned about passing HPV on to their partner during oral sex and the potential for it to lead to oral cancer

2.4.4.4.1: Source of HPV infection

The first theme included women's questions and concerns about where their HPV infection had come from.

Where did the infection come from?

A common response from women who had tested HPV positive was to question where the infection had come from (Kosenko et al., 2014; Kosenko et al., 2012; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al.,

2011; Patel et al., 2018; Verhoeven et al., 2010; Waller et al., 2007b). Women wondered whether they were infected by a previous partner or their current partner:

> *"I was thinking how did I get it? How was it transmitted before?...Did I already have the virus with me or did he give me the virus or what's going on?"* (P) (McCurdy et al., 2011).

Some women reported blaming their partner for the infection (Jeng et al., 2010; Waller et al., 2007b). For some women, not knowing the source of their HPV infection led to uncertainty and stress (Kosenko et al., 2014; Kosenko et al., 2012):

> *"The stressful part is I honestly don't know where it came from. That's one thing that would really put me at ease a little bit, if I knew how I got it. That would really put some questions to rest"* (P) (Kosenko et al., 2012).

Some women sought information about the source of their HPV infection from previous partners which led to feelings of anger:

> *"I was just really angry because I didn't know who gave it to me. When I confronted my last partner, he was not really receptive, and he did not want to acknowledge that he had it. Yeah, that made me even more angry"* (P) (Kosenko et al., 2014).

One woman reported that uncertainty about who gave her HPV led to her current relationship ending:

> *"There's no way to find out. So, I have no idea if it was him or if it wasn't him or if it was the person before. That actually did lead to us breaking up"* (P) (Kosenko et al., 2012).

Infidelity Concerns

Testing HPV positive led some women to express concerns that their partner had been unfaithful (Jeng et al., 2010; Lin et al., 2011; McCaffery et al., 2006; Parente Sa Barreto et al., 2016; Verhoeven et al., 2010; Waller et al., 2007b):

> *"I was angry with my partner, I trusted him blindly and I was disappointed, but he denies cheating on me, however I don't trust him completely"* (P) (Parente Sa Barreto et al., 2016).

Some women "*teasingly accused"* (P) (Jeng et al., 2010) their partners of being unfaithful to try and find out how they acquired the infection. A lack of trust in a partner following HPV infection was described:

> *"After I found out I have HPV, I don't trust in my partner as I used to, and now I am suspicious of him all the time…I already thought to divorce, but then I thought about my children, and of the possibility I had got HPV from a toilet seat somewhere"* (P) (Parente Sa Barreto et al., 2016).

A small number of women were concerned about being accused of infidelity (McCurdy et al., 2011; Parente Sa Barreto et al., 2016) and although uncommon, some women reported that their partners had left as a result of infidelity concerns (McCurdy et al., 2011). One study suggested that younger women were less concerned about being accused of infidelity than older women who were more likely to be in established relationships (McCurdy et al., 2011).

2.4.4.4.2: Transmission of HPV

The second theme related to women's concern about transmitting HPV to a sexual partner. Women were concerned about passing HPV on to their partner and the consequences of HPV for male partners if they were to transmit the infection. They were also concerned about being re-infected with HPV.

Transmitting HPV to a partner

Passing on HPV to a partner was a commonly expressed concern (Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Rask et al., 2017; Verhoeven et al., 2010):

> *"I was absolutely terrified that I would pass on the infection"* (P) (McCaffery et al., 2006).

Women had questions about the likelihood of infecting their partner (McCaffery & Irwig, 2005) and which specific sexual practices could lead to infection:

> *"The theme transmission was further subcategorized in sexual transmission (n=65), in which people mainly wanted to know which specific sexual practices (sex without penetration, oral sex, anal sex, kissing) could lead to infection…"* (A) (Verhoeven et al., 2010).

Women questioned what they could do to avoid passing HPV on and whether there were any practices (i.e. using condoms) that would protect their partner from acquiring HPV:

> *"What can I do and is there any way I can stop passing it on?"* (P) (McCaffery & Irwig, 2005).

The potential consequences of HPV for male partners were discussed and this was a topic women wanted more information about (McCaffery & Irwig, 2005).

Being re-infected with HPV

Worry about being re-infected with HPV was mentioned by some women (Jeng et al., 2010; McCaffery & Irwig, 2005; Verhoeven et al., 2010; Waller et al., 2007b). There were concerns about having a new partner because of a fear of being re-infected:

> *"…I am not ready to have a boyfriend at present for fear he will give me this kind of infection again"* (P) (Jeng et al., 2010).

Women were also worried about HPV recurring and the *"vicious circle"* of infection whereby two partners continually infect each other, not allowing the virus to be cleared and increasing the risk of developing cervical cancer (McCaffery & Irwig, 2005; Verhoeven et al., 2010):

> *"I have HPV, and probably my husband will have it too. Won't we infect each other all the time?"* (P) (Verhoeven et al., 2010).

2.4.4.4.3: Impact of HPV on sex and relationships

The third theme related to the impact of an HPV infection on sex and relationships. This theme included the impact on both interpersonal and sexual relationships. While some women reported that HPV did not have an impact on their relationship, others reported reduced frequency and interest in sex and a

negative impact on their sexual self-image. The risks associated with oral sex were also raised by some women.

Impact of HPV on relationships

While some women were concerned HPV might negatively impact their relationship (Lin et al., 2011; McCurdy et al., 2011), others reported that it did not have a significant impact (Jeng et al., 2010). A small number reported that their partners were accepting, supportive and had shown concern for their wellbeing (McCurdy et al., 2011; Newton & McCabe, 2008b; Patel et al., 2018):

> *"…I [said] I have a virus that I apparently got from him. He didn't know anything about it so he was in shock. He was surprised about it, too. And he was very supportive…"* (P) (McCurdy et al., 2011).

Some reported that HPV had a positive impact on their relationship and that they had become closer to their partner:

> *"I found out I had HPV three years into my current relationship. Nothing changed. He still accepts me and respects me regardless of HPV. Since I ultimately passed this virus onto him, I was afraid that he would start to resent me and our relationship. But just the opposite happened. We became closer and our love grew in leaps and bounds"* (P) (Newton & McCabe, 2008b).

A small number of women felt that testing HPV positive had a negative impact on their relationship, feeling that their partner was distant from them or that HPV was causing conflict (Lin et al., 2011; Newton & McCabe, 2008b; Patel et al., 2018).

Frequency and interest in sex

Several studies reported that interest in and frequency of sex declined following an HPV positive result and some women stopped having sex altogether (Jeng et al., 2010; Lin et al., 2011; McCurdy et al., 2011; Newton & McCabe, 2008b; Verhoeven et al., 2010):

> *"No desire for lovemaking"* (P) (Jeng et al., 2010);

> *"Sex is no longer in the picture and abstinence is the best way"* (P) (Newton & McCabe, 2008b).

There were various reasons for this; some women thought that people with HPV should not have sex, while others were concerned about passing the infection on. Some women were concerned that having sex would further worsen their abnormal cervical cells (Jeng et al., 2010; McCaffery et al., 2006).

Negative sexual self-image

Some studies reported that HPV had a negative impact on women's sexual self-image (McCaffery et al., 2006; Newton & McCabe, 2008b; Rask et al., 2017; Waller et al., 2007b). For some women, the stigma associated with HPV led them to feel *"dirty"*, *"sexually unattractive"* and unworthy of sexual attention from others (McCaffery et al., 2006; Newton & McCabe, 2008b; Rask et al., 2017):

> *"I feel like I am a less desirable woman since I have contracted HPV. I feel that most men will reject me and that I am not going to be wanted anymore"* (P) (Newton & McCabe, 2008b).

Some felt the stigma of having an STI restricted their sexual advances towards others, affected their sexual spontaneity, and felt they had to alter their sexual activities (Newton & McCabe, 2008b).

Concerns about risks associated with oral sex

The risks associated with oral sex were mentioned by a small number of women (Kosenko et al., 2012; McCaffery & Irwig, 2005). Women were concerned about passing HPV on to their partners in this way and the potential for it to lead to oral cancer, and sometimes abstained from oral sex because of this:

> *"I think it can lead to, if you have oral sex, to mouth cancer, too. I thought I read somewhere or heard that from somebody. So I'm like, God, now I can't even have oral sex! I don't have oral sex either way, giving or receiving, because of that"* (P) (Kosenko et al., 2012).

2.5: Discussion

2.5.1: Main findings

This review synthesises the existing literature on the psychosexual impact of testing positive for high-risk cervical HPV. The diversity of quantitative study designs and inclusion of study populations with abnormal cytology or other conditions makes it difficult to determine the impact that an HPV positive result would have in the context of routine HPV primary screening. However, some studies suggest that testing HPV positive can have a psychosexual impact. The qualitative literature suggests that psychosexual concerns are raised by some women who test HPV positive and that these concerns cover a broad range of aspects relating to their current and past relationships, both interpersonal and sexual.

2.5.2: Interpretation

As described in Chapter 1, previous studies have shown that receiving an abnormal cytology result can have a negative impact on frequency of sex, interest in sex and satisfaction with sex (Campion et al., 1988; Drolet et al., 2012; Wardle et al., 1995). The quantitative studies included in this review that compared HPV positive and HPV negative women with abnormal cytology found inconsistent evidence of psychosexual impact (Kwan et al., 2011; Maissi et al., 2005; Wang et al., 2010; Wang et al., 2011). Some of my findings are consistent with previous reviews. A review by Fleurence et al. (2007) found that most studies reported changes in women's sexual relationships following an HPV positive result. A second review by Graziottin and Serafini (2009) found no conclusive evidence regarding the psychosexual consequences of an HPV positive result. There was a small amount of overlap in the studies included in Fleurence et al. (2007) and Graziottin and Serafini (2009) and my systematic review. Of the 25 studies included in my review, 5 studies were included in these previous reviews (Kitchener et al., 2008; Maggino et al., 2007; McCaffery et al., 2004; Reed et al., 1999; Waller et al., 2007b). My review therefore identified 20 additional studies.

The results of the qualitative synthesis highlight that following an HPV positive result, women have a number of questions. Some of the questions and concerns raised by women such as the source of the infection, whether partners can re-infect each other, whether an individual can give or get HPV from oral sex and how to prevent the transmission of HPV were identified as frequently asked questions by the American Social Health Association HPV Resource Centre staff members who collected a large number of calls, emails, letters and lecture questions over a 9-month period (Gilbert, Alexander, Grosshans, & Jolley, 2003).

While some studies included in the review did use validated measures, a validated measure specific to HPV testing that assesses aspects of psychosexual and interpersonal relationships (discussed in the qualitative literature) would help to ensure contextually valid items are included and provide a tool that can allow comparisons between studies. Only two papers included in the review measured psychosexual impact longitudinally. Future studies should measure the psychosexual impact of testing HPV positive over time to ascertain if psychosexual impact changes. Knowledge of when psychosexual impact is greatest could help to determine when interventions are most appropriate.

Including quantitative and qualitative articles in the review allowed me to highlight the range of psychosexual concerns that women testing HPV positive have. Traditional psychosexual measures used in the quantitative studies assessed specific aspects of sexual behaviour in line with medical classifications of psychosexual disorders (e.g. sexual interest and arousal (American Psychiatric Association, 2013)). Conversely, the qualitative literature suggested that the concerns of women with HPV are more about where the infection came from, infectivity and the impact this can have on relationships. Concerns about infectivity were only assessed by two quantitative measures included in the review (HIP and PEAPS-Q), both of which had used qualitative research when developing their questionnaire. However, the studies that used these measures reported overall psychosexual impact scores, rather than individual psychosexual outcomes. Assessing the prevalence of concerns about infectivity and other concerns raised in the qualitative literature is important. Including these aspects in quantitative measures would ensure a more inclusive

assessment of the components that influence psychosexual outcomes among women who test HPV positive.

2.5.3: Strengths and limitations

A limitation of the review is that it was not possible to conduct a meta-analysis because of the heterogeneous measures used and outcomes reported. A meta-analysis is a statistical method for combining and analysing data from different studies (Egger & Smith, 1997). An advantage of meta-analysis is that, regardless of the sample size of an individual study, when data from individual studies are combined, statistical power is increased and a more precise estimate of the effect size can be produced (Egger & Smith, 1997; Lee, 2018). As several the quantitative studies included in the review had small sample sizes, it would have been beneficial to combine them and conduct a meta-analysis to determine a more precise estimate of the psychosexual impact of testing HPV positive.

There are also limitations of the papers included in the review. Comparison groups, measures and the setting from which participants were recruited differed between studies and psychosexual outcome data were collected at different time points (from immediately after a screening test result to more than a year later). The heterogeneity in study design and time from receipt of an HPV positive result to when data were collected could provide an explanation for the mixed findings. However, this makes it difficult to form conclusions about the prevalence and severity of psychosexual impact following an HPV positive result. Please see Chapter 3 for a further discussion of strengths and limitations which apply to my systematic review as a whole.

2.5.4: Conclusion

This review synthesises the literature on the psychosexual impact of testing positive for high-risk cervical HPV. The qualitative studies included in the review provide rich information about the source and nature of psychosexual distress experienced by some women. In particular, women were concerned about transmitting HPV to a partner and where the HPV infection came from. The diversity of quantitative study designs and samples makes it difficult to draw

conclusions about the magnitude of psychosexual impact in the context of HPV primary screening. In the next chapter I will describe additional findings from this review focusing on concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

CHAPTER 3: CONCERNS ABOUT DISCLOSING A HIGH-RISK CERVICAL HPV INFECTION TO A SEXUAL PARTNER: A SYSTEMATIC REVIEW OF THE LITERATURE (STUDY 1B)

3.1: Roles and contributions

Roles and contributions are described in Chapter 2. A version of this chapter has been published in *BMJ Sexual and Reproductive Health* (Appendix 3.1)

3.2: Introduction

In Chapter 2 I described the findings exploring the psychosexual impact of testing positive for high-risk cervical HPV. In this chapter I will describe additional findings from my systematic review exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

As described in Chapter 1, a key concern among individuals with an STI is disclosing their diagnosis to a sexual partner (Duncan et al., 2001; Mills et al., 2006). In studies with participants with genital herpes and chlamydia, disclosure is described as something that is difficult, fear-inducing and a considerable source of worry (Duncan et al., 2001; Mills et al., 2006). This may be due to the feelings of stigma and shame that are associated with having an STI, which has been found to be a barrier to disclosing some STI diagnoses (Bickford et al., 2007; Jeynes et al., 2009; Nack, 2000). Participants' concerns about disclosure include worry that they will receive a negative reaction from their partner, concern about being rejected by their partner, or that their partner would end their relationship, and worry that their partner would inform others of the STI (Duncan et al., 2001; Green et al., 2003; Melville et al., 2003; Myers et al., 2016; Scrivener et al., 2008). An early qualitative study of HPV testing in cervical screening suggested that some women with HPV have concerns about disclosing an HPV positive test result to their partner (McCaffery et al., 2006).

With the introduction of HPV primary screening in England and elsewhere, it is important to understand women's information needs around disclosure so that

these can be met through information provision and guidance from healthcare professionals. I aimed to review the existing qualitative and quantitative literature exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

3.3: Methods

My systematic review aimed to explore:

1. The psychosexual impact of testing positive for high-risk cervical HPV and;
2. Concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

Findings are reported separately. One search was carried out and the selection process, data extraction, quality assessment and analyses for each research question were carried out concurrently in the same way. Details of the methods are reported in full in Chapter 2.

In this chapter I will describe findings exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner. The results of the review exploring the psychosexual impact of testing positive for high-risk cervical HPV are reported in Chapter 2.

3.4: Results

3.4.1: Search results

After the removal of duplicates and exclusions, 30 papers were included in the review. Of these, 13 studies assessed concerns about disclosing HPV to a sexual partner and are included in the analysis in this chapter. Figure 3.1 shows the study selection process.

Studies were conducted in the USA (n=7), England (n=2), Australia (n=2), Taiwan (n=1) and Brazil (n=1) and were published between 2005 and 2016. Studies were predominantly qualitative (n=12) (Barnack-Tavlaris, Serpico, Ahluwalia, & Ports, 2016; Bertram & Magnussen, 2008; Kahn et al., 2005; Kosenko et al., 2012; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al.,

2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Perrin et al., 2006; Waller et al., 2007b), with one quantitative study (Daley, Vamos, Wheldon, Kolar, & Baker, 2015). Most studies collected data using individual interviews (n=11) (Bertram & Magnussen, 2008; Kahn et al., 2005; Kosenko et al., 2012; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Perrin et al., 2006; Waller et al., 2007b). One qualitative study collected anonymous patient narratives of having HPV from a website of patient experiences and analysed these using content analysis (Barnack-Tavlaris et al., 2016). Participant and study characteristics of studies reporting concerns about disclosing HPV to a sexual partner are shown in Table 3.1.

3.4.2: Quality assessment

Based on the NICE quality appraisal checklist for qualitative studies, all qualitative studies (n=12) were judged to be well conducted. The single quantitative study was judged to have been designed or conducted in such a way as to minimise the risk of bias and had good internal and external validity See Table 3.2 for quality assessment scores.

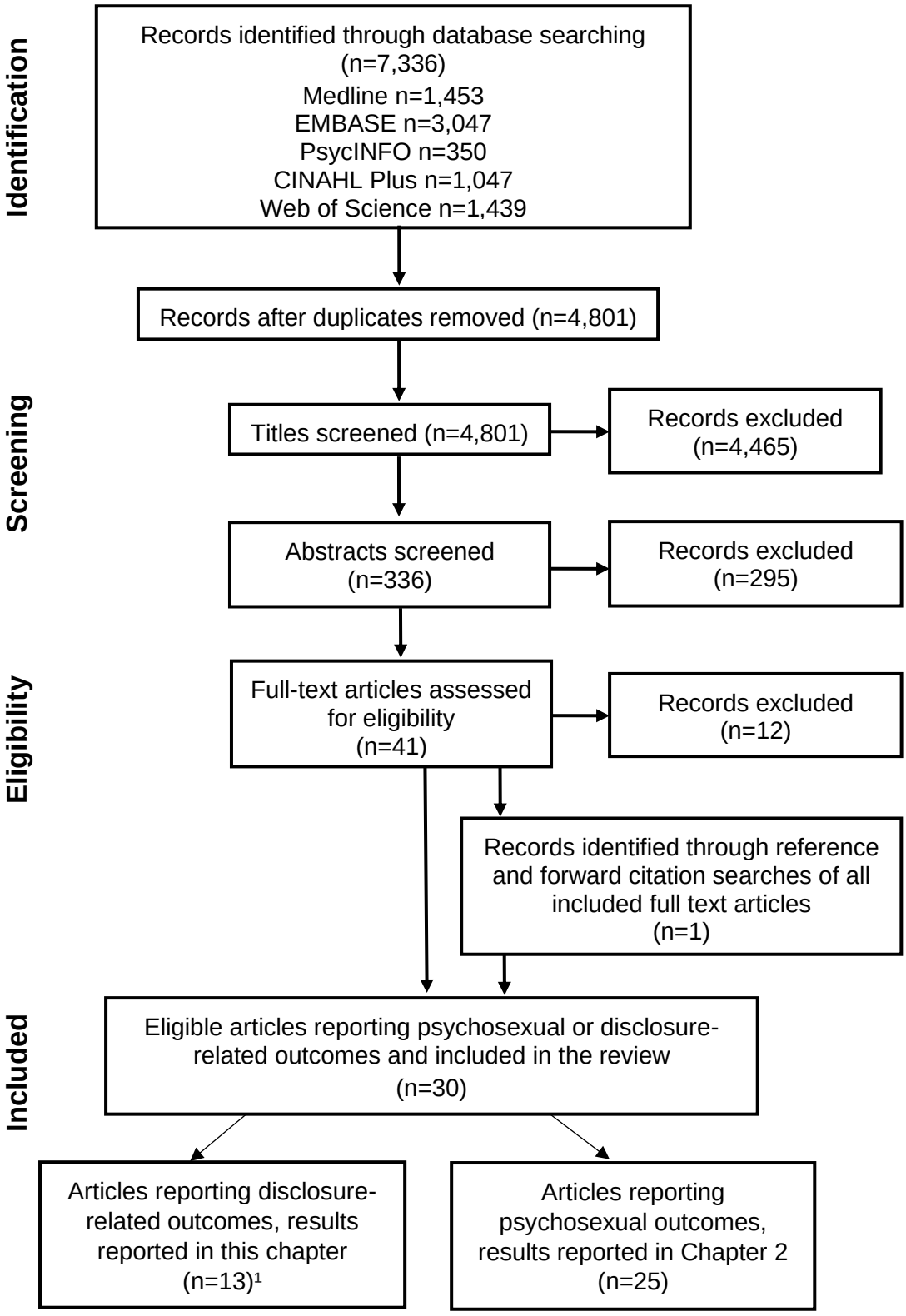

Figure 3.1: Flow diagram of study selection

(adapted from Moher et al. (2009))

[1] Of the 13 articles included in this review, 8 articles included both psychosexual and disclosure-related outcomes and are reported in this chapter and Chapter 2.

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Daley et al. (2015) USA	2003-2005	Male (n=190) and female (n=154)	Men: 18-66, Women: 18-65	Not reported	344	Questionnaire completed following receipt of an HPV positive result	Within 3 months of testing HPV positive	Women attending a student health service clinic and planned parenthood clinics for a gynaecological examination and cervical screening
Barnack-Tavlaris et al. (2016) Not reported	2013	Not reported	Not reported	Not reported	127 blog posts	Content analysis of HPV blog posts	Not reported	Individuals who posted a blog to the *Experience Project* website experience of "I have HPV"
Bertram et al. (2008) USA	Not reported	Female	18-65	Not reported	10	Unstructured interviews	Within 5 years of receiving an abnormal cytology result	Women with a history of an abnormal cytology result recruited at the time of their annual gynaecological examination from a women's health clinic in Hawaii

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Kosenko et al. (2012)[1] USA	Not reported	Female	19-56	Not reported	25	Semi-structured interviews	Time since HPV positive result ranged from 1 to 17 years	Women answering an advertisement posted online (social media websites and online support groups) and in community centres, libraries, restaurants, coffee shops, supermarkets and buildings in college campuses in cities in the southeastern USA about the stress and coping of women with HPV
Kahn et al. (2005) USA	2002	Female	14-21, mean: 17.2	Low-risk and high-risk HPV	100	Individual interviews	At the time of receiving HPV results	Women attending an urban, hospital-based teen health centre who were tested for HPV

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Lin et al. (2011)[1] Taiwan	2008	Female	27-56	High-risk	20	Semi-structured interviews	Not reported	Women who had tested HPV positive who were attending a gynaecology outpatient clinic of a university-based hospital in Taipei, Taiwan
McCaffery & Irwig (2005)[1] Australia	2002	Female	Range unknown. 53% were <35 years, 47% were >35 years	High-risk	19	In-depth, unstructured interviews.	Not reported.	Women who had tested HPV positive following routine cervical screening were recruited from family planning clinics, general practice and specialist gynaecologist practices in Sydney, Australia, and the surrounding area

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
McCaffery et al. (2006)[1] England	2001-2003	Female	Age categories reported: 20-29, 30-39, 40-49, 50-64	High-risk	74	In-depth interviews	Not reported	Women taking part in clinical trials of HPV testing or attending colposcopy clinics where HPV testing is carried out
McCurdy et al. (2011)[1] USA	2003-2004	Female	18-47 (women that the article focuses on were aged between 21 and 45)	High-risk	42 (article focuses on 18 women who were aware of their HPV status)	In-depth interviews	Not reported	Women attending three private primary care clinics who were found to have abnormal cytology and a high-risk HPV type
Newton & McCabe (2008b)[1] Australia	Not reported	Male (n=30) and female (n=30)	19-59	Not reported	60 (30 with genital herpes, 30 with HPV)	Semi-structured interviews	Not reported	Men and women responding to an advertisement about the study posted on STI websites, support groups and online STI communities

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Parente Sa Barreto et al. (2016)[1] Brazil	2012	Female	20-42	Not reported	14	Semi-structured interviews	Not reported	Women attending a Specialised Medical Carer Service unit (a public service supporting sexual and reproductive care) who had HPV. Women were excluded from the study if they were attending the unit for the first time

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Perrin et al. (2006) USA	Not reported	Female	18-44	High-risk, low-risk and high-risk and low risk	52	In-depth, semi-structured interviews	Within 30 days of testing HPV positive	Women diagnosed as having one or more types of HPV attending one of 3 clinical sites (Planned Parenthood clinics or the Student Health Service clinic at the University of South Florida) for an annual gynaecological examination

Table 3.1: Characteristics of studies assessing concerns about disclosing HPV to a sexual partner included in the review (continued)

Reference and country	Years of study conduct	Gender	Age (years)	HPV type	Number of participants	Study design	Time of data collection	Study population
Waller et al. (2007b)[1] England	2003	Female	21-64	High-risk	30	In-depth, semi-structured interviews	Not reported	Women taking part in the ARTISTIC trial of HPV testing (a randomised trial of HPV testing in primary cervical screening). Women were HPV positive with normal cytology at baseline and had attended for a repeat HPV test 12 months later

[1] Study included both psychosexual and disclosure-related outcomes and is reported in this chapter and Chapter 2.

Table 3.2: Quality assessment rating for studies assessing concerns about disclosing HPV to a sexual partner included in the review

Study	Internal validity[1]	External validity[1]	Overall assessment score[2]
Daley et al. (2015)	++	+	
Barnack-Tavlaris et al. (2016)			++
Bertram & Magnussen (2008)			++
Kosenko et al. (2012)			++
Kahn et al. (2005)			++
Lin et al. (2011)			+
McCaffery & Irwig (2005)			++
McCaffery et al. (2006)			++
McCurdy et al. (2011)			++
Newton & McCabe (2008b)			+
Parente Sa Barreto et al. (2016)			+
Perrin et al. (2006)			++
Waller et al. (2007b)			++

[1] For quantitative studies

[2] For qualitative studies

Overall assessment score (qualitative studies)

++ Indicates that all or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.

+ Indicates that some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.

– Indicates that few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

Internal and external validity (quantitative studies)

++ Indicates that the study was designed or conducted in such a way as to minimise the risk of bias.

+ Indicates that the study was partly designed to minimise bias, may not have addressed all potential sources of bias, or it was not clear from the way the study was reported.

− Indicates that the study had significant sources of bias across all aspects of the study design.

3.4.3: Quantitative study

Only one quantitative study reported outcomes assessing concerns about disclosing HPV to a sexual partner (Daley et al., 2015). The study was carried out in the USA and included HPV positive male (n=190) and female (n=154) participants aged 18 to 66 years. Female participants were recruited from a university student health service and Planned Parenthood clinics where they were attending for cervical screening. Participants completed a paper survey assessing HPV-related negative emotions and stigma beliefs. A single statement assessed feelings about disclosure: 'Disclosing my test result is risky'. Women more likely to agree with the statement than men (60% vs. 50%), however the difference was not significant (p=0.051).

3.4.4: Qualitative studies

3.4.4.1: Participant characteristics

Qualitative studies predominantly included female participants only (n=10) (Bertram & Magnussen, 2008; Kahn et al., 2005; Kosenko et al., 2012; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Parente Sa Barreto et al., 2016; Perrin et al., 2006; Waller et al., 2007b). One study included male and female participants (Newton & McCabe, 2008b). In the remaining study the gender of participants was unknown (Barnack-Tavlaris et al., 2016). The number of participants across studies ranged from 10 to 100. One study analysed 127 anonymous blog posts from a website (Barnack-Tavlaris et al., 2016). In the nine studies where the age range was provided, women ranged from 14 to 65 years (Bertram & Magnussen, 2008; Kahn et al., 2005; Kosenko et al., 2012; Lin et al., 2011; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Perrin et al., 2006; Waller et al., 2007b).

3.4.4.2: Recruitment

Most studies recruited participants from clinical settings (e.g. women's health clinics, family planning and sexual health services, gynaecology outpatient clinics) (n=7) (Bertram & Magnussen, 2008; Kahn et al., 2005; Lin et al., 2011;

McCaffery & Irwig, 2005; McCurdy et al., 2011; Parente Sa Barreto et al., 2016; Perrin et al., 2006). Participants were also recruited from clinical trials of HPV testing (n=2) (McCaffery et al., 2006; Waller et al., 2007b) and by advertising the study in community settings and/or online (n=2) (Kosenko et al., 2012; Newton & McCabe, 2008b). One study carried out a content analysis of HPV narratives from a website and did not recruit participants (Barnack-Tavlaris et al., 2016).

3.4.4.3: Time of data collection

In most studies, the time from receipt of HPV test results to when data were collected was not described (n=8) (Barnack-Tavlaris et al., 2016; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016; Waller et al., 2007b). In one study, women had received an abnormal cytology result within the last 5 years (Bertram & Magnussen, 2008) and in another, the time since testing HPV positive ranged from 1 to 17 years (Kosenko et al., 2012). The remaining studies (n=3) collected data at the time of receiving HPV test results (Kahn et al., 2005), within 30 days of testing HPV positive (Perrin et al., 2006) and within 3 months of testing HPV positive (Daley et al., 2015).

3.4.4.4: Themes

Three major themes were identified from a thematic synthesis of twelve studies assessing concerns about disclosing HPV to a sexual partner: (1) Anticipated psychological impact of disclosure, (2) When is disclosure necessary? and, (3) Managing disclosure. Each theme and subtheme are described, along with example quotes with (P) denoting a participant comment and (A) denoting an author comment. Table 3.3 gives a brief description of each theme and shows the studies associated with it.

Table 3.3: A brief description of themes assessing concerns about disclosing HPV to a sexual partner and the studies associated with them

Theme	Sub-theme	Studies	Explanation
Anticipated psychological impact of disclosure	General concerns about disclosure	Barnack-Tavlaris et al. (2016) Bertram and Magnussen (2008) Kosenko et al. (2012) McCaffery et al. (2006) McCurdy et al. (2011) Newton and McCabe (2008b)	Women reported feeling anxious, worried and fearful about disclosing HPV to a sexual partner
	The stigma of having an STI	Bertram and Magnussen (2008) Kosenko et al. (2012) McCaffery et al. (2006) McCurdy et al. (2011) Perrin et al. (2006) Waller al. (2007b)	Women were concerned about disclosing the infection because of the perception of promiscuity that is associated with having an STI
	How will others respond?	Barnack-Tavlaris et al. (2016) Kahn et al. (2005) Kosenko et al. (2012) McCaffery and Irwig (2005) McCaffery et al. (2006) McCurdy et al. (2011) Newton and McCabe (2008b) Parente Sa Barreto et al. (2016)	Women were concerned how their partner would respond to disclosure, for example, whether their partner's perception of them would change, or that a partner might reject them (sexually, or by ending the relationship)

Table 3.3: A brief description of themes assessing concerns about disclosing HPV to a sexual partner and the studies associated with them (continued)

Theme	Studies	Explanation
When is disclosure necessary?	Bertram and Magnussen (2008) Kosenko et al. (2012) Lin et al. (2011) McCaffery and Irwig (2005) McCaffery et al. (2006) McCurdy et al. (2011)	Women questioned whether it was necessary to disclose, particularly to male partners, as women were unsure of the impact that HPV would have for them. Women also questioned to whom they should disclosure to and the best time to disclose
Managing disclosure	Bertram and Magnussen (2008) Kosenko et al. (2012) Lin et al. (2011) McCaffery et al. (2006) Perrin et al. (2006)	Some women chose to focus on their abnormal cytology result rather than testing HPV positive

3.4.4.4.1: Anticipated psychological impact of disclosure

The first theme describes the thoughts, feelings and concerns women had prior to disclosing HPV to a sexual partner. Women expressed concerns about disclosure, in part because of the stigma associated with having an STI and concerns about how their partner would respond.

General concerns about disclosure

While some women were not worried about disclosing their HPV infection, others reported feeling that the prospect of disclosure was challenging, complicated and something that they wished to avoid (Barnack-Tavlaris et al., 2016; Bertram & Magnussen, 2008; Kosenko et al., 2012; McCaffery et al., 2006; Newton & McCabe, 2008b). Women reported feeling anxious, worried, fearful and stressed about discussing HPV with their sexual partners (Barnack-Tavlaris et al., 2016; Bertram & Magnussen, 2008; Kosenko et al., 2012; McCaffery et al., 2006; Newton & McCabe, 2008b):

> *"The thought of having it, deciding when to do it and how and what to say - it was extremely stressful"* (P) (Kosenko et al., 2012).

Women's anxiety about disclosure was partly due to concern that they may have transmitted their HPV infection to their partner:

> *"Women repeatedly described feeling highly anxious about informing their partner, with descriptions of "bursting into tears" and feeling intensely "guilty" and worried that they may have infected anxiety their partner with the virus"* (A) (McCaffery et al., 2006).

Feeling that partners had a poor understanding of HPV also enhanced anxiety around disclosure (McCaffery et al., 2006; McCurdy et al., 2011). Although not frequently reported, women reported feeling depressed at the prospect of disclosure (Newton & McCabe, 2008b).

The stigma of having an STI

Women's concerns about anticipated disclosure were partly due to the stigma of having an STI. Women were worried about being perceived as promiscuous (Kosenko et al., 2012; McCurdy et al., 2011):

> *"Sexually transmitted disease is just um…it seems like dirty…It's not like I'm promiscuous or anything, it's just that like it happened. I don't think they are going to understand that it's not something that…well it is bad but they would look bad at me"* (P) (McCurdy et al., 2011).

For some women, the stigma associated with having an STI was more distressing than worry about cancer (Bertram & Magnussen, 2008). The stigma associated with having an STI led women to feel embarrassed and ashamed about disclosure (McCaffery et al., 2006; McCurdy et al., 2011), and the authors of one paper commented that for some women, these feelings may affect willingness to disclose an HPV infection to a sexual partner (Perrin et al., 2006).

How will others respond?

Because of the negative connotations associated with having an STI, women were concerned about how others would respond and react to HPV disclosure (Barnack-Tavlaris et al., 2016; Kahn et al., 2005; Kosenko et al., 2012; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011; Newton & McCabe, 2008b; Parente Sa Barreto et al., 2016). Women were concerned that their partner might perceive them differently and their opinion of them would change (McCaffery & Irwig, 2005; McCaffery et al., 2006):

> *"I was more worried about my partner reading it and saying "aha". I was worried about him thinking it was sexually transmitted and that I picked it up before I met him which would have concerned him a lot as we had only been together about 4 or 5 months at that stage...I was worried that it might change his opinion of me and being early in a relationship [it was a] bit of a concern"* (P) (McCaffery & Irwig, 2005).

Women feared being rejected by a partner following disclosure (Barnack-Tavlaris et al., 2016; Kahn et al., 2005; Newton & McCabe, 2008b):

> *"What about when I tell a guy I want to be with that I have HPV? Will he run away as if I'm some dirty girl that sleeps around, which I'm anything but?"* (P) (Barnack-Tavlaris et al., 2016).

Some women had specific worries about being sexually rejected:

> "*If I told men that I had it they might not want to have sex with me"* (P) (McCaffery et al., 2006).

Some women were apprehensive that their partner would react angrily following disclosure, question the source of the infection or accuse them of infidelity (McCurdy et al., 2011; Parente Sa Barreto et al., 2016):

> *"I'm sort of embarrassed to tell my husband that I have it. Not only because he is going to say, "Where did you pick it up?" We've been married for 14 years, so he'd be like, "How did it come about?""* (P) (McCurdy et al., 2011).

Consequently, this led to concerns that disclosure could harm a relationship or lead to it ending (Kahn et al., 2005; McCurdy et al., 2011; Parente Sa Barreto et al., 2016). Although uncommon, some women ended relationships before they became sexual because they feared rejection (Newton & McCabe, 2008b).

3.4.4.4.2: When is disclosure necessary?

The second theme related to women's views on whether it was necessary to disclose an HPV infection to a sexual partner. Some women felt obligated to disclose the infection to current and future partners because they were potentially susceptible to HPV (Bertram & Magnussen, 2008; Kosenko et al., 2012). However, for others the perceived lack of serious physical consequences of HPV for men led them to question whether it was necessary to disclose to male partners (Bertram & Magnussen, 2008; Lin et al., 2011; McCaffery & Irwig, 2005; McCaffery et al., 2006; McCurdy et al., 2011):

> *"I guess there aren't many repercussions for the male partner. That is the hardest part: it's the partner piece. That was the biggest issue. It was really hard to find any information on it (HPV in men) even to find something that says it won't affect them"* (P) (Bertram & Magnussen, 2008).

A lack of clear, consistent information from healthcare professionals contributed to women's confusion about whether it was necessary to disclose:

> *"Should I be telling sexual partners that I have this? And one person would say yes of course you must and another would say don't be silly almost all the population's been exposed to it…I couldn't get to the truth…they were giving me conflicting advice…I found that very distressing that I couldn't actually get real information that I could trust"* (P) (McCaffery et al., 2006).

Uncertainty about the source of the infection led some women to question which previous partners they should disclose to:

> *"It's not like I had tons of partners, but it really could've been any of them. I don't know when, I don't know where, I don't know who. I don't know who I'm supposed to tell…"* (P) (Kosenko et al., 2012).

3.4.4.4.3: Managing disclosure

The third theme related to managing disclosure. Women reported that they were uncertain about how to approach disclosure (Kosenko et al., 2012; Lin et al., 2011) and wondered about the most appropriate time to disclose:

> *"It's always in the back of your head. You know, "Is he going to ask me back to his place? If he does, should I tell him?" It was just, "When do I tell him?"…So, it was very much like "What's the best timing?"...It was a lot of planning and stressing out and asking my friends, "Do you think I need to tell him?""* (P) (Kosenko et al., 2012).

Some women chose not to disclose their HPV result and instead told their partner about their abnormal cytology result, potential cervical cancer or having a gynaecological disease (Bertram & Magnussen, 2008; Lin et al., 2011; McCaffery et al., 2006; Perrin et al., 2006). Women chose to take this approach to minimise anxiety and avoid the embarrassment and challenges of explaining HPV and its sexually transmitted nature (Bertram & Magnussen, 2008; McCaffery et al., 2006; Perrin et al., 2006). Some women chose not to disclose to male partners because they perceived the impact of an HPV infection to be minimal for men and did not know what information to give their partner (McCaffery et al., 2006). The authors of one paper describe the decision not to disclose as being "…*motivated by women's desire to minimise their own anxiety during an already stressful period and to avoid dealing with a difficult issue of which they had only limited understanding"* (A) (McCaffery et al., 2006).

3.5: Discussion

3.5.1: Main findings

To my knowledge, this is the first review to synthesise the literature on women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner. The qualitative literature identified a range of concerns about disclosing HPV to a sexual partner. These concerns were partly because of the stigma associated with having an STI and the ways in which women anticipated their partners might respond. Some HPV positive women used strategies to manage disclosure of their HPV diagnosis to a sexual partner, for example focusing on having an abnormal cytology result rather than HPV *per se*. The qualitative literature also found that women questioned how, when and to whom they should disclose their result. While quantitative and qualitative articles were included in the review, only one quantitative article was identified which found that over half of HPV positive participants felt that disclosing their HPV positive result was 'risky'.

3.5.2: Interpretation

The results of this review suggest that some women feel anxious, worried, and fearful about disclosing HPV to a sexual partner and described it as something they wished to avoid. These feelings were partly related to the stigma of having an STI and concerns about how others would respond to the disclosure of an HPV positive result. These findings are consistent with previous research with individuals diagnosed with other STIs such as genital herpes and chlamydia, where disclosure has been described as something that is difficult, fear-inducing and a considerable source of worry with feelings of stigma, shame and concerns about negative reactions from a sexual partner also reported (Duncan et al., 2001; Melville et al., 2003; Mills et al., 2006; Myers et al., 2016; Scrivener et al., 2008). Although HPV is very common, one study that explored knowledge of HPV across the UK, USA and Australia found that less than half of participants knew that most sexually active individuals would acquire HPV at some point in their life (Marlow et al., 2013). Increasing knowledge of HPV and how common it is may help to reduce stigma around having the infection and reduce anxiety about disclosure (Waller, Marlow, & Wardle, 2007a).

In the one quantitative study identified by my review, over half of HPV positive participants felt that disclosing their HPV positive result was 'risky' (Daley et al., 2015). It is unclear exactly why participants felt this way, but their feelings may be due to the concerns about disclosure highlighted in my qualitative synthesis such as how their partner would respond. My review focused on women's views about disclosing HPV to a sexual partner, but the findings from this study suggested that women may be more concerned about disclosing than men (60% vs. 50% felt 'disclosing is risky', p=0.051). Other findings from the study by Daley et al. (2015) suggest that women are more likely to have HPV-related stigma beliefs than men, with significantly more women reporting that they felt unclean, ashamed and guilty following their HPV positive result. This is consistent with a review exploring the stigma associated with STIs which suggested that women are more affected by STI-related stigma than men and feel greater internalised stigma, shame, blame and guilt (Hood & Friedman, 2011). This may provide an explanation as to why women in Daley et al. (2015) were more concerned about disclosure than men.

During disclosure some women deliberately avoided mentioning HPV, focusing instead on their abnormal cytology or other aspects of their screening results. Managing the psychological implications of disclosure may be more challenging for women undergoing HPV primary screening who are told they are HPV positive with normal cytology, given that HPV will be the only abnormal result they receive. They could, however, choose to focus on the normal cytology result. Now that HPV primary screening has been fully rolled-out across England, it may be necessary to have additional support available for women. Healthcare professionals, particularly those carrying out cervical screening, are ideally placed to give brief information during screening which could help to mitigate the psychological impact of an HPV positive result.

Some women had questions about disclosing the infection to sexual partners, including whether disclosure was necessary. Contact tracing, the process of identifying individuals who may be at risk of infection because they have been in sexual contact with an individual diagnosed with an STI, is important for some STIs so individuals can be tested and treated if necessary. However, the World Health Organisation (WHO) do not recommend contact tracing for HPV, possibly because there is no treatment and most people will be infected with

HPV at some point in their life so it is difficult to determine where the infection came from (World Health Organisation, 2018a). Therefore, the decision to disclose HPV to a sexual partner is a personal choice. In England, women who test HPV positive now receive brief information stating that they do not need to tell anyone they have HPV if they do not want to. However, it is possible that this could create confusion and concern if women do not fully understand the reasons why they do not need to disclose. Future research should explore women's understanding of this guidance and whether there are any additional questions about disclosure that should be addressed.

3.5.3: Strengths and limitations

Only one quantitative paper was identified that reported concerns about disclosing HPV to a sexual partner, compared with the twelve quantitative papers exploring the psychosexual impact of testing HPV positive (described in Chapter 2). While the qualitative synthesis allowed me to highlight the range of different factors that contribute to women's concerns about disclosure, assessing the prevalence and predictors of these concerns using quantitative methods is important and should be a priority for future research.

Many of the studies included in this review focused on disclosure-related outcomes among women currently in a relationship. It is possible that women who are not currently in a relationship may have concerns about disclosing to future sexual partners. Daley et al. (2015) found that compared to women who were cohabitating or married, women who were single were more likely to report a greater number HPV-related stigma beliefs, however the difference between the two groups was not statistically significant. Future research should explore concerns about disclosure among women with different relationship statuses.

3.5.4: Strengths and limitations of the systematic review

The strengths and limitations in this section apply to my systematic review as a whole (i.e. to Studies 1a and 1b). A strength of my review is that it was systematic and followed PRISMA guidelines. In addition, a broad search strategy was used with no date restrictions. This was a mixed methods review, with both quantitative and qualitative studies eligible for inclusion. The

quantitative studies allowed me to explore the prevalence and magnitude of psychosexual impact and concerns about disclosing HPV. The qualitative studies allowed me to gain a more in-depth understanding of the reasons why some women experienced negative psychosexual consequences following an HPV positive result and had concerns about disclosing HPV to a sexual partner, and identify other relevant issues not measured by quantitative studies. It is possible that because of the range of terms that can be used to describe psychosexual and disclosure-related outcomes some eligible studies may not have been identified in my search. However, I conducted forward and backward citation searching for all included studies to reduce the likelihood of this. I extracted data from studies, with another researcher (MR[8]) independently extracting data for 20% of studies. It is possible that if MR had extracted data from all the studies the results of the review could have changed, however I feel this is unlikely as the agreement rate between myself and MR was very good.

Several studies included in the review did not specify whether participants had high-risk or low-risk HPV. While I excluded any articles that explicitly focused on low-risk types of HPV, it is possible that some of these articles included participants with low-risk HPV. High-risk and low-risk HPV differ in that high-risk HPV usually does not have any visible symptoms, whereas low-risk HPV can cause visible genital warts. Two studies which explored psychosexual-related outcomes compared women with different HPV-related conditions (e.g. normal cytology result, abnormal cytology result, genital warts and HPV positive after an abnormal cytology result) and both found that sexual impact, and overall psychosocial impact, was greatest among women with genital warts (Wang et al., 2010; Wang et al., 2011). In addition, it is possible that feelings about disclosing low-risk HPV would be different because of its symptomatic, visible nature. Therefore, the inclusion of participants with low-risk HPV may have biased studies results.

Based on the NICE quality appraisal checklist for quantitative and qualitative studies, most quantitative studies included in the review were judged to have been designed or conducted in such a way as to minimise the risk of bias and had good internal validity. External validity was more mixed. Most studies were partly designed to minimise bias, may not have addressed all potential sources

[8] Mairead Ryan, Research Assistant, Department of Behavioural Science and Health, UCL.

of bias, or it was not clear from the way the study was reported. External validity was reduced in a number of studies because of small sample sizes, poor response rates, and because information about response rate was not provided which limits confidence in how generalisable the results are. Most qualitative studies included in the review were judged to be well conducted. Despite this, qualitative research does not intend to be statistically representative of a population and there may have been a bias towards taking part in a study if the topic was of personal relevance. Despite the limitations of qualitative research, it is positive that there were similar findings across studies, which increases confidence in the generalisability of the results.

The studies included in my systematic review were published between 1988 and 2018. The variation in awareness and knowledge of HPV between studies may provide an explanation for the mixed findings. In some of the older studies it is likely that awareness and knowledge of HPV was very low which may be why, in some studies, testing HPV positive did not appear to have a psychosexual impact or cause women to have concerns about disclosing their HPV infection to a sexual partner.

3.5.5: Conclusion

This chapter synthesises the literature on women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner. The studies included in the review provide rich information about the range of concerns women have, the reasons for these concerns, and the questions women have about disclosing HPV to sexual partners. Some of these concerns may be allayed by information that is now sent to women in England who test HPV positive stating that they do not need to tell anyone they have HPV if they do not want to. The studies included in this review were published between 2005 and 2016. Since then, HPV-based cervical screening has been introduced in several countries and research should explore women's concerns about disclosure in this context. In addition, many studies focused on disclosure-related outcomes among women who were currently in a relationship.

While this review draws together what is currently known, it also highlights the need for further quantitative research in the context of HPV primary screening, both shortly after women receive their results and over time. Chapter 4 explores

psychosexual distress following HPV primary screening among women receiving different HPV and cytology results, at three time points over a year.

CHAPTER 4: PSYCHOSEXUAL DISTRESS FOLLOWING ROUTINE HPV PRIMARY TESTING: A LONGITUDINAL EVALUATION WITHIN THE ENGLISH CERVICAL SCREENING PROGRAMME (STUDY 2).

4.1: Roles and contributions

This study was carried out in the context of the NHS Cervical Screening Programme HPV primary screening pilot in England. Data were collected as part of the Psychological Impact of Primary Screening for HPV (PIPS) study which was funded by Public Health England. The primary aim of the study was to assess the impact of HPV primary screening on anxiety and distress (results reported elsewhere (McBride et al., 2020b)). Psychosexual functioning was a secondary outcome. The study was designed, and baseline data collection had begun before I started my PhD. Dr Jo Waller, Dr Laura Marlow, Dr Alice Forster and Professor Henry Kitchener conceived the study. Dr Jo Waller, Dr Laura Marlow, Dr Alice Forster and Dr Emily McBride developed the measures. Dr Emily McBride obtained the ethical approvals required for the study. Lauren Rockliffe, Dr Emily McBride and I assisted with participant recruitment and data entry. Dr Emily McBride and Deborah Ridout generated population weights. I conducted all analyses in relation to psychosexual functioning with assistance from Dr Giorgio Di Gessa. A version of this chapter has been published in *BJOG: An International Journal of Obstetrics and Gynaecology* (see Appendix 4.1).

4.2: Introduction

My systematic review of 30 studies described in Chapters 2 and 3 identified a range of HPV-related psychosexual concerns and concerns about disclosure in the qualitative literature. These included concern about where the infection came from and transmitting HPV to a sexual partner. For some women, testing HPV positive had an impact on interpersonal and sexual relationships. However, the quantitative studies found mixed evidence for differences in

psychosexual outcomes between HPV positive women and comparison groups (usually those not tested for HPV or those with an HPV negative result).

Under the new screening pathway, as outlined in Chapter 1, women who are HPV positive are either told they are HPV positive with normal cytology (and will be re-screened at 12 months) or HPV positive with abnormal cytology (and will be referred to colposcopy). Only a small number of studies included in my systematic review compared psychosexual impact among these two groups of women. In addition, there will also be women who have previously tested HPV positive who are returning for their 12-month, or 24-month follow-up appointment (for women who have previously tested HPV positive with normal cytology twice). These women will either be told they still have HPV or have cleared the infection and are HPV negative. To my knowledge, no previous research has explored psychosexual distress among these two groups of women.

Previous studies exploring psychosexual functioning following HPV testing in England have all been carried out in the context of co-testing or HPV triage, and never in the context of HPV primary screening (Kitchener et al., 2008; Maissi et al., 2005; McCaffery et al., 2004). One study found that HPV positive women were more likely to report feeling worse about their sexual relationships a week after receiving their result than HPV negative women, irrespective of their cytology result (McCaffery et al., 2004). In a second study, women with normal cytology had a similar level of psychosexual functioning regardless of whether they were HPV positive or HPV negative (Kitchener et al., 2008). However, among women with mild or borderline abnormal cytology, women who were HPV positive had better psychosexual functioning than women who were HPV negative. A third study compared three groups of women with abnormal cytology and different HPV results (HPV positive, HPV negative and no HPV test) (Maissi et al., 2005). Six months after receiving their test results, sexual worries were significantly higher among HPV positive women than women in the other two groups. A longitudinal Taiwanese study of HPV positive women found that impact on sexual relationships appeared to decline between one and six months after screening but remained similar at six and twelve months (Hsu et al., 2018).

Evaluating psychosexual distress following receipt of different HPV and cytology results will help to establish whether taking part in HPV testing or receiving particular results causes concern or has an adverse effect on women's relationships. Understanding the time points at which the impact is greatest could inform decisions about the timing of interventions. The aim of this study was to explore psychosexual distress following HPV primary screening in the context of the English Cervical Screening Programme among women receiving different HPV and cytology results, at three time points over a year. The hypothesis of the study was that receiving an HPV positive result would be associated with elevated psychosexual distress compared to receiving a normal cytology result.

4.3: Methods

4.3.1: Study design and population

A between-groups design was used to assess women at three time points: shortly after receiving their screening result ('baseline'), and 6 and 12 months later. Participants included screening-eligible women (i.e. those aged 24 to 65 years) who had taken part in the NHS Cervical Screening Programme in one of five HPV primary screening pilot sites in England in 2016 and 2017 (North West London, Sheffield, Norwich and Norfolk, Liverpool and Manchester NHS Trusts).

Potential participants received invitation packs by post within three weeks of receiving their screening result. Those who wished to take part returned a completed consent form and questionnaire booklet. A reminder letter and questionnaire was sent to non-responders three weeks later. Participants who returned a consent form were mailed questionnaire packs 6 and 12 months later.

Three groups of women were recruited following their first HPV test: those who tested HPV negative, those who were HPV positive with normal cytology (HPV positive, normal cytology), and those who were HPV positive with abnormal cytology (HPV positive, abnormal cytology). In addition, two groups of women who had initially tested positive for HPV (with normal cytology) who were attending their 12-month follow-up appointment were recruited: those who were

still found to have HPV (HPV persistent), and those who tested HPV negative at the follow-up appointment (HPV cleared). A group of women who had taken part in cytology-based screening and had received a normal result were recruited as a control group. These women were from the same five HPV primary screening pilot sites as HPV primary screening had only been partially introduced.

4.3.2: Ethical approval

Ethical approval for the study was obtained in August 2016 from the London-Surrey NHS Research Ethics Committee (REC) (REC reference: 16/LO/0902). Health Research Authority (HRA) approval was obtained in September 2016. To approach participants about the study, Section 251 approval was obtained from the Confidentiality Advisory Group (CAG) in August 2016, to allow participants to be invited to take part without their prior consent for their name and address to be used (CAG reference: 16/CAG/0047).

4.3.3: Measures

4.3.3.1: Psychosexual functioning

Psychosexual functioning was assessed using six items, five of which were taken from the PEAPS-Q, a validated questionnaire used to measure distress experienced by women undergoing follow-up investigation after an abnormal Pap smear result (Bennetts et al., 1995). The items selected from the PEAPS-Q measured two dimensions of psychosexual distress: worry about infectivity (2 items) and effect on sexual relationships (3 items). An additional item asked women about whether their result had impacted their relationship (‘Have you been worried about whether your test result would have a bad effect on your relationship with your partner?’). This item was taken from Maissi et al. (2005) who added it to the five PEAPS-Q items in their study exploring the psychological impact of HPV testing (in the context of HPV triage), as it was an issue that was raised by women in the initial stages of their research. All six items used a 5-point Likert response scale: Not at all (1), A little (2), A fair bit (3), Quite a lot (4), Very much (5), with an additional ‘not applicable’ option. Psychosexual impact was calculated as the mean of all six items (α=0.93,

n=898), with higher scores indicating greater psychosexual distress. Psychosexual functioning was assessed using the same six items at all three time points. See Appendix 4.2 for the psychosexual functioning items that were used in the PIPS study.

4.3.3.2: Sociodemographic variables

Sociodemographic variables including self-reported ethnicity (White British or White other, Mixed/Multiple ethnic groups, Asian, Black, Other, Prefer not to say) educational attainment (Degree or Higher degree, Higher education (below degree level), A Levels, ONC/BTEC, GCSE/O Levels, No formal qualifications, Still studying) and relationship status (Single, In a relationship, Separated, Living with partner, Married/Civil Partnership, Widowed, Divorced, Other) were collected.

Age and Index of Multiple Deprivation (IMD) quintile were collected from NHS clinical records. IMD, a measure of relative deprivation for small areas in England, was assigned to participants based on their postcode (Ministry of Housing, 2015). IMD takes income deprivation, employment deprivation, education, skills and training deprivation, health deprivation and disability, crime, barriers to housing services and living environment into account and combines information from these seven domains to produce an overall measure of deprivation (Ministry of Housing, 2015). Sociodemographic variables were collected at baseline only.

4.3.4: Response rate

Of the 5,494 women who were invited to take part in the study, 21% (n=1,154) returned a consent form and questionnaire booklet at baseline. Table 4.1 shows response rate at baseline by screening result group. Response rate varied by screening result group and was highest in the HPV persistent (27.8%) and HPV cleared groups (26.7%) and lowest in the control group who were not tested for HPV (16%). The demographic characteristics of responders and non-responders in the PIPS study were compared and are reported in the primary outcomes paper (McBride et al., 2020b). In brief, responders and non-responders differed by age, IMD, number of previous screens, NHS site and

screening result group (McBride et al., 2020b). Population weights based on age group and IMD were calculated to adjust for the possibility that the approached sample may not have been representative of the screening population in the HPV testing pilot sites. With permission from the Office for Data Release, post-stratification weights were calculated using data from 955,387 women attending screening in the five sites included in the PIPS study between 2017 and 2018 (McBride et al., 2020b). I was not involved in the generation of the weights. Participants returning a questionnaire >90 days after date of identification and those who were aged >65 years and therefore ineligible to take part in the study were excluded (n=21). Of the remaining 1,133 participants, 1,132 consented to receive follow-up questionnaires; 67.8% (n=768) returned a questionnaire booklet at 6 months and 47.9% (n=542) at 12 months.

Table 4.1: Response rate at baseline by screening result group

	Responder n (%)	**Non-responder n (%)**	**Total**
HPV negative	250 (20.3)	979 (79.7)	1229 (22.4)
HPV positive, normal cytology	264 (22.0)	934 (78.0)	1198 (21.8)
HPV positive, abnormal cytology	173 (21.4)	637 (78.6)	810 (14.7)
HPV persistent	184 (27.8)	479 (72.2)	663 (12.1)
HPV cleared	70 (26.7)	192 (73.3)	262 (4.8)
Control (normal cytology)	213 (16.0)	1119 (84.0)	1332 (24.2)
Total	**1154 (20.9)**	**4340 (79.1)**	**5494 (100.0)**

4.3.5: Attrition, missing data and ‘not applicable’ responses

I explored patterns in the data that was available to understand if there were consistent biases in (1) Attrition, (2) Missing data and, (3) Not applicable responses. The methodology used for these analyses are described in Appendix 4.3.

4.3.5.1: Attrition

Table 4.2 shows the number of participants responding at one or more time point. In total, 40.8% (n=462) returned questionnaire booklets at baseline, 6 and

12 months. A further 25.2% (n=285) only returned questionnaire booklets at baseline, with 27% (n=306) returning questionnaire booklets at baseline and the 6-month follow-up and 7.1% (n=80) returning questionnaire booklets at baseline and the 12-month follow-up.

Table 4.2: The number of participants responding at one or more time point[1]

	n	**%**
Responded at all time points	462	40.8
Responded at baseline only	285	25.2
Responded at baseline and 6-month follow-up	306	27.0
Responded at baseline and 12-month follow-up	80	7.1
Total	**1133**	**100.0**

[1] Due to rounding up or down, percentages may not add up to 100%.

Of the 1,132 participants who responded to the baseline questionnaire and consented to receive follow-up questionnaires, 364 (32.2%) did not respond to the 6-month follow-up and 590 (52.1%) did not respond to the 12-month follow-up.

Differences in non-response at the 6 and 12-month follow-ups by screening result group, demographic characteristics and baseline psychosexual distress are shown in Appendices 4.4 and 4.5. In brief, compared to women of White ethnicity, women from an ethnic minority group were significantly less likely to respond to the 6 and 12-month follow-ups (6 months: $p<0.001$; 12 months: $p=0.022$). In addition, there were significant differences by IMD, with those in the most deprived quintile less likely to respond to the 6 and 12-month follow-ups compared to those in the least deprived quintile (6 months: $p<0.001$; 12 months: $p=0.013$). Compared to women who were educated to degree level or above, those with qualifications below degree level were also less likely to respond (6 months: $p=0.028$; 12 months: $p=0.034$) as were those with no formal qualifications (6 months: $p=0.010$; 12 months: $p=0.044$).

4.3.5.2: Missing Data

The number of participants responding to all six psychosexual functioning items (including those who responded ‘not applicable’) was high at all three time points: 98.0% (n=1,110) at baseline, 98.2% (n=748) at the 6-month follow-up

and 97.8% (n=525) at the 12-month follow-up. The remaining 2.0% (n=23) at baseline, 1.8% (n=14) at the 6-month follow-up and 2.2% (n=12) at the 12-month follow-up had missing data for one or more item. In total, 1.2% (n=14) at baseline, 0.9% (n=7) at the 6-month follow-up and 0.7% (n=4) at the 12-month follow-up had missing data for all six psychosexual items. Table 4.3 shows the number of missing psychosexual responses at baseline, 6 and 12 months.

Table 4.3: Missing psychosexual responses at baseline, 6 and 12 months[1]

Number of missing responses	Baseline n (%)	6 months n (%)	12 months n (%)
0	1110 (98.0)	748 (98.2)	525 (97.8)
1	4 (0.4)	7 (0.9)	5 (0.9)
2	1 (0.1)	-	2 (0.4)
3	3 (0.3)	-	-
4	1 (0.1)	-	-
5	-	-	1 (0.2)
6	14 (1.2)	7 (0.9)	4 (0.7)
Total	**1133 (100.0)**	**762 (100.0)**	**537 (100.0)**

[1]Due to rounding up or down, percentages may not add up to 100%.

Appendix 4.6 shows the proportion of missing data for each psychosexual item at baseline, 6 and 12 months.

Differences in the number of participants who had missing data for one or more psychosexual item by screening result group and demographics characteristics at baseline, 6 and 12 months are shown in Appendix 4.7.

4.3.5.3: Not applicable responses

The number of participants who responded not applicable to one or more of the six psychosexual functioning items was 18.9% (n=214) at baseline, 22.6% (n=172) at the 6-month follow-up and 21% (n=113) at the 12-month follow-up. A small number responded not applicable to all six psychosexual items: 2.6% (n=30) at baseline, 2.6% (n=20) at the 6-month follow-up and 5.4% (n=29) at the 12-month follow-up. It is unknown exactly why women responded not applicable. A possible explanation is that they did not currently have a sexual partner and therefore felt that the items were not applicable. Of the participants

who did not respond 'not applicable' to any psychosexual items, a small number at each time point had missing data for one or more item: 0.8% (n=7) at baseline, 0.3% (n=2) at 6 months and 0.5% (n=2) at 12 months. Table 4.4 shows the number of 'not applicable' responses at baseline, 6 and 12 months.

Table 4.4: The number of not applicable responses at baseline, 6 and 12 months.

Number of not applicable responses	Baseline n (%)	6 months n (%)	12 months n (%)
0	905 (79.9)[1]	583 (76.5)[3]	420 (78.2)[3]
1	66 (5.8)	51 (6.7)	29 (5.4)
2	32 (2.8)	23 (3.0)	10 (1.9)
3	35 (3.1)	37 (4.9)	18 (3.4)
4	20 (1.8)	19 (2.5)	12 (2.2)
5	31 (2.7)	22 (2.9)	15 (2.8)
6	30 (2.6)	20 (2.6)	29 (5.4)
Total	**1119 (98.8)[2]**	**755 (99.1)[4]**	**533 (99.3)[5]**

[1] Includes 7 participants who had missing data for one or more psychosexual item.
[2] 14 (1.2%) participants had missing data for all six psychosexual items.
[3] Includes 2 participants who had missing data for one or more psychosexual item.
[4] 7 participants (0.9%) had missing data for all six psychosexual items.
[5] 4 participants (0.7%) had missing data for all six psychosexual items.

Appendix 4.8 shows the number of not applicable responses for each psychosexual item at baseline, 6 and 12 months. The percentage of not applicable responses ranged from 7.1 to 11.6% at baseline, 8.3 to 13.1% at the 6-month follow-up and 9.9 to 14.9% at the 12-month follow-up. At all three time points the percentage of not applicable responses was highest for the item 'Have you been worried about whether your test result would have a bad effect on your relationship with your partner' and the two items assessing concern about infectivity ('Have you been worried that you could give the problem to a sexual partner' and 'Have you been worried a sexual partner will think they can catch the problem from you').

Differences in responding not applicable to one or more psychosexual item by screening result group and demographic characteristics at baseline, 6 and 12 months are shown in Appendices 4.9 and 4.10.

At each time point, compared to women of White ethnicity, women from an ethnic minority group were significantly more likely to respond not applicable to one or more item (baseline: p=0.029, 6 months: p=0.049, 12 months: p=0.003). In addition, compared to women with a partner, women without a partner were also more likely to respond not applicable to one or more item at all three time points (baseline: p<0.001, 6 months: p<0.001, 12 months: p<0.001). Compared to women in the control group, women who were HPV positive with normal cytology were less likely to respond not applicable (p=0.045), as were women in the HPV persistent group (p=0.014). There were also differences by screening result group at the 12-month follow-up (p=0.049) with women in the HPV persistent group less likely to respond not applicable compared to the control group (p=0.011).

4.3.6: Analyses

4.3.6.1: Psychosexual distress across results groups[9]

Univariate linear regression models were used to explore the association between screening result group and psychosexual distress cross-sectionally at baseline, 6 and 12 months. Following univariate analyses, multiple linear regression models were used to adjust for confounding factors.

Conditional change linear regression models were used to examine changes in psychosexual distress by screening result group between baseline and 6 months and baseline and 12 months. Using this approach, the baseline psychosexual distress score is controlled for so the regression coefficients indicate how the screening result group is associated with changes in psychosexual distress over time (Twisk, 2013). It has been suggested that if there are differences between groups in baseline values, comparing values over time is flawed because the comparison is not made across ‘similar’ groups (Aickin, 2009). In addition, the statistical phenomenon of regression to the mean, when individuals who at baseline are found to have values higher than the mean are likely to have lower values (that are closer to the mean) when followed-up, can lead to inaccurate conclusions (Linden, 2013). Using

[9] For these analyses I received statistical support from Dr Giorgio Di Gessa

conditional change linear regression models reduces or sometimes removes baseline differences and the effect of regression to the mean (Aickin, 2009).

Only women who had responded to all six psychosexual items were included in these analyses: 79% (n=898) at baseline, 76% at 6 months (n=581) and 78% at 12 months (n=418). I excluded women who answered 'not applicable' to one or more questions (19% (n=214) at baseline, 22% (n=167) at 6 months and 21% (n=113) at 12 months). Due to the small proportion of missing data (less than 3% at all three timepoints), I did not use multiple imputation to impute the missing items of data as I felt it was unlikely that this would have a significant impact on the overall results.

In all models, I adjusted for baseline sociodemographic characteristics (age, ethnicity, education, relationship status and IMD quintile). I chose to adjust for these variables as previous research suggests that there may be socioeconomic variations in adverse emotional responses to testing HPV positive (Giorgi Rossi, Baldacchini, & Ronco, 2014; O'Connor et al., 2018). Collapsed variables were used for ethnicity (White, British or other vs. Ethnic minority group), education (Degree or higher, Qualification below degree, No formal qualifications, Still studying) and relationship status (Current partner vs. No partner). Weights were applied to adjust for the possibility that the approached sample may not have been representative of the screening population in the HPV testing pilot sites (details described elsewhere (McBride et al., 2020b). Wald tests were used to determine the overall association between each independent variable and the dependent variable. Adjusted and weighted Beta coefficients (the degree of change in psychosexual distress for each screening result group compared to the reference group (i.e. the control group), with 95% confidence intervals, p-values and robust standard errors were calculated. Analyses were carried out using Stata SE, Version 15 (StataCorp., 2017).

4.3.6.2: Demographic differences in psychosexual distress

Demographic differences in psychosexual distress at baseline, 6 and 12 months were assessed using Pearson correlation (for continuous variables) and ANOVA (for categorical variables). Only women who had responded to all six psychosexual items were included in these analyses. As the aim was to assess

psychosexual distress and the magnitude of this, I excluded women who answered ‘not applicable’ to one or more item. After using ANOVA to establish the main effects, post-hoc tests using the Bonferroni correction were used to explore which groups differed. The Bonferroni correction was chosen as it is reported to control the Type 1 error rate well and was recommended for use in ANOVA (Field, 2013). Analyses were carried out using IBM SPSS Statistics for Windows, Version 22 (IBM Corp., 2013).

4.3.6.3: Psychosexual distress by individual item

In addition to overall psychosexual distress, I also explored between-group differences on each individual psychosexual item at baseline, 6 and 12 months. All women who had responded to an item, regardless of whether they were excluded from the overall psychosexual distress analyses, were included in the individual item analyses. In the original PEAPS-Q development paper, Bennetts et al. (1995) classified a woman as ‘distressed’ if she responded ‘Quite a lot’ or ‘Very much’ to an item. I dichotomised responses in the same way coding women as ‘distressed’ (if they responded ‘Quite a lot’ or ‘Very much’ to an item) or ‘not distressed’ (if they responded ‘Not at all’, ‘A little’ or ‘A fair bit’ to an item). The percentage of women reporting psychosexual distress was calculated for each psychosexual item and is reported by screening result group. Analyses were carried out using IBM SPSS Statistics for Windows, Version 22 (IBM Corp., 2013).

See Figure 4.1 for an overview of recruitment and response and the numbers included in the analyses.

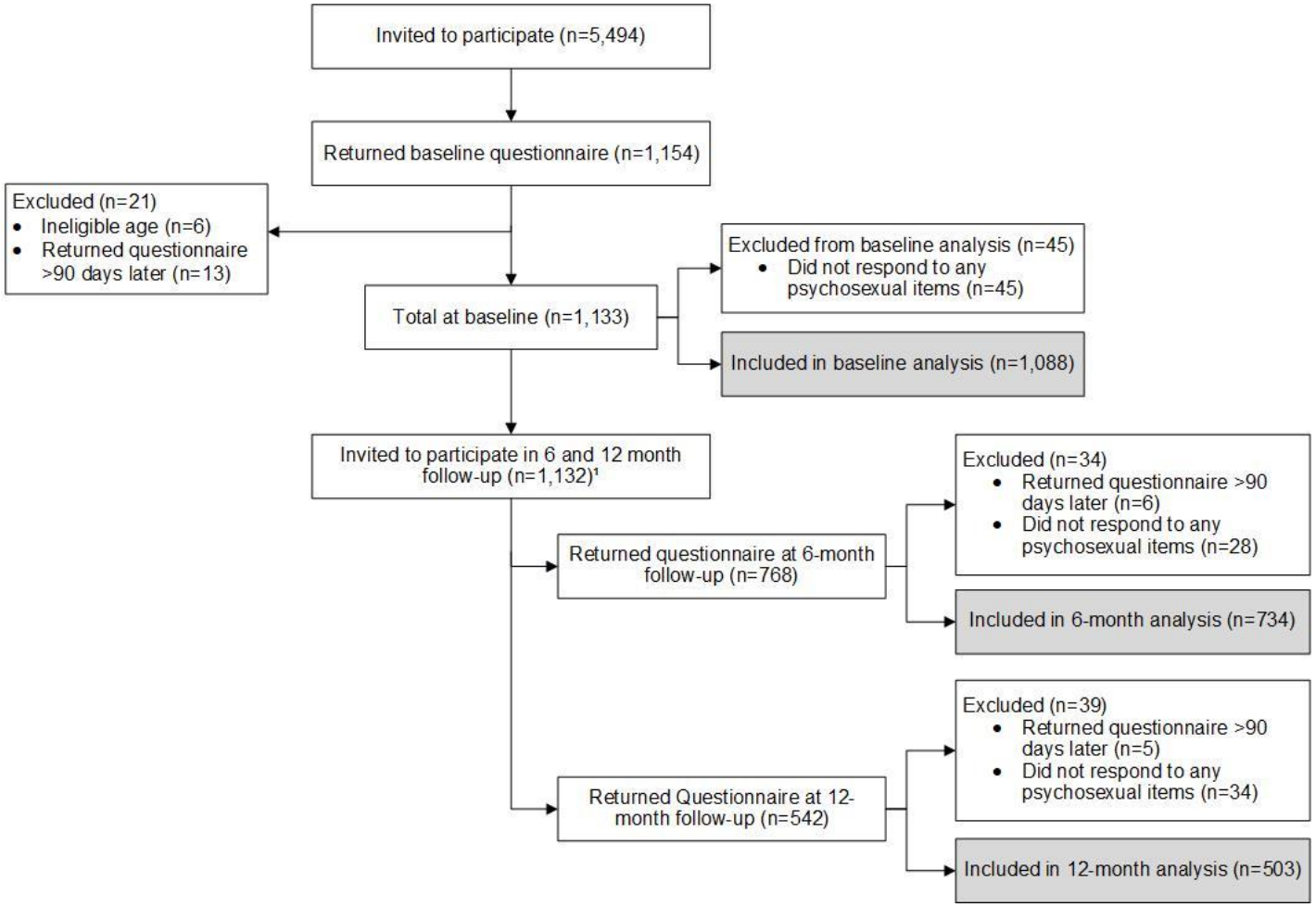

Figure 4.1: An overview of recruitment and response and numbers included in the analyses

[1]One participant did not provide consent to be followed-up so was not invited to participate in the 6 and 12-month follow-up

4.4: Results

4.4.1: Characteristics of the sample

Characteristics of women responding to at least one psychosexual item at baseline, 6 and 12 months are shown in Table 4.5. At baseline (n=1,088), women had a mean age of 41 years, were predominantly white (90.7%) and nearly half were educated to degree level or above (43.5%) and were married or in a civil partnership (39.6%).

Table 4.5: Demographic characteristics of the sample included in analyses at baseline (n=1088), 6-month follow-up (n=734) and 12-month follow-up (n=503)[1]

	Baseline n (%)	6 months n (%)	12 months n (%)
Screening result group			
HPV negative	233 (21.4)	176 (24.0)	115 (22.9)
HPV positive, normal cytology	251 (23.1)	169 (23.0)	105 (20.9)
HPV positive, abnormal cytology	167 (15.3)	106 (14.4)	70 (13.9)
HPV persistent	177 (16.3)	115 (15.7)	88 (17.5)
HPV cleared	63 (5.8)	41 (5.6)	34 (6.8)
Control (normal cytology)	197 (18.1)	127 (17.3)	91 (18.1)
Age (mean years/SD)	40.82 (SD=11.67)	42.76 (SD=11.68)	42.67 (SD=11.87)
Ethnicity			
White (British or other)	987 (90.7)	680 (92.6)	467 (92.8)
Mixed ethnicity	18 (1.7)	11 (1.5)	6 (1.2)
Asian	32 (2.9)	12 (1.6)	11 (2.2)
Black	20 (1.8)	12 (1.6)	8 (1.6)
Other	13 (1.2)	8 (1.1)	6 (1.2)
Prefer not to say	2 (0.2)	-	-
Education			
Degree or higher	473 (43.5)	331 (45.1)	232 (46.1)
Higher education (below degree level)	136 (12.5)	89 (12.1)	53 (10.5)
A Levels	125 (11.5)	82 (11.2)	59 (11.7)
ONC/BTEC	45 (4.1)	29 (4.0)	18 (3.6)
GCSE’s/O Levels	211 (19.4)	145 (19.8)	98 (19.5)
No formal qualifications	55 (5.1)	32 (4.4)	24 (4.8)
Still studying	20 (1.8)	14 (1.9)	12 (2.4)

Table 4.5: Demographic characteristics of the sample included in analyses at baseline (n=1088), 6-month follow-up (n=734) and 12-month follow-up (n=503) (continued)[1]

	Baseline n (%)	**6 months n (%)**	**12 months n (%)**
Marital Status			
Single	176 (16.2)	115 (15.7)	73 (14.5)
In a Relationship	200 (18.4)	125 (17.0)	85 (16.9)
Separated	10 (0.9)	8 (1.1)	5 (1.0)
Living with partner	214 (19.7)	131 (17.8)	97 (19.3)
Married/Civil Partnership	431 (39.6)	313 (42.6)	214 (42.5)
Widowed	8 (0.7)	6 (0.8)	9 (1.8)
Divorced	34 (3.1)	26 (3.5)	15 (3.0)
IMD Quintile			
1 (most deprived)	165 (15.2)	92 (12.5)	62 (12.3)
2	204 (18.8)	126 (17.2)	85 (16.9)
3	265 (24.4)	184 (25.1)	149 (29.6)
4	182 (16.7)	135 (18.4)	95 (18.9)
5 (least deprived)	192 (17.6)	139 (18.9)	83 (16.5)

[1] The samples included in these analyses differ from the total sample at each time point as only women responding to one or more of the psychosexual items are included

4.4.2: Psychosexual distress across results groups

Descriptive characteristics for psychosexual distress score at baseline, 6 and 12 months, overall and by group, are presented in Table 4.6. Medians and interquartile ranges (IQR) are reported as data were positively skewed. See Appendices 4.11 to 4.13 for histograms showing the distribution of scores overall and by result group at baseline, 6 and 12 months.

Adjusted and weighted Beta coefficients (with 95% confidence intervals) and robust standard errors for the relationship between psychosexual distress and result group cross-sectionally at baseline, 6 and 12 months are presented in Table 4.7 (see Appendix 4.14 for unadjusted analysis). Adjusted mean psychosexual distress scores for each group at baseline, 6 and 12 months are presented in Figure 4.2. Associations between psychosexual distress and screening result group were similar in unadjusted and adjusted analyses so only findings from the adjusted analyses are described.

At baseline there was a significant association between screening result and psychosexual distress ($p<0.001$). The multiple linear regression model predicted 28.1% of the variance in psychosexual distress ($F(15,795)=22.90$, $p<0.001$, $R^2=0.281$). Compared with the control group, psychosexual distress was higher among women in the HPV positive, normal cytology group (by 1.15 points), the HPV positive, abnormal cytology group (by 1.01 points), the HPV persistent group (by 0.91 points) and the HPV cleared group (by 0.62 points; all $p<0.001$). There was no significant difference between the control group and the HPV negative group ($p=0.974$).

At the 6 and 12-month follow-ups, the association between result group and psychosexual distress remained significant ($p<0.001$). The multiple linear regression models predicted 22.2% and 22.1% of the variance in psychosexual distress at the 6 and 12-month follow-ups respectively (at 6 months: $F(15,504)=9.89$, $p<0.001$, $R^2=0.222$; at 12 months: $F(15,367)=7.35$, $p<0.001$, $R^2=0.221$). The pattern of results was similar to that seen at baseline although coefficients were smaller. Psychosexual distress remained highest and significantly different from the control group ($p<0.001$) in all three HPV positive groups. Compared to the control group, psychosexual distress was higher among women in the HPV positive, normal cytology group (by 0.68 points at 6

months and 0.81 points at 12 months), the HPV positive, abnormal cytology group (by 0.64 points at 6 months and 0.50 points at 12 months) and the HPV persistent group (by 0.68 points at 6 months and 0.69 points at 12 months). For the HPV cleared group, psychosexual distress was not significantly higher than the control group at 6 months (p=0.076) but was at 12 months (by 0.37 points, p=0.024). There was no significant difference between the control group and the HPV negative group at 6 months (p=0.767) or 12 months (p=0.931).

Adjusted and weighted Beta coefficients (with 95% confidence intervals) and standard errors for the association between change in psychosexual distress and screening result group at 6 and 12 months are presented in Table 4.8. There were significant reductions in psychosexual distress among women in the HPV positive, normal cytology group (by 0.45 points at 6 months and 0.54 points at 12 months), the HPV positive, abnormal cytology group (by 0.44 points at 6 months and 0.33 points at 12 months) and the HPV persistent group (by 0.47 points at 6 months and 0.46 points at 12 months). There were no significant changes in psychosexual distress among women in HPV cleared group at 6 months (p=0.405) or 12 months (p=0.227) or the HPV negative group at 6 months (p=0.767) or 12 months (p=0.931).

Table 4.6: Descriptive characteristics for psychosexual distress score at baseline, 6 and 12 months, overall and by group (unweighted and unadjusted)

	Baseline			6 months			12 months		
	Range	**Median**	**IQR**	**Range**	**Median**	**IQR**	**Range**	**Median**	**IQR**
Control (normal cytology)	1-3	1.00	1.00-1.00	1-3	1.00	1.00-1.00	1-3	1.00	1.00-1.08
HPV negative	1-3	1.00	1.00-1.00	1-4	1.00	1.00-1.00	1-2	1.00	1.00-1.00
HPV positive, normal cytology	1-5	1.83	1.33-2.83	1-5	1.50	1.00-2.00	1-5	1.42	1.00-2.50
HPV positive, abnormal cytology	1-5	1.83	1.33-2.83	1-5	1.42	1.00-2.17	1-4	1.33	1.00-1.92
HPV persistent	1-5	1.67	1.17-2.63	1-5	1.33	1.00-2.08	1-5	1.33	1.00-2.04
HPV cleared	1-5	1.17	1.00-1.67	1-4	1.00	1.00-1.50	1-5	1.00	1.00-1.67
Overall	**1-5**	**1.17**	**1.00-2.00**	**1-5**	**1.00**	**1.00-1.67**	**1-5**	**1.00**	**1.00-1.67**

Table 4.7: Cross-sectional associations between psychosexual distress and screening result group at baseline, 6 and 12 months (weighted[1] and adjusted[2])

	Baseline		6 months		12 months	
	B[3] (95% CI)	**SE[4]**	**B[3] (95% CI)**	**SE[4]**	**B[3] (95% CI)**	**SE[4]**
Screening result group						
Control group (normal cytology)	Reference		Reference		Reference	
HPV negative	0.001 (-0.090,0.087)	0.045	-0.016 (-0.125,0.092)	0.055	0.004 (-0.086,0.094)	0.046
HPV positive, normal cytology	1.148 (0.960,1.336)***	0.096	0.675 (0.493,0.857)***	0.093	0.810 (0.558,1.061)***	0.128
HPV positive, abnormal cytology	1.014 (0.771,1.256)***	0.124	0.639 (0.374,0.903)***	0.135	0.503 (0.217,0.788)**	0.145
HPV persistent	0.905 (0.705,1.105)***	0.102	0.676 (0.434,0.918)***	0.123	0.690 (0.471,0.909)***	0.111
HPV cleared	0.616 (0.330,0.901)***	0.145	0.239 (-0.026,0.504)	0.135	0.368 (0.049,0.686)*	0.162
Age	0.002 (-0.004,0.008)	0.003	0.004 (-0.002,0.010)	0.003	0.003 (-0.004,0.010)	0.004
Ethnicity						
White (British or other)	Reference		Reference		Reference	
Ethnic minority	-0.115 (-0.365,0.136)	0.128	0.038 (-0.264,0.340)	0.154	0.261 (-0.285,0.808)	0.278
Marital Status						
Current partner	Reference		Reference		Reference	
No partner	0.385 (0.152,0.618)**	0.119	0.318 (0.063,0.573)*	0.130	0.322 (0.061,0.584)*	0.133
Education						
Degree or higher	Reference		Reference		Reference	
Qualification below degree	0.041 (-0.097,0.180)	0.070	0.039 (-0.098,0.177)	0.070	0.028 (-0.141,0.196)	0.086
No formal qualifications	-0.126 (-0.430,0.179)	0.155	0.352 (-0.066,0.770)	0.213	0.032 (0.396,0.459)	0.218
Still studying	0.340 (-0.297,0.978)	0.325	0.084 (-0.367,0.536)	0.230	-0.348 (-0.638,-0.059)*	0.147

Table 4.7: Cross-sectional associations between psychosexual distress and screening result group at baseline, 6 and 12 months (weighted[1] and adjusted[2]) (continued)

	Baseline		6 months		12 months	
	B[3] (95% CI)	**SE[4]**	**B[3] (95% CI)**	**SE[4]**	**B[3] (95% CI)**	**SE[4]**
IMD Quintile						
1 (most deprived)	0.296 (0.054,0.538)*	0.123	0.198 (-0.048,0.444)	0.125	0.238 (-0.038,0.514)	0.140
2	0.092 (-0.110,0.294)	0.103	-0.046 (-0.255,0.164)	0.107	0.189 (-0.050,0.429)	0.122
3	-0.054 (-0.239,0.131)	0.094	0.047 (-0.135,0.229)	0.093	0.085 (-0.119,0.289)	0.104
4	-0.005 (-0.201,0.191)	0.100	0.040 (-0.133,0.212)	0.088	0.125 (-0.096,0.346)	0.113
5 (least deprived)	Reference		Reference		Reference	
Constant	0.866 (0.584,1.149)***	0.144	0.829 (0.530,1.128)***	0.152	0.766 (0.417,1.115)***	0.177
Model *F*	22.90***		9.89***		7.35***	
Number of observations	801		520		383	
R^2	0.281		0.222		0.221	

[1] Weighted by age group and IMD quintile.

[2] Adjusted for age, ethnicity, marital status, education and IMD.

[3] Unstandardised Beta coefficients (with 95% CIs) indicating the degree of change in psychosexual distress for each screening result group compared to the reference group (i.e. the control group).

[4] Robust standard errors.

*p<0.05 **p<0.01 ***p<0.001

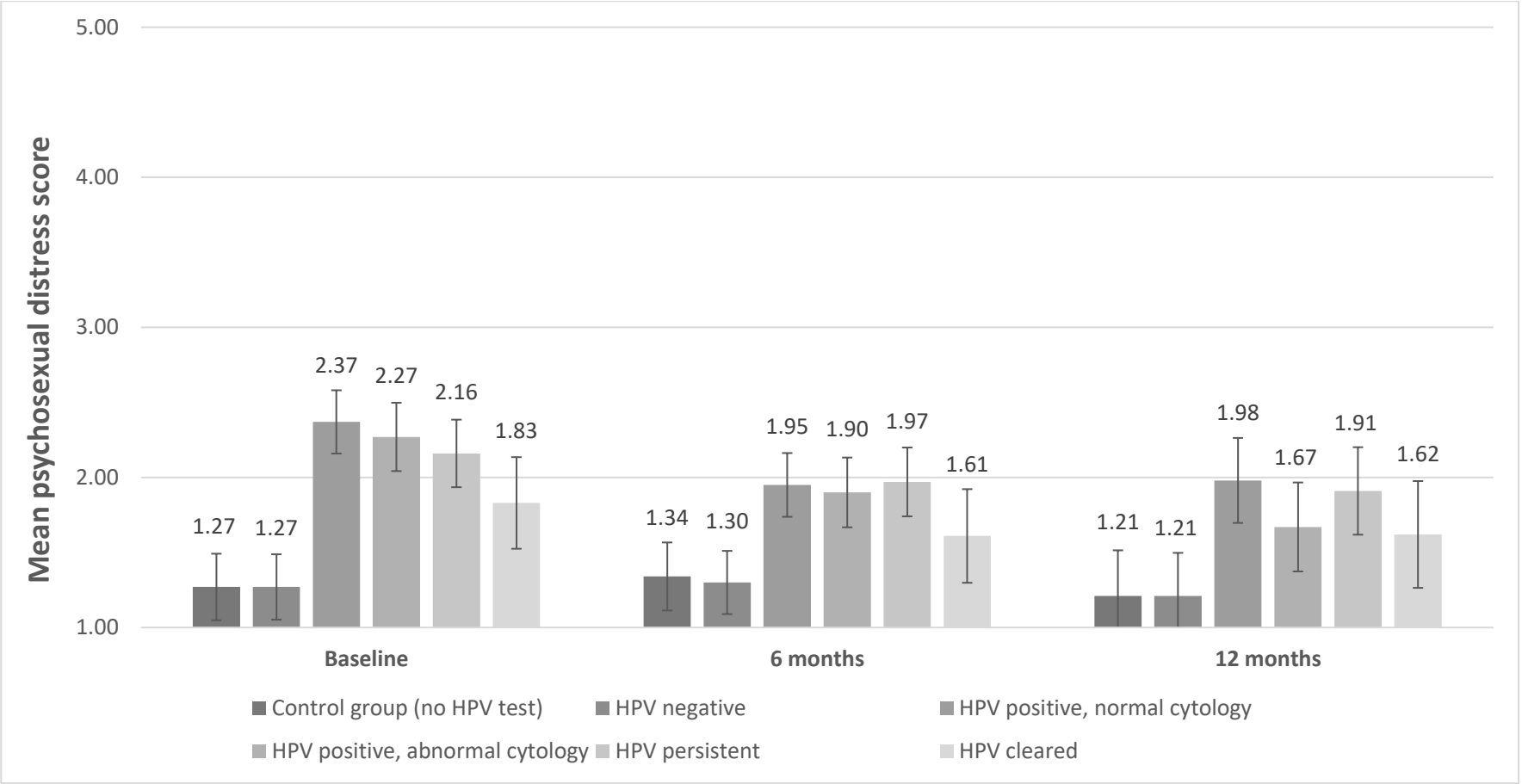

Figure 4.2: Adjusted[1] mean scores for psychosexual distress at baseline, 6 and 12 months by result group with 95% confidence intervals (unweighted)

[1]Adjusted for age, ethnicity, marital status, education and IMD.

Table 4.8: Change in psychosexual distress by 6 and 12 months (weighted[1] and adjusted[2])

	6 months		12 months	
	B[3] (95% CI)	**SE[4]**	**B[3] (95% CI)**	**SE[4]**
Screening result group				
Control group (normal cytology)	Reference		Reference	
HPV negative	0.022 (-0.118,0.161)	0.071	0.091 (-0.027, 0.209)	0.060
HPV positive, normal cytology	-0.450 (-0.636,-0.263)***	0.095	-0.543 (-0.776,-0.310)***	0.118
HPV positive, abnormal cytology	-0.438 (-0.700,-0.176)**	0.133	-0.325 (-0.607,-0.044)*	0.143
HPV persistent	-0.471 (-0.694,-0.250)***	0.113	-0.463 (-0.676,-0.250)***	0.108
HPV cleared	-0.108 (-0.364,0.147)	0.130	-0.174 (-0.457,0.109)	0.144
Age	-0.004 (-0.009,0.001)	0.003	-0.004 (-0.011,0.003)	0.004
Ethnicity				
White (British or other)	Reference		Reference	
Ethnic minority	-0.045 (0.349,0.260)	0.155	-0.225 (-0.730,0.281)	0.257
Marital Status				
Current partner	Reference		Reference	
No partner	-0.121 (-0.364,1.222)	0.124	-0.095 (-0.363,0.173)	0.136
Education				
Degree or higher	Reference		Reference	
Qualification below degree	-0.015 (-0.140,0.110)	0.064	0.007 (-0.149,0.162)	0.079
No formal qualifications	-0.274 (0.699,0.151)	0.216	0.114 (-0.374,0.602)	0.248
Still studying	0.036 (-0.455,0.528)	0.250	0.396 (0.137,0.656)**	0.132

Table 4.8: Change in psychosexual distress by 6 and 12 months (weighted[1] and adjusted[2]) (continued)

	6 months		12 months	
	B[3] (95% CI)	**SE[4]**	**B[3] (95% CI)**	**SE[4]**
IMD Quintile				
1 (most deprived)	-0.173 (-0.389,0.043)	0.110	-0.218 (-0.477,0.041)	0.132
2	0.065 (-0.122,0.251)	0.095	-0.154 (-0.383,0.075)	0.116
3	-0.109 (-0.272,0.053)	0.083	-0.124 (-0.314,0.066)	0.097
4	-0.021 (-0.182,0.139)	0.082	-0.059 (-0.278,0.160)	0.111
5 (least deprived)	Reference		Reference	
Baseline psychosexual distress	0.729 (0.645,0.814)***	0.043	0.778 (0.676,0.880)***	0.052
Constant	-0.465 (-0.782,-0.147)**	0.161	-0.538 (-0.892,-0.184)**	0.180
Model *F*	21.34***		20.66***	
Number of observations	517		382	
R^2	0.626		0.647	

[1] Weighted by age group and IMD quintile.

[2] Adjusted for age, ethnicity, marital status, education, IMD and baseline psychosexual distress.

[3] Beta coefficients (with 95% CIs) indicating the degree of change in psychosexual distress for each screening result group compared to the reference group (i.e. the control group).

[4] Robust standard errors.

*p<0.05 **p<0.01 ***p<0.001

4.4.2.1: Assumptions of linear regression

There are several assumptions that should be considered when running linear regression models (Field, 2018). I have outlined each of these below and how they relate to my analysis decisions.

1. Independence of observations

Data should have independence of observations. This means that the errors of adjacent observations are not related or correlated. The rationale for testing for independence of observations is related to the design of the study. For study designs where it is unlikely that observations will be related, it is not necessary to test for independence of observations. In this study, there was no reason why observations would be related, therefore, testing for independence of observations was not necessary.

2. Normally distributed residuals

The residuals (errors) of the model should be approximately normally distributed. This assumption was assessed visually using Kernel density, probability-probability (P-P) and quantile-quantile (Q-Q) plots (see Appendices 4.15 to 4.17 for plots). At baseline, 6 and 12 months all plots suggested that the residuals of the model were not normally distributed.

One potential way to address issues with normality is to transform the data (Field, 2018). Log and square-root transformations were appropriate for these data as they can correct for positive skew. I applied a log transformation to the dependent variable, but this did not correct the issue with normality at baseline, 6 or 12 months (see Appendices 4.18 to 4.20 for log transformed plots). I then applied a square-root transformation to the dependent variable. This also did not correct the issue with normality at any time point (see Appendices 4.21 to 4.23 for square-root transformed plots).

Although the residuals of the model were not normally distributed, Lumley et al. (2002) suggest that that it is rarely necessary to be concerned about non-normality. This is because of the Central Limit Theorem which states that '…when samples are large the sampling distribution will take the shape of a

normal distribution regardless of the shape of the population from which the sample was drawn' (Field, 2018). Although the definition of a large sample is said to depend on the population distribution, Field (2018) suggests an accepted value is a sample size of 30. Lumley et al. (2002) performed simulations using extremely non-normal public health data to determine the sample size needed for the Central Limit Theorem to provide reliable results and found that a sample size of around 500 is 'sufficiently large'. They concluded that in public health research where sample sizes are often large, the linear model is appropriate for analysing differences and trends in data, regardless of whether the data are normally distributed. Consequently, although the residuals of the model were not normally distributed, because the sample size far exceeded the accepted size of 30 at each time point, I felt it was likely that the Central Limit Theorem would apply and decided to proceed.

3. Multicollinearity

Data should not show multicollinearity. Multicollinearity occurs when there are two or more independent variables that are highly correlated with each other. There was no evidence of multicollinearity at baseline, 6 or 12 months, as assessed by variation inflation factor values less than 10 and tolerance values greater than 0.1.

4. Linearity

An assumption of linear regression with several independent variables (confounding variables are considered independent variables) is that the independent variables are collectively linearly related to the dependent variable and each continuous independent variable is linearly related to the dependent variable.

5. Homoscedasticity of residuals

Data should show homoscedasticity of residuals. When testing groups of cases (i.e. when you have a categorical independent variable), the assumption of homoscedasticity is that groups come from populations with the same variance. In correlational designs when you have a continuous independent variable, the

variance should be approximately equal at different points of the independent variable (Field, 2018).

Linearity and homoscedasticity were assessed visually using a plot of studentised residuals against (unstandardised) predicted values. At baseline, 6 and 12 months, graphs suggested a non-linear relationship and heteroscedasticity, violating the assumptions of linearity and homoscedasticity (see Appendix 4.24 for plots of studentised residuals against the predicted values at each time point). Transforming the dependent variable using a log transformation and square-root transformation did not correct the issues with linearity and heteroscedasticity (See Appendix 4.25 for log transformed plots and Appendix 4.26 for square-root transformed plots).

When heteroscedasticity is present, standard errors are biased and consequently test statistics and confidence intervals are biased (Williams, 2020). To address the issue of heteroscedasticity, I used Eiker-White-Huber standard errors to compute test statistics and confidence intervals which are robust to heteroscedasticity (Field & Wilcox, 2017).

4.4.2.2: Sensitivity analyses

As the data violated several assumptions of linear regression, sensitivity analyses were carried out. Logistic regression models were used to assess the robustness of the results of the linear regression models and to see whether they produced similar results. Mean psychosexual distress score was recoded into a binary variable. Those who had a mean psychosexual distress score of two or less (those responding ‘Not at all’ or ‘A little’ to the six psychosexual items) were coded as ‘Little/no psychosexual distress’ and those who had a mean psychosexual distress score of more than two were coded as ‘Some psychosexual distress’. Only women who had responded to all six psychosexual items were included in the sensitivity analyses: 79% (n=898) at baseline, 76% at 6 months (n=581) and 78% at 12 months (n=418).

Similar to linear regression, there are also assumptions that should be considered when running logistic regression models (Field, 2018):

1. Data should have independence of observations (no relationship between the observations in each category of the dependent variable or in each category of any independent variables)
2. Data should not show multicollinearity
3. There should be a linear relationship between the continuous independent variables and the logit transformation of the dependent variable.

As reported above, at all three time points data showed no evidence of multicollinearity. In addition, data had independence of observations. The only continuous independence in the model was age. Linearity between age and the logit transformation of the dependent variable was assessed using the Box-Tidwell procedure. Based on this procedure, age was found to be linearly related to the logit of the dependent variable at all three time points (at baseline: p=0.343; at 6 months: p=0.616; at 12 months: p=0.221). Therefore, all the assumptions of logistic regression were met.

Odds ratios with 95% confidence intervals for the relationship between psychosexual distress and screening result group at baseline, 6 and 12 months are shown in Appendix 4.27. At each time point, the logistic regression models were statistically significant (at baseline: $x^2(15)=114.80$, $p<0.001$; at 6 months: $x^2(15)=83.64$, $p<0.001$; at 12 months: $x^2(14)=55.08$, $p<0.001$). At each time point the pattern of results were similar to that found in the cross-sectional linear regression models.

As the findings from the logistic regression models were consistent with the findings from the linear regression models, I concluded that, although the data violated several assumptions of linear regression, the results from the linear regression models were robust (Thabane et al., 2013).

4.4.3: Demographic differences in psychosexual distress

Demographic differences in mean psychosexual distress score at baseline, 6 and 12 months are shown in Table 4.9.

At baseline, a Pearson correlation revealed a small negative correlation between age and psychosexual distress which was statistically significant (r=-0.115, n=894, p=0.001). There were also significant differences in psychosexual

distress by marital status (F(6,879)=15.78, p<0.001). Psychosexual distress was highest among women who were single ($\bar{X}$=2.25, SE=0.13) and lowest among women who were married or in a civil partnership ($\bar{X}$=1.40, SE=0.04). Post-hoc tests revealed that compared to women who were married or in a civil partnership, psychosexual distress was significantly higher among women who were single (p<0.001), in a relationship (<0.001), living with a partner (p=0.031) or divorced (p=0.006). In addition, there were significant differences by IMD (F(4,823)=5.65, p<0.001). Psychosexual distress was highest among those in the most deprived quintile ($\bar{X}$=2.03, SE=1.05) and lowest among those in the least deprived quintile ($\bar{X}$=1.56, SE=0.78). Post-hoc tests revealed that this difference was statistically significant (p=0.001).

At the 6-month follow-up, the association between psychosexual distress and marital status remained significant (F(6,568)=10.85, p<0.001), as did the association between psychosexual distress and IMD (F(4,530)=3.62, p=0.006). Psychosexual distress was highest among women who were divorced ($\bar{X}$=2.09, SE=0.34) and lowest among women who were married or in a civil partnership ($\bar{X}$=1.27, SE=0.04). Post-hoc tests revealed that the difference between these groups was statistically significant (p=0.005). In addition, there were significant differences between women who were married or in a civil partnership and women who were single (p<0.001) and in a relationship (p<0.001). There were also differences between women who were single and women who were living with a partner (p=0.001) and women who were in a relationship and women who were living with a partner (p=0.007). With regards to IMD, as at baseline, psychosexual distress was highest among those in the most deprived quintile ($\bar{X}$=1.79, SE=0.12) and lowest among those in the least deprived quintile ($\bar{X}$=1.38, SE=0.07), with post-hoc tests revealing significant differences between these groups (p=0.005). There were also significant differences between IMD quintile 1 and 2 (p=0.04) and IMD quintile 1 and 3 (p=0.02).

At the 12-month follow-up, the association between psychosexual distress and marital status remained significant (F(6,408)=5.48, p<0.001). Psychosexual distress was highest among women who were divorced ($\bar{X}$=2.00, SE=0.43) and lowest among women who were widowed ($\bar{X}$=1.06, SE=0.06) and married or in a civil partnership ($\bar{X}$=1.29, SE=0.05). Post-hoc tests revealed significant differences between women who were married or in a civil partnership and

women who were single ($p<0.001$) and women who were in a relationship ($p=0.01$) and between women who were single and women who were living with a partner ($p=0.03$).

Table 4.9: Demographic differences in psychosexual distress at baseline, 6 and 12 months

	Baseline Mean (SE)	p	6 months Mean (SE)	p	12 months Mean (SE)	p
Age (Pearson correlation)	-0.115	0.001	-0.053	0.206	0.032	0.51
Ethnicity		0.929		0.997		0.07
White (British or other)	1.73 (0.037)		1.50 (0.04)		1.47 (0.04)	
Mixed ethnicity	1.63 (0.228)		1.56 (0.41)		1.08 (0.08)	
Asian	1.72 (0.202)		1.52 (0.30)		2.20 (0.74)	
Black	1.74 (0.287)		1.45 (0.28)		2.23 (0.66)	
Other	1.40 (0.159)		1.58 (0.23)		1.50 (0.24)	
Prefer not to say	1.33 (0.333)		-			
Education		0.093		0.148		0.57
Degree or higher	1.68 (0.050)		1.45 (0.05)		1.49 (0.06)	
Higher education (below degree level)	1.87 (0.107)		1.60 (0.11)		1.59 (0.16)	
A Levels	1.54 (0.091)		1.44 (0.10)		1.57 (0.13)	
ONC/BTEC	1.95 (0.190)		1.65 (0.18)		1.51 (0.15)	
GCSE’s/O Levels	1.73 (0.083)		1.41 (0.06)		1.38 (0.08)	
No formal qualifications	1.68 (0.145)		1.85 (0.21)		1.58 (0.23)	
Still studying	2.09 (0.267)		1.44 (0.26)		1.08 (0.07)	
Marital Status		<0.001		<0.001		<0.001
Single	2.25 (0.130)		1.89 (0.14)		1.93 (0.15)	
In a Relationship	2.04 (0.083)		1.77 (0.09)		1.66 (0.10)	
Separated	2.10 (0.440)		1.88 (0.49)		1.50 (0.29)	
Living with partner	1.68 (0.068)		1.39 (0.06)		1.44 (0.09)	
Married/Civil Partnership	1.40 (0.040)		1.27 (0.04)		1.29 (0.05)	
Widowed	1.56 (0.556)		1.87 (0.55)		1.06 (0.06)	
Divorced	2.23 (0.315)		2.09 (0.34)		2.00 (0.43)	

Table 4.9: Demographic differences in psychosexual distress at baseline, 6 and 12 months (continued)

	Baseline Mean (SE)	p	6 months Mean (SE)	p	12 months Mean (SE)	p
IMD Quintile		<0.001		0.006		0.38
1 (most deprived)	2.03 (0.105)		1.79 (0.12)		1.65 (0.13)	
2	1.71 (0.080)		1.44 (0.08)		1.51 (0.11)	
3	1.57 (0.060)		1.44 (0.06)		1.43 (0.08)	
4	1.80 (0.084)		1.50 (0.08)		1.57 (0.10)	
5 (least deprived)	1.56 (0.078)		1.38 (0.07)		1.38 (0.07)	

4.4.4: Psychosexual distress by individual item

The percentage of participants who were categorised as ‘distressed’ at baseline, 6 and 12 months for each item overall, and by screening result group, are presented in Tables 4.10, 4.11 and 4.12 respectively.

At baseline, the percentage who were distressed was lowest among the control group (range: 0 to 2.9%) and the HPV negative group (range: 0 to 1.4%), and highest among the three HPV positive groups (HPV positive, normal cytology range: 16.5 to 31%; HPV positive, abnormal cytology range: 15.2 to 26.3%; HPV persistent range: 11.8 to 27.8%). At the 6 and 12-month follow-ups the pattern of results were similar. The percentage distressed continued to be lowest among the control group (6-month range: 0 to 2.7%; 12-month range: 0 to 1.1%) and the HPV negative group (6-month range: 0 to 0.7%; 12-month range: 0 to 0.9%). At the 6-month follow-up the percentage who were distressed was highest among the three HPV positive groups (HPV positive with normal cytology range: 4.9 to 16.5%; HPV positive with abnormal cytology range: 7.1 to 20.8%; HPV persistent range: 10.5 to 18.5%). At the 12-month follow-up the percentage who were distressed was highest among the HPV positive with normal cytology (range: 8.2 to 23%) and HPV persistent groups (range: 6 to 16.7%).

At all three time points, distress was most prevalent for the two items assessing concern about infectivity (‘Have you been worried that you could give the problem to a sexual partner’ and ‘Have you been worried a sexual partner will think they can catch the problem from you’).

Table 4.10: Percentage 'distressed'[1] for individual psychosexual questions by screening result group at baseline

	% (n) 'distressed'						
	Whole sample	**Control group**	**HPV negative**	**HPV positive, normal cytology**	**HPV positive, abnormal cytology**	**HPV persistent**	**HPV cleared**
Have you been worried…	n=1088	n=251	n=167	n=177	n=197	n=233	n=63
…whether you should continue having sex?	9.5 (98)	0 (0)	0.4 (1)	18.8 (44)	18.8 (29)	12.0 (20)	6.6 (4)
…others think you have had more sexual partners than you should?	10.2 (105)	0 (0)	1.4 (3)	17.9 (42)	16.1 (26)	15.9 (28)	9.7 (6)
…about whether your test result would have a bad effect on your relationship with your partner?	11.0 (108)	1.1 (2)	0.5 (1)	20.5 (45)	16.2 (23)	18.6 (30)	12.3 (7)
…whether having sex will make the problem worse?	9.2 (92)	1.1 (2)	1.0 (2)	16.5 (38)	15.2 (24)	11.8 (20)	9.8 (6)
… that you could give the problem to a sexual partner?	17.0 (169)	2.3 (4)	0.5 (1)	28.3 (66)	26.3 (41)	27.8 (47)	16.4 (10)
…a sexual partner will think they can catch the problem from you?	16.7 (164)	2.9 (5)	0 (0)	31.0 (72)	24.3 (37)	24.6 (41)	15.0 (9)

[1] Percentage of women who responded 'Quite a lot' or 'Very much' on the Likert scale.

Table 4.11: Percentage 'distressed'[1] for individual psychosexual questions by screening result group at the 6-month follow-up

	% (n) 'distressed'						
	Whole sample	**Control group**	**HPV negative**	**HPV positive, normal cytology**	**HPV positive, abnormal cytology**	**HPV persistent**	**HPV cleared**
Have you been worried…	n=734	n=127	n=176	n=169	n=106	n=115	n=41
…whether you should continue having sex?	4.5 (33)	2.4 (3)	0.6 (1)	5.1 (8)	7.1 (7)	10.5 (11)	7.5 (3)
…others think you have had more sexual partners than you should?	5.4 (40)	0 (0)	0 (0)	4.9 (8)	17.8 (18)	12.1 (13)	2.6 (1)
…about whether your test result would have a bad effect on your relationship with your partner?	5.6 (41)	1.7 (2)	0.6 (1)	9.4 (14)	9.0 (8)	13.3 (14)	5.6 (2)
…whether having sex will make the problem worse?	6.1 (45)	2.7 (3)	0.7 (1)	7.0 (11)	13.0 (13)	11.7 (13)	10.5 (4)
… that you could give the problem to a sexual partner?	9.7 (71)	0.9 (1)	0.7 (1)	16.5 (26)	20.8 (20)	18.3 (20)	7.7 (3)
…a sexual partner will think they can catch the problem from you?	8.6 (63)	0 (0)	0.7 (1)	15.3 (24)	16.7 (16)	18.5 (20)	5.1 (2)

[1] Percentage of women who responded 'Quite a lot' or 'Very much' on the Likert scale.

Table 4.12: Percentage 'distressed'[1] for individual psychosexual questions by screening result group at the 12-month follow-up

	% (n) 'distressed'						
	Whole sample	**Control group**	**HPV negative**	**HPV positive, normal cytology**	**HPV positive, abnormal cytology**	**HPV persistent**	**HPV cleared**
Have you been worried…	n=503	n=91	n=115	n=105	n=70	n=88	n=34
…whether you should continue having sex?	5.8 (29)	1.1 (1)	0.9 (1)	12.2 (12)	7.7 (5)	8.5 (7)	9.1 (3)
…others think you have had more sexual partners than you should?	6.8 (34)	0 (0)	0.9 (1)	10.7 (11)	11.8 (8)	11.8 (10)	11.8 (4)
…about whether your test result would have a bad effect on your relationship with your partner?	5.0 (25)	0 (0)	0 (0)	14.0 (13)	5.2 (3)	7.2 (6)	9.7 (3)
…whether having sex will make the problem worse?	4.4 (22)	0 (0)	0 (0)	8.2 (8)	7.7 (5)	6.0 (5)	12.5 (4)
… that you could give the problem to a sexual partner?	9.1 (46)	0 (0)	0 (0)	23.0 (23)	7.7 (5)	16.3 (14)	12.5 (4)
…a sexual partner will think they can catch the problem from you?	8.9 (45)	0 (0)	0 (0)	20.6 (20)	10.8 (7)	16.7 (14)	12.5 (4)

[1] Percentage of women who responded 'Quite a lot' or 'Very much' on the Likert scale

4.5: Discussion

4.5.1: Main Findings

Women testing HPV positive at cervical screening reported higher psychosexual distress than those receiving a normal cytology result who were not tested for HPV. The differences were observed immediately after screening and were attenuated but remained significant 6 and 12 months later. HPV negative women who had tested positive 12 months previously ('HPV cleared') also had higher psychosexual distress immediately after their HPV negative result and 12 months later. The findings suggest that psychosexual distress declines over time among HPV positive women. This appears to happen in the first 6 months following an HPV positive result.

4.5.2: Interpretation

This study was conducted in the context of the English HPV primary screening pilot. My findings are similar to those by Hsu et al. (2018). Although Hsu et al. (2018) only included HPV positive women and the study was not carried out in the context of HPV primary screening, they found that the impact on sexual relationships declined between 1 and 6 months and remained similar at 6 and 12 months. My findings are also consistent with Maissi et al. (2005) who found that 6 months after receiving screening results, psychosexual outcomes were virtually the same for women testing HPV negative and those not tested for HPV, but significantly higher for women who were HPV positive. Psychosexual distress scores for HPV positive women in my study were slightly lower than in Maissi et al. (2005), however increased awareness and knowledge of HPV since 2005 may have helped to reduce the negative psychosexual consequences of testing HPV positive.

The percentage of women classified as distressed for each individual item at baseline ranged from 9 to 17%. Distress was more prevalent than reported by Bennetts et al. (1995) who classified 3 to 11% of women as distressed during follow-up investigation after an abnormal Pap smear result. When Bennetts et al. (1995) carried out their study it is likely that awareness of HPV was very low, so it is probable that women would not have been aware that their abnormal

Pap smear result was caused by HPV. The diagnosis of a sexually transmitted infection can be associated with feelings of stigma and shame so it is possible that having HPV, an STI, may have a greater impact on psychosexual functioning than receiving an abnormal cytology result (Bickford et al., 2007; Jeynes et al., 2009; Nack, 2000). This is supported by qualitative research which suggested some women chose not to disclose their HPV infection to their partner and instead focused on their abnormal cytology result which did not carry the same negative connotations (McCaffery et al., 2006).

The most commonly endorsed items at all three time points were those assessing infectivity, with around 25% of women who were HPV positive indicating infectivity concerns at baseline. This finding is consistent with the qualitative findings from my systematic review exploring the psychosexual impact of testing HPV positive which found that a common theme was concern about transmitting HPV to a partner (Study 1a, described in Chapter 2). Transmission and the impact of HPV on a sexual partner have been identified as key topics that women want more information on, and uncertainty about these aspects of HPV can influence women's psychological response to HPV (McCaffery & Irwig, 2005).

At baseline, psychosexual distress was highest among women in the HPV positive with normal cytology group. Testing HPV positive with normal cytology is a new result created by the HPV primary screening pathway and since knowledge of HPV can be low it is possible that women unfamiliar with this new result lack understanding about what it means for their sexual relationships (Dodd et al., 2014). This is supported by a content analysis of free-text responses that were collected as part of the PIPS study which found that women testing HPV positive with normal cytology in particular, had questions about the implications of their result for sexual relationships (Marlow et al., 2020). With no abnormal cytology result, there may be a greater focus on HPV which, as an STI, may have greater potential for psychosexual impact. Psychosexual distress may also be exacerbated by the prospect of having to wait a year to see whether the infection has cleared. Reassuringly, psychosexual distress declined between baseline and 6 months among women in the HPV positive with normal cytology group.

At 12 months, psychosexual distress was still highest among women in the HPV positive with normal cytology group. However, there were smaller reductions in psychosexual distress between baseline and 12 months in the HPV positive with abnormal cytology group than the HPV positive with normal cytology group. Women in the HPV positive with normal cytology group were due their 12-month follow-up screening around this time, and some women had been screened and received their result by the time they completed the 12-month follow-up questionnaire, which may have affected their responses. It is also possible that women in the HPV positive with normal cytology group who returned the 12-month questionnaire were the most concerned (due to responder bias) which is why cross-sectionally, psychosexual distress was highest in this group.

Compared to women not tested for HPV, the HPV cleared group had significantly higher psychosexual distress at baseline and this remained significantly higher 12 months later. While the mean psychosexual distress score was not as high in the HPV cleared group as the three HPV positive groups, this suggests that some women who had previously tested HPV positive may still have residual psychosexual concerns, despite an HPV negative result. A qualitative study exploring women's experiences of repeat HPV testing found that some had concerns about the infection recurring and worried that it was lying dormant and might reappear in the future (Waller et al., 2007b). Future research should explore psychosexual concerns specific to this group.

At each time point around 20% of women responded 'not applicable' to one or more psychosexual distress item. Responding 'not applicable' was strongly associated with relationship status. Women who did not currently have a partner were significantly more likely to respond 'not applicable' to one or more item than women who did have a partner at all three time points. It is possible that women who did not have a partner may have responded not applicable as they felt some of the items were not relevant to them. Despite this, at baseline psychosexual distress was highest among women who were single and at the 6 and 12-month follow-ups psychosexual distress continued to be significantly higher than among women who were married or in a civil partnership. Future quantitative assessments of psychosexual distress should ensure that

questions are worded in a way that are relevant for all women regardless of their relationship status. Psychosexual concerns among women who do not currently have a partner may differ from concerns among women who do have a current partner and future research should explore this.

It is possible that women may have additional psychosexual concerns not captured by the items used in this study. The items used to assess psychosexual functioning were selected before I began my PhD. The findings from my systematic review suggest that assessing the prevalence of concerns raised in the qualitative literature such as where an HPV infection came from and disclosing HPV to a sexual partner may be important. Future research should use qualitative methodology to explore the full range of psychosexual questions and concerns among women taking part in HPV-based cervical screening.

4.5.3: Implications

The findings suggest that receiving an HPV positive result can lead to elevated psychosexual distress, particularly in the short-term. It should be noted that the differences between the three HPV positive groups and the control group were small at baseline (a difference of ~1 point on a 5-point scale) and smaller still at follow-up (<1 point difference). For most women, it is unlikely that testing HPV positive would have a meaningful impact on psychosexual functioning. There is not an established 'normal' range for the PEAPS-Q so it is difficult to determine if these differences are clinically significant. While I am unable to determine the number of women who are likely to present with psychosexual concerns requiring clinical services (e.g. psychosexual counselling), the study suggests that there are women who have concerns, therefore efforts to address these at a population level are important. As the individual psychosexual items suggest concerns about infectivity are relatively common, simple interventions such as including information about this in screening materials and results letters for women who test HPV positive should be considered.

4.5.4: Strengths and Limitations

This is the first longitudinal study to explore psychosexual distress following routine HPV primary screening among women with different HPV and cytology results. It is also the first study to include a group of women who previously tested HPV positive and were found to have cleared the infection 12 months later. The main limitation of the study was the low response rate at baseline. This varied by screening result group and ranged from 16% in the control group (who were not tested for HPV) to 27.8% among those with a persistent HPV infection. In addition, a third of women who participated at baseline did not complete the 6-month follow-up, and a further 20% did not complete the 12-month follow-up. At all three timepoints, the number of participants in some of the result groups was small, therefore the study may not have been adequately powered to detect differences between groups. There is no psychosexual functioning data for the women who did not respond, so I cannot rule out the possibility that response to the survey was systematically associated with psychosexual distress. However, I was able to weight the data to the screening population in the HPV primary screening pilot sites for age group and IMD quintile, helping to improve representativeness with respect to demographic characteristics. At the time this study was conducted the HPV information women received, both prior to screening and with their results, was minimal. Since the completion of the roll-out of HPV primary screening across England in December 2019 more information has been provided. Therefore, the findings from this study may not reflect the psychosexual response now that the information that is provided has improved.

This study consisted predominantly of women of White ethnicity, which is reflective of the screening population in Great Britain (Moser, Patnick, & Beral, 2009). Previous research suggests that the stigma of testing HPV positive may be greater among some ethnic minority groups (McCaffery et al., 2003; McCaffery et al., 2006). Research specifically designed to explore psychosexual distress following HPV testing in ethnic minority groups is needed.

All individuals with a cervix should attend cervical screening. This includes transgender men and those of non-binary gender who have not had their cervix removed. Individuals who had taken part in the NHS Cervical Screening

Programme in one of the five HPV primary screening pilot sites in England were invited to take part in the study, regardless of gender identity. However, in the study questionnaire booklet, information on gender identity was not collected. Therefore, the number of participants with a cervix who do not identity as female in the study is unknown. The number of individuals with a cervix who do not identify as female in England is also unknown, however it is estimated that there are approximately 200,000 to 500,000 transgender individuals in the UK (Government Equalities Office, 2018). It is possible that the level of psychosexual distress differs between individuals with a cervix who do not identity as female and cisgender individuals. In addition, specific psychosexual concerns may also be different. To my knowledge, no research has compared psychological or psychosexual-related outcomes between individuals with a cervix who do not identify as female and cisgender individuals. However, research suggests that transgender populations have high levels of clinical depression and anxiety (44 and 33% respectively in one study) and have concerns about sex and their bodies (e.g. feeling worried that other people would find their bodies unattractive, feeling that few people would want to have sex with them and feeling ashamed about their body) (Bockting, Miner, Romine, Hamilton, & Coleman, 2013; McNeil, Bailey, Ellis, Morton, & Regan, 2012). Therefore, it is possible that psychosexual distress may be higher among individuals with a cervix who do not identify as female. Future research should not assume that all participants eligible for cervical screening identify as female and collect data on gender identity to allow psychosexual distress by gender identity to be explored.

4.5.5: Conclusion

This study suggests that testing HPV positive can result in elevated psychosexual distress, particularly in the short-term. It is reassuring that psychosexual distress decreased over time; however, even at the 12-month follow-up there were small differences between the control group (who were not tested for HPV) and women who were HPV positive or had cleared a previous HPV infection. It is possible that women may have additional psychosexual concerns not captured by the items used. Chapter 5 will use qualitative

methodology to explore the full range of psychosexual questions and concerns women taking part in HPV-based cervical screening have.

CHAPTER 5: THE PSYCHOSEXUAL IMPACT OF TESTING POSITIVE FOR HPV: A QUALITATIVE STUDY (STUDY 3).

5.1: Roles and contributions

I conceived and designed the study with Dr Laura Marlow, Dr Jo Waller and Dr Julia Bailey. I developed the topic guide with assistance from Dr Laura Marlow, Dr Jo Waller and Dr Julia Bailey. I obtained the ethical approvals required for the study. Dr Julia Bailey and I attended the REC review meeting. Participants were predominantly recruited through Saros, a market research participant recruitment agency. Saros assessed participants eligibility for the study and scheduled interviews. I collected the data. Interviews were transcribed by Devon Transcription. I analysed and interpreted the data with assistance from Dr Laura Marlow, Dr Jo Waller and Dr Julia Bailey.

5.2: Introduction

The findings from Study 2, described in Chapter 4, suggested that testing HPV positive can result in elevated psychosexual distress, particularly in the short-term. However, psychosexual distress was assessed using six items and it is possible that women may have additional psychosexual concerns that were not captured by the items used.

The findings from the qualitative synthesis I carried out as part of my systematic review suggest that psychosexual concerns cover a broad range of aspects relating to current and past relationships, both interpersonal and sexual (Study 1a, described in Chapter 2). The qualitative synthesis also suggested feelings about disclosing to a sexual partner may be important (Study 1b, described in Chapter 3), but these were not assessed in Study 2. Moreover, while Study 2 provided information on the prevalence of psychosexual distress, it did not allow an in-depth exploration of the reasons why women experienced, or did not experience, psychosexual distress.

Previous studies exploring both the psychosexual impact of testing positive for HPV and concerns about disclosing HPV to a sexual partner have

predominantly focused on outcomes among women who are in a relationship, however concerns may differ between women who are in a relationship and those who are not in a relationship. Previous quantitative research suggests that psychosexual distress may be greater among women who are not in a relationship. In Study 2, compared to women who were married or in a civil partnership, women who were single had significantly higher psychosexual distress scores shortly after they received their screening results and 6 and 12 months later. Hsu et al. (2018) explored factors associated with psychosexual adjustment 12 months after receiving an HPV positive result. Compared to women who did not have a sexual partner, women who had a sexual partner had better outcomes on the sexual relations subscale. In addition Daley et al. (2015) found that compared to women who were cohabitating or married, women who were single were more likely to report a greater number of negative emotional responses (e.g. anger, confusion, shock) and HPV-related stigma beliefs (one of which was the statement 'disclosing is risky'), although for the HPV-related stigma beliefs the difference was not statistically significant.

Exploring the views of women who are in a relationship and those who are not in a relationship may help to ensure that screening information materials and results letters meet the needs of a greater number of women. The aim of this study was to qualitatively explore the psychosexual impact and disclosure experiences of women who had tested HPV positive in the context of HPV-based cervical screening, and whether there were any differences by cytology result and between women who were in a relationship and women who were not in a relationship.

5.3: Methods

5.3.1: Ethical approval

Ethical approval for the study was obtained on 12/06/2019 from the UCL REC (6930/003) (see Appendix 5.1). An amendment to the study was approved by the UCL REC on 22/05/2020.

5.3.2: Patient and public involvement

I recruited four women who had attended cervical screening and self-reported having tested HPV positive as Patient and Public Involvement (PPI) representatives for the study. I advertised for PPI representatives on the People in Research website, which is part of NIHR INVOLVE (https://www.peopleinresearch.org/), and Twitter.

Three women reviewed study materials (i.e. topic guide, patient information sheet, consent form, etc.) to ensure that they were readable, understandable, and appropriate. One woman took part in a pilot interview. The study materials were revised based on feedback from the PPI representatives. Each PPI representative received a £50 Love2shop voucher as a thank you for their time.

5.3.3: Study design and participants

In-depth interviews were conducted with women of screening age in England (i.e. those aged 24 to 65 years) who self-reported having tested HPV positive (with normal or abnormal cytology) in the context of cervical screening in the last twelve months. Women were eligible to take part in the study if they spoke English and were able to give informed consent.

5.3.4: Recruitment

Participants were predominantly recruited through Saros (https://www.sarosresearch.com/), a market research participant recruitment agency with a database of over 300,000 participants. As Saros did not have information on women's cervical screening history, all women who were aged 24 to 65 years and living in England were invited by email to take part in the study (n=37,159). Of the women who were invited, 4.8% (n=1,793) expressed an interest in taking part. To assess eligibility for the study and to enable me to recruit a range of women with different characteristics, Saros asked all women who were interested in taking part in the study to complete an online version of the pre-interview questionnaire (Appendix 5.2). The pre-interview questionnaire assessed age, relationship status, ethnicity, highest level of education attained, cytology result and HPV knowledge. In addition, two items from the HPV Impact

Profile (HIP) assessed sexual impact following their most recent cervical screening result: “After my most recent cervical screening test result, I am having less sex” and “After my most recent cervical screening test result, I feel satisfied with my sex life”. The range for both items was 0 to 10, with 0 indicating ‘Not at all’ and 10 indicating ‘Extremely’ (Mast et al., 2009).

Saros reviewed the information women who had expressed an interest in taking part in the study had provided (n=1,793) and excluded anyone who had not tested HPV positive in the last twelve months, was outside the age range for the study, did not live in England, did not complete the pre-interview questionnaire in full, or did not feel comfortable talking about their sexual relationships (n=1,704). Saros did not collect information on the specific reasons why women were excluded. In total, 5% of women who expressed an interest in taking part in the study met the study’s eligibility criteria (n=89). Saros forwarded me the pre-interview questionnaire results of these 89 women. I wished to explore whether the psychosexual impact of testing positive for HPV differed by cytology result (normal and abnormal) and relationship status (women who were in a relationship and women who were not in a relationship) so I purposively sampled 20 participants based on these characteristics.

Table 5.1 shows the characteristics and number of women from each group that I aimed to recruit. Women were also sampled to represent a range of demographic characteristics (e.g. age, education, ethnicity) and self-reported sexual impact. Once I had chosen the women I wished to interview, Saros telephoned each woman to verify the answers they had given in the pre-interview questionnaire, check that they understood what taking part in the study would involve and, if they were happy to take part, arrange a suitable time for the interview.

Table 5.1: Characteristics and the number of women from each group the study aimed to recruit

	In a relationship	Not in a relationship	Total
HPV positive with normal cytology	5	5	10
HPV positive with abnormal cytology	5	5	10
Total	**10**	**10**	**20**

In addition to recruiting participants through Saros, an advert was placed on the Jo's Cervical Cancer Trust 'Take part in new research' webpage (https://www.jostrust.org.uk/get-involved/volunteer/research). Jo's Cervical Cancer Trust is a UK cervical cancer charity which provides information and support to women affected by cervical cancer and cervical abnormalities. I wanted to recruit women from two settings to gain a broader range of views and experiences. I anticipated that there may be differences in the views and experiences of women recruited from Jo's Cervical Cancer Trust and from Saros. Women looking at the Jo's Cervical Cancer Trust website are likely to be seeking additional information and support and I anticipated that the psychosexual impact of testing HPV positive may be greater among these women. I had initially planned to recruit equal numbers of women from both settings. The advert included a brief description of the study and my contact details for women who were interested in taking part in the study or those who wanted more information (see Appendix 5.3). The study was advertised on the Jo's Cervical Cancer Trust webpage from September 2019 to July 2020. During this period, three women expressed an interest in taking part in the study, of which, one participant was recruited to the study.

5.3.5: Sample Size

There are no set guidelines for sample size in qualitative research and it has been suggested that it will depend on a number of factors including the quality of the data, the scope of the study, the nature of the topic, the amount of useful information obtained from each participant and the qualitative method and study design used (Morse, 2000). As this was an exploratory study and I was unsure of how much data would be generated from each interview, I initially aimed to recruit 20 women.

I followed the principles for determining data saturation outlined by Francis et al. (2010) which suggest that once three consecutive interviews have been conducted with no new emerging themes it can be concluded that data saturation has been achieved and data collection can end. I planned to continue interviewing women until three consecutive interviews had been conducted (up to a maximum of 30 interviews) with no new themes emerging. I felt that the proposed sample size would be sufficient in providing data to provide a range of

different views, while being manageable in terms of the budget and resources that were available.

I initially interviewed 17 women who were recruited from Saros. Following this, three further interviews were conducted in which no new emerging themes emerged. I concluded that data saturation had been achieved and data collection ended. Shortly after this, a woman who had seen the study advertised on the Jo's Cervical Cancer Trust webpage expressed an interest in taking part. As she met the eligibility criteria, I decided to interview her to see if there were any differences in her views and experiences compared to women recruited from Saros.

5.3.6: Data collection

Interviews were arranged at a convenient time for the participant and took place in June and July 2020. Due to the coronavirus disease (COVID-19) pandemic, participants were given the choice to do the interview over the telephone or by video call (Microsoft Teams or Skype). I emailed participants a copy of the study information sheet at least 48 hours prior to the interview, which gave a summary of the study and what was involved (see Appendix 5.4). I also sent participants a consent form and asked them to complete and return this to me prior to the interview taking place (see Appendix 5.5). Participants who did not return the consent form prior to the interview, or were unable to complete the consent form electronically, gave verbal consent to take part in the study at the start of the interview. All participants were given the opportunity to ask me questions before signing the consent form and before the interview began.

A topic guide was used to guide the interviews (see Appendix 5.6). This covered knowledge of cervical screening and HPV, women's experiences of cervical screening and testing HPV positive, the impact their HPV positive result had on sex and relationships (women who were not currently in a relationship were asked their feelings about future relationships) and their HPV information needs. All participants consented to the interview being audio-recorded. Participants were reminded throughout the interview that they did not have to answer any questions that they did not want to. At the end of the interview, participants were asked if they had any further comments or questions about HPV or cervical screening that were important to them that they had not raised

in the interview. Following the interview, participants received a £40 Love2shop voucher via email as a thank you for their time and taking part in the study[10]. Participants were also emailed a study debrief sheet (see Appendix 5.7) which included some websites and helplines where they could find out more information or speak to someone if they had any concerns about HPV or cervical cancer. The study debrief sheet also included my contact details if they had any further questions about the study or wished to make any additional comments after the interview.

After the interview, audio-recordings were transferred via a secure portal to Devon Transcription (https://www.devontranscription.co.uk/), a trusted UCL approved external transcription company, and transcribed verbatim. I anonymised the transcripts by removing any names or locations participants mentioned and checked all transcripts against the recordings for accuracy.

5.3.7: Data analysis

Data were analysed using Framework Analysis, a "matrix-based method for ordering and synthesising data" which is frequently used to analyse qualitative data in health research (Ritchie & Lewis, 2010). Framework Analysis aims to identify similarities and differences, and subsequently look for relationships in qualitative data, with the aim of generating descriptive and/or explanatory conclusions centred around themes (Gale, Heath, Cameron, Rashid, & Redwood, 2013). Framework Analysis was chosen as it is a systematic and flexible approach to categorising and organising qualitative data and it allows comparisons to be made between and within cases (Gale et al., 2013). Framework Analysis was chosen over other approaches (e.g. discourse analysis, Grounded Theory) as it is not aligned with a particular theoretical or philosophical approach (Gale et al., 2013).

Framework Analysis consists of five main steps: (1) Familiarisation, (2) Constructing a thematic framework, (3) Indexing, (4) Charting and, (5) Interpretation. After familiarising myself with the data by listening to and reading

[10] Originally I had planned to offer women a £50 Love2shop voucher, the same amount that PPI representatives were offered, however the UCL REC felt this amount was excessive and could be seen as an unnecessary inducement to take part. The incentive amount was therefore reduced to £40.

the transcripts, recurring themes or ideas were identified and a working thematic framework or 'index' of recurrent themes was created. Themes were sorted and grouped into a smaller number of higher order categories or main themes. The thematic framework was then applied to the data. The developers of Framework Analysis refer to this process as 'indexing' – labelling or tagging the data to identify the theme or concept to which it relates.

Thematic charts were constructed using the thematic framework and data from the transcripts were synthesised and placed in the thematic charts. Each theme was displayed in a separate chart, with columns representing subthemes and each row representing a participant. The thematic framework was an iterative process until I was satisfied that the framework was appropriate for the data. Data were analysed in NVivo 12 PRO and stored and managed in Microsoft Excel.

I presented and discussed my initial thematic framework with my supervisory panel (Dr Laura Marlow, Dr Jo Waller and Dr Julia Bailey). During the interpretation phase of the analysis several further discussions took place between myself and my supervisory panel where I presented emerging findings. The interpretation phase was an iterative process and any uncertainties I had about how findings should be interpreted were discussed with Dr Laura Marlow.

5.3.8: Impact of COVID-19

I was required to make some changes to the design of this study because of the COVID-19 pandemic. When designing the study, it was intended that participants would be recruited from Jo's Cervical Cancer Trust and through Primary Care. I prepared an ethics application and attended the REC review meeting with Dr Julia Bailey. The study gained a favourable ethical opinion from the London-Bloomsbury Research Ethics Committee (19/LO/1762) on 22/11/2019 (see Appendix 5.8) and once the conditions outlined in the favourable ethical opinion had been met, REC and HRA approval for the study on 23/12/2019 (see Appendices 5.9 and 5.10). However, at the time I was due to begin recruitment in Primary Care (March 2020), research taking place in this setting was paused due to COVID-19.

I had planned to seek help from the Clinical Research Network (CRN) to invite general practice (GP) surgeries within Hillingdon Clinical Commissioning Group (CCG) in North West London, who were included in the HPV primary screening pilot, to take part in the study. GPs who agreed to take part would have been asked to identify all women who had tested HPV positive (with any cytology result) in the last year from their medical records. After excluding any women who they felt were unsuitable for the study (e.g. women with a serious illness, intellectual difficulties or those unable to speak fluent English), it was intended that GPs would send a letter to all remaining women describing the research and inviting them to take part in the study.

When it became apparent that I would not be able to begin recruitment in Primary Care for some time, I revised my recruitment strategy and submitted a substantial amendment to the UCL REC to allow me to recruit participants from Saros. The substantial amendment also included a change to the way I would interview participants. I had planned to offer participants the choice of doing the interview face-to-face or by telephone, but face-to-face interviews were not possible and so I amended my approach to instead offer participants the choice of doing the interview by telephone or video call.

5.4: Results

5.4.1: Sample characteristics

Interviews were carried out with 21 women and lasted from 21 to 70 minutes. Participants included ten women who were in a relationship (i.e. in a relationship, living with a partner, married or in a civil partnership), ten women who were not in a relationship (i.e. single) and one woman who was dating/in a casual relationship. Women reported that they were HPV positive with normal cytology (n=10) or HPV positive with abnormal cytology (n=11) and ranged in age from 25 to 64 years (mean age: 39.8 years). The sample included women with a range of educational qualifications, including GCSEs (n=3), A Levels (n=5), university degree (n=8) and post-graduate university degree or higher (n=5). The sample varied by ethnicity, with women from White (n=14), Asian (n=3), Black (n=1) and mixed or multiple ethnic groups (n=3) interviewed. Women's self-reported HPV knowledge was 'Good' (n=5), 'Fair' (n=9), 'Poor'

(n=5) or ‘Very poor’ (n=2). The mean score for the item “After my most recent cervical screening test result, I am having less sex” was 5.66. The mean score for the item “After my most recent cervical screening test result, I feel satisfied with my sex life” was 3.95 (potential range for both items: 0-10). For both items women’s scores ranged from 0 to 10, where 0 indicated ‘Not at all’ and 10 indicated ‘Extremely’. Participant characteristics are shown in Table 5.2.

When asked about their screening history during the interviews, most women reported that it was their first HPV positive result (n=14) with the others (n=7) reporting having received between two and eight HPV positive results. In the pre-interview questionnaire, women were asked about their cytology result and some women reported that they had tested HPV positive with abnormal cytology, however during the interview their description of their results suggested that they had tested HPV positive with normal cytology. A few women had *“vaguely”* heard of HPV before testing HPV positive because of the HPV vaccine or had heard about it because friends or family had tested HPV positive, but *“had not really paid a lot of attention to it”.* Most women commented that they had not heard of HPV before testing positive and reported having looked online or having spoken to a healthcare professional for more information.

Table 5.2: Participant characteristics

	Number
Age	
25-34	7
35-44	8
45-54	5
55-65	1
Cytology result	
Normal	10
Abnormal	11
Relationship status	
In a relationship[1]	10
Not in a relationship (i.e. single)	10
Dating/in a casual relationship	1
Ethnicity	
White (British or other)	14
Asian	3
Black	1
Mixed/multiple	3
Education	
Master's degree or higher	5
Degree	8
A Levels	5
GCSEs	3
Self-reported HPV knowledge	
Very good	-
Good	5
Fair	9
Poor	5
Very poor	2
Having less sex (mean score (range))[2]	5.66 (0-10)
Satisfaction with sex life (mean score (range))[2]	3.95 (0-10)

[1] This included women who were in a relationship, living with a partner, married or in a civil partnership.

[2] Scale range: 0-10, where 0 indicates 'Not at all' and 10 indicates 'Extremely'.

5.4.2: Psychosexual responses to an HPV positive result

Women's responses to testing HPV positive were largely driven by the topic guide and fitted into four categories: (1) Emotional responses, (2) Psychosocial responses, (3) Disclosing an HPV infection to others and, (4) Feelings about future sexual relationships and disclosure. Several factors appeared to influence women's emotional and psychosocial responses and minimise the

potential negative impact of testing HPV positive: (1) How women conceptualised HPV, (2) HPV dormancy, (3) Concern about transmitting HPV, (4) Persistent HPV infection and, (5) Knowledge of HPV. Women's responses and the influencing factors are described in the following sections, along with example quotes. A model of psychosexual responses to an HPV positive result and the influencing factors are shown in Figure 5.1.

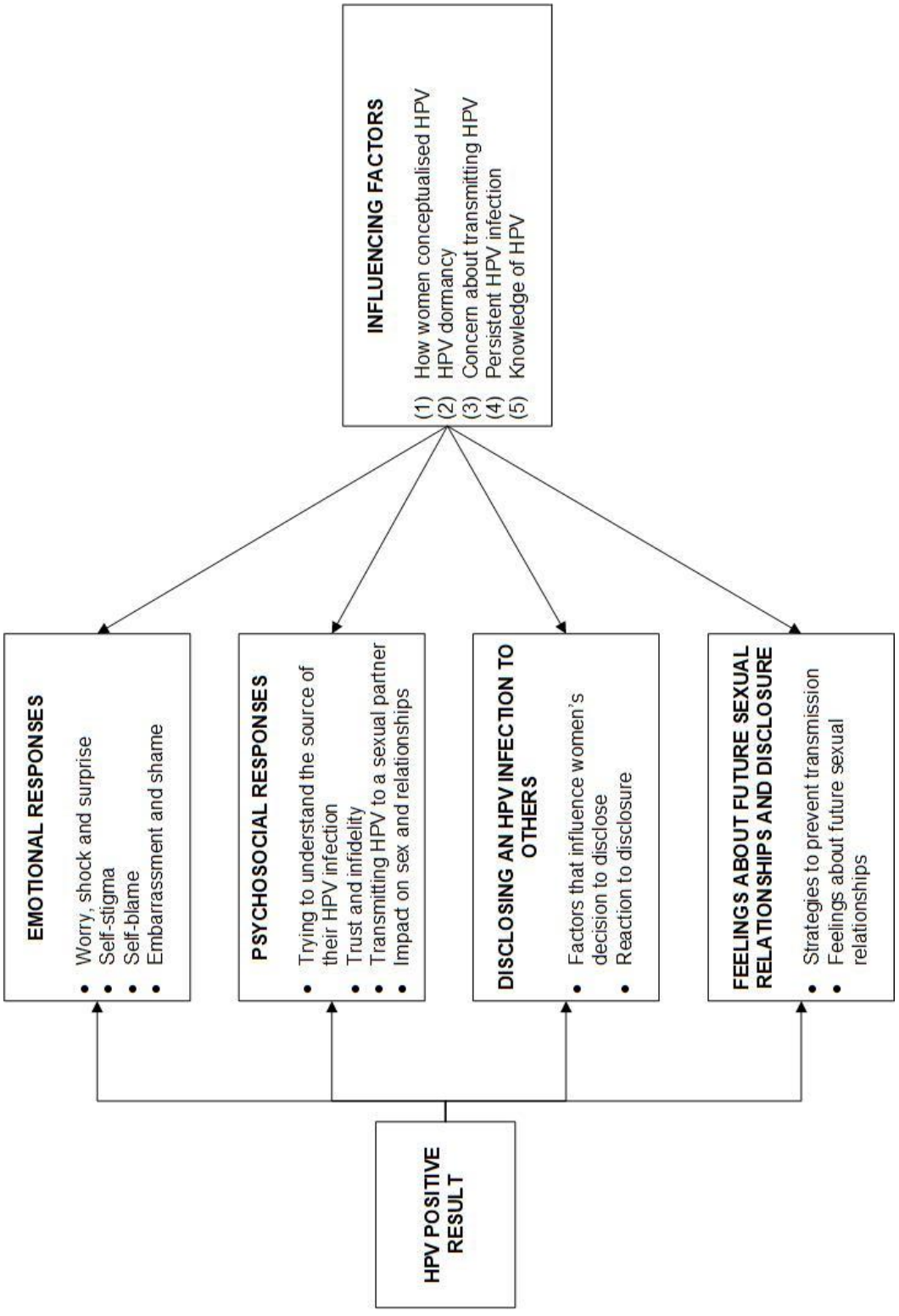

Figure 5.1: A model of psychosexual responses to an HPV positive result.

5.4.2.1: Emotional responses

Worry, shock and surprise

Many women described feeling worried and concerned when they received their HPV positive result. This was often because they didn't know what HPV was or were concerned about it developing into cancer. Some felt shocked, surprised or panicked at having a sexually transmitted infection because they had been with their current partner for several years, or had not had unprotected sex, and questioned whether their HPV positive result was correct because they weren't *"that sort of person"*.

> *"I thought, 'Oh my God, I've probably got vaginal warts,' and obviously thinking, 'Oh no, I haven't' because obviously I knew it was something to do… it's like a… well, I believe it's something like a wart virus and I was absolutely panic-stricken because I thought, 'Oh my God, this sounds awful. I've got a sexually transmitted disease at my age. Where have I got this from?' You know. Ohhh!"*
>
> (Participant 15, 44 years, normal cytology, not in a relationship)[11].

Self-stigma[12]

Women also reported feeling *"dirty"*, *"horrible"*, *"grim, and infected and nasty"* when they received their HPV positive result. Women commented on the stigma or negative connotation that is associated with *"…anything that's sort of a bit sexually orientated".* For one woman, negative feelings about herself and her body because of her HPV infection affected her sexual confidence and self-esteem.

Self-blame

Women blamed themselves for acquiring HPV because they had had unprotected sex or had several sexual partners around the same time, or felt

[11] Participant ID number, age, cytology result and relationship status.
[12] Stigma is prejudice and discrimination towards a group. Self-stigma is when individuals internalise these negative attitudes (Corrigan & Rao, 2012; Corrigan, Watson, & Barr, 2006)

that if there were issues in the future regarding fertility or pregnancy that it could be viewed as their fault.

Embarrassment and shame

Feeling embarrassed and ashamed at having something that had been acquired through sexual activity was mentioned. This often seemed to be the case where women conceptualised HPV as an STI or something they had got through unprotected sex:

> *"Because I think I thought it was an STI at the time…So it was that whole stereotype of who gets HPV...So I suppose I was shocked. Um, and maybe, like, a little bit shameful because of the stigma"*
>
> (Participant 9, 35 years, normal cytology, not in a relationship).

Feeling ashamed because they associated having an STI with promiscuity and questioning how they had got HPV when they hadn't had *"loads of partners"* and *"didn't sleep around"* was described. One woman felt that the information she had received with her results letter implied HPV was associated with promiscuity. The stereotype of someone who gets HPV often didn't match the view women had of themselves which made them feel uncomfortable:

> *"…this stereotype of someone that get, that gets HPV, people that h-have unprotected sex and lots of partners. And because that wasn't the case with me I think that brought up the shame. It's like oh, they probably think I'm promiscuous or... Do you know what I mean? So it was definitely uncomfortable"*
>
> (Participant 9, 35 years, normal cytology, not in a relationship).

Women who had received an abnormal cytology result in addition to their HPV positive result, either in the past or at their most recent cervical screening test, described how receiving an HPV positive result felt different due to its sexually transmitted nature and the stigma associated with this:

"But, erm, yeah, 'cause that's different, it takes away that kind of like dirty, shameful stigma of it I guess, if you know, knowing that it's not something that's kind of been caught or picked up. It was just a change in cells, it was, yeah. You can associate that differently I guess"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

5.4.2.2: Psychosocial responses[13]

Trying to understand the source of their HPV infection

A common response, regardless of relationship status, was for women to try to understand where their HPV infection had come from:

"…I was trying to track in my head all of my sexual - all of my; it makes me sound like I've had hundreds [laughter] – my sexual partners for the last decade"

(Participant 17, 43 years, normal cytology, in a relationship).

Women who had been with their current partner for several years were particularly confused about where their HPV infection might have come from. In some cases, women assumed that the infection had come from their current, or a recent, sexual partner because their previous cervical screening test result had been normal, or HPV had not been found:

"…I'm now thinking like well who did I get it from, who did I, who did I pick it up from. It must have been, you know. I'm, in my head I'm thinking it must have been somebody recently because otherwise it would have been picked up on my first two smears"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

In contrast, other women felt unable to determine which sexual partner had given them HPV and were unsure whether their partner had given them HPV, or they had given it to their partner. Women who were single when they received their HPV positive result questioned how they had got HPV as they hadn't recently been sexually active:

[13] Psychosocial responses were affective responses which related to social interactions with others (Melville et al., 2003).

"I didn't know anything about it and I was quite intrigued… not intrigued by it, but I was like, oh, I wonder why I've got it, you know, or how because at that point I was like… I'd not had sex for a few years, couple of years"

(Participant 21, 44 years, abnormal cytology, dating or in a casual relationship).

Trust and infidelity

Women's attempts to understand the source of their HPV infection led to some issues around trust of their partner and this had the potential to have an impact on their relationship. This seemed to particularly be the case for women who lacked knowledge about HPV:

"Um with the previous relationship um when I first had the screening and the results, it definitely did have an impact and I think that was quite um… I suppose quite young at that point and because of the lack of understanding of it, you just… you are not sure. I suppose trust plays a part in it and it makes like your partner reflect on your history and how did you get it and um did I give it or did you have it before, those sorts of questions…"

(Participant 4, 31 years, abnormal cytology, in a relationship).

While some women commented that they completely trusted their partner and did not suspect any infidelity, others raised concerns about whether their partner had been unfaithful and whether that was how they had acquired their HPV infection:

"…my immediate reaction to him was, 'Well, what have you been up to?' [laughter] and I just thought, 'Well, you've got it off somebody. It's not off me'…I was a bit like… you know, 'have you been cheating on me?' [laughter]"

(Participant 15, 44 years, normal cytology, not in a relationship).

One woman had concerns about her partner's behaviour during a break in their relationship, did not trust what he had told her and blamed him for her HPV infection. Her partner also accused her of having other sexual partners, suspecting that that was how she had acquired her HPV infection.

"I know that he was seeing other people, but then he was always saying that he was practising like safe sex, so then I was thinking, 'Well, how could I have got it if he was doing that?'"

(Participant 19, 50 years, abnormal cytology, in a relationship).

Questioning their partner about whether they were the source of their HPV infection had an impact on women's relationships because partners were unhappy about being accused of infidelity and this led to tension or arguments. For one woman, perceiving her partner to be the source of her HPV infection was having an ongoing impact on her relationship and she questioned whether she had *"…done the right thing"* getting back with her partner after a relationship break, feeling that she didn't like him as much as she used to. Her partner being the source of her HPV infection was always on her mind, including during sex:

"I'm sort of always thinking, even in the moment that, 'You gave me HPV'"

(Participant 19, 50 years, abnormal cytology, in a relationship).

Transmitting HPV to a sexual partner

There was uncertainty around whether it was possible to transmit HPV to a male sexual partner. Women reported feeling *"guilty"* and worried about potentially having transmitted HPV to their partner and were concerned that there was no way of them knowing if they had the virus. One woman questioned whether she was 'allowed' to have sex with HPV:

"…I said to the nurse 'oh am I still allowed to have sex whilst I've got this?' and she was like 'yeah of course you are' and then I was like but am I gonna pass it on to someone, you know. So, erm, yeah, that, that would be my biggest concern"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

Concerns about HPV potentially harming or having an impact on their partners' health were predominantly mentioned by women who had only received one HPV positive result. One woman reported that her and her partner's lack of understanding about the possible impact of HPV resulted in her partner being hesitant to have sex:

"I think he was quite apprehensive to have a sexual relationship 'cause he didn't really understand what it meant, what the implications for him were, and I didn't really understand it either so I couldn't say, oh, you know, 'It's fine, don't worry about it, you know, it's not gonna do anything"

(Participant 4, 31 years, abnormal cytology, in a relationship).

Concern about transmitting HPV to a sexual partner and their partner then passing HPV onto someone else in the future resulting in a *"chain of people that could be affected"* was mentioned*:*

"…I wouldn't like to think that I did and then if we broke up, they pass it on to someone else. I wouldn't like to think that's sort of… you know, it was a never-ending cycle and someone else could be in the position that I'm in in the future"

(Participant 21, 44 years, abnormal, dating or in a casual relationship).

Women queried whether it was possible to be reinfected with HPV, either by their current sexual partner or a new sexual partner in the future. Due to her concern about being reinfected with HPV, one woman asked her partner to use a condom until they had *"evidence"* that he couldn't reinfect her.

"…I couldn't find any information, whether you can sort of re-get it from the same partner, so my thing is that if it has gone away on its own, could he re-give it to me…"

(Participant 19, 50 years, abnormal cytology, in a relationship).

Impact on sex and sexual relationships

For some women, having HPV had an impact on their sexual relationship or feelings or attitudes towards sex. Reduced interest in and frequency of sex were the changes most frequently described. Some stopped having sex completely because they or their partner were concerned that they would transmit HPV:

"Well, we haven't had sex since. So that's a long time…Um, I think he is... I, I would, personally, um, but my boyfriend is unsure. He doesn't wanna catch anything and then resent me for it"

(Participant 12, 38 years, normal cytology, in a relationship).

Self-stigma also had an impact on women's interest in sex, affecting their confidence, self-esteem and sexual self-image:

"So, for the next few weeks, I really did avoid sex, erm because I just felt grim, and infected and nasty"

(Participant 17, 43 years, normal cytology, in a relationship).

Being less interested in having sex with someone who they perceived was the source of their HPV infection was mentioned. One woman was concerned that her relationship with her partner might end if they had sex less frequently. Another woman reported that having HPV had led to her relationship ending:

"…I was seeing someone at the time and I just kind of assumed that they had given it to me. Erm, and it probably actually ended our relationship, it, I, I had no interest like in that, like in having sex with him again"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

Other concerns about having sex included making abnormal cells or an HPV infection worse. Experiencing pain or discomfort during or after sex was mentioned and women questioned whether this was due to having HPV, however it was generally felt that the impact this had on their sexual pleasure was due to physical symptoms, rather than knowing that they had HPV:

"I didn't think it was psychological. I felt it was physical…But it certainly, it's got nothing to do with the fact that I was told about the HPV. Um, it, it's purely the physical pain of having the sex that, that I don't like"

(Participant 11, 52 years, normal cytology, not in a relationship).

Having HPV had a positive impact on one woman's relationship with her partner as it had improved the way they communicated with each other and made them appreciate each other more:

"It helped me understand what I stood to lose if we broke up and I think it's helped him understand that he didn't want to lose me. Um, otherwise we would have broken up. And so it, it's helped us both be, be more honest and straight-talking and it's helped us both appreciate what we've got in each other"

(Participant 12, 38 years, normal cytology, in a relationship).

5.4.2.3: Disclosing an HPV infection to others

Most women said that they had spoken to at least one person about their HPV positive result (i.e. partner, friends or family). A small number of women who were HPV positive with abnormal cytology chose to focus on their abnormal cytology result rather than their HPV positive result, partly because of the stigma associated with having an STI:

"…I wouldn't go out of my way to tell someone I had the HPV virus. It would be more just like I've had abnormal cells, changes in my cervix, something like that…I guess because it, 'cause it is sexually transmitted. Erm. Yeah, I guess it has that stigma about it"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

Disclosure was described as *"awkward"* or *"hard work"* and explaining the circumstances surrounding acquiring HPV embarrassing and difficult:

"I mean, I explained the circumstances, and about going to the sexual health clinic, and the whole, [pause] whole situation, which is embarrassing, that I was actually involved with somebody that, umm, wasn't, well, I thought they were being honest, but they weren't being honest…it hurt me to have to talk to somebody in that way, when, [sighing] I hadn't, I hadn't been promiscuous"

(Participant 18, 64 years, abnormal cytology, in a relationship).

Some women reported showing or giving their partner their results letter to read because they had found the letter informative or reassuring. The high prevalence of HPV was mentioned during disclosure. One woman felt that the information she had received did not help with disclosure and so she *"stuck to the facts"*:

"There was nothing to, to help me tell him. Erm the letter itself said you don't even have to tell them, so there was no help in that letter erm to actually have the conversation. And I kind of felt, I found myself scrabbling and holding onto the statistics. So, I said "Oh, I'm just erm like one in five women who are under 50 who have it, so I'm just 20% of the population," so I stuck to the facts. I clung onto that statistic when I told him about it"

(Participant 17, 43 years, normal cytology, in a relationship).

Women felt embarrassed talking to family members, because of the sexually transmitted nature of HPV:

"It's still very much, because it is transmitted, sexually transmitted isn't it? Like I don't know if there's any other way of getting it. Erm, so it's definitely, it still very much feels like I'm telling someone I've got an STI… It's a taboo subject isn't it anyway [laughs], like talking to my mum about sex, erm, it's just a bit weird anyway, but talking about, talking about something that somebody has potentially given me as a result of me having sex with them is even more embarrassing [laughs]"

(Participant 23, 33 years, abnormal cytology, not in a relationship).

Factors that influence women's decision about whether to disclose HPV

Several factors appeared to influence women's decision about whether to disclose their HPV infection.

Sharing health-related information or making others aware of their personal situation was considered normal practice for some. In contrast, others felt cervical screening was infrequently discussed and because having HPV had not *"come up"* in conversation they had not mentioned it, although it was felt that they would disclose having HPV if someone else raised that they also had it. As a result of their own, and others perceived lack of knowledge about HPV, some women felt they would only disclose to individuals who also had HPV as they felt others would not understand or be able to *"relate"* or they might not be able to answer others' questions about HPV.

Knowledge and beliefs about transmitting HPV, and the potential impact of HPV for a male sexual partner, appeared to influence women's decision about

whether to disclose. Some believed that HPV would not adversely affect their partner so there *"isn't really any need to discuss it".* Uncertainty about whether it was possible to transmit HPV and the potential impact for a male sexual partner led women to question whether it was necessary to disclose. Conflicting information about disclosure online and knowing that condoms would not necessarily prevent transmission of HPV resulted in women feeling *"quite confused and concerned about that area of my, erm, life".* Being told that HPV was sexually transmitted but receiving guidance with their results informing them that they did not need to tell their partner was seen as *"really confusing, and upsetting"* and made women feel like they *"had to hide it, by them saying that".*

Concern about the impact of disclosure on their relationships with others influenced women's decisions regarding disclosure. Disclosure was described as a *"nerve-racking experience"* as women were unsure how to approach disclosure and how their partner would respond. Feeling that their partner might want to *"walk away"* from their relationship or question how they got HPV were mentioned. Concern about the potential impact of disclosure on a relationship, or that their partner might think that they had been unfaithful and that was how they had acquired HPV was also mentioned:

> *"…I certainly didn't want to cause erm anxiety in the relationship, erm, because certain things might have triggered a reaction which I wasn't sure if I wanted to erm go down that road with him. So, I thought maybe on balance, I decided not to tell him. And he still doesn't know now… As it's something that your body can clear itself of quite quickly, or over a period of, you know, and it doesn't cause any symptoms, I didn't want him to think maybe I'd been having an affair [laughs] with someone or anything, which I wasn't, erm, but I just didn't want to create that atmosphere"*
>
> (Participant 13, 48 years, normal cytology, not in a relationship).

Fear of being viewed negatively or feeling *"too embarrassed"* to tell others that they had HPV due to its sexually transmitted nature were cited as reasons why women hadn't disclosed:

I'm not, I don't know why I should be so worried about it, because like I say, it's nothing, it's not really a problem, I'm fully healthy and everything, but I just don't want people to, I suppose, judge me, really"

(Participant 13, 48 years, normal cytology, not in a relationship).

Although concerns about disclosure were expressed, worry about transmission or feeling that telling their partner about their HPV infection was the honest, right and *"fair"* thing to do, regardless of the guidance they had received with their results, resulted in disclosure:

"Erm, the letter where it said "You don't have to tell your partner," when I read that line, I immediately thought "I would never do that, I would never not tell someone, they have a right to know." So, instantly I thought I should tell him. I never thought, I never considered not telling him"

(Participant 17, 43 years, normal cytology, in a relationship).

A desire to gain social support or additional information, particularly from others who had tested HPV positive or received an abnormal cytology result, also appeared to influence women's decision to disclose their HPV infection. Some women felt they were not looking to gain any additional information and cited this as a reason for not disclosing having HPV.

Not wanting others to worry about their HPV positive result was mentioned. One woman's partner, who had family members who had died from cancer, had been anxious and worried when she had recently found a lump in her breast and she did not want to go through something similar again, particularly when having HPV probably would not cause any long-term issues:

"…about three months before I had that letter, I'd had erm, I'd found a lump in my breast. Which was clear, it was all fine, there were no issues, but I didn't want to go through that whole cycle again of, of telling him and then him being anxious and worried and stressed, and knowing that this was probably, I wouldn't get tested again for a year, and there probably wouldn't be any, any problems with it, I didn't want to, you know, go through all of that again"

(Participant 13, 48 years, normal cytology, not in a relationship).

One woman, who had spoken to family and friends about her screening results,

was dating someone when she received her HPV positive result. Although she felt she would *"probably"* tell future sexual partners about having HPV she did not tell the person she was dating at the time because she felt she needed space and time to focus on herself after having treatment which she found very unpleasant:

> *"I don't know. I just thought… I just sort of thought um… I just… I don't know, I just… I – I think in my head I thought it was like a really big deal, especially – especially after the hospital appointment before I found out the biopsy results. I thought it was like a really big deal and I thought it warranted like a bit of space and just wanted to like focus on me kind of thing and like my own mental health…"*
>
> (Participant 20, 30 years, abnormal cytology, not in a relationship).

Reaction to disclosure

For some women, there was little or no reaction from their partner when they disclosed their HPV infection, with women describing their partner as being *"pretty laid back about it all",* not *"bothered"* and satisfied with the information that they had given them. Where women showed little worry or concern about their result often partners reacted similarly:

> *"I was like, "You haven't had any symptoms, you probably won't, but obviously keep an eye on it." Erm and that was that really. He wasn't too bothered either because I think he was just the same as me; the people, the right people know about it, and if there's an issue, they'll find it at the next screening…"*
>
> (Participant 16, 25 years, normal cytology, in a relationship).

In contrast, one woman, who was concerned about her partners reaction to disclosure commented that he *"…wasn't interested at all"*. While she was upset and worried about her result her partner didn't seemed concerned and was dismissive of her feelings:

"And I was like, and I said, "I'm devastated about it," and he was like, "Why?" And I said erm, "Well, because it's sexually transmitted, and erm I don't know how I got it, and you know," and he just said, "Oh, it's fine, don't worry about it.""

(Participant 17, 43 years, normal cytology, in a relationship).

Others' lack of knowledge or understanding about HPV was mentioned by a couple of women following disclosure. Women described how their partner or friends *"didn't have a clue what it [HPV] was"* and did not understand what their result meant. Having heard of the HPV vaccine did not necessarily help partners understand an HPV positive result. Some women felt their partners lack of reaction to disclosure was because they had little knowledge about HPV:

"I think most men… if you have this discussion with them, they don't… from my experience, they don't particularly know what it is and I don't think most men particularly care. I think they just think, 'Oh it's… you know, I think unless it's something that men can put a name to like syphilis or gonorrhoea or chlamydia, they're not bothered, you know, to them, it's just something that women just tend to have, which I know that's necessarily not the case at all, but from my experience, I wouldn't say most men are particularly… well, most men I've known, and I haven't known that many, are particularly bothered"

(Participant 15, 44 years, normal cytology, not in a relationship).

Women's partners, friends and family were supportive and understanding following disclosure. Some were concerned about the impact that HPV might have:

"…she was just, um, worried that now I'm gonna have more issues and that… like worried that I will be one of the people that would, um, turn into cervical cancer because I sort of do get quite a lot of illnesses since I had this virus. I've got a really, really bad immune system and, um, she was really annoyed and saying that, 'Trust him to…' and then, obviously, knowing you that you'll be one of the people that, um, would like not go on its own, go away on its own and it would turn into, um, cervical cancer"

(Participant 19, 50 years, abnormal cytology, in a relationship).

Partners were *"taken aback"* and *"overwhelmed"* following disclosure and felt it was something they needed to get their "*head round".* Some women's partners responded defensively to disclosure, informing them that they hadn't acquired their HPV infection from them or expressed concerns about transmission of HPV and the impact that might have.

A couple of women reported that their partner reacted with humour about the sexually transmitted nature of HPV. One woman and her partner joked about her having HPV:

> *"To be honest, it's not a joke, but we almost took it like that [laughter]. It didn't bother us, [laughs] because it was almost a bit like, "Oh, you've got an STI, ha ha," it was kind of told like that. We didn't, we didn't see it as anything serious, erm, because I hadn't had any symptoms and yeah, it's quite a common thing to get, so it, we almost saw it as a bit of a joke"*
>
> (Participant 16, 25 years, normal cytology, in a relationship).

In contrast, another woman was upset by a stigmatising joke her partner made about her having HPV. He made this joke on more than one occasion, including when she had told him she was taking part in this research:

> *"And then later, he made this joke, erm ringing a bell and saying "unclean", and I said to him, "I don't find that funny, I'm really not happy with this." And he was like, "Oh okay, sorry," [laughs] and he actually made it, I told him about this research, and he went, "Oh, the unclean phone-call," and rang the little bell again. And I was like, "You're not funny, you're really not funny.""*
>
> (Participant 17, 43 years, normal cytology, in a relationship).

5.4.2.4: Feelings about future sexual relationships and disclosure

Strategies to prevent transmission

Women wondered about what they could do to prevent HPV transmission and avoid being reinfected in the future. Strategies to prevent transmission were predominantly mentioned by women not in a relationship. Using condoms in future sexual relationships was one approach that was mentioned. Some

women wondered if condoms could help prevent transmission of HPV and help them clear their HPV infection. Others felt there was *"no point"* as their partner had probably already been infected with HPV. For some women, they described receiving an HPV positive result as *"a wake-up call"* and felt they would be more likely to use condoms to prevent transmission of other STIs as well as HPV:

> *"I'm just more concerned about just making sure that we use adequate protection, just for the benefit of both people, you know, myself and the guy I'm with, just to make sure that you know, you don't get anything. Not just HPV, but anything else as well, just you know, just be cautious on that front"*
>
> (Participant 13, 48 years, normal cytology, not in a relationship).

Due to concern about transmitting HPV to a sexual partner, some women described waiting until their next screening test before having sex to see if their HPV infection had cleared. This was an approach taken by a woman at the start of her relationship but was also mentioned in relation to beginning a new sexual relationship:

> *"I, I, I would probably wait until September because, erm, my next smear is in September... And if I get a pos-, like you know, like a negative result then, then I'd be happy to, but until then I don't, I don't feel like I want to, I don't feel like I'd want to at all… Erm, just in case I have still got it and then I pass it on to somebody else"*
>
> (Participant 23, 33 years, abnormal cytology, not in a relationship).

Before starting a new sexual relationship, some women mentioned that they would ask a sexual partner to have a sexual health check, predominantly to prevent transmission of another STI. For some women this was something they had done prior to having HPV but since being told that they had HPV they felt it was even more important.

"…if there is a new partner then I will definitely ask, you know, when was the last time you had a check and just so that I'm sure that there isn't anything else. I think it has made me worried… not worried, but cautious in a sense of um I – I definitely want to know from a new partner if they have sexual health checks and if they have anything and if everything is you know, normal and there isn't any risk there involved"

(Participant 4, 31 years, abnormal cytology, in a relationship).

A small number of women mentioned HPV testing for men. One woman questioned whether HPV was tested for as part of a sexual health screening and felt that if it was not that individuals should be made aware of this[14]. She viewed HPV testing potentially not being included as part of a sexual health screening a *"fall down in the system"*. Other women felt that if there was an HPV test for men, they might be able to prevent passing on the infection to women.

Feelings about future sexual relationships

In addition to concerns about transmitting HPV to a sexual partner, women were also concerned about acquiring another STI:

"Erm I suppose, I mean there's all the things. I wouldn't want to just have sex with anyone without knowing. I think in my head now, if I've got an STI, they could have an STI too; you just, it makes you more aware about that kind of thing. Erm yeah, I just wouldn't want to risk it, knowing that I had something, and then in turn maybe getting [laughs] something else"

(Participant 16, 25 years, normal cytology, in a relationship).

Concerns about acquiring an STI led women to feel *"wary"* or *"cautious"* about future sexual relationships and that they would need to consider future partners more carefully. Some women felt particularly wary because they had had a sexual health screening before starting a new relationship and had used protection but had still acquired HPV:

[14] Testing for HPV is not part of a routine STI screening in England for men or women.

"Initially I probably thought oh my gosh, I never wanna have sex again, um, thinking that, you know, if you can catch it when you've used protection and you've been careful about the choice of partners, there was definitely that bit of is it worth it. Is it worth having sex if you can catch these viruses…"

(Participant 9, 35 years, normal cytology, not in a relationship).

For other women, having HPV had not affected their feelings about future relationships or sexual relationships:

"I think it is something that I can put to the back of my m- head. Um, and, you know, I'm not gonna let it stop me but, um, I've just gotta look out for any symptoms, you know. I'm not gonna put my life on hold because of that. Um, and then just look out for any symptoms, any changes and then just call the doctors if I need it. But I'm not gonna put my life on hold really"

(Participant 10, 28 years, normal cytology, not in a relationship).

5.4.2.5: Factors influencing emotional and psychosocial responses

Several factors appeared to influence women's emotional and psychosocial responses and minimise the potential negative psychosexual impact of testing HPV positive.

How women conceptualised HPV

When asked how they thought someone would get HPV, all women mentioned aspects related to sexual transmission, however a more detailed understanding of the sexually transmitted nature of HPV varied. Some women believed that HPV was caused by having unprotected sex while others mentioned that HPV could be transmitted by any sexual or skin-to-skin contact and not just sexual intercourse, and therefore using a condom might not prevent transmission. HPV was described as *"…like an STD",* but also as something that was transmitted *"…through sexual contact…but not an STI"*. The term 'HPV positive' contributed to women's conceptualisation of HPV as an STI and this was seen as something negative because of the similarity to 'HIV positive'. When they initially received their result, there was uncertainty around how HPV should be classified or labeled:

"I didn't know if it was an STI, like a sexually transmitted infection, or if it was a virus or if it was something that was pre-cancerous"

(Participant 9, 35 years, normal cytology, not in a relationship).

Although all women mentioned the sexually transmitted nature of HPV, women's certainty about HPV being sexually transmitted varied, with some women less certain than others that this was the cause of HPV. The information women had received from healthcare professionals appeared to influence their beliefs.

Alongside their understanding about the sexually transmitted nature of HPV, women described the influence other factors might have in causing HPV, such as whether all women have HPV and it is *"activated"* by stress or hormones, and the role the immune system plays:

"I probably shouldn't, but I googled it and, um, was trying to sort of find out more about it, but I couldn't find stuff… it sort of just was basically saying when I was looking online and that, that it's spread by di- direct contact and it could be from having a low immune system, so even that confused me because I was thinking, 'Could I get it… because I've got a low immune system and, um, not through direct contact'"

(Participant 19, 50 years, abnormal cytology, in a relationship).

"And obviously they're saying it's sexually transmitted but I, I, my understanding was that also it's a bit like a herpes virus in that everybody has it in them but in some people it's activated and in other it lies dormant. Um, so I, the only thing I'm not clear on is if it's something we all have in us that is just activated now and then, by stress or hormones or whatever, or if it is actually only got from sexual transmission"

(Participant 11, 52 years, normal cytology, not in a relationship).

Some women conceptualised HPV as an STI or something that was acquired through unprotected sex; however others did not view HPV in this way or felt it was different to other STIs and this appeared to minimise the negative emotional and psychosocial impact of testing HPV positive. It was felt that if HPV was not tested for as part of a sexual health screening then it could not be a *"serious sexual thing".* Women who did not consider HPV an STI did not feel

embarrassed or ashamed disclosing their HPV infection as they felt it was just a *"biological medical thing"* similar to an abnormal cytology result. A lack of concern about transmitting HPV to a sexual partner because HPV was not *"…like gonorrhoea or syphilis or HIV or something where you could endanger somebody else"* was also mentioned. HPV was viewed differently to other STIs because of its high prevalence and asymptomatic nature.

> *"I think that the taboo of having an STI can be really embarrassing, err so yeah, I think probably people could be embarrassed by it. Not, not me so much, because I know, I'm in, you know, a long-term relationship and it's just something I could have picked up… Erm I think a lot of people know what Chlamydia is, well, I didn't know what HPV was, but if someone said Chlamydia, you know what it is, and you associate it with certain… It's wrong, but you stereotype it a little bit. Whereas because I hadn't heard of HPV, to me it wasn't kind of in the same area as Chlamydia"*
>
> (Participant 16, 25 years, normal cytology, in a relationship).

HPV dormancy

Participants understood that an HPV infection could stay in the body for several years or lie dormant. Knowing that HPV could lie dormant led some women to believe that they may have acquired the infection several years previously.

> *"…I think I know that you can carry this virus around yourself for years and years and years and it might not come to anything and then all of a sudden… so it could have been something from years previously, as it most probably was with me"*
>
> (Participant 15, 44 years, normal cytology, not in a relationship).

The realisation that an HPV infection could have been acquired several years previously and had been lying dormant provided reassurance that HPV had not come from their current partner and reduced concerns about infidelity. However, the idea that HPV could lie dormant also caused confusion. Women questioned how long the virus could lie dormant for, why it had not *'shown up'* on previous screening tests and how it could be present when they had not recently been sexually active. Understanding how HPV can lie dormant influenced women's

beliefs about the source of their HPV infection, for example one woman felt that unless an HPV infection could lie dormant for many years, her partner must be the source of her HPV infection:

> *"…he denies that I got it from him, but unless you can keep it dormant more than fifteen years ago, um, it's gotta have come from him…"*
>
> (Participant 19, 50 years, abnormal cytology, in a relationship).

Concern about transmitting HPV

While some women were concerned about transmitting their HPV infection to their partner, others felt that HPV was something that was *"more harmful to a female than it was to a male".* Believing that HPV was not something that would affect a male sexual partner allowed women to justify why they had not disclosed having HPV to a male sexual partner. Some women felt that they would be more concerned about transmitting HPV if they were single, however believing that they had probably already transmitted their HPV infection to their long-term partner provided reassurance.

Persistent HPV infection

Having a persistent HPV infection appeared to influence the negative emotional and psychosocial impact of testing HPV positive. A small number of women who had tested HPV positive more than once mentioned that HPV did have an impact on their sexual relationship when they received their first result. However, at the time of the interview it was no longer having an impact, partly because their knowledge about HPV had increased. Among this group of women, their main concern was that they had not cleared their HPV infection.

> *"I think originally I'd been worried you know, like, who did I get it from or how did I get it? And now that I think like it's – it's quite normal, I don't worry about it as much"*
>
> (Participant 4, 31 years, abnormal cytology, in a relationship).

Knowledge of HPV

Awareness of the high prevalence of HPV and that it was something that could go away by itself without any treatment also appeared to reduce the negative emotional and psychosocial impact of testing HPV positive:

> *"…it was explained to me that it, that basically it, it's very common, a lot of people have it, um, it clears itself, there's nothing you can take for it, um that it comes and goes, they could test me again next month and it could not be there. Um, you know, that, that basically it was nothing to worry about"*
>
> (Participant 11, 52 years, normal cytology, not in a relationship).

In contrast, not having thought about the potential impact HPV could have on a relationship because of a lack of knowledge also appeared to act as a buffer to negative emotional and psychosocial responses:

> *"Yeah, I suppose I don't know what… the impact it could have. This – this may be a very different answer once I've now gone and done some research"*
>
> (ID 21, 44 years, abnormal cytology, dating or in a casual relationship).

5.4.2.6: The role of relationship status

The study aimed to explore the psychosexual impact and disclosure experiences of women both in a relationship and not in a relationship. Some psychosexual responses were only described by women who were in a relationship, such as the impact of an HPV positive result on sex and sexual relationships (e.g. reduced interest in and frequency of sex and ending a relationship) and concerns about trust and infidelity. Some of the factors that influenced women's decision to disclose were unique to women in a relationship, for example, concern about transmitting HPV. Concerns about disclosing to a partner were only mentioned by women in a relationship. Only one woman mentioned disclosing her HPV positive result to a previous partner.

Relationship status also appeared to influence how women reflected on psychosexual impact. Women in a relationship spoke more about the impact

testing HPV positive had on their current relationship and women not in a relationship spoke more about the potential impact on their future relationships. Some of the woman who had received more than one HPV positive result who were not currently in a relationship, described the impact that their HPV positive result had on their previous relationship.

Emotional responses to an HPV positive result such as worry, shock and surprise, self-stigma, self-blame and embarrassment and shame were mentioned by women regardless of their relationship status. Questioning the source of their HPV infection and concerns about transmitting HPV were also described by women in a relationship and women not in a relationship.

5.5: Discussion

5.5.1: Main Findings

This study qualitatively explored the psychosexual impact and disclosure experiences of women who had tested HPV positive in the context of HPV-based cervical screening. The magnitude and extent of psychosexual impact among women testing HPV positive varied. This allowed me to go beyond previous literature and identify several factors which appear to influence women's psychosexual response to testing HPV positive. The sexually transmitted nature of HPV, and aspects relating to the transmission of HPV and where their HPV infection had come from, had an impact on women's current, past and future interpersonal and sexual relationships. Women's psychosexual response to testing HPV positive was influenced by how they conceptualised HPV, their understanding of key aspects of HPV such as its high prevalence and dormancy, concerns about transmitting HPV and having a persistent HPV infection.

5.5.2: Interpretation

Several of the emotional and psychosocial responses to testing HPV positive described by women in this study, such as questioning the source of their HPV infection, being concerned about transmitting HPV to a sexual partner and reduced interest in and frequency of sex, are consistent with the qualitative

synthesis I carried out as part of my systematic review (Study 1a, described in Chapter 2). Some of women's disclosure-related responses, such as questioning whether disclosure is necessary and feeling concerned about disclosure because of the stigma that was attached to having an STI, and how their partner would respond, are also consistent with my qualitative synthesis (Study 1b, described in Chapter 3).

My findings are also similar to those of a previous study which explored the psychosocial impact of testing positive for the genital herpes virus (Melville et al., 2003). Melville et al. (2003) identified three main themes from their data: (1) Short-term emotional responses (e.g. anger, fear, guilt), (2) Short-term psychosocial responses (emotional responses but related to potential social interactions, e.g. anger at the perceived source of the infection, fear of telling a sexual partner about their genital herpes diagnosis, guilt over potentially infecting a partner) and, (3) Ongoing responses due to the chronic nature of genital herpes. Based on these results, Melville et al. (2003) developed a model of psychosocial responses to a genital herpes diagnosis. This acted as the foundation for the model I have developed of psychosexual responses to an HPV positive result.

In my model, how women conceptualised HPV, HPV dormancy, concern about transmitting HPV, having a persistent HPV infection and knowledge of HPV were factors which appeared to influence women's psychosexual response to testing HPV positive. Previous qualitative research has identified knowledge of HPV's high prevalence, spontaneous clearance, aspects relating to transmission and dormancy and how women conceptualise HPV as factors which can influence and potentially minimise the adverse psychosocial impact of testing HPV positive (McCaffery et al., 2006; O'Connor et al., 2014; Waller, McCaffery, Nazroo, & Wardle, 2005). Future research will need to explore the influence of these factors in quantitative studies, but my model provides a starting point for explaining the variation in psychosexual response among women testing HPV positive.

Feeling 'dirty', embarrassed and ashamed, and concerned about disclosure, are common responses among individuals diagnosed with other STIs such as genital herpes, genital warts and chlamydia (Melville et al., 2003; Mortensen & Larsen, 2010; Pavlin, Gunn, Parker, Fairley, & Hocking, 2006). The similarities

in responses between testing HPV positive and testing positive for other STIs suggests that some women may view HPV as an STI. Although all women were aware that HPV is sexually transmitted, some did not view HPV as an STI or felt it was different to other STIs and this appeared to minimise the negative psychosexual impact of testing HPV positive. While HPV is classified as an STI, it differs from other STIs as it is normally asymptomatic, does not require treatment and it is not necessary to disclose the infection to a sexual partner. Highlighting these key differences may help women differentiate HPV from other STIs, helping to reduce the stigma and negative psychosexual impact of testing HPV positive. Future research should explore this, because this finding potentially has implications for how information about HPV should be framed.

This study included women who had received more than one HPV positive result, which allowed me to explore psychosexual responses among women with a persistent HPV infection. Some of these women mentioned that HPV did have an impact on their sexual relationship when they received their first HPV positive result, however none reported any adverse impact when they received their most recent HPV positive result. This is in contrast to the findings from Study 2 (described in Chapter 4), which found that women with a persistent HPV infection had similar levels of psychosexual distress to other women testing HPV positive, shortly after they received their results and 6 and 12 months later.

A previous study found that the emotional impact of testing HPV positive a second time was greater for some women, with continued negative psychosexual consequences such as feeling ‘unclean’ and being concerned about transmission and sexual relationships (Waller et al., 2007b). The difference in findings could be due to the heterogeneity among participants in my study. Women in Waller et al. (2007b) were all HPV positive with normal cytology and had received two HPV positive results. In contrast, the women in my study (n=7) had received between two and eight HPV positive results. In addition, all these women had received abnormal cytology results (with their most recent result or previously). Concerns about their HPV infection not having cleared were mentioned, and it is possible that these concerns may have overridden any psychosexual concerns about testing HPV positive. Under the HPV primary screening pathway women with normal cytology could receive up

to three consecutive HPV positive results. Given that these women will not receive any medical intervention between screening tests, future research should explore the information needs among women with a persistent HPV infection as they may differ from those of women testing HPV positive for the first time.

My study explored women's views about future sexual relationships. Previous quantitative research suggests that HPV positive women feel significantly worse about future sexual relationships than HPV negative women (McCaffery et al., 2004). My study found that concern about transmitting HPV or acquiring another STI led some women to feel wary and cautious about future sexual relationships. Concern about transmission and being reluctant to engage in future relationships has been found in previous research with individuals with genital herpes (Melville et al., 2003). To prevent transmission of HPV some women said that they would use condoms or wait until their next screening test before having sex to see if their HPV infection had cleared. While receiving an HPV positive result could be a teachable moment and lead to positive behaviour change (e.g. using condoms to prevent other STIs), it is important that women are made aware that using condoms may not prevent transmission of HPV and that there is no need to wait until their HPV infection has cleared before having sex. Communicating the rationale for this in screening materials may help to reduce concerns about future sexual relationships.

My study explored whether psychosexual impact differed between women who were in a relationship and women who were not in a relationship. Previous research suggests that women who do not currently have a partner have poorer psychosexual outcomes and more negative emotions than women who currently have a partner (Daley et al., 2015; Hsu et al., 2018). My findings did not support this previous research, however there were differences in psychosexual responses between women in a relationship and women not in a relationship. Only women in a relationship mentioned the impact of an HPV positive result on sex and sexual relationships (e.g. reduced interest in and frequency of sex and ending a relationship) and concerns about trust and infidelity. In addition, women in a relationship spoke more about the impact testing HPV positive had on their current relationship and women not in a relationship spoke more about the potential impact on their future relationships.

Negative emotions, questions about the source of the HPV infection and concerns about transmitting HPV were mentioned by both women in a relationship and women not in a relationship. Overall, my findings suggest that regardless of relationship status, testing HPV positive can have a psychosexual impact. This highlights the importance of ensuring that information about HPV and relationships that is provided with screening results is relevant for both women in a relationship and women not in a relationship.

Most women had disclosed their HPV infection to at least one person. The findings from this study suggest that there are a range of factors that influence women's decision to disclose, such as feeling like disclosure was the right thing to do, wanting to be honest with their partner, feeling embarrassed, and concern about others' reactions. Similar factors influence disclosure decisions among participants with genital herpes and (low-risk) HPV (Keller, von Sadovszky, Pankratz, & Hermsen, 2000; Myers et al., 2016).

It is reassuring that no women experienced any long-lasting negative effects of disclosure. Previous research with participants with genital warts has found that partners were more supportive than they had expected following disclosure and participants who had disclosed were less anxious than those who had not disclosed (Scrivener et al., 2008). Contact tracing is not recommended for HPV and therefore the decision to disclose to a sexual partner is a personal choice (World Health Organisation, 2018a). There are likely to be women that choose to disclose and providing narratives of women who have disclosed may be reassuring and reduce concerns about disclosure.

Some women questioned whether it was necessary to disclose HPV to a sexual partner. In England, women who test HPV positive now receive brief information stating that they do not need to tell anyone they have HPV if they do not want to. It is unclear how many women in this study received this guidance and for some, receiving this information may have resolved the questions they had around disclosure. However, some women said that they found the guidance confusing and unhelpful. Future research should explore women's understanding of this guidance and whether there are any additional questions about disclosure that should be addressed.

5.5.3: Strengths and Limitations

While previous qualitative studies have reported psychosexual and disclosure-related outcomes, this is the first study to explore these issues in-depth. A strength of this study is that the sample included women who varied by age, ethnicity and education. I was also able to include women who felt that their HPV positive result had not had any psychosexual impact as well as those who felt that it had. This allowed me to gain an understanding of the factors which influence women's psychosexual response to testing HPV positive.

I recruited four women who had attended cervical screening and self-reported having tested HPV positive as PPI representatives for the study. Three women reviewed study materials to ensure that they were readable, understandable, and appropriate and one woman took part in a pilot interview. Rather than reviewing study materials once they had been produced, the PPI representatives could have played a larger role in my study and helped me to co-produce the research. Co-producing a research project is an approach whereby researchers and members of the public work together throughout a project, from beginning to end (National Institute for Health Research (NIHR), 2021). Using PPI representatives can have a positive impact on all aspects of a research study including developing patient-relevant research questions, using more appropriate recruitment strategies, ensuring the interpretation of data is patient-focused and enhancing the implementation and dissemination of study results (Brett et al., 2014). It is possible that co-producing my study with PPI representatives may have enhanced the quality, appropriateness and relevance of the research (Brett et al., 2014). Due to the COVID-19 pandemic I was required to make changes to the design of the study. Women recruited from Saros have chosen to be a member of a market research panel, therefore the panel may be subject to self-selection bias. Furthermore, women on the research panel chose to take part in my study, therefore my results may be subject to additional self-selection bias. Recruiting participants in this way may have excluded certain groups from taking part in my study and the results may not be transferable to other women who have tested HPV positive. It is possible that if I had been able to recruit participants from primary care as originally planned, a broader range of women who had tested HPV positive would have been invited to take part in the study and my findings may have been different.

Although I was only able to recruit one woman from Jo's Cervical Cancer Trust, this woman's views and experiences were similar to women who were recruited from Saros.

The interviews were carried out during the COVID-19 pandemic when individuals were being advised to stay at home as much as possible. It is possible that women may not have been in a private setting and their responses may have been influenced by others who were nearby (e.g. partners, family).

The timing from when women received their screening results to when they were interviewed ranged from a few weeks to nearly a year, so it is possible that interviewees were susceptible to recall bias. It has been suggested that an emotional response at the time of an experience may not match the emotional response that is remembered in the future, and the experience may be remembered more intensely (i.e. overestimation) or less intensely (i.e. underestimation) (Colombo et al., 2020).

In this study, I did not collect data on women's sexual orientation. Some women felt a lack of concern about transmitting HPV to a male sexual partner because they believed it was not something that would adversely affect them. Women who have sex with women may have different psychosexual concerns compared to women who have sex exclusively with men. Future research should explore this to ensure that the information about relationships and disclosure that is provided to women who test HPV positive is appropriate to all women regardless of their sexual orientation.

The information materials for this study (e.g. study advert, participant information sheet) referred to 'women' which may have excluded individuals with a cervix who do not identify as female from volunteering to take part. Research suggests that transgender men and non-binary individuals find the language and design of cervical screening information materials female focussed, and that this should be avoided as it is a barrier to screening (Berner et al., 2021). Attending cervical screening can cause gender dysphoria among transgender men and non-binary individuals and it is possible that psychosexual distress following an HPV positive result may be different among these groups compared to cisgender individuals (Connolly, Hughes, & Berner, 2020). Research specifically with individuals with a cervix who do not identify as female

is needed, however in general, cervical screening research should aim to use gender neutral language to encourage individuals with a cervix who do not identify as female to take part.

It is possible that some women may not have tested HPV positive in the context of HPV primary screening and so I cannot be sure that all women received the same information with their HPV positive result. The information women received or did not receive with their HPV positive result may have influenced their psychosexual response to testing HPV positive.

5.5.4: Conclusion

This study provides rich information on women's psychosexual response to testing HPV positive and their experiences of disclosing HPV. The findings of this study suggest that testing HPV positive can result in adverse emotional and psychosocial responses which have an impact on women's current, past and future interpersonal and sexual relationships. However, some women appeared to be relatively unaffected by their HPV positive result. In this study, several factors appeared to influence women's psychosexual response to testing HPV positive. Increasing knowledge of the key aspects of HPV, such as its high prevalence and that it can clear spontaneously without any treatment, and the differences between HPV and other STIs, may increase women's understanding of their screening result and reduce any potential negative psychosexual consequences of testing HPV positive

CHAPTER 6: OVERALL DISCUSSION AND CONCLUSIONS

6.1: Aim of the thesis

HPV primary screening has been introduced in the NHS Cervical Screening Programme in England and, due to the sexually transmitted nature of HPV, there may be psychosexual consequences of testing HPV positive. A greater number of women will receive an HPV positive result following HPV primary screening than the number who previously received an abnormal screening result following cytology-based screening. I therefore explored the psychosexual impact of testing positive for high-risk cervical HPV to determine whether additional information and support will be required for women receiving an HPV positive result.

In the following section I will summarise the main findings for each objective of the thesis (aims and objectives are presented in full in Chapter 1).

6.2: Summary of main findings

6.2.1: Review of the existing qualitative and quantitative literature exploring the psychosexual impact of testing positive for high-risk cervical HPV

The objective of Study 1a (described in Chapter 2) was to review the existing quantitative and qualitative literature exploring the psychosexual impact of testing positive for high-risk cervical HPV. In total, 25 studies assessed the psychosexual impact of testing positive for HPV, 12 quantitative studies and 13 qualitative studies. Quantitative studies reported an overall psychosexual impact score and/or aspects of psychosexual functioning such as sexual satisfaction and pleasure, frequency of sex, sexual interest, thoughts about sex and sexual arousal, and feelings about sexual partners and sexual relationships. Two studies measured psychosexual impact longitudinally. Overall, the findings were mixed with some studies reporting that testing HPV positive had a psychosexual impact, while others reported no psychosexual impact.

My thematic synthesis of qualitative studies identified three major themes relating to psychosexual impact: (1) Source of HPV infection, (2) Transmission of HPV and, (3) Impact of HPV on sex and relationships. In contrast to the quantitative studies which assessed specific aspects of sexual behaviour (e.g. sexual interest and arousal), my thematic synthesis highlighted common questions and concerns not measured in the quantitative studies such as the source of the infection, whether partners can re-infect each other and how to prevent the transmission of HPV.

While my review drew together what was currently known about the psychosexual impact of testing positive for high-risk cervical HPV, the diversity of the quantitative study designs and comparison groups made it difficult to conclusively determine the psychosexual impact of testing HPV positive. However, some studies suggested that testing HPV positive did have a psychosexual impact. This highlighted the need for further research, particularly in the context of HPV primary screening, as none of the studies included in the review were carried out in this setting.

6.2.2: Review of the existing literature exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner

The objective of Study 1b (described in Chapter 3) was to review the existing quantitative and qualitative literature exploring concerns about disclosing a high-risk cervical HPV infection to a sexual partner. In total, thirteen studies, which were predominantly qualitative (n=12), were included. Only one quantitative study reported outcomes regarding concerns about disclosing HPV to a sexual partner, with 60% of HPV positive women feeling that disclosing their HPV positive result was ‘risky’.

My thematic synthesis of qualitative studies identified three major themes: (1) Anticipated psychological impact of disclosure, (2) When is disclosure necessary? and, (3) Managing disclosure. Women reported feeling anxious, worried and fearful about disclosing HPV to a sexual partner. These concerns were partly because of the stigma associated with having an STI and the ways in which women anticipated their partners might respond. Women questioned whether it was necessary to disclose, particularly to male partners, as they were

unsure of the impact HPV might have for them. Some women who had tested HPV positive used strategies to manage disclosure of their HPV positive result to a sexual partner, such as focusing on having an abnormal screening result rather than HPV, which helped to minimise anxiety and avoid embarrassment or the complication of explaining about HPV.

6.2.3: Assessing psychosexual distress following routine HPV primary screening in the context of the English Cervical Screening Programme

The objective of Study 2 (described in Chapter 4) was to assess psychosexual distress following routine HPV primary screening in the context of the English Cervical Screening Programme among women receiving different HPV and cytology results, at three time points over a year: shortly after they received their results ('baseline') and 6 and 12 months later. My second study addressed some of the limitations of the studies included in my systematic review. It was carried out in the context of HPV primary screening, assessed psychosexual distress over time and used a validated measure specific to receiving an abnormal Pap smear result (PEAPS-Q) which had been used in a previous study assessing the psychosocial impact of HPV testing in the context of HPV triage (Maissi et al., 2005).

At all three time points, women who tested HPV positive, regardless of their cytology result, reported higher psychosexual distress than women who received a normal cytology result and were not tested for HPV. HPV negative women who had tested positive 12 months previously ('HPV cleared' group) also had higher psychosexual distress shortly after receiving their HPV negative result and 12 months later. Psychosexual distress declined between baseline and 6 months among HPV positive women and women in the HPV cleared group. The decline in psychosexual distress from baseline was similar at the 12-month follow-up to the 6-month follow-up. The most endorsed items at all three time points concerned infectivity. Shortly after receiving their screening results, around 25% of women who were HPV positive reported that they were concerned about giving HPV to their partner.

6.2.4: Exploring the psychosexual impact and disclosure experiences of women who have tested HPV positive in the context of HPV-based cervical screening

The objective of Study 3 (described in Chapter 5) was to explore the psychosexual impact and disclosure experiences of women who had tested HPV positive in the context of HPV-based cervical screening. I interviewed 21 women aged 25 to 64 years who self-reported having tested HPV positive (with normal or abnormal cytology) following cervical screening in the last 12 months.

The study suggested that testing HPV positive can result in adverse emotional and psychosocial responses and that this can have an impact on women's current, past, and future sexual relationships. However, some women appeared to be relatively unaffected by their HPV positive result. Most women had disclosed their HPV infection to someone (i.e. partner, family or friends), however the factors influencing their decision to disclose varied. These factors included feeling like disclosure was the right thing to do, wanting to be honest with their partner, feeling embarrassed, and concern about others' reactions.

This study added to the literature on the psychosexual impact of testing HPV positive by identifying factors which appeared to influence women's psychosexual response. Women's psychosexual response to testing HPV positive was influenced by how they conceptualised HPV, their understanding of key aspects of HPV such as its high prevalence and dormancy, concerns about transmitting HPV and having a persistent HPV infection. While previous studies have identified factors which may influence women's psychological response to testing HPV positive (e.g. anxiety), to my knowledge this is the first study to identify factors which may influence psychosexual response.

6.3: Overall findings of the thesis

This thesis provides both quantitative and qualitative evidence that testing positive for high-risk cervical HPV can have a psychosexual impact. There were several similarities in findings across my studies. Concern about transmitting HPV to a sexual partner was identified as a theme in my qualitative synthesis (Study 1a). In my quantitative study (Study 2), around 25% of women who were HPV positive reported that they were concerned about transmitting HPV to their partner. Concerns about transmission were also raised by women in my

qualitative study (Study 3), and moreover, concern about transmitting HPV was a factor which appeared to influence women's psychosexual response to testing HPV positive.

There were several other findings which were consistent across studies. Questioning the source of an HPV infection, infidelity concerns and reduced interest in and frequency of sex were identified as common themes in both my qualitative synthesis (Study 1a) and qualitative study (Study 3). Concerns about disclosure and questions about whether it is necessary to disclose were also highlighted in both my qualitative synthesis (Study 1b) and qualitative study (Study 3).

The only theme in my qualitative synthesis (Study 1a) that was not mentioned by any women in my qualitative study was concern about the risks associated with oral sex. In my qualitative synthesis, women were concerned about passing on HPV to their partner in this way and the potential for it to lead to oral cancer. It is interesting that no women in my qualitative study discussed this given that they recognised that HPV could be transmitted through any type of sexual activity and concerns about transmitting HPV were common. However, knowledge of HPV as a risk factor for oral cancer has been found to be low, with a systematic review suggesting that between 1 and 44% of the general population are aware of the association (Dodd, Waller, & Marlow, 2016). I did not ask women directly if they had concerns about oral sex. It is possible that women were not aware that HPV is a risk factor for oral cancer, and this is why it was not mentioned.

While this thesis provides evidence that testing positive for high-risk cervical HPV can have a psychosexual impact, findings from all three of my studies suggest that the magnitude and extent of psychosexual impact among women testing HPV positive varies and some women appear to be relatively unaffected by an HPV positive result. The findings from my quantitative study (Study 2) suggested that overall, levels of psychosexual distress were low, even among women testing HPV positive. The (adjusted) mean psychosexual distress score for women in the HPV positive with normal cytology group at baseline was 2.37. A score of 2 on the PEAPS-Q scale indicates that women experienced 'A little' psychosexual distress. Therefore, for most women, it is unlikely that testing HPV positive would have a meaningful impact on psychosexual functioning.

However, the findings from all three of my studies suggest that there are women who have concerns. Even if a very small percentage of women attending screening experience adverse psychosexual consequences following an HPV positive result, this could have a negative impact on a large number of women. Efforts to address psychosexual concerns at a population level are important because the benefits of screening should outweigh the harms (Public Health England, 2015).

6.4: Strengths and limitations of the thesis

The strengths and limitations of each individual study can be found in the corresponding discussion section (Chapters 2 to 5). The strengths and limitations presented here apply to the thesis as a whole.

6.4.1: Methodological approach

My thesis used both quantitative and qualitative methodology. This allowed me to triangulate some of my findings. Triangulation, using more than one approach to address a research question, is a method that can be used to increase the validity and confidence in findings (Heale & Forbes, 2013; Noble & Heale, 2019). Triangulation can also be used to potentially overcome bias that may arise from using either quantitative or qualitative research alone (Williamson, 2005). Methodological triangulation was used in this thesis (comparing findings generated using different methods), however other forms of triangulation such as triangulation of sources, triangulation through multiple analysis and theory triangulation, exist (Ritchie & Lewis, 2010).

Although different research methods were used, there were several similarities in findings across my three studies (these have been described in the previous section of this Chapter). For example, concern about transmitting HPV was identified as a theme in my qualitative synthesis (Study 1a). Similar concerns were raised by women in my qualitative study (Study 3), and concerns about infectivity were the most endorsed items in my quantitative study (Study 2). The consistency between studies increases the credibility and confidence in these findings.

Triangulation can also be used to explain research findings and provide a more balanced view (Heale & Forbes, 2013). In my thesis, quantitative and qualitative methods complemented each other and provided equally important insights into the psychosexual impact of testing HPV positive. For example, my quantitative study (Study 2) provided information on the prevalence and magnitude of psychosexual distress, while my qualitative study (Study 3) provided a more in-depth exploration of the psychosexual consequences and disclosure experiences of women testing HPV positive and why there might be variation in psychosexual response. In addition, had I not included both quantitative and qualitative studies in my systematic review, I would not have identified some of the psychosexual concerns women have, such as concern about where the infection came from and transmitting HPV to a partner, which were not measured by the quantitative studies.

6.4.2: Selection bias

Studies 2 and 3 involved the recruitment of participants. As participation in these studies was voluntary, it is likely that self-selection bias occurred. It is possible that participants chose to take part in the research for reasons related to the topic of study (e.g. because they were interested in, or affected by it), which may have biased my findings.

In my quantitative study (Study 2), the response rate at baseline was 21%. Of the women responding to the baseline questionnaire, 32.2% did not respond to the 6-month follow-up and 52.1% did not respond to the 12-month follow-up. Therefore, the participants who chose to take part in the study may not represent the HPV primary screening pilot population. To adjust for this, I was able to apply population weights based on age group and socioeconomic status (IMD), two of the characteristics that differed between responders and non-responders at all three time points. I was unable to apply population weights for other variables which may have been important, such as marital status, as I did not have this data for non-responders. However, there were no differences in baseline psychosexual distress score between responders and non-responders at either the 6 or 12-month follow-up, suggesting that psychosexual distress was not associated with responding to the questionnaire.

In my qualitative study (Study 3) I used a market research participant recruitment agency to recruit participants. It is likely that members of a market research recruitment panel are motivated to, and experienced with, taking part in research. The market research agency did not have information on the number of eligible participants (i.e. the total number of women testing HPV positive in the last 12 months), so I was unable to calculate a response rate. In addition, I was not able to interview all women who were eligible and expressed an interest in taking part in the study due to the large number of responses (n=89).

However, because of the large number of responses, I was able to recruit a diverse sample of women who varied by age, education, ethnicity, self-rated HPV knowledge and sexual impact. I was interested in exploring differences in psychosexual response by relationship status and was able to recruit equal numbers of women in a relationship and not in a relationship. In addition, I was able to achieve data saturation. I followed the principles for determining data saturation outlined by Francis et al. (2010) which suggests that once three consecutive interviews have been conducted with no new emerging themes it can be concluded that data saturation has been achieved and data collection can end. I initially interviewed 17 women. Following this, three further interviews were conducted in which no new themes emerged, and I was therefore able to conclude that data saturation had been achieved.

However, as I used a market research agency to recruit participants it is possible that some groups of women may have been excluded from my research. Individuals with low literacy or limited English language skills may be less likely to be a member of a market research panel. Individuals with limited digital skills, or those who do not have access to digital technologies (e.g. computer, mobile phone, email etc.) may also be less likely to be a member of a research panel. Distrust in research has been found to be more prominent amongst ethnic minority groups, so it is possible that some ethnic minority groups may also be underrepresented in the research panel (Sheridan et al., 2020). It is possible that women recruited in different ways (e.g. by post or from ethnic minority community groups) may have differed in terms of demographic characteristics and may have different views or experiences.

There may also be women who were members of the market research panel who were less likely to take part in my research. There may have been practical barriers to taking part, for example women may have had caring or employment responsibilities and therefore may not have had time to take part (Sheridan et al., 2020). Women may not have wanted to disclose that they had tested HPV positive, either to the market research agency or myself. After initially agreeing to take part in my research, one woman later declined as she did not want to talk about her sexual relationships. It is possible that other women chose not to express an interest in taking part in my studies because they did not feel comfortable thinking or talking about the impact of testing HPV positive on their sexual relationships with a researcher that they did not know.

In addition to recruiting women from a market research agency, I aimed to recruit women via an advert placed on the Jo's Cervical Cancer Trust website as I anticipated that the psychosexual impact of testing HPV positive may be greater among these women (because they are likely to be looking at the website for additional information or support). However, I was only able to recruit one woman this way. In addition to some of the reasons described above (e.g. not wanting to disclose that they had tested HPV positive and not feeling comfortable discussing the impact of testing HPV positive on their sexual relationships), there may be other reasons why this method of recruitment was not more successful. Although my name was given on the advert, it was not clear that the interview would be with me, or with a female researcher. The incentive for taking part was also not mentioned, which may have been a barrier to taking part for some women. These aspects were both mentioned on the market research agency advert. Finally, it is possible that woman did not come across the advert as it was separate to the information and support sections on the Jo's Cervical Cancer Trust website (the advert was under the section 'Get involved').

All individuals with a cervix should attend cervical screening. In my qualitative study (Study 3), the information materials (e.g. study advert, participant information sheet) referred to 'women' which may have excluded individuals with a cervix who do not identify as female from volunteering to take part in the study. The views and experiences of individuals with a cervix who do not identify as female are important and it is a limitation that I was not able to recruit

anyone from this population. Using more gender-neutral language and a more targeted approach to recruitment, for example advertising the study in a sexual health service for transgender and non-binary individuals or a gender identity clinic, may have allowed me to recruit individuals from these groups.

In recent years the discussion around sex and gender as distinct concepts has increased and healthcare approaches and policies have become more inclusive (Bewley, McCartney, Meads, & Rogers, 2021; Ion, Patrick, Hayter, & Jackson, 2021). The Royal College of General Practitioners recommends that sex and gender are recorded separately in medical records, and it has been suggested that gender-affirming health care should be included in the curricula for health care students (de Vries, Kathard, & Müller, 2020; The Royal College of General Practitioners, 2019). In addition, the Sex and Gender Equity in Research (SAGAR) guidelines now exist to promote the reporting of sex and gender information in research publications (Heidari, Babor, De Castro, Tort, & Curno, 2016). Given this, had I been starting my PhD now, in 2021, it is likely that greater consideration would have been given to gender identity from the outset.

In summary, these biases in recruitment and participation may have an impact on how transferable my findings are. My findings may be transferable to individuals with similar characteristics to my sampled population, however as I did not recruit individuals from all populations who are eligible for screening, it is possible that my findings may not be transferable to all individuals who test HPV positive. The biases in recruitment and participation may also have an impact on the implications of the research included in this thesis as it is possible that the findings may be an under or over representation of psychosexual impact in different populations (e.g. transgender men, non-binary individuals and ethnic minority groups).

6.4.3: Influence of the researcher

It is important to acknowledge the influence that I might have had on the collection and interpretation of data.

In my systematic review (Studies 1a and 1b), the approach taken in selecting studies for inclusion, extracting data from studies and the coding of qualitative studies was largely carried out independently and could be viewed as

subjective. In my review I screened all article titles independently and it is possible that I may have excluded some titles that should have been included. However, I feel this is unlikely as I searched the reference lists and carried out forward reference searching for all included articles. I also extracted data for each included article, developed a coding frame and coded each qualitative study that was eligible for inclusion. Data extraction and second coding was carried out on a subset of articles to reduce the likelihood of error and bias. In addition, I discussed the coding frame and findings, and any uncertainties regarding data extraction or coding, with other researchers.

Study 3 used qualitative methodology. It is important to acknowledge that my social position (e.g. gender, age, ethnicity, professional role), personal experiences and beliefs may have influenced research processes and outcomes (Berger, 2015; Richards & Emslie, 2000). My qualitative study was the final study I carried out and it is possible that the inferences I drew from the data may have been influenced by my knowledge of what was found in my previous two studies. It is possible that I subconsciously looked for data which confirmed previous findings, overlooked new data, or data which was inconsistent with previous findings (Smith & Noble, 2014). However, I held regular meetings to discuss emerging findings during the analysis phase of this study with my supervisory panel which should have helped to ensure that my analysis was rigorous and reflected the data.

6.4.4 Patient and Public Involvement (PPI)

PPI representatives can be involved in all stages of a research study including the development of the research questions as well as the design, analyses, write-up and dissemination of research findings. It is a limitation that PPI representatives were not involved in all aspects of my research. Since beginning my PhD, using PPI representatives in research studies has become increasingly more common and it is now expected that PPI representatives should be involved in all stages of a research study. When I was designing my studies, although I was aware of the importance and benefits of using PPI in research studies, involving PPI representatives in the development of the research questions was not expected as it is today, which is why PPI representatives were not involved in this aspect of my research. Involving PPI

representatives from the outset of my PhD may have influenced the studies I carried out and subsequently, my findings.

6.4.5 Approach to the thesis

This thesis took a pragmatic approach, rather than a theoretical approach, to address the aim of exploring the psychosexual impact of testing positive for high-risk cervical HPV. The focus of my PhD was on establishing practical recommendations for screening programmes introducing HPV primary screening. This was largely driven by the PIPS study which was the starting point for my thesis (described in Chapter 4). The PIPS study was commissioned by PHE who wished to identify any psychological issues experienced by women testing HPV positive. However, there are a lack of theoretical frameworks in the HPV and wider STI field and previous attempts to explain psychological and psychosexual responses to testing HPV positive have been largely atheoretical (McBride et al., 2020c). Discussing my findings in the context of a theoretical framework may have helped to advance our understanding of this topic by exploring the reasons why women experience psychosexual distress. Not doing so is a limitation of this thesis.

My quantitative study (Study 2) had been designed prior to me beginning my PhD and so it was not possible to use theory in this study. In my qualitative study (Study 3) I designed a conceptual model, but this was not based on an existing theoretical framework. Leventhal's Common Sense Model of Self-Regulation provides an explanation for why individuals vary in their response to a health threat (Leventhal, Meyer, & Nerenz, 1980). According to the model, individuals cognitive and emotional representations of a health threat may motivate individuals to form an appropriate coping response (e.g. avoidance, cognitive reappraisal, seeking social support) (Leventhal, Diefenbach, & Leventhal, 1992). An individual's coping response can in turn influence emotional and illness outcomes (Leventhal et al., 1992). Leventhal's model suggests that cognitive illness representations fall into five dimensions: (1) Identity (the label given to, and the symptoms of, an illness, (2) Perceived cause of the illness, (3) Timeline (how long the illness will last), (4) Consequences (the possible effects of the illness) and, (5) Control (whether the illness can be prevented or treated) (Leventhal et al., 1980). I explored whether the data from

my qualitative study mapped on to the five illness representation dimensions, however it only appeared to do so partially and there were several findings which did not map on to any of the illness representations. Melville et al. (2003) developed a model of psychosocial responses to a genital herpes diagnosis and this acted as the foundation for the model I developed of psychosexual responses to an HPV positive result. As there were several similarities between my results and Melville et al.'s, I felt that an adapted version of this model was a better fit for my data.

I also could have attempted to map the findings from my systematic review to a theoretical framework. A systematic review by McBride et al. (2020) mapped emotional responses to an HPV positive result to an adapted version of the cognitive behavioural model, illustrating how emotions, behaviours and cognitions interact to influence one another. In addition to Leventhal's Common Sense Model of Self-Regulation, Taylor's Theory of Cognitive Adaptation may also have been an appropriate theoretical framework to structure both the results from my qualitative study and my systematic review (Taylor, 1983). Taylor's Theory of Cognitive Adaption proposes that when individuals experience a threatening event, such as illness, they readjust to their new situation. The readjustment process focuses on three components: (1) The search for meaning (attempting to understand why something has happened and its impact, (2) Gaining a sense of mastery over the threatening event, to manage it or prevent it from occurring again and, (3) The process of self-enhancement (attempting to restore self-esteem).

Establishing the theoretical constructs which predict or explain variation in psychosexual response is important. Theoretical constructs which negatively influence psychosexual response can be targeted in interventions with the aim of improving psychosexual outcomes. Interventions are more likely to be effective if they target the causal determinants of a behavioural outcome (Michie, Johnston, Francis, Hardeman, & Eccles, 2008).

6.5: Implications for policy

There are several advantages of HPV primary screening over cytology-based screening, the main one being its increased sensitivity for detecting high-grade cell changes (Cuzick et al., 2006; Ronco et al., 2014; Ronco et al., 2010).

Despite the advantages of HPV testing, an essential criterion for any screening programme is that the benefit gained by individuals should outweigh the harms (Public Health England, 2015). Therefore, it is important to understand, address and minimise any adverse psychosexual consequences of testing HPV positive.

The findings from my three studies suggest that testing HPV positive can have a psychosexual impact, particularly in the short-term. Efforts to address the psychosexual concerns women have are important given that 12.7% of women received an HPV positive result in the English HPV primary screening pilot (Rebolj et al., 2019b). In England between 2018 and 2019, around 3.5 million women attended cervical screening (Screening & Immunisations Team (NHS Digital) & PHE Screening (Public Health England), 2019). If the number of women receiving an HPV positive result is similar to the English HPV primary screening pilot, this would equate to around 450,000 women. Even if a very small percentage of women experience adverse psychosexual consequences following an HPV positive result, this could have a negative impact on a large number of women. To help mitigate any psychosexual consequences of testing HPV positive, additional information may be required. The following sections will describe: (1) What information to provide, (2) Who might need this information the most, (3) How the information could be provided and, (4) When to provide this information.

What information should be provided?

It is important to increase knowledge and awareness that HPV is very common and that it can clear without treatment. In my qualitative study (Study 3), women who were aware of these aspects of HPV mentioned fewer negative psychosexual consequences of testing HPV positive. In a previous hypothetical study where women were asked to imagine that they had tested HPV positive, women who were aware that HPV was very common had lower levels of stigma and shame, suggesting that normalising HPV may be beneficial (Waller et al., 2007a).

Information addressing concerns about transmitting HPV to a sexual partner should be provided as the findings from all three of my studies highlighted that women have concerns about this. Information should also address concerns about where the infection came from. This was another concern raised by

women in my qualitative synthesis of the existing literature (Study 1a) and my qualitative study (Study 3). Addressing these concerns may help to mitigate any psychosexual consequences of testing HPV positive.

Providing additional information to minimise any unnecessary concern surrounding disclosure would benefit women. Whether it is necessary to disclose HPV was mentioned by women in both my qualitative synthesis (Study 1b) and my qualitative study (Study 3). In England, women who test HPV positive now receive targeted information on the back of their results letter stating that they do not need to tell anyone they have HPV if they do not want to. However, some women in my qualitative study found this guidance confusing. Information explaining *why* it is not necessary to disclose may be needed. In addition, some women will choose to disclose and information to support them to have this conversation with their partner may be helpful and provide reassurance.

The findings from my qualitative study (Study 3) suggest that some women conceptualised HPV as an STI, however others did not view HPV in this way, or felt it was different to other STIs, and this appeared to minimise the psychosexual consequences of testing HPV positive. Although HPV is sexually transmitted, it differs from other STIs as it is normally asymptomatic and does not usually need treatment or cause any long-term problems. Communicating these differences to women is important and may help to reduce any psychosexual impact triggered by the STI label. In addition, rather than describing HPV as an STI, it may be beneficial to refer to it as an infection that is passed on by skin-to-skin contact during any type of sexual activity. This is an approach already being advocated by Jo's Cervical Cancer Trust in an attempt to reduce stigma, fear and confusion about HPV (Jo's Cervical Cancer Trust, 2020c, 2020e).

Who might need this information the most?

It is likely that women receiving their first HPV positive result will benefit from this information the most. The findings from my qualitative study (Study 3) suggest that having a persistent HPV infection (i.e. having received more than one HPV positive result) reduced the negative psychosexual consequences of

testing HPV positive. In addition, in my quantitative study (Study 2), psychosexual distress was slightly lower among women in the HPV persistent group (who had received two consecutive HPV positive results) than women in the HPV positive with normal cytology and HPV positive with abnormal cytology groups. Psychosexual distress was highest among women in the HPV positive with normal cytology group. Given that women receiving this result will not receive any medical intervention between screening tests, or have the opportunity to discuss the meaning of their results with a healthcare professional, providing high-quality reassuring information to this group is particularly important.

There are also groups of women at greater risk of experiencing psychosexual distress who are likely to benefit from this information. For example, in my quantitative study (Study 2), I found there were significant differences in psychosexual distress by marital status and socioeconomic status (IMD). Women who were single and those living in the most deprived areas had the highest levels of psychosexual distress, while women who were married or in a civil partnership and those living in the least deprived areas had the lowest levels of psychosexual distress. In the NHS Cervical Screening Programme printed materials (i.e. screening leaflets and results letters) are used so it is currently unfeasible to provide additional information to these specific groups. However, the move towards using digital methods for providing screening information may present an opportunity for tailored information to be used in the future (Public Health England, 2019c).

How to provide this information?

Information should be provided in screening materials and results letters for women testing HPV positive. However, not all women will find written information engaging. In addition, some women may find the information difficult to understand. Previous research suggests that interpretations of the cervical screening information leaflet that is sent to women when they are invited for screening are less accurate among women with lower education and lower numeracy and women from ethnic minority backgrounds (Okan, Petrova, Smith, Lesic, & Bruine de Bruin, 2019). Determining the optimal amount of information

to provide is also important. It is likely that a multifaceted approach to information provision will be needed.

In my qualitative study (Study 3), many women reported having looked online or having spoken to a healthcare professional for more information. This is consistent with other studies in the context of HPV primary screening (Marlow et al., 2020; McBride et al., 2020a). Previous research has found that women who felt inadequately informed about HPV sought further information, frequently on the internet, which led some women to come across information on genital warts (low-risk HPV) which increased embarrassment and shame (McCaffery & Irwig, 2005). Providing a link to a reputable website in screening materials and results letters would allow women to seek accurate additional information if required. In addition, videos could also be created and placed on this website to explain different screening results, which some women may find more accessible. In my qualitative study (Study 3), many women reported looking at the NHS website as this was a trusted source of information. Some women looked on the Jo's Cervical Cancer Trust website and found the information useful and easy to understand, however the reference to cervical cancer in the charity's name was disconcerting to some women. This suggests that the website where any additional information is provided is important.

Healthcare professionals can play a key role in minimising any adverse psychosexual consequences of testing HPV positive. Healthcare professionals carrying out cervical screening should be trained to give brief information during screening to ensure that women understand their results when they receive them.

In England, most cervical screening is carried out in primary care and it is likely that healthcare professionals working in this setting will be the first point of call for many women testing HPV positive who have psychosexual concerns. However, given that HPV is sexually transmitted, healthcare professionals working in sexual health services may also be approached by women. Previous research with GPs and practice nurses has identified a number of barriers to discussing an HPV infection with women, many due to HPV's sexually transmitted nature (e.g. embarrassment, not wanting to pass judgement on patients' sexual behaviour, concern that a patient might think they have a sexually transmitted infection or think that their partner is being unfaithful)

(McSherry et al., 2012). It is crucial that healthcare professionals have adequate knowledge about HPV and cervical cancer risk and feel comfortable and confident responding to women's concerns, which may require additional training.

When to provide this information?

The findings from my quantitative study (Study 2) suggest that receiving an HPV positive result can lead to elevated psychosexual distress shortly after receiving the result, which declines in the following six months. These findings have implications for when interventions to reduce psychosexual distress may be most impactful. Although not carried out in the context of HPV primary screening, previous research has also found that the impact on sexual relationships declined between 1 and 6 months and remained similar at 6 and 12 months (Hsu et al., 2018). Taken together, this suggests that interventions to reduce psychosexual distress are likely to be most beneficial around the time that women receive their results.

6.6: Recommendations for future research

6.6.1: Psychosexual impact in the context of HPV primary screening

6.6.1.1: Further research at a population level

There is currently minimal research exploring the psychosexual impact of testing HPV positive in the context of HPV primary screening because screening in this context has only been introduced relatively recently. Further quantitative research is needed to gain a more comprehensive understanding of the prevalence and magnitude of psychosexual distress following HPV testing among women with different screening results.

To my knowledge, since I carried out my systematic review synthesising the psychosexual impact of testing positive for HPV (Study 1a), seven additional quantitative studies have explored the psychosexual impact of testing HPV positive (Alay et al., 2020; Arrossi et al., 2020; Dodd et al., 2020; Ilgen, Kurt, Kula, & Celiloglu, 2020; Mercan et al., 2019; Sakin et al., 2019; Uysal, Bas,

Gokulu, Okcu, & Destegul, 2018). Most of these studies were carried out in Turkey (n=5) (Alay et al., 2020; Ilgen et al., 2020; Mercan et al., 2019; Sakin et al., 2019; Uysal et al., 2018), and of these, two were carried out in the context of routine cervical screening (Alay et al., 2020; Uysal et al., 2018). Of the five studies carried out in Turkey, psychosexual impact was assessed using the Female Sexual Function Index (FSFI) and/or the Arizona Sexual Experiences Scale (ASEX). Neither of these measures were used by any of the studies included in my systematic review (Study 1a). One study included HPV positive women only (Alay et al., 2020) while the others compared HPV positive and HPV negative women (Ilgen et al., 2020; Mercan et al., 2019; Sakin et al., 2019; Uysal et al., 2018). One study only included women who were HPV positive with normal cytology (Sakin et al., 2019), two studies included women who were HPV positive with normal cytology and HPV positive with abnormal cytology (Alay et al., 2020; Mercan et al., 2019) and the cytology of HPV positive women in the remaining two studies is unknown (Ilgen et al., 2020; Uysal et al., 2018). Of the studies that compared HPV positive and HPV negative women, the findings were mixed with two studies reporting poorer psychosexual outcomes for HPV positive women (Mercan et al., 2019; Uysal et al., 2018) and two reporting no differences in psychosexual outcomes between HPV positive and HPV negative women (Ilgen et al., 2020; Sakin et al., 2019).

The remaining two quantitative studies were carried out in the context of HPV primary screening. One study was carried out in Argentina and used the Psycho-Estampa Scale to measure the psychosocial impact of an HPV positive result (Arrossi et al., 2020). The Psycho-Estampa Scale is a validated measure and consists of five domains, one of which is ‘sexuality’. The sexuality domain assessed interest in sex, frequency of sex and concerns about infectivity. The study included HPV positive women with normal or abnormal cytology. Women who were HPV positive with abnormal cytology had poorer outcomes on the sexuality domain than women who were HPV positive with normal cytology, however the difference between groups was not significantly different.

A second study was carried out in Australia and used the PEAPS-Q to measure psychosexual impact; the same measure that was used in my quantitative study (Study 2) (Dodd et al., 2020). Only HPV positive women were asked to complete the PEAPS-Q items. The mean PEAPS-Q score was 6.14 (potential

range 3-15). This study only used three items from the PEAPS-Q and appeared to calculate the mean score differently (as the potential range of scores in my study was 1-5), so the mean values between the two studies are not comparable.

6.6.1.2: Further research with sub-groups of women

Further research should also be carried out with women who may have been underrepresented in my quantitative and qualitative studies (Studies 2 and 3). This includes women with low literacy, those with limited digital skills, those who do not have access to digital technologies and women who have sex with women. Additional research should also be carried out with women for whom testing HPV positive may have a greater psychosexual impact.

In my quantitative study (Study 2), 90.7% of women were of White ethnicity and 7.6% of women were from ethnic minority groups. The proportion of women of White ethnicity in my study is slightly higher than the figure from the 2011 Census for England and Wales, which found that 86% of the population were of White ethnicity (Office for National Statistics, 2018). However, given that this figure is 10 years old, the proportion of ethnic minority groups in England and Wales may now be higher and it is therefore possible that ethnic minority women were underrepresented in my study. In my qualitative study (Study 3) I was able to recruit seven women from Black, Asian and mixed or multiple ethnic groups. Most of these women were educated to degree level or higher, so it may be beneficial to explore the views and experiences of ethnic minority women with different levels of educational attainment.

My quantitative study (Study 2) used broad ethnicity categories (e.g. Asian/Asian British), however it is possible that there may be differences in psychosexual outcomes between sub-groups of ethnic minority groups (e.g. the Asian/Asian British category comprises of individuals of Bangladeshi, Chinese, Indian and Pakistani ethnic background) (Office for National Statistics, 2018). In addition, there may be important differences in other ethnicity-related factors such as a person's place of birth (i.e. whether they are a migrant or not) and whether they speak English.

Given that the stigma of testing HPV positive may be greater among some ethnic minority groups, research to explore psychosexual distress following HPV testing in ethnic minority groups, migrant populations and those who do not speak English requires further exploration (McCaffery et al., 2003; McCaffery et al., 2006).

Attending cervical screening can cause gender dysphoria among transgender men and non-binary individuals and it is possible that psychosexual distress following an HPV positive result may be different among these groups compared to cisgender individuals. Regardless of gender identity, all individuals who had taken part in the HPV primary screening pilot were invited to take part in my quantitative study (Study 2). However, information on gender identity was not collected and therefore it was not possible to explore differences in psychosexual distress between participants with different gender identities. In addition, I did not recruit any transgender men or non-binary individuals to my qualitative study (Study 3). Quantitative and qualitative research with individuals with a cervix who do not identify as female is needed.

My quantitative study (Study 2) found that HPV negative women who had tested positive 12 months previously ('HPV cleared' group) had significantly higher psychosexual distress compared to the control group (who received a normal cytology result and were not tested for HPV), shortly after receiving their result and 12 months later. While psychosexual distress was not as high in this group as the three HPV positive groups, it suggests that women in this group may still have residual psychosexual concerns despite testing HPV negative. Future qualitative research should explore the psychosexual concerns women in this group have.

6.6.2: Measurement of psychosexual impact and concerns about disclosing HPV

The studies included in my systematic review which synthesised the existing literature on the psychosexual impact of testing HPV positive (Study 1a) used a diverse range of measures and comparison groups to assess psychosexual impact. This made it difficult to summarise the overall impact testing HPV positive might have. The additional studies that have been carried out since then add to the literature on the psychosexual impact of testing HPV positive,

however they are constrained by the same limitations. Future studies should use validated measures specific to HPV testing such as the HPV Impact Profile (HIP) (Mast et al., 2009) and define the cytology results of women testing HPV positive, which would allow comparisons between studies.

My systematic review only identified one existing quantitative article which reported disclosure-related outcomes (Study 1b). To my knowledge, since the review was conducted, no further quantitative research has explored this topic. Concerns about disclosure were described by women in my qualitative study (Study 3) and have been mentioned by women in other qualitative research published since I carried out my systematic review (McBride et al., 2020a). Assessing the prevalence and predictors of these concerns is important. To my knowledge, there is not an existing measure which focuses on concerns about disclosing HPV or an STI so it is likely that one would need to be developed. This measure could include the concerns raised by women in my systematic review and qualitative study (Studies 1b and 3), such as being viewed as promiscuous and concern about how others would react, to ensure that items are contextually appropriate.

In my quantitative and qualitative studies (Studies 2 and 3), participants were not asked whether they had been diagnosed with a generalised anxiety disorder (GAD). Research suggests that women with a current anxiety or depression diagnosis have higher anxiety scores following an HPV positive result (McBride, Marlow, Chilcot, Moss-Morris, & Waller, 2021). It is therefore possible than an existing GAD may also have exacerbated the psychosexual impact of testing HPV positive and concerns about disclosing HPV. Future research should assess whether participants have GAD so this association can be explored and, if necessary, GAD can be adjusted for in any analyses.

6.6.3: Research with partners of women with HPV

In my qualitative study (Study 3), some women described how their partners were uncertain or concerned about the impact that HPV might have for them. Interviewing women who have tested HPV positive, and their partners, would help to gain a broader perspective regarding the impact that testing HPV positive can have on a relationship. It is possible that partners may have questions or concerns about HPV which may have an impact on their

relationship, and their information needs should be explored. Research has been carried out previously with HPV-related head and neck cancer patients and their partners (Dodd, Forster, Marlow, & Waller, 2019). The findings of this study suggested that some patients were concerned about transmitting HPV to their partner and one partner decided to be tested privately for HPV. In the study by Dodd et al. (2019), participants were asked about changes to their relationships, but were not asked specifically about their sexual relationships.

6.6.4: Quantitative research exploring predictors of psychosexual response

My qualitative study (Study 3) identified several factors which appeared to influence women's psychosexual response to testing HPV positive. I used my findings to create a model of psychosexual responses to an HPV positive result (see Figure 5.1) and this could be tested. Future research will need to explore the influence of these factors in quantitative studies, but they provide a starting point for explaining the variation in psychosexual response among women testing HPV positive. Factors which influence psychosexual response could potentially be targeted in screening materials and results letters in the future to minimise psychosexual impact.

6.6.5: Evaluation of existing cervical screening information materials

Since the completion of the roll-out of HPV primary screening across England in December 2019, information about HPV and HPV testing has been provided in screening materials, and women testing HPV positive receive additional information with their results which includes a section on HPV and relationships. This brief information states that most men and women will have HPV at some point in their lives and it does not usually cause any problems. Women are advised that they do not need to tell anyone they have HPV if they do not want to. The information also informs women that using a condom or dental dam during sexual activity can reduce the risk of transmitting HPV to a sexual partner but will not provide complete protection. Future research should evaluate this information to ensure that it is clear and meets women's information needs. In addition, it is important to explore whether the information provided meets the needs of women with different HPV and cytology test results. This is important as the findings from my studies suggest that a 'one

size fits all' approach may not be appropriate. For example, in my qualitative study (Study 3) I found that women who had a persistent HPV infection and had tested HPV positive more than once had fewer psychosexual concerns than women who had recently received their first HPV positive result. In addition, in my quantitative study (Study 2) I found that HPV negative women who had tested positive 12 months previously ('HPV cleared' group) had significantly higher psychosexual distress scores than women who had a normal cytology result who were not tested for HPV. This suggests that women who had previously tested HPV positive may still have residual psychosexual concerns, despite an HPV negative result, and may require additional information.

Qualitative methods could be used to evaluate the screening information that is currently provided to women. Previous studies have used think aloud tasks, individual interviews and focus groups to evaluate cervical screening information (Goldsmith, Bankhead, Kehoe, Marsh, & Austoker, 2007; Okan et al., 2019). Screening information could also be evaluated using survey-based methods which could be posted to women shortly after they receive their screening results. Carrying out research in the context of the NHS Cervical Screening Programme can potentially lead to improvements to the programme and participant experience. However, there can be challenges to carrying out research in this setting, including the need to obtain Research Advisory Committee (RAC) support for any research involving NHS Cervical Screening Programme participants, in addition to REC and HRA approval, which can be a time-intensive process.

Ideally, carrying out an RCT to evaluate the effectiveness of the screening information in reducing psychosexual concerns would have been carried out prior to the introduction of HPV primary screening. However, it would have been unethical to not provide any information to a control group. In addition, it is likely that carrying out an RCT prior to the introduction of HPV primary screening would have required a significant amount of time. Carrying out an RCT after the introduction of HPV primary screening may have biased the results if the control group had read the information materials. As described above, women with psychosexual concerns may require additional information. Future research could develop additional information to specifically address psychosexual concerns and evaluate its effectiveness using an RCT. RCTs are considered

the ‘gold standard’ for effectiveness research as randomisation can balance participant characteristics so any differences in outcome can be attributed to the intervention (Hariton & Locascio, 2018).

6.6.6: Future theory-based research

This thesis took a pragmatic approach, rather than a theoretical approach, to address the aim of exploring the psychosexual impact of testing positive for high-risk cervical HPV. My quantitative study (Study 2) had been designed prior to me beginning my PhD and theory was not used in the study. A similar study could be designed in the future which includes a theoretically derived measure to explore whether there are theoretical constructs which predict or explain variation in psychosexual response. For example, the nine-item Brief Illness Perception Questionnaire (Brief IPQ) could be used (Broadbent, Petrie, Main, & Weinman, 2006). The Brief IRQ assesses the cognitive illness representations which form part of Leventhal’s Common Sense Model of Self-Regulation (identity, perceived cause, timeline, consequences and personal and treatment control) and an individual’s comprehension and emotional representations of their illness (Leventhal et al., 1980). Using a theoretically derived measure in addition to a measure of psychosexual distress would allow an exploration of the association between psychosexual distress and theoretical constructs. Theoretical constructs which negatively influence psychosexual response can be targeted in interventions with the aim of improving psychosexual outcomes.

6.7: Overall conclusions

In this thesis I used a mixed-methods approach to explore the psychosexual impact of testing positive for high-risk cervical HPV. The thesis examined what is currently known about the psychosexual impact of testing HPV positive and concerns about disclosing HPV to a sexual partner. It also assessed the prevalence and magnitude of psychosexual distress over time in the context of the NHS Cervical Screening Programme in England. Finally, it explored the psychosexual consequences and disclosure experiences of women testing HPV positive following HPV-based cervical screening and some of the factors which may influence women’s psychosexual responses to testing HPV positive. The move to HPV primary screening in England, and elsewhere, will mean hundreds

of thousands of women will receive an HPV positive result each year. Although there are limitations of the studies in my thesis and further research is needed, my findings suggest that testing HPV positive in the context of cervical screening can have an adverse psychosexual impact. Providing clear and consistent information in screening materials and results letters and developing interventions to minimise the psychosexual burden of testing HPV positive will be essential for avoiding unnecessary harm to the millions of women around the world who test HPV positive each year.

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APPENDICES

APPENDIX 2.1: STUDY 1A PUBLISHED PAPER

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REVIEW

WILEY

The psychosexual impact of testing positive for high-risk cervical human papillomavirus (HPV): A systematic review

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Abstract

Objectives: Many countries are implementing human papillomavirus (HPV)-based cervical screening due to the higher sensitivity of the test compared with cytology. As HPV is sexually transmitted, there may be psychosexual consequences of testing positive for the virus. We aimed to review the literature exploring the psychosexual impact of testing positive for high-risk cervical HPV.

Methods: MEDLINE, PsycINFO, CINAHL Plus, Web of Science, and EMBASE were searched with no date limits. We also searched the grey literature, reference lists of included articles and carried out forward citation searching. Eligible studies reported at least one psychosexual outcome among HPV-positive women. Qualitative and quantitative papers were included. We extracted data using a standardised form and carried out a quality assessment for each article. We conducted a narrative synthesis for quantitative studies and a thematic synthesis for qualitative studies.

Results: Twenty-five articles were included. Quantitative study designs were diverse making it difficult to determine the impact that an HPV positive result would have in the context of routine screening. The qualitative literature suggested that psychosexual concerns cover a broad range of aspects relating to women's current and past relationships, both interpersonal and sexual.

Conclusions: The psychosexual impact of testing positive for high-risk cervical HPV is unclear. This review highlights the need for further research in the context of HPV-based cervical screening. As primary HPV testing is introduced more widely, it is important to understand women's responses to testing HPV positive in the cancer screening context to minimise any adverse psychosexual impact.

KEYWORDS

cancer, early detection of cancer, oncology, papillomavirus infections, psychological, sexual dysfunctions, systematic review

1 | BACKGROUND

It is well-established that virtually all cervical cancers are caused by infection with a high-risk type of human papillomavirus (hrHPV),[1-3] a very common sexually transmitted infection (STI)[4] which most sexually active individuals will acquire in their life.[5] There are many types of HPV, some which do not cause cancer but can cause genital warts or verruca's (low-risk HPV) and some which can develop into cancer (high-risk HPV). Fifteen HPV types have been classified as high-risk.[6] Although the underlying cause of cervical cancer is infection with hrHPV, infection with hrHPV does not always cause cancer, and most infections resolve spontaneously in less than 2 years.[7]

Until recently, most cervical screening programmes in high-income countries used cytology to detect cervical abnormalities.[8] However, HPV primary testing, which will detect the presence of the virus rather than abnormalities, is expected to provide higher sensitivity for identifying high-grade precancerous disease,[9-11] and several countries have moved, or plan to move, to primary HPV testing. In England, the NHS Cervical Screening Programme is currently rolling this out.

The move to primary HPV testing will change the cervical screening results women receive. In the primary HPV testing pilot in England, approximately 13% of the screened population received an HPV positive result.[12] Due to the sexually transmitted nature of HPV,[4] there may be psychosexual consequences of testing positive for the virus. Research suggests that diagnosis with an STI such as genital warts, herpes simplex virus (HSV), or chlamydia can have a negative psychosexual impact. Consequences include reduced sexual desire,[13,14] reduced sexual satisfaction,[14,15] and feeling sexually unattractive,[13] sexually anxious or depressed.[15] An early qualitative study of HPV testing in cervical screening suggested that similar concerns might apply to women who are told they are HPV positive.[16]

An essential criterion for any screening programme is that the overall benefits should outweigh the harms[16]; therefore, it is important to understand and address any psychosexual consequences of testing positive for HPV, particularly as there will be large numbers of women receiving an HPV positive result. Two previous reviews (published in 2007 and 2009) have explored the psychosexual impact of testing positive for HPV,[17,18] but the increasing use of HPV testing in cervical screening (e.g., for triage and test of cure) and the current introduction of primary HPV testing have led to significant research activity since these were published. There are also differences between these previous reviews and the current review. One[17] focused on the economic and quality of life burden of cervical HPV and did not include psychosexual outcomes in the search strategy and the other[18] had a broad scope and reviewed the psychosexual impact of genital warts and their treatment and HPV-related genital, oral, and anal precancerous lesions. In advance of the introduction of HPV primary testing in England, we aimed to provide an up-to-date systematic review of the qualitative and quantitative literature that has explored psychosexual concerns following an HPV positive test result.

2 | METHODS

This review was registered with PROSPERO (CRD42018083969) and followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.[19]

2.1 | Search strategy for identifying papers

The search included terms relating to (a) high-risk cervical HPV and (b) a psychosexual or disclosure-related outcome (eg, sexual behaviour, sexual function, and disclosure of HPV status to a partner) and were linked using Boolean operators (see Supporting Information 1 for the search strategy). The search was conducted in MEDLINE, PsycINFO, CINAHL Plus, Web of Science, and EMBASE on 09/01/2019. There were no study design, date, or language limits applied to the initial search, and both qualitative and quantitative papers were included. Additional papers were identified by searching the grey literature using OpenGrey (www.opengrey.eu), PsycEXTRA, the reference lists of included articles, and forward citation searching.

2.2 | Selection process

Studies were included if they mentioned (a) HPV and (b) a psychosexual or disclosure-related outcome. Reviews, conference abstracts, commentaries, opinion pieces, and editorials were excluded. Studies were also excluded if they were not in English, explicitly focused only on low-risk HPV or focused on the psychosexual impact of cervical cancer, treatment for cervical cancer, or colposcopy.

Titles were screened by K.B. Two reviewers (K.B. and M.R.) screened the abstracts of the remaining papers (agreement rate = 85%). Where a paper could not be assessed using the abstract, the fulltext was obtained. Disagreements were resolved by discussion.

2.3 | Data extraction

Using a standardised data extraction form (see Supporting Information 2), one reviewer (K.B.) extracted information from each paper. A second reviewer (M.R.) independently extracted information for 20% of the studies. Extracted data included participant characteristics, study methods, and a summary of psychosexual outcomes. Inconsistencies were resolved through discussion.

2.4 | Quality assessment

The quality of studies was assessed using modified versions of the National Institute for Health and Care Excellence (NICE) quality appraisal checklists for quantitative and qualitative studies (see Supporting Information 3 and 4). Quality assessment was carried out by one reviewer (K.B.) with a second reviewer (M.R.) independently conducting 20% of assessments. The agreement rate was

80%. Disagreements regarding study quality were resolved by discussion.

2.5 | Analysis

Quantitative and qualitative findings were analysed separately. For quantitative studies, a narrative synthesis was conducted and the results reported descriptively. We used Popay et al's[20] framework for narrative synthesis, following three of the suggested elements: (a) a preliminary synthesis of findings was developed, (b) relationships in the data were explored, and (c) the robustness of the synthesis was assessed.

For qualitative studies, we conducted a thematic synthesis, following the three stages outlined by Thomas and Harden[21]: (a) Line-by-line coding of text in the results and discussion sections; (b) "descriptive themes" were identified; and (c) "analytic themes" were generated—this involves "going beyond" the content of the studies to generate new interpretive constructs or explanations.

A coding frame was developed and applied to the data (by K.B.). A second reviewer (M.R.) independently coded 20% of these papers, and any inconsistencies were resolved through discussion.

3 | RESULTS

3.1 | Search results

The search yielded 4801 articles after the removal of duplicates. Following exclusions, 40 fulltexts were reviewed. Twelve articles were excluded during the full-text review, and two were included following backward/forward citation searches, resulting in 30 papers (see Figure 1). Twenty-five studies measured the psychosexual impact of testing positive for HPV and are included in this analysis.[16,22-44] The remaining studies described disclosure-related outcomes only and are not included in the analysis.

Studies were conducted in the United Kingdom (n = 7), United States (n = 5), Taiwan (n = 4), Australia (n = 2), Greece, Hong Kong, Italy, China, Brazil, Sweden, and Belgium (all n = 1) and were published between 1988 and 2018. Studies were quantitative (n = 12; see Table 1) and qualitative (n = 13; see Table 2). All quantitative studies used survey-based methods,[22-33] and most (n = 8) compared women who were HPV positive (HPV+) with women who were HPV negative (HPV−).[25-30,32,33] Validated measures included the HPV Impact Profile (n = 3), Psychosocial Effects of Abnormal Pap Smears Questionnaire (n = 2), Symptom Checklist of Sexual Function, Sexual Rating Scale, Brief Index of Sexual Functioning of Women, and Psychosocial Adjustment to Illness Scale-SR (all n = 1). Aspects of psychosexual functioning reported in quantitative studies included sexual satisfaction and pleasure (n = 7), frequency of sex (n = 4), sexual interest, thoughts about sex and sexual arousal (n = 4), and feelings about sexual partners and sexual relationships (n = 4). Some quantitative studies reported an overall psychosexual impact score (n = 6). Most qualitative studies (n = 12) conducted individual interviews.[16,35-41,43-45]

3.2 | Quality assessment

Most of the quantitative studies were judged to have been designed or conducted in such a way as to minimise the risk of bias and had good internal validity (n = 7). The quality of external validity was mixed. Most qualitative studies were judged to be well conducted (n = 12) (see Tables 1 and 2 for details).

3.3 | Quantitative studies

3.3.1 | Overall psychosexual impact

Six studies reported an overall psychosexual impact score.[24-26,28,31,32] Study designs (including measures used, comparison groups, and point of data collection) were diverse making it challenging to summarise the overall psychosexual impact of testing HPV+.

In a study of women with abnormal cytology in England,[28] women who were HPV+ had significantly more worries about their sexual health 6 months after receiving their results (compared with women who were HPV− and women not tested for HPV). Two studies (in Taiwan and China) collected data from women who had a range of HPV-related diagnoses around 3-months post-diagnosis.[31,32] In both studies, women with abnormal cytology who were also HPV+ had similar sexual impact profiles to those with abnormal cytology who were not tested for HPV. Whilst these groups were not directly compared, both groups scored significantly higher than women with normal cytology who were not tested for HPV. In the latter of these studies,[32] a group of women who were HPV− with abnormal cytology were also included and had similar sexual impact profiles to those who were HPV+, but again, these groups were not directly compared.

Another study[26] reported an overall psychosocial impact score which included questions on sex, relationship issues, and concerns about transmitting HPV. Psychosocial scores at result notification were worse in women who were HPV+ than women who were HPV− (all women had abnormal cytology), and although scores decreased 6 months later in both groups, they were still significantly worse in women who were HPV+.[26] However, since this scale assessed a range factors, it is unclear if the between-group differences were driven by psychosexual or more general concerns.

In a Chinese study of women who were HPV+, many of whom also had abnormal cytology,[24] psychosexual impact was reported shortly after HPV diagnosis and 1, 6, and 12 months later. At diagnosis, 14% of women had mean subscale scores indicating "significant distress." At the follow-up time-points, psychosexual impact was assessed using a different scale, but all mean scores were low.

In one large, high-quality study of women tested for HPV in England,[25] psychosexual functioning was assessed approximately 2 weeks after women received their results. Among women with normal cytology, psychosexual functioning did not differ between those who received an HPV+ or HPV− result. However, among women with abnormal cytology (mild/borderline), psychosexual functioning was better in women who were HPV+ than women who were HPV−.

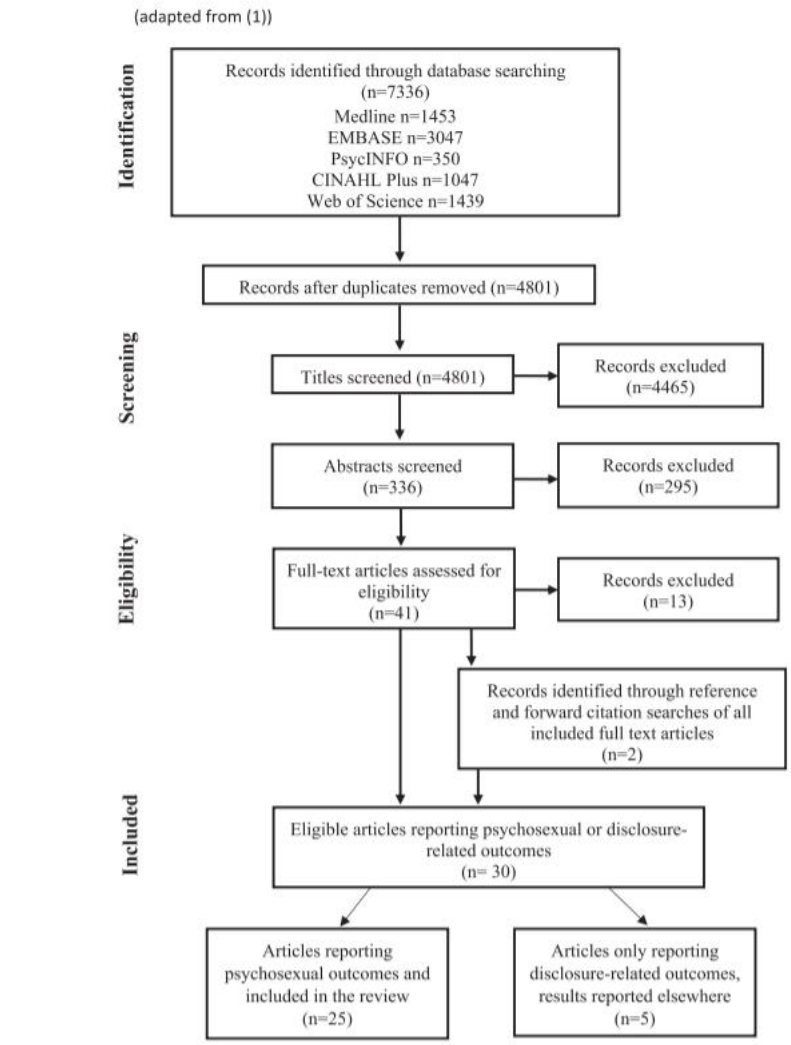

FIGURE 1 Flow diagram of study selection(adapted from Walboomers et al[1])

3.3.2 | Sexual satisfaction and pleasure

Seven studies assessed sexual satisfaction or sexual pleasure, with three reporting no impact of testing HPV+.[26,27,30] In a study of 72 women attending a gynaecological clinic,[27] there were no significant differences in sexual satisfaction or sexual pleasure/orgasm between women who were HPV+ and women who were HPV− approximately 6 to 12 months post-diagnosis. In a second study of 155 women with vaginitis,[30] there were no significant differences in sexual satisfaction between women who were HPV+ and women who were HPV−. A

TABLE 1 Characteristics of quantitative studies measuring psychosexual outcomes included in the review

Reference	Country	Age (y)	Psychosexual Outcomes Measured	Number of Participants	Survey Instrument	Time of Data Collection	Study Population	Comparison Groups	Quality Assessment Score Internal Validity/ External Validity[†]
Campion et al (1988)[22]	UK	17-26	Sexual interest, frequency of sex, sexual arousal, orgasm, negative feelings about sex.	105	Questionnaire	Baseline: 6 mo before attending colposcopy or a genitourinary clinic. Follow-up: approximately 5-6 mo later.	Women attending a colposcopy or a genitourinary clinic	1. Abnormal smear test result and cervical intraepithelial neoplasia (CIN), HPV+. 2. Women traced as the regular sexual partner of a man with penile condylomata acuminata: a) HPV+ or HPV+ with CIN. b) No cervical disease. 3. Women referred as the regular sexual partner of a man diagnosed with urethritis who had no evidence of cervical disease.	++/+
Ferenidou et al (2011)[23]	Greece	20-50+	Sexual interest, frequency of sex, sexual satisfaction, orgasm, impact on relationships (measured by the Symptom Checklist of Sexual Function).	51	Questionnaire	Questionnaire completed after a gynaecological examination, having been diagnosed with HPV at a previous visit.	Women attending a gynaecological clinic.	HPV+ participants only.	+/+
Hsu et al (2018)[24]	Taiwan	20-61	Effect on sexual relationships (measured by the Psychosocial Effects of Abnormal Pap Smears Questionnaire [baseline] and Psychosocial Adjustment to Illness Scale-SR [1, 6, and 12 mo follow-up])	70	Questionnaire	Baseline: at the first follow-up appointment after HPV diagnosis Follow-up: 1, 6, and 12 mo following diagnosis.	Women attending a gynaecological clinic	HPV+ participants only.	+/+
Kitchener et al (2007)[25]	UK	20-64	Sexual satisfaction (measured by the Sexual Rating Scale)	2508	Questionnaire data initially collected in face-to-face interviews (n = 106) and subsequently	2 wks after receiving screening results.	Women eligible for routine cervical screening in the National Cervical Screening Programme	Revealed arm: 1. HPV−, normal cytology 2. HPV+, normal cytology 3. HPV−, mild/borderline cytology 4. HPV+, mild/borderline cytology Concealed arm: 1. HPV−, normal cytology 2. HPV+, normal cytology	++/++

(Continues)

TABLE 1 (Continued)

Reference	Country	Age (y)	Psychosexual Outcomes Measured	Number of Participants	Survey Instrument	Time of Data Collection	Study Population	Comparison Groups	Quality Assessment Score Internal Validity/ External Validity[†]
					by postal questionnaire			3. HPV−, mild/borderline cytology 4. HPV+, mild/borderline cytology	
Kwan et al (2011)[26]	Hong Kong	36.8 (mean)	Relationship and sexual satisfaction, overall psychosocial burden (which included sexual impact and concerns about infectivity and transmission). (measured by the HPV Impact Profile)	299	Questionnaire	Baseline: after result disclosure. Follow-up: 6 mo later.	Women attending routine cervical screening	1. ASCUS, HPV+ 2. ASCUS, HPV−	+/+
Maggino et al (2007)[27]	Italy	20-45	Sexual interest, sexual thoughts, frequency of sex, sexual arousal, sexual satisfaction, sexual pleasure, orgasm (measured by the Brief Index of Sexual Functioning for Women)	72	Questionnaire	Time between HPV diagnosis and questionnaire delivery varied; participants received the questionnaire 0-6 mo after diagnosis (50%), 6-12 mo after diagnosis (39%), or 1 + y after diagnosis (11%).	Women attending a gynaecological clinic	1. HPV+ 2. HPV−	+/+
Maissi et al (2005)[28]	UK	Mean age by group: Abnormal, HPV+: 32.7 Abnormal, HPV−: 41.6 Abnormal, HPV not tested: 36.6	Effect on sexual relationships. (measured by the Psychosocial Effects of Abnormal Pap Smears Questionnaire)	1011	Postal questionnaire	Baseline: sent within a week of the research team being informed that an individual's screening test result had been sent. Follow-up: 6 mo later.	Women undergoing routine cervical screening at one of two centres taking part in the English pilot study of liquid-based cytology and HPV testing	1. Abnormal cytology, HPV+ 2. Abnormal cytology, HPV− 3. Abnormal cytology, HPV not tested.	++/++
McCaffery et al (2004)[29]	UK	20-64	Feelings about current, previous, and future sexual partners.	271	Postal questionnaire	One week after receiving screening test results.	Women attending a National Health Service (NHS) well-woman clinic for routine cervical screening.	1. Normal cytology, HPV+ 2. Normal cytology, HPV− 3. Abnormal/unsatisfactory cytology, HPV+ 4. Abnormal/unsatisfactory cytology, HPV−	++/++

(Continues)

TABLE 1 (Continued)

Reference	Country	Age (y)	Psychosexual Outcomes Measured	Number of Participants	Survey Instrument	Time of Data Collection	Study Population	Comparison Groups	Quality Assessment Score Internal Validity/ External Validity[†]
Reed et al (1999)[30]	USA	18-50	Sexual thoughts, frequency of sex, sexual arousal, sexual satisfaction, negative feelings about relationships.	169	Postal questionnaire	Participants enrolled in a Vaginitis study for at least 6 mo were asked to assess current psychosexual activities and changes in these activities since enrolment, without specific reference to HPV infection.	Women enrolled in the University of Michigan Vaginitis study.	1. HPV+ 2. HPV−	++/+
Wang et al (2010)[31]	Taiwan	18-65	Sexual impact, concerns about infectivity and transmission (measured by the HPV Impact Profile)	249	Face-to-Face interviews	Within 3 mo of an HPV-related diagnosis.	Women recruited from outpatient clinics at three hospitals during routine gynaecological visits.	1. Normal Pap 2. Abnormal Pap 3. CIN 1/2/3 4. Genital warts 5. Abnormal Pap, HPV+	+/++
Wang et al (2011)[32]	China	18-65	Sexual impact, concerns about infectivity and transmission (measured by the HPV Impact Profile)	2605	Questionnaire completed in the presence of a trained interviewer.	Within 3 mo of an HPV-related diagnosis.	Women attending routine clinical hospital visits.	1. Normal Pap 2. Abnormal Pap, no HPV test 3. Genital warts 4. Precancer 5. Abnormal Pap, HPV+ 6. Abnormal Pap, HPV−	++/++
Youngkin et al (1998)[33]	USA	17-29+	Sexual satisfaction (measured by the Self-Concept and Satisfaction with Intimate Relationships Scale)	58	Questionnaire given during a clinic visit and returned by post.	Baseline: when participants were randomised. Follow-up: 4 wk after baseline questionnaire.	Women from a university student health service and a family planning clinic.	1. HPV+, self-help module plus routine counselling (intervention group). 2. HPV+, routine counselling (control group)	++/+

[†]++ Indicates that the study was designed or conducted in such a way as to minimise the risk of bias.

+ Indicates that the study was partly designed to minimise bias, may not have addressed all potential sources of bias, or it was not clear from the way the study was reported.

- Indicates that the study had significant sources of bias across all aspects of the study design.

TABLE 2 Characteristics of qualitative studies measuring psychosexual outcomes included in the review

Reference	Country	Age (y)	Number of Participants	Study Design	Study Population	Quality Assessment Score†
Kosenko et al (2012)[44]	USA	19-56	25	Semi-structured interviews	Women answering an advertisement posted online (on social media websites and support groups) and in community settings.	++
Jeng et al (2010)[34]	Taiwan	27-52	20	Semi-structured interviews	Women attending a gynaecological outpatient clinic at a university-based hospital.	–
Kosenko et al (2014)[35]	USA	19-56	25	Semi-structured interviews	Women answering an advertisement posted online (on social media websites and support groups) and in community settings	++
Lin et al (2011)[36]	Taiwan	27-56	20	Semi-structured interviews	Women attending a gynaecological outpatient clinic at a university-based hospital.	+
McCaffery et al (2006)[16]	UK	20-64	74	In-depth interviews	Women taking part in clinical trials of HPV testing or attending colposcopy clinics where HPV testing was used.	++
McCaffery & Irwig (2005)[37]	Australia	Range unknown, 53% were < 35 y; 47% were > 35 y.	19	In-depth, unstructured interviews	Women attending family planning clinics, general practices and specialist gynaecologist practices.	++
McCurdy et al[38]	USA	21-45	18	In-depth interviews	Women attending three private primary care clinics. Women had atypical squamous cells of undetermined significance (ASCUS) or a low-grade squamous intraepithelial lesion as well as a high-risk HPV type.	++
Newton & McCabe (2008)[39]	Australia	19-59	60 (30 with HPV)	Semi-structured interviews	Men (n = 30) and women (n = 30) responding to an advertisement about the study posted on STI websites, support groups, and online communities.	+
Parente Sa Barreto et al (2016)[40]	Brazil	20-42	14	Semi-structured interviews	Women attending a specialised unit supporting sexual and reproductive care. First-time attenders were excluded from the study.	+
Patel et al (2018)[45]	UK	25-63	46	Semi-structured interviews	Women recruited from colposcopy clinics and community settings.	+
Rask et al (2017)[41]	Sweden	29-53	10	Individual interviews	Women attending a women's health clinic who had been diagnosed with CIN 1/2/3.	++
Waller et al (2007)[43]	UK	21-64	30	Semistructured interviews	Women participating in the ARTISTIC trial (a randomised trial of HPV testing in primary cervical screening).	++
Verhoeven et al (2010)[42]	Belgium	Not specified	527 email messages (n = 432 from women).	Qualitative analysis of questions asked by visitors to an HPV website.	Individuals who emailed questions about HPV to a website with HPV information.	++

†++ Indicates that the study was designed or conducted in such a way as to minimise the risk of bias.

+ Indicates that the study was partly designed to minimise bias, may not have addressed all potential sources of bias, or it was not clear from the way the study was reported.

– Indicates that the study had significant sources of bias across all aspects of the study design.

third study of 299 women with abnormal cytology[26] found no difference in sexual satisfaction at baseline (result notification) or 6 months later between women who were HPV+ and women who were HPV–.

A randomised controlled trial of 58 women who were HPV+ and 40 women who were HSV+ (exploring the effect of counselling and providing information on HPV or HSV) found that, in the control group (who only received counselling), women who were HPV+ had slightly greater satisfaction with intimate relationships than women who were HSV+; however, in the experimental group women with HPV had slightly lower satisfaction with intimate relationships than women with HSV. In this study, the HPV and HSV groups were not statistically directly compared, and the range of potential scores was not reported.

In a descriptive study of 51 women who had recently been informed that they were HPV+,[23] 22% reported feeling dissatisfied with their sex life, and 22% experienced problems reaching orgasm following HPV diagnosis. In another study of 105 women attending a colposcopy or genitourinary clinic,[22] frequency of orgasm among women who were HPV+ (with or without cervical intraepithelial neoplasia [CIN]) decreased between baseline (6-months prior to diagnosis) and follow-up (6-months post-treatment). There was no change in frequency of orgasm among women without HPV.

3.3.3 | Frequency of sex

Four studies assessed frequency of sex following an HPV+ result.[22,23,27,30] In a descriptive study of 51 women who had recently been told they were HPV+,[23] 41% reported decreased frequency of sex following HPV diagnosis. In a study of 105 women attending a colposcopy or genitourinary clinic,[22] frequency of sex among women who were HPV+ (with or without CIN) decreased between baseline (6months prior to diagnosis) and follow-up (6months post-treatment). There was no change in frequency of sex among women without HPV.

Two studies reported no difference in frequency of sex between women who were HPV+ and women who were HPV−.[27,30] In a study of 72 women attending a gynaecological clinic,[27] there were no significant differences in sexual satisfaction between women who were HPV+ and women who were HPV− approximately 6 to 12 months following HPV diagnosis. In a second study of 155 women who had been taking part in a study about vaginitis for at least 6 months,[30] there were no significant differences between women who were HPV+ and women who were HPV−.

3.3.4 | Interest in sex, thoughts about sex, and sexual arousal

Four studies assessed interest in sex, thoughts about sex, and sexual arousal following HPV diagnosis.[22,23,27,30] In a descriptive study of 51 women who were recently told they were HPV+,[23] 41% reported decreased sexual desire. In a second study, women who were HPV+ (with or without CIN) who were attending a colposcopy or a genitourinary clinic[22] reported decreased spontaneous interest in sex and sexual arousal and increased negative feelings towards sexual intercourse between baseline (6months prior to diagnosis) and follow-up (6months post-treatment). There was no change in interest in sex among women without HPV. In contrast, among 72 women attending a gynaecological clinic,[27] there were no significant differences in interest in sex, sexual arousal, or sexual thoughts between women who were HPV+ and women who were HPV− 6 to 12+ months after their visit. In a fourth study of 155 women participating in a study about vaginitis,[30] there were no differences in sexual arousal or thinking about sex between women who were HPV+ and women who were HPV−.

3.3.5 | Feelings about partners and relationships

Four studies assessed feelings about partners and relationships.[23,26,29,30] In a study of 51 women who had recently been told they were HPV+,[23] 12% reported feeling their relationship was negatively affected by their result. In a second study of 271 women, conducted in the context of routine cervical screening,[29] women who were HPV + (with normal or abnormal cytology) were more likely to report feeling worse about their current, previous, and future sexual partners than women who were HPV− 1 week after receiving their test result.

Two studies found no evidence that an HPV+ result affected feelings about partners or relationships.[26,30] One study of 299 women with abnormal cytology[26] reported no differences between women who were HPV+ and women who were HPV− in relationship satisfaction at result notification or 6months later. In a second study of women participating in a study about vaginitis,[30] there were no significant differences between women who were HPV+ and women who were HPV− in frequency of negative feelings about relationships, or anger at current or previous partner.

3.4 | Qualitative studies

A thematic synthesis of 13 studies identified three major themes relating to psychosexual impact: (a) source of HPV infection, (b) transmission of HPV, and (c) impact of HPV on sex and relationships. Supporting Information 5 gives a brief description of each theme and provides example quotes.

3.4.1 | Source of HPV infection

Where did the infection come from?

A common response from women with HPV was to question which partner (current or previous) the infection had come from.[16,35,37,38,42-45] Not knowing the source of the infection sometimes led to uncertainty and stress[35,44] and in severe cases to relationship breakdown[44] or angry confrontation with a previous partner.[35]

Infidelity concerns

Some women expressed concerns that their partner had been unfaithful.[16,34,40,42,43] Lack of trust was described.[40] A small number of women were concerned about being accused of infidelity,[38,40] and there were reports that partners had left due to infidelity concerns,[38] though this was uncommon.

3.4.2 | Transmission of HPV

Transmitting HPV to a partner

Concern about passing HPV on to a partner was common.[16,36-38,41,42] Women had questions about the likelihood of infecting their partner[37] and which sexual practices could lead to infection.[42] Women wondered what they could do to avoid passing on the infection.[37] There was uncertainty and a desire for information about the consequences of HPV for male partners.[37]

Being re-infected with HPV

Worry about re-infection and recurrence was common.[43] In some cases, this led to concerns about having new partners, because of a fear of being re-infected.[34] Some women were worried about infecting their partner and then their partner re-infecting them, not allowing the virus to be cleared and increasing the risk of cervical cancer.[37,42]

3.4.3 | Impact of HPV on sex and relationships

Impact of HPV on relationships

Whilst some women were concerned HPV might negatively impact their relationship[36,38]; others reported that it had not. A small number reported that their partners were accepting,[39] supportive,[38,45] had shown concern for their wellbeing,[45] and that they had become closer to their partner following HPV diagnosis.[39] A small number described their HPV diagnosis having a negative impact on their relationship, feeling that their partner was distant from them,[45] or that HPV was causing conflict.[36,39]

Frequency and interest in sex

Several studies identified a reduced interest in and frequency of sex,[34,36,38,39,42] with some women reporting that they had stopped having sex.[34,36,39] Some thought that people with HPV should not have sex,[34] whilst others were concerned about passing the infection on. There was also concern that having sex would worsen any abnormal cervical cells.[16]

Negative sexual self-image

HPV had a negative impact on some women's sexual self-image.[16,39,43,46] The stigma associated with HPV led women to feel "*dirty*," "*contaminated*," and unworthy of sexual attention.[16,39,41] The stigma of having an STI sometimes restricted sexual advances towards others, affected sexual spontaneity, and made women feel they had to alter their sexual activities.[39]

Concerns about risks associated with oral sex

The risks associated with oral sex were mentioned by a few women[37,44] who were concerned about passing HPV on to their partners in this way, with the potential for it to cause oral cancer. This sometimes resulted in abstention from oral sex.

4 | DISCUSSION

This review synthesises the existing literature on the psychosexual impact of testing positive for high-risk cervical HPV. The diversity of quantitative study designs and inclusion of study populations with abnormal cytology or other conditions makes it difficult to determine the impact that an HPV+ result would have in the context of routine primary HPV testing; however, some studies suggested that testing HPV+ can have a psychosexual impact. The qualitative literature suggested that psychosexual concerns are raised by some women who test HPV+ and that these concerns cover a broad range of aspects relating to their current and past relationships, both interpersonal and sexual.

Including quantitative and qualitative articles in the review allowed us to highlight the range of psychosexual concerns that women testing HPV+ have. Traditional psychosexual measures used in the quantitative studies assessed specific aspects of sexual behaviour in line with medical classifications of psychosexual disorders (eg, sexual interest and arousal[47]). Conversely, the qualitative literature suggested that the concerns of women with HPV are more about where the infection came from, infectivity, and the impact this can have on relationships. Concerns about infectivity were only assessed by two quantitative studies included in the review, both of which had used qualitative research when developing their questionnaire. Assessing the prevalence of other concerns raised in the qualitative literature is important. Including these aspects in quantitative measures would ensure a more inclusive assessment of the components that influence psychosexual outcomes in women who have HPV.

Previous studies have shown that receiving an abnormal cytology result can have a negative impact on frequency of sex,[22,48] interest in sex,[22,49] and satisfaction with sex.[48] The quantitative studies included in this review that compared HPV+ and HPV− women with abnormal cytology found inconsistent evidence of psychosexual impact.[26,28,31,32] Our findings both differ and are consistent with previous reviews. One review[17] found that most studies reported changes in women's sexual relationships following a HPV diagnosis and the other[18] found no conclusive evidence regarding the psychosexual consequences of an HPV diagnosis.

Comparison groups, measures, and the setting from which participants were recruited differed between studies, and psychosexual outcome data were collected at different time points (from immediately after the test result to more than a year later). The heterogeneity in study design and time from receipt of HPV test results to when data were collected could provide an explanation for the mixed findings, and this makes it difficult to form conclusions about the prevalence and severity of the psychosexual impact of an HPV+ diagnosis. Whilst some studies included in the review did use validated measures, a validated measure specific to HPV testing that assesses aspects of psychosexual and interpersonal relationships (discussed in the qualitative literature) would help to ensure contextually valid items are included and provide a tool that can allow comparisons between studies. Only two papers included in the review measured psychosexual impact longitudinally. Future studies should measure the psychosexual impact of testing HPV+ over time to ascertain if psychosexual impact changes. Knowledge of when psychosexual impact is greatest could help to determine when interventions are most appropriate.

4.1 | Study limitations

Since the quantitative papers included a range of psychosexual outcomes, it was not possible to conduct a meta-analysis. Whilst we excluded any articles that explicitly focused on low-risk types of HPV, some of the papers included in the review did not describe the type of HPV participants had and it is possible that some articles included participants with low-risk HPV.

4.2 | Clinical implications

It is important to understand, and minimise, any psychosexual impact of testing HPV+ in the context of primary HPV testing. In line with previous studies (52,53), the qualitative synthesis highlights that women who test HPV+ have a number of questions about HPV such as the source of the infection, whether partners can re-infect each other and how to prevent the transmission of HPV. Information materials could increase knowledge and address some of these concerns. Additionally, health care professionals carrying out cervical screening could be trained to give brief information during screening to ensure that women understand their results when they receive them. Whilst HPV is classified as an STI, it differs from other STI's as it is normally asymptomatic, does not need treatment, and does not usually cause any long-term problems. Communicating this information to women is important and may help to reduce psychosexual impact.

5 | CONCLUSIONS

This review synthesises the literature on the psychosexual impact of testing HPV+. The qualitative studies included in the review provide rich information about the source and nature of psychosexual distress experienced by some women. In particular, women were concerned about transmitting HPV to a partner and where the HPV infection came from. The diversity of quantitative study designs and samples makes it difficult to draw conclusions about the magnitude of psychosexual impact in the context of primary HPV testing. Whilst this review draws together what is currently known, it also highlights the need for further quantitative and qualitative research in the context of primary HPV testing. It is important to understand the psychosexual impact of testing HPV+ in a routine context to minimise undue concern among women, and to avoid compromising future screening re-attendance.

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CONFLICT OF INTEREST STATEMENT

No conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Bennett KF, Waller J, Ryan M, Bailey JV, Marlow LAV. The psychosexual impact of testing positive for high-risk cervical human papillomavirus (HPV): A systematic review. *Psycho-Oncology*. 2019;28:1959–1970. https://doi.org/10.1002/pon.5198

APPENDIX 2.2: SYSTEMATIC REVIEW SEARCH STRATEGY

	MEDLINE, EMBASE, PsycINFO	CINAHL Plus	Web of Science
HPV	1) HPV.mp. 2) "Human Papilloma Virus".mp. 3) "Human Papillomavirus".mp. 4) exp Papillomavirus Infections/ 5) "Cervical intraepithelial neoplasia".mp. 6) Cervical Intraepithelial Neoplasia/ 7) "Genital Warts".mp. 8) Condylomata Acuminata/ 9) "Cervical Dysplasia".mp. 10) Uterine Cervical Dysplasia/	11) HPV 12) “Human Papilloma Virus” 13) “Human Papillomavirus” 14) MH “Papillomavirus Infections” 15) “Cervical intraepithelial neoplasia” 16) MH “Cervical Intraepithelial Neoplasia” 17) “Genital Warts” 18) MH “Warts, Veneral” 19) “Cervical Dysplasia”	1) HPV 2) “Human Papilloma Virus” 3) “Human Papillomavirus” 4) “Cervical Intraepithelial Neoplasia” 5) “Genital Warts” 6) “Cervical Dysplasia”
PSYCHOSEXUAL OUTCOMES	12) Psychosexual.mp. 13) Psychosocial.mp. 14) Psych*.mp. 15) “Quality of Life”.mp 16) "Quality of Life"/ 17) Sexual Dysfunctions, Psychological/ 18) “Sex* Impact” 19) Disclos*.mp. 20) Disclosure/	1) Psychosexual 2) Psychosocial 3) Psych* 4) “Quality of Life” 5) MH “Quality of Life” 6) (MH “Sexual Dysfunction, Female”) OR (MH “Psychosexual Disorders”) 7) “Sex* Impact” 8) Disclos*	8) Psychosexual 9) Psychosocial 10) Psych* 11) “Quality of Life” 12) “Sex* Impact” 13) “Sex* Function*” 14) Disclos*
SEARCH COMBINATIONS	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 11 and 21	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 10 and 19	1 or 2 or 3 or 4 or 5 or 6 8 or 9 or 10 or 11 or 12 or 13

APPENDIX 2.3: DATA EXTRACTION FORM

ID Number (on Excel spreadsheet)	
Date form completed	
Authors	
Title	
Journal	
Year	
Volume	
Issue	
Pages	
Participants	
HPV status determined?	YES NO
Type of HPV (HR, HR and LR, unsure)	
Number of participants	
Age range of participants	
Gender of participants	
Other relevant sociodemographics	
Methods	
Study design	
Aim of study	
Recruitment method	
Recruitment setting	
Outcomes measured	
Method(s) of analysis	
Results	
(Psycho)sexual outcomes reported?	YES NO
If yes, give summary of results	
Disclosure outcomes reported?	YES NO
If yes, give summary of results	
Other notes	

APPENDIX 2.4: QUALITY APPRAISAL CHECKLIST (QUANTITATIVE STUDIES)

ID Number (on Excel spreadsheet)		
Date form completed		
Assessed by		
Authors		
Title		
Journal		
Year		
Volume		
Issue		
Pages		
POPULATION		
Is the source population or source area well described? Was the country, setting, location, population demographics etc. adequately described?	++ + - NR NA	Comments:
Is the eligible population or area representative of the source population or area? Was the recruitment of individuals, clusters or areas well defined? Was the eligible population representative of the source? Were important groups under-represented?	++ + - NR NA	Comments:
Do the selected participants or areas represent the eligible population or area? Was the method of selection of participants from the eligible population well described? What % of selected individuals or clusters agreed to participate? Were there any sources of bias? Were the inclusion or exclusion criteria explicit and appropriate?	++ + - NR NA	Comments:
OUTCOMES		
Were the outcome measures reliable? How reliable were outcome measures (e.g. inter- or intra-rater reliability scores)? Was there any indication that measures has been validated (e.g. validated against a gold standard measure or assessed for content validity?	++ + - NR NA	Comments:
Were outcomes relevant? Where surrogate outcome measures were used, did they measure what they set out to measure? (e.g. a study to assess impact on physical activity assesses gym membership – a potentially objective outcome measure – but is it a reliable predictor of physical activity?)	++ + - NR NA	Comments:

Was follow-up time meaningful? Was follow-up long enough to assess long-term benefits or harms? Was it too long, e.g. participants lost to follow-up?	++ + - NR NA	Comments:
ANALYSES		
If applicable, were exposure and comparison groups similar at baseline? If not, were these adjusted? Were there any differences between groups in important confounders at baseline? If so, were these adjusted for in the analyses (e.g. multivariate analyses or stratification). Were there likely to be any residual differences of relevance?	++ + - NR NA	Comments:
Was the study sufficiently powered to detect an intervention effect (if one exists)? A power of 0.8 (that is, it is likely to see an effect of a given size if one exists, 80% of the time) is the conventionally accepted standard. Is a power calculation presented? If not, what is the expected effect size? Is the sample size adequate?	++ + - NR NA	Comments:
Were the estimates of effect size given or calculable? Were effect estimates (e.g. relative risks, absolute risks) given or possible to calculate?	++ + - NR NA	Comments:
Were the analytical methods appropriate? Were important differences in follow-up time and likely confounders adjusted for? If a cluster design, were analyses of sample size (and power), and effect size performed on clusters (and not individuals)? Were subgroup analyses pre-specified?	++ + - NR NA	Comments:
Was the precision of intervention effects given or calculable? Were they meaningful? Were confidence intervals or p values for effect estimates given or possible to calculate? Were CI's wide or were they sufficiently precise to aid decision-making? If precision is lacking, is this because the study is under-powered?	++ + - NR NA	Comments:
SUMMARY		
Are the study results internally valid (i.e. unbiased)?	++ +	Comments:

How well did the study minimise sources of bias (i.e. adjusting for potential confounders)? Were there significant flaws in the study design?	- NR NA	
Are the findings generalisable to the source population (i.e. externally valid)? Are there sufficient details given about the study to determine if the findings are generalisable to the source population? Consider: participants, interventions and comparisons, outcomes, resource and policy implications.	++ + - NR NA	Comments:

++	Indicates that for that particular aspect of study design, the study has been designed or conducted in such a way as to minimise the risk of bias.
+	Indicates that either the answer to the checklist question is not clear from the way the study is reported, or that the study may not have addressed all potential sources of bias for that particular aspect of study design.
−	Should be reserved for those aspects of the study design in which significant sources of bias may persist.

APPENDIX 2.5: QUALITY APPRAISAL CHECKLIST (QUALITITATIVE STUDIES)

ID Number (on Excel spreadsheet)		
Date form completed		
Assessed by		
Authors		
Title		
Journal		
Year		
Volume		
Issue		
Pages		
THEORETICAL APPROACH		
Is a qualitative approach appropriate? *For example:* • *Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?* • *Could a quantitative approach better have addressed the research question?*	Appropriate Inappropriate Not sure	Comments:
Is the study clear in what it seeks to do? *For example:* • *Is the purpose of the study discussed – aims/objectives/research question/s?* • *Is there adequate/appropriate reference to the literature?* • *Are underpinning values/assumptions/theory discussed?*	Clear Unclear Mixed	Comments:
STUDY DESIGN		
How defensible/rigorous is the research design/methodology? *For example:* • *Is the design appropriate to the research question?* • *Is a rationale given for using a qualitative approach?* • *Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?* • *Is the selection of cases/sampling strategy theoretically justified?*	Defensible Indefensible Not sure	Comments:
DATA COLLECTION		
How well was the data collection carried out? *For example:* • *Are the data collection methods clearly described?*	Appropriately Inappropriately Not sure/ inadequately reported	Comments:

• *Were the appropriate data collected to address the research question?* • *Was the data collection and record keeping systematic?*		
Is the context clearly described? *For example:* • *Are the characteristics of the participants and settings clearly defined?* • *Were observations made in a sufficient variety of circumstances* • *Was context bias considered*	Clear Unclear Not sure	Comments:
Were the methods reliable? *For example:* • *Was data collected by more than 1 method?* • *Is there justification for triangulation, or for not triangulating?* • *Do the methods investigate what they claim to?*	Reliable Unreliable Not sure	Comments:
ANALYSIS		
Is the data analysis sufficiently rigorous? *For example:* • *Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?* • *How systematic is the analysis, is the procedure reliable/dependable?* • *Is it clear how the themes and concepts were derived from the data?*	Rigorous Not rigorous Not sure/not reported	Comments:
Is the data 'rich'? *For example:* • *How well are the contexts of the data described?* • *Has the diversity of perspective and content been explored?* • *How well has the detail and depth been demonstrated?* • *Are responses compared and contrasted across groups/sites?*	Rich Poor Not sure/not reported	Comments:
Is the analysis reliable? *For example:* • *Did more than 1 researcher theme and code transcripts/data?* • *If so, how were differences resolved?* • *Did participants feedback on the transcripts/data if possible and relevant?* • *Were negative/discrepant results addressed or ignored?*	Reliable Unreliable Not sure/not reported	Comments:
Are the findings convincing?	Convincing	Comments:

For example: • *Are the findings clearly presented?* • *Are the findings internally coherent?* • *Are extracts from the original data included?* • *Are the data appropriately referenced?* • *Is the reporting clear and coherent?*	Not convincing Not sure	
Are the findings relevant to the aims of the study?	Relevant Irrelevant Partially relevant	Comments:
Conclusions *For example:* • *How clear are the links between data, interpretation and conclusions?* • *Are the conclusions plausible and coherent?* • *Have alternative explanations been explored and discounted?* • *Does this enhance understanding of the research topic?* • *Are the implications of the research clearly defined?* • *Is there adequate discussion of any limitations encountered?*	Adequate Inadequate Not sure	Comments:
ETHICS		
How clear and coherent is the reporting of ethics? *For example:* • *Have ethical issues been taken into consideration?* • *Are they adequately discussed e.g. do they address consent and anonymity?* • *Have the consequences of the research been considered i.e. raising expectations, changing behaviour?* • *Was the study approved by an ethics committee?*	Appropriate Inappropriate Not sure/not reported	Comments:
OVERALL ASSESSMENT		
As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)	++ + −	Comments:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.

– Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

APPENDIX 3.1: STUDY 1B PUBLISHED PAPER

Review

OPEN ACCESS

Concerns about disclosing a high-risk cervical human papillomavirus (HPV) infection to a sexual partner: a systematic review and thematic synthesis

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ABSTRACT

Background Human papillomavirus (HPV)-based cervical screening is now replacing cytology-based screening in several countries and many women in screening programmes will consequently receive HPV-positive results. Because of the sexually transmitted nature of HPV, receiving an HPV-positive result may raise questions about disclosing the infection to a sexual partner.

Objective To review the quantitative and qualitative literature exploring women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

Methods We searched MEDLINE, PsycINFO, CINAHL Plus, Web of Science and EMBASE for studies reporting at least one disclosure-related outcome among women with high-risk HPV. We also searched the grey literature and carried out forward/backward citation searches. A narrative synthesis for quantitative studies and a thematic synthesis for qualitative studies were conducted.

Results Thirteen articles met the inclusion criteria (12 qualitative, 1 quantitative). In the quantitative study, 60% of HPV-positive women felt disclosing an HPV result was 'risky'. Concerns about disclosing HPV to a sexual partner were influenced by the stigma that is associated with having an STI and uncertainty about how their partner would respond. Women questioned how, when and to whom they should disclose their HPV-positive status.

Conclusions The studies included in this review provide rich information about the range of concerns women have, the reasons for these concerns, and the questions women have about disclosing HPV to sexual partners. As studies were predominantly qualitative, the prevalence of concerns is unclear.

Key messages

- This is the first review to synthesise the literature on women's concerns about disclosing a high-risk cervical HP Vinfection to a sexual partner.
- This review identified that concerns about disclosing HPV to a sexual partner are partly because of the stigma associated with having an STI and uncertainty about how a partner might respond.
- Some women have questions about disclosure including who they should disclose to and how to approach and manage these conversations.
- Increasing knowledge of the high prevalence of HPV and providing clear information in screening letters and leaflets about disclosing may help women understand their screening result and minimise unnecessary concerns.

INTRODUCTION

Virtually all cervical cancers are caused by persistent infection with a high-risk type of human papillomavirus (hrHPV).[1–3] HPV is a sexually transmitted infection (STI)[4] which affects both men and women, and it has been estimated that 80% of individuals will acquire a genital HPV infection by the age of 50 years.[5] There are many types of HPV and these are divided into low-risk types (which do not cause cancer but can cause genital warts or verrucas) and high-risk types (which can cause cells to become abnormal and, over time, can

lead to cancer if left untreated). While infection with hrHPV is the underlying cause of almost all cervical cancers, hrHPV rarely causes cancer and most infections resolve spontaneously within 2 years.[6]

Until recently, most cervical screening programmes in high-income countries used cytology to detect cervical abnormalities, with HPV testing used as a triage for women with borderline or low-grade cell changes.[7] However, using HPV testing as the primary test in cervical screening has higher sensitivity for detecting high-grade cervical abnormalities[8–10] and as a result several countries have moved, or plan to move, to primary HPV testing.[11–13] In England, primary HPV testing in the NHS Cervical Screening Programme will be fully rolled-out by the end of 2019. In a screening programme that uses primary HPV testing, women who test positive for hrHPV will be told they have HPV alongside receiving a normal or abnormal cytology result.[14]

Research suggests that a key concern among individuals with an STI is disclosing their diagnosis to a sexual partner. In studies with participants with herpes simplex virus (HSV) and chlamydia, disclosure is described as something that is difficult, fear-inducing[15] and a considerable source of worry.[16] This may be due to the feelings of stigma and shame that are associated with having an STI,[17–19] which has been found to be a barrier to disclosing some STI diagnoses.[19] Participants' concerns about disclosure include worry that they will receive a negative reaction from their partner,[16 20–22] concern about being rejected by their partner,[20 23] or that their partner will end their relationship[20] and worry that their partner would inform others of the infection.[20 22] An early qualitative study of HPV testing in cervical screening suggested that some women with HPV have concerns about disclosing an HPV-positive test result to their partner.[24]

Contact tracing (identifying individuals who have come into contact with an infected individual) is important for some STIs so that previous partners can be screened and treated for the infection if necessary. However, there is no treatment for HPV and the World Health Organization (WHO) advise against routine contact tracing for HPV.[25] Therefore, the decision about whether to disclose HPV to a sexual partner is a personal choice. It is important to understand women's information needs around disclosure so that these can be met through information provision and guidance from healthcare professionals. We reviewed the quantitative and qualitative literature exploring women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner.

METHODS

This review was registered with PROSPERO (CRD42018083969) and followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.[26] The review explored two research questions with findings reported separately. Details of the methods used for both reviews are reported in full elsewhere.[27]

Search strategy for identifying papers

We searched MEDLINE, PsycINFO, CINAHL Plus, Web of Science and EMBASE on 9 January 2019. The search included terms relating to (i) high-risk cervical HPV and (ii) a psychosexual or disclosure-related outcome (eg, sexual behaviour, sexual function, disclosure of HPV status to a partner) and were linked using Boolean operators (see online supplementary material 1 for the full search strategy). Both qualitative and quantitative papers were eligible for inclusion and no study design, date, or language limits were applied to the initial search. We also searched the reference lists of included articles, conducted forward citation searching and searched the grey literature using OpenGrey (www.opengrey.eu) to identify any additional eligible articles.

Study selection process

The titles of all articles identified from the search were screened by one reviewer (KFB). Two reviewers (KFB and MR) screened the abstracts of the remaining articles. Articles were included if they mentioned (i) HPV and (ii) a psychosexual or disclosure-related outcome. Reviews, conference abstracts, commentaries, opinion pieces and editorials were excluded. Articles were also excluded if they were not written in English, focused on the psychosexual impact of cervical cancer, or treatment for cervical cancer or colposcopy. We decided not to include articles that focused exclusively on low-risk types of HPV (ie, genital warts) because (i) primary HPV testing will be for high-risk types of HPV and (ii) feelings about disclosing low-risk HPV were expected to be distinct because of its symptomatic, visible nature. Full-texts were obtained where an article could not be assessed from the abstract. Disagreements were resolved by discussion.

Data extraction

Data were extracted from each article using a standardised data extraction form (see online supplementary material 2). Extracted data included participant characteristics, study methods and a summary of disclosure-related outcomes. One reviewer (KFB) extracted information from each article with a second reviewer (MR) independently extracting information for 30% of the studies. Inconsistencies were resolved through discussion.

Quality assessment

A quality assessment was carried out for each article using modified versions of the National Institute for Health and Care Excellence (NICE) quality appraisal checklists for quantitative and qualitative studies (see online supplementary material 3 and 4). One reviewer (KB) carried out the quality assessments with a second

reviewer (MR) independently conducting 30% of assessments. The agreement rate between reviewers was 75%. Disagreements about study quality were resolved through discussion.

Analysis

For qualitative studies we conducted a thematic synthesis, following three stages outlined by Thomas and Harden:[28] (1) line-by-line coding of text in the results and discussion sections according to the meaning and content, (2) identifying 'descriptive themes' by looking for similarities and differences between codes and beginning to group them together into a hierarchy, (3) and generating 'analytic themes' which involves going beyond the content of the studies to generate new interpretive constructs or explanations. One author (KFB) developed a coding frame and applied it to the data with a second reviewer (MR) independently coding 25% of the included articles. Any inconsistencies were resolved through discussion. There was only one quantitative study which has been reported descriptively.

RESULTS

Search results

The initial search returned 7336 articles, which reduced to 4801 after the removal of duplicates. Of these, 4465 were excluded on the basis of their title, leaving 336 abstracts to be reviewed. Following exclusions, 41 full-texts were reviewed. Thirteen articles were excluded during the full-text review and an additional two articles were identified following backward and forward citation searches, resulting in 30 papers (see figure 1). Thirteen studies assessed concerns about disclosing an HPV infection to a sexual partner and are included in this analysis.[24 29–40] figure 1 shows the study selection process.

Studies were conducted in the US (n=7), UK (n=2), Australia (n=2), Taiwan (n=1) and Brazil (n=1) and were published between 2005 and 2016. Studies were predominantly qualitative (n=12),[24 29 30 32–40] with one quantitative study.[31] Most studies collected data using individual interviews (n=11).[24 30 32–40] One qualitative study[29] collected patient narratives of having HPV from a website of patient experiences and analysed these using content analysis. Participant and study characteristics are shown in table 1.

Quality assessment

All qualitative studies were judged to be well conducted. The single quantitative study was judged to have been designed or conducted in such a way as to minimise the risk of bias and had good internal and external validity (see table 2 for details).

Qualitative studies

We conducted a thematic synthesis of the 12 qualitative studies that assessed concerns about disclosing an HPV infection to a sexual partner. Three major themes were identified: (i) Anticipated psychological impact of disclosure, (ii) When is disclosure necessary? and (iii) Managing disclosure. Table 3 gives a brief description of each theme and provides additional example quotes.

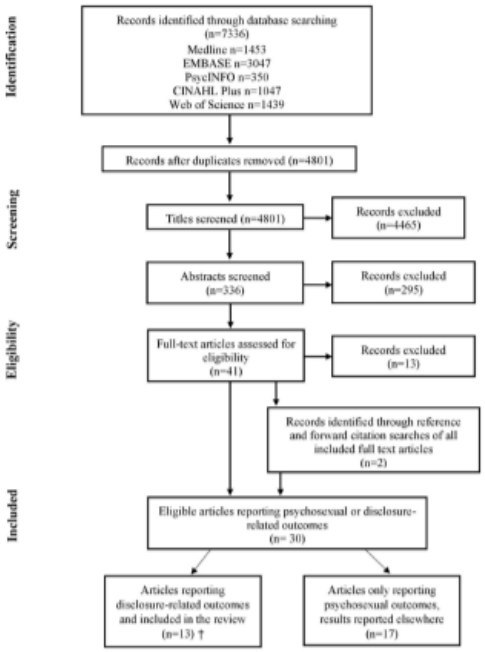

Figure 1 Flow diagram of study selection (adapted from Moher *et al*[26]) Of the 13 articles included in this review, eight articles included both disclosure and psychosexual-related outcomes and are reported in this article and elsewhere.[27]

Anticipated psychological impact of disclosure

The first theme describes the thoughts, feelings and concerns women had prior to disclosing HPV to a sexual partner. In addition to expressing general concerns, women were concerned about the stigma that was attached to having an STI and how their partner would respond.

General concerns about disclosure

While some women were not worried about disclosing the infection, others felt that the prospect of disclosure was challenging, complicated and something they wished to avoid. Women were often anxious, worried, fearful and stressed about discussing HPV with their sexual partners:[24 29 30 32 37 38]

> *"The thought of having it, deciding when to do it and how and what to say - it was extremely stressful"* [P = participant comment].[32]

Their concerns about disclosing were partly due to the stigma and shame associated with having an STI and how others would respond. Concern that they may

Table 1 Characteristics of studies measuring disclosure-related outcomes included in the review

Reference	Country	Years study conducted	Age (years)	Participants (n)	Study design	Study population	Disclosure outcomes reported
Daley *et al* (2015)[31]	USA	2003–2005	Men: 18–66 Women: 18–65	344	Questionnaire completed following receipt of an HPV-positive result	Women (n=154) attending a student health service clinic and planned parenthood clinics for a gynaecological examination and Pap smear Men (n=190) participating in the HPV in men study (HIM)*	Anticipated psychological impact of disclosure
Barnack-Tavlaris *et al* (2016)[29]	USA	2013	Not specified	127 blog posts	Content analysis of HPV blog posts	Individuals who posted a blog to the *Experience Project* website experience of "I have HPV"*	Anticipated psychological impact of disclosure
Bertram & Magnussen (2008)[30]	USA	Not specified	18–65	10	Unstructured interviews	Women with a history of an abnormal Pap smear recruited at the time of their annual gynaecological examination from a women's health clinic in Hawaii	Anticipated psychological impact of disclosure, when is disclosure necessary?, managing disclosure
Koseniko *et al* (2012)[32]	USA	Not specified	19–56	25	Semi-structured interviews	Women answering an advertisement posted online (on social media websites and online support groups) and in community centres, libraries, restaurants, coffee shops, supermarkets and buildings in college campuses in cities in the southeastern United States about the stress and coping of women with HPV	Anticipated psychological impact of disclosure, managing disclosure
Kahn *et al*. (2005)[33]	USA	2002	14–21, mean: 17.2	100	Individual interviews	Women attending an urban, hospital-based teen health centre who were tested for HPV	Anticipated psychological impact of disclosure
Lin *et al* (2011)[34]	Taiwan	2008	27–56	20	Semi-structured interviews	Women attending a gynaecological outpatient clinic of a university-based hospital in Taipei, Taiwan	When is disclosure necessary?, managing disclosure
McCaffery & Irwig (2005)[35]	Australia	2002	Range unknown, 53% were <35 years, 47% were >35 years	19	In-depth, unstructured interviews	Women attending family planning clinics, general practice and specialist gynaecologist practices in Sydney, Australia, and the surrounding area	Anticipated psychological impact of disclosure, When is disclosure necessary?
McCaffery *et al* (2006)[24]	UK	2001–2003	Age categories reported: 20–29, 30–39, 40–49, 50–64	74	In-depth interviews	Women taking part in clinic clinical trials of HPV testing or attending colposcopy clinics where HPV testing is carried out	Anticipated psychological impact of disclosure, when is disclosure necessary?, managing disclosure
McCurdy *et al* (2011)[27]	USA	2003–2004	18–47 (women that the article focuses on were aged between 21 and 45)	42 (article focuses on 18 women who were aware of their HPV status)	In-depth interviews	Women attending three private primary care clinics who were found to have atypical squamous cells of undetermined significance (ASCUS) or a low-grade squamous intraepithelial lesion as well as a high-risk HPV type	Anticipated psychological impact of disclosure
Newton & McCabe (2008)[28]	Australia	Not specified	19–59	60 (30 with genital herpes, 30 with HPV)	Semi-structured interviews	Men (n=30) and women (n=30) responding to an advertisement about the study posted on STI websites, support groups and online STI communities	Anticipated psychological impact of anticipated disclosure, when is disclosure necessary?
Parente Sa Barreto *et al* (2016)[26]	Brazil	2012	20–42	14	Semi-structured interviews	Women attending a Specialised Medical Carer Service unit (a public service supporting sexual and reproductive care). Women were excluded from the study if they were attending the unit for the first time	Anticipated psychological impact of disclosure, managing disclosure
Perrin *et al* (2006)[40]	USA	Not specified	18–44	52	In-depth, semi-structured interviews	Women diagnosed as having one or more types of HPV attending one of three clinical sites (two Planned Parenthood clinics or the Student Health Service clinic at the University of South Florida) for an annual gynaecological examination	Anticipated psychological impact of disclosure, managing disclosure

Continued

Table 1 Continued

Reference	Country	Years study conducted	Age (years)	Participants (n)	Study design	Study population	Disclosure outcomes reported
Waller *et al* (2007)[36]	UK	2003	21–64	30	In-depth, semi-structured interviews	Women taking part in the ARTISTIC trial of HPV testing (a randomised trial of HPV testing in primary cervical screening)	Anticipated psychological impact of disclosure

*The focus of this review was women's concerns about disclosing HPV and therefore the findings from men taking part in this study were not included in the review.
HPV, human papillomavirus; STI, sexually transmitted infection.

have transmitted the infection to their partner and perceptions that partners had a poor understanding of HPV also enhanced anxiety around disclosure:[24 37] "*Women repeatedly described feeling highly anxious about informing their partner, with descriptions of 'bursting into tears' and feeling intensely 'guilty' and worried that they may have infected their partner with the virus*" [A = author comment].[24] Feeling depressed about having to disclose the infection to sexual partners was reported, although this was uncommon.[38]

The stigma of having an STI

Women's concerns about anticipated disclosure were partly due to the stigma of having an STI. Women were apprehensive that they might be viewed as being promiscuous.[29 32 37] For some, the stigma of having an STI had a greater impact than concern about cancer.[30] Women felt ashamed and embarrassed about having an STI,[24 37] and the authors of one paper reported that these feelings may affect willingness to disclose an HPV infection to a sexual partner.[40]

How will others respond?

Concerns about how others would respond and react to HPV disclosure seemed to be influenced by the negative connotations of having an STI. Women were concerned that their partner would perceive them differently:[24 35] "*I was more worried about my partner reading it and saying 'aha'. I was worried about him thinking it was sexually transmitted and that I picked it up before I met him which would have concerned him a lot as we had only been together about 4 or 5 months at that stage… I was worried that it might change his opinion of me and being early in a relationship* [it was a] *bit of a concern*" [P].[35] There were concerns about being rejected by a partner following disclosure[29 33 38] and some women had specific concerns that they might be sexually rejected: "*If I told men that I had it they might not want to have sex with me*" [P].[24] Some women were worried that their partner would accuse them of infidelity[37 39] and felt that disclosure might cause harm to their relationship or even lead to it ending.[33 37 39] In extreme cases, women ended relationships because of a fear of rejection following disclosure.[38]

When is disclosure necessary?

The second theme related to women's views on whether it was necessary to disclose their HPV-positive status to a sexual partner. While some women felt obligated to disclose the infection to current and prospective partners,[30 32] a common response was to question whether it was necessary to disclose to current and previous partners.[24 30 34 35 37] This was often due to the perceived lack of serious physical consequences of HPV for men.[24 30 34] A lack of clear, consistent information

Table 2 Quality assessment rating for studies included in the review

Study	Internal validity*	External validity*	Overall assessment score†
Daley *et al* (2015)[31]	‡	§	
Barnack-Tavlaris *et al* (2016)[29]			‡
Bertram & Magnussen (2008)[30]			‡
Kosenko *et al* (2012)[32]			‡
Kahn *et al* (2005)[33]			‡
Lin *et al* (2011)[34]			§
McCaffery & Irwig (2005)[35]			‡
McCaffery *et al* (2006)[24]			‡
McCurdy *et al* (2011)[37]			‡
Newton & McCabe (2008)[38]			§
Parente Sa Barreto *et al* (2016)[39]			§
Perrin *et al* (2006)[40]			‡
Waller *et al* (2007)[36]			‡

*For quantitative studies.
†For qualitative studies.
‡Indicates that the study was designed or conducted in such a way as to minimise the risk of bias.
§Indicates that the study was partly designed to minimise bias, may not have addressed all potential sources of bias, or it was not clear from the way the study was reported.
¶Indicates that the study had significant sources of bias across all aspects of the study design.

also led women to question whether it was necessary to disclose:[24] "*Should I be telling sexual partners that I have this? And one person would say yes of course you must and another would say don't be silly almost all the population's been exposed to it … I couldn't get to the truth … they were giving me conflicting advice … I found that very distressing that I couldn't actually get real information that I could trust*" [P].[24]

Managing disclosure

The third theme related to managing disclosure. Some women reported that they were uncertain about how to approach disclosure[32 34] and wondered about the most appropriate time to disclose:[32] "*It's always in the back of your head. You know, 'Is he going to ask me back to his place? If he does, should I tell him?' It was just, 'When do I tell him?'… So, it was very much like 'What's the best timing?'… It was a lot of planning and stressing out and asking my friends, 'Do you think I need to tell him?'*" [P].[32] Some women chose not to disclose their HPV result and instead chose to tell their partners about their abnormal cytology result, potential cervical cancer, or having a gynaecological disease.[24 30 34] This was seen as a way to minimise anxiety[24] and avoid the embarrassment or complication of explaining about HPV.[24 30] Other women described being deliberately vague about how HPV was transmitted because they were concerned about how their partner would react.[24] Some chose not to disclose the infection to male partners because they perceived that HPV did not have an impact or did not know what to tell their partner.[24] The authors of one paper describe the decision not to disclose as being "… *motivated by women's desire to minimise their own anxiety during an already stressful period and to avoid dealing with a difficult issue of which they had only limited understanding*" [A].[24]

Quantitative study

Only one quantitative study reported outcomes relating to disclosure of HPV to a sexual partner.[31] HPV-positive women (n=154) aged 18–45 years were recruited through student health services and planned parenthood clinics in Florida and were asked to complete a paper survey about negative emotions (eg, anger, worry, confusion) and HPV-related stigma beliefs in relation to their HPV test result. A single statement assessed feelings about disclosure: 'Disclosing my HPV test result is risky', with 60% of women agreeing with this statement.

DISCUSSION

To our knowledge, this is the first review to synthesise the literature on women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner. The qualitative literature identified a range of concerns about disclosing HPV to a sexual partner. These concerns were partly because of the stigma associated with having an STI and the ways in which women anticipated their partners might respond. Some HPV-positive women used strategies to manage disclosure of their HPV diagnosis to a sexual partner, for example, focusing on having an abnormal screening result rather than HPV per se. The qualitative literature also found that women questioned how, when and to whom they should disclose their result. While quantitative and qualitative articles were included in the review, only

Table 3 Brief description of themes relating to the psychological impact of disclosing a human papillomavirus infection to a sexual partner and the studies associated with them

Theme	Subtheme	Studies	Explanation	Quote(s)
Anticipated psychological impact of disclosure	General concerns about disclosure	Barnack-Tavlaris *et al*[29] Bertram & Magnussen[30] Kosenko *et al*[32] McCaffery *et al*[24] McCurdy *et al*[37] Newton & McCabe[38]	Women reported feeling anxious, worried and fearful about disclosing HPV to a sexual partner.	*"For some, the stress of disclosure appeared to be the most difficult aspect of managing the HPV infection." [A][24]* *"I feel apprehensive about having to disclose this information to a sexual partner. I know that I will feel vulnerable at that moment." [P][38]*
	Stigma of having an STI	Bertram & Magnussen[30] McCaffery *et al*[24] McCurdy *et al*[37] Perrin *et al*[40] Waller *et al*[36]	Women were concerned about disclosing the infection because of the perception of promiscuity that is associated with having an STI.	*"Feelings of shame and stigma associated with having an STI may affect willingness to disclose HPV to a sexual partner." [A][40]* *"The stigma of HPV as a sexually transmitted infection was more devastating to some than the fear of cancer." [A][30]*
	How will others respond?	Barnack-Tavlaris *et al*[29] Kosenko *et al*[32] Kahn *et al*[33] McCaffery & Irwig[35] McCaffery *et al*[24] McCurdy *et al*[37] Newton & McCabe[38] Parente Sa Barreto *et al*[39]	Women were concerned how their partner would respond to disclosure, for example, whether their partner's perception of them would change or that a partner might reject them (sexually or by ending the relationship).	*"What about when I tell a guy I want to be with that I have HPV? Will he run away as if I'm some dirty girl that sleeps around, which I'm anything but?" [P][29]*
When is disclosure necessary?		Bertram & Magnussen[30] Kosenko *et al*[32] Lin *et al*[34] McCaffery & Irwig[35] McCaffery *et al*[24] McCurdy *et al*[37]	Women questioned whether it was necessary to disclose, particularly to male partners, as women were unsure of the impact for them. Women also questioned to whom they should disclosure to and the best time to disclose.	*"I guess there aren't many repercussions for the male partner. That is the hardest part: it's the partner piece. That was the biggest issue. It was really hard to find any information on it [HPV in men] even to find something that says it won't affect them." [P][30]* *"It's not like I had tons of partners, but it really could've been any of them. I don't know when, I don't know where, I don't know who. I don't know who I'm supposed to tell…". [P][32]*
Managing disclosure		Bertram & Magnussen[30] Kahn *et al*[33] Lin *et al*[34] McCaffery *et al*[24] Perrin *et al*[40]	Some women chose to focus on the abnormal cervical screening result rather than on testing positive for HPV.	*"I have told my partner that they don't know where it comes from … obviously because he'd look at me in a different light because … he'd be like, have I got it or has she been with someone else?" [P][24]* *"To manage the anxiety many women chose not to tell their partner about their HPV infection, instead focusing on their abnormal cytology result which did not carry direct connotations of sexual transmission." [A][24]*

[P] denotes a participant comment; [A] denotes an author comment. Superscript number in the Quote(s) column denotes the number of the study in the reference list.
HPV, human papillomavirus; STI, sexually transmitted infection.

one quantitative article was identified which found that over half of HPV-positive participants felt that disclosing their HPV-positive result was 'risky'.

The results of this review suggest that some women feel anxious, worried and fearful about disclosing HPV to a sexual partner and described it as something they wished to avoid. These feelings were partly related to the stigma of having an STI and concerns about how others would respond to the disclosure of an HPV diagnosis. These findings are consistent with previous research with individuals diagnosed with other STIs such as HSV and chlamydia, where disclosure has been described as something that is difficult, fear-inducing[15] and a considerable source of worry[16] with feelings of stigma, shame and concerns about negative reactions from a sexual partner also reported.[15 16 20 22 23] Although HPV is very common,[41] one study that explored knowledge of HPV across the UK, USA and Australia found that less than half of the participants knew that most sexually active individuals would acquire HPV at some point in their life.[42] Increasing knowledge of HPV and how common it is may help to reduce stigma around having the infection and reduce anxiety about disclosure. This review focused on women's views about disclosing HPV to a sexual partner, but interestingly findings from the only quantitative study included in the review suggested that women may be more concerned about disclosing than men (60% vs 50% felt 'disclosing is risky', p=0.051). Future research could explore whether partners consider disclosure to be important.

During disclosure some women deliberately avoided mentioning HPV, focusing instead on their abnormal cytology or other aspects of their screening results. Managing the psychological implications of disclosure may be more challenging for women undergoing primary HPV testing who are told they are HPV-positive with normal cytology, given that HPV will be the only abnormal result they receive. They could, however, choose to focus on the normal cytology result. Following the introduction of primary HPV testing, it may be necessary to have additional support available for women. Healthcare professionals, particularly those carrying out cervical screening, are ideally placed to give brief information during screening

which could help to mitigate the psychological impact of an HPV-positive result.

There are several advantages of primary HPV testing over cytology including increased sensitivity for detecting high-grade cervical abnormalities;[8–10] and unlike cytological screening, HPV testing is not subjective so screening error rates are likely to be reduced. Despite the advantages of HPV testing, an essential criterion for any screening programme is that the benefit gained by individuals should outweigh the harms,[43] therefore it is important to understand and address any adverse psychological consequences of testing HPV-positive. Alongside concerns about disclosing an HPV infection to a sexual partner, other research has found that receiving an HPV-positive result can lead to elevated anxiety, distress and concern about sexual relationships.[44 45] However, research conducted in the context of the English cervical screening programme, where HPV testing was used as a triage to cytological screening, suggests that psychological effects are likely to be short-lived.[46]

Some women had questions about disclosing the infection to sexual partners, including whether disclosing was necessary. Disclosure is important for some STIs so that previous partners can be screened and treated for the infection if necessary, and future transmission of the infection can be prevented. However, while HPV is classified as an STI, it differs from other infections in that it does not usually need any treatment or cause any long-term problems. In addition, because most people will be infected with HPV at some point in their life,[3] it is often difficult to determine where an HPV infection came from. Another systematic review,[27] which explored the psychosexual impact of testing positive for hrHPV, identified concerns about where an HPV infection had come from as a common theme in the qualitative literature. Contact tracing for HPV is not routinely recommended by the WHO[25] and therefore the decision to disclose HPV to a sexual partner is a personal choice. Cervical screening information materials should provide information about disclosing HPV to sexual partners to ensure that women are informed and that questions about disclosure do not cause any undue concern.

Strengths and limitations

A strength of this review is that it was systematic and followed PRISMA guidelines. In addition, a broad search strategy was used with no date restrictions. It is possible that because of the range of terms that can be used to describe disclosure, some eligible studies may not have been identified in our search; however, we conducted forward and backward citation searching for all included studies to reduce the likelihood of this. Data were extracted by one author, with a second reviewer independently extracting data for 30% of the studies. It is possible that if the second reviewer extracted data from all the studies the results of the review could have changed; however, we feel this is unlikely as the agreement rate between reviewers was very good.

Only one quantitative paper was identified that reported disclosure-related outcomes, compared with six exploring the broader psychosexual impact of HPV, as identified by our related review.[27] While the qualitative synthesis allowed us to highlight the range of different factors that contribute to women's concerns about disclosure, we were unable to provide information on the percentage of women reporting each theme, as most of the papers included in the review did not quantify these. Assessing the prevalence and predictors of these concerns using quantitative methods is important and should be a priority for future research.

Additional Educational Resources

Human papillomavirus: https://www.nhs.uk/conditions/human-papilloma-virus-hpv/
NHS cervical screening - helping you decide: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/827426/Cervical_screening_helping_you_decide_HPV.pdf
Screening, colposcopy, and cervical cancer: https://www.jostrust.org.uk/professionals

CONCLUSIONS

This review synthesises the literature on women's concerns about disclosing a high-risk cervical HPV infection to a sexual partner. The studies included in the review provide rich information about the range of concerns women have, the reasons for these concerns, and the questions women have about disclosing HPV to sexual partners. Increasing knowledge of HPV and providing clear information in screening information letters and leaflets about disclosing HPV to sexual partners may help women understand their screening result and minimise any unnecessary concern surrounding disclosure.

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Contributors KFB, JW and LAVM conceived the study and developed the search strategy. KFB and MR screened articles, extracted data and conducted quality appraisals. KFB and LAVM interpreted the data. All the authors were involved in contributing to the study design and drafting the manuscript.

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APPENDIX 4.1: STUDY 2 PUBLISHED PAPER

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Original Article
Psychosexual health

Psychosexual distress following routine primary human papillomavirus testing: a longitudinal evaluation within the English Cervical Screening Programme

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Objective To assess psychosexual distress over a 12-month period among women receiving different human papillomavirus (HPV) and cytology results in the context of the English HPV primary screening pilot.

Design Longitudinal, between-group study.

Setting Five sites in England where primary HPV testing was piloted.

Population Women aged 24–65 years (n = 1133) who had taken part in the NHS Cervical Screening Programme.

Methods Women were sent a postal questionnaire soon after receiving their screening results (baseline) and 6 and 12 months later. Data were analysed using linear regression models to compare psychosexual outcomes between groups receiving six possible combinations of HPV and cytology screening results, including a control group with normal cytology and no HPV test.

Main outcome measures Psychosexual distress, assessed using six items from the Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q).

Results At all time points, there was an association between screening result group and psychosexual distress (all $P < 0.001$). At baseline, mean psychosexual distress score (possible range: 1–5) was significantly higher among women with HPV and normal cytology (B = 1.15, 95% CI 0.96–1.34), HPV and abnormal cytology (B = 1.02, 95% CI: 0.78–1.27) and persistent HPV (B = 0.90, 95% CI 0.70–1.10) compared with the control group (all $P < 0.001$). At the 6 and 12 month follow ups the pattern of results were similar, but coefficients were smaller.

Conclusions Our findings suggest receiving an HPV-positive result can cause psychosexual distress, particularly in the short-term. Developing interventions to minimise the psychosexual burden of testing HPV-positive will be essential to avoid unnecessary harm to the millions of women taking part in cervical screening.

Keywords Cervical screening, human papillomavirus, psychosexual distress.

Tweetable abstract Receiving an HPV-positive result following primary HPV testing can cause psychosexual distress, particularly in the short-term.

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Introduction

Several countries, including England, have introduced primary human papillomavirus (HPV) testing for cervical screening because of its higher sensitivity for identifying high-grade precancerous disease compared with cytology-based testing.[1–3] All women taking part in cervical screening in England are informed whether they are positive or negative for high-risk HPV. When HPV is found, the residual sample is used for cytology triage. Women with HPV and normal cytology are re-screened after 12 months and those with abnormal cytology are referred for colposcopy.[4] Because HPV is sexually transmitted, primary HPV testing may have implications for psychosexual functioning.[5]

Psychosexual functioning includes feelings, worries and concerns that relate to, or impact on, sexual behaviour or sexual relationships. A systematic review of 25 studies[5] identified a range of HPV-related psychosexual concerns in the qualitative literature. These included concern about where the infection came from and transmitting HPV to a sexual partner. For some women, testing HPV-positive had an impact on interpersonal and sexual relationships. However, quantitative studies found mixed evidence for differences in psychosexual outcomes between HPV-positive women and comparison groups (usually those not tested for HPV or those with an HPV-negative result).

Previous studies exploring psychosexual functioning following HPV testing have all been carried out in co-testing contexts in England, and never in the context of HPV primary screening.[6–8] One study found that HPV-positive women were more likely to report feeling worse about their sexual relationships a week after receiving their result than HPV-negative women, irrespective of their cytology result.[8] Another compared three groups of women with abnormal cytology and different HPV results (HPV-positive, HPV-negative and no HPV test).[6] Six months after receiving their test results, sexual worries were significantly higher among HPV-positive women than in the other two groups. One longitudinal Taiwanese study of HPV-positive women found that impact on sexual relationships appeared to decline between 1 and 6 months after screening but remained similar at 6 and 12 months.[9]

Evaluating psychosexual distress following receipt of different HPV and cytology results will help to establish whether receiving particular results causes concern or has an adverse effect on women's relationships. Understanding the time-points at which the impact is greatest could inform decisions about the timing of interventions. The aim of this study was to assess psychosexual distress following primary HPV testing among women receiving different HPV and cytology results, at three time-points over a year.

Methods

Study design and population

Data were collected as part of the Psychological Impact of Primary Screening for HPV (PIPS) study (details reported elsewhere[10]), which was funded by Public Health England (PHE). A between-group design was used to assess women at three time-points: shortly after receiving their screening result ('baseline'), and 6 and 12 months later. Participants included screening eligible women (i.e. those aged 24–65 years) who had taken part in the NHS Cervical Screening Programme in one of five primary HPV screening pilot sites. Potential participants received invitation packs by post within 3weeks of receiving their screening result. Those who wished to take part returned a completed consent form and questionnaire booklet. Participants who returned a consent form were mailed questionnaire packs 6 and 12 months later. Patients were not involved in the development of this research.

Of the 5488 women who were invited to take part in the study, 21% (n = 1154) returned a questionnaire booklet at baseline. Participants returning a questionnaire >90 days after date of identification and those who were aged >65 years and ineligible to take part in the study were excluded (n = 21). Of the remaining 1133 participants, 1132 consented to receive follow-up questionnaires, 67% (n = 768) returned a questionnaire booklet at 6 months and 47% (n = 542) at 12 months. Altogether, 40.3% (n = 456) returned questionnaire booklets at baseline, 6 months and 12 months. Women were included in the analyses if they returned a questionnaire at one or more time-points. Please see Figure S1 for an overview of recruitment and response.

Three groups of women were recruited following their first HPV test: those who tested HPV-negative, those who were HPV-positive with normal cytology (HPV-positive, normal cytology) and those who were HPV-positive with abnormal cytology (HPV-positive, abnormal cytology). In addition, two groups of women who had initially tested positive for HPV and were attending their 12-month follow-up appointment were recruited: those who were still found to have HPV (HPV persistent), and those who tested HPV-negative at the follow-up appointment (HPV cleared). A group of women who had taken part in cytology-based screening and had received a normal result were recruited as a control group. Throughout this paper, when we refer to screening result, we mean one of the five groups we recruited based on combinations of HPV and cytology test results that women would receive in the screening programme.

Measures

The primary outcome measures for the PIPS study (anxiety and distress) are reported elsewhere.[11] Psychosexual functioning was a secondary outcome, assessed using six items, five of which were taken from the Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q), a validated measure of distress experienced by women undergoing follow-up investigation after an abnormal Pap smear result.[12] These items measured two dimensions of psychosexual distress: worry about infectivity (2 items) and effect on sexual relationships (3 items). An additional item asked: 'Have you been worried about whether your test result would have a bad effect on your relationship with your partner?' This item was taken from Maissi et al.[6] All six items used a 5-point Likert response scale: Not at all (1), A little (2), A fair bit (3), Quite a lot (4), Very much (5), with an additional 'not applicable' option.

Overall psychosexual distress was calculated as the mean of all six items, as they showed good internal reliability

($\alpha = 0.93$, $n = 898$). The potential range was 1–5, with higher scores indicating greater distress. Only women who had responded to all six psychosexual items were included in these analyses: 79% ($n = 898$) at baseline, 76% at 6 months ($n = 581$) and 78% at 12 months ($n = 418$). As the aim of the study was to assess the prevalence and magnitude of psychosexual distress following HPV testing, we excluded women who answered 'not applicable' to one or more questions (19% [$n = 214$] at baseline, 22% [$n = 167$] at 6 months and 21% [$n = 113$] at 12 months).

Socio-demographic variables including self-reported ethnicity (white, ethnic minority, prefer not to say), educational attainment (degree or higher, qualification below degree, no formal qualifications) and relationship status (current partner versus no partner) were collected. Age and Index of Multiple Deprivation (IMD) quintile (a postcode-based measure of relative deprivation for small areas in England[13]) were collected from NHS clinical records.[10] Socio-demographic variables were collected at baseline only.

Analyses

Analyses were carried out using SPSS v22 (IBM Corp, Armonk, NY, USA) and STATA SE v15 (StataCorp LLC, College Station, TX, USA).

We used linear regression models to explore the association between screening result group and psychosexual distress cross-sectionally at baseline, 6 and 12 months.

We also used conditional change linear regression models to examine changes in psychosexual distress by screening result group between baseline and 6 and 12 months. Using this approach, the baseline psychosexual distress score is controlled for, so the regression coefficients indicate how the screening result group is associated with changes in psychosexual distress over time.[14]

In all models, we adjusted for baseline demographic characteristics (age, ethnicity, education, marital status and IMD quintile) and applied weights to adjust for the possibility that the approached sample may not have been representative of the screening population in the HPV testing pilot sites (details described elsewhere).[11]

We also explored between-group differences for each individual PEAPS-Q item at baseline, 6 and 12 months. All women who had responded to an item, regardless of whether they were excluded from the overall psychosexual distress analyses, were included in the individual item analyses. In the original PEAPS-Q development paper, Bennetts et al.[12] classified a woman as 'distressed' if she responded 'Quite a lot' or 'Very much' to an item. We dichotomised responses in this way, coding women as 'distressed' (if they responded 4 or 5) or 'not distressed' (if they responded 1–3). The percentage of women reporting 'psychosexual distress' was calculated for each item and is reported by screening result group. Where we report 'distress' we are referring to psychosexual distress rather than general psychological distress.

Results

Characteristics of the 1088 women who responded to at least one psychosexual item at baseline are shown in Table 1. Demographic characteristics of the sample by screening result group are presented elsewhere.[11] At baseline, women had a mean age of 41 years, were predominantly white (92%), half had a qualification below degree level (49%) and most had a current partner (79%).

Psychosexual distress across result groups

Adjusted and weighted beta coefficients (with 95% confidence intervals) and *P*-values for the relation between psychosexual distress and result group cross-sectionally at baseline, 6 and 12 months are presented in Table 2. Adjusted mean psychosexual distress scores for each group at baseline, 6 and 12 months are presented in Figure 1.

At baseline, there was a significant association between screening result and psychosexual distress ($P < 0.001$). Compared with the control group, psychosexual distress was higher among women in the HPV-positive, normal cytology group (by 1.15 points), the HPV-positive, abnormal cytology group (by 1.01 points), the HPV persistent group (by 0.91 points) and the HPV cleared group (0.62 points higher; all $P < 0.001$). There was no significant difference between the control group and the HPV-negative group ($P = 0.974$) (see Table 2).

At the 6 and 12 month follow up, the association between result group and psychosexual distress remained significant ($P < 0.001$). The pattern of results was similar to that seen at baseline, although coefficients were smaller. Psychosexual distress remained highest and significantly different from the control group ($P < 0.001$) in all three HPV-positive groups. Compared with the control group, psychosexual distress was higher among women in the HPV-positive, normal cytology group (by 0.68 points at 6 months and 0.81 points at 12 months), the HPV-positive, abnormal cytology group (by 0.64 points at 6 months and 0.50 points at 12 months) and the HPV persistent group (by 0.68 points at 6 months and 0.69 points at 12 months). For the HPV cleared group, psychosexual distress was not significantly higher than the control group at 6 months ($P = 0.076$) but was at 12 months (by 0.37 points, $P = 0.024$). There was no significant difference between the control group and the HPV-negative group at 6 months ($P = 0.767$) or 12 months ($P = 0.931$).

Adjusted and weighted beta coefficients (with 95% confidence intervals) and *P*-values for the association between changes in psychosexual distress by screening result group

Table 1. Demographic characteristics of the sample included in analysis at baseline (n = 1088)*, 6-month follow up (n = 734) and 12-month follow up (n = 503)

	Baseline *n* (%)	6 mo *n* (%)	12 mo *n* (%)
Screening result group			
HPV-negative	233 (21.4)	176 (24.0)	115 (22.9)
HPV-positive, normal cytology	251 (23.1)	169 (23.0)	105 (20.9)
HPV-positive, abnormal cytology	167 (15.3)	106 (14.4)	70 (13.9)
HPV persistent	177 (16.3)	115 (15.7)	88 (17.5)
HPV cleared	63 (5.8)	41 (5.6)	34 (6.8)
Control (normal cytology)	197 (18.1)	127 (17.3)	91 (18.1)
Age (mean years/SD)	40.84 (SD = 11.68)	42.78 (SD = 11.70)	42.70 (SD = 11.86)
Ethnicity			
White (British or other)	982 (92.0)	676 (92.1)	464 (92.2)
Ethnic minority	83 (7.8)	43 (5.9)	32 (6.4)
Prefer not to say	2 (0.2)	0 (0)	0 (0)
Education			
Degree or higher	470 (44.3)	329 (44.8)	231 (45.9)
Qualification below degree	516 (48.6)	344 (46.9)	227 (45.1)
No formal qualifications**	75 (7.1)	46 (6.3)	36 (7.2)
Marital status* **			
Current partner	841 (78.7)	566 (77.1)	394 (78.3)
No partner	228 (21.3)	155 (21.1)	102 (20.3)
IMD quintile			
1 (most deprived)	165 (16.4)	92 (12.5)	62 (12.3)
2	204 (20.2)	126 (17.2)	85 (16.9)
3	265 (26.3)	185 (25.1)	149 (29.6)
4	182 (18.1)	135 (18.4)	95 (18.9)
5 (least deprived)	192 (19.0)	139 (18.9)	83 (16.5)

*The samples included in these analyses differ from the total sample at each time-point, as only women responding to one or more of the psychosexual items are included.
**No formal qualifications included those with no qualifications and those still studying.
***Marital status: 'current partner' included those who were married, in a civil partnership, living with a partner or in a relationship. 'No partner' included those who were single, divorced, separated or widowed.

at 6 and 12 months are presented in Table 2. There were significant reductions in psychosexual distress among women in the HPV-positive, normal cytology group (by 0.45 points at 6 months and 0.54 points at 12 months), the HPV-positive, abnormal cytology group (by 0.44 points at 6 months and 0.33 points at 12 months) and the HPV persistent group (by 0.47 points at 6 months and 0.46 points at 12 months). There were no significant changes in psychosexual distress among women in HPV cleared group at 6 months (P = 0.405) or 12 months (P = 0.227) or the HPV-negative group at 6 months (P = 0.767) or 12 months (P = 0.931).

Psychosexual distress by individual item

The overall percentage of participants who were categorised as 'distressed' for each item at baseline, 6 and 12 months is presented in Table 3. The table also shows the proportion who were distressed at baseline by screening result group (see Table S1 and S2 for 6 and 12 month follow-up data by group).

At baseline, the percentage who were distressed was lowest among the control group (range: 0–2.9%) and the HPV-negative group (range: 0–1.4%) and highest among the three HPV-positive groups (HPV-positive, normal cytology range: 16.5–31%; HPV-positive, abnormal cytology range: 15.2–26.3%; HPV persistent range: 11.7–27.9%). Overall, the percentage classed as distressed decreased over time for all items. At all three time-points, distress was most prevalent for the two items assessing worry about infectivity.

Discussion

Main findings

Women testing positive for HPV at cervical screening reported higher psychosexual distress than those receiving a

Table 2. Cross-sectional associations between psychosexual distress and screening result group and change in psychosexual distress (weighted[1] and adjusted[2,3])

	Cross-sectional associations[2]			Change in psychosexual distress[3]		
	At baseline B^4 (95% CI)	At 6 mo B^4 (95% CI)	At 12 mo B^4 (95% CI)	By 6 mo B^4 (95% CI)	By 12 mo B^4 (95% CI)
Screening result group					
Control group (normal cytology)	Reference	Reference	Reference	Reference	Reference
HPV-negative	0.001 (−0.090,0.087)	−0.016 (−0.125,0.092)	0.004 (−0.086,0.094)	0.022 (−0.118,0.161)	0.091 (−0.267, 0.209)
HPV-positive, normal cytology	1.148 (0.960,1.336)***	0.675 (0.493,0.857)***	0.810 (0.558,1.061)***	−0.450 (−0.636,−0.263)***	−0.543 (−0.776,−0.310)***
HPV-positive, abnormal cytology	1.014 (0.771,1.256)***	0.639 (0.374,0.903)***	0.503 (0.217,0.788)**	−0.438 (−0.700,−0.176)**	−0.325 (−0.607,−0.044)*
HPV persistent	0.905 (0.705,1.105)***	0.676 (0.434,0.918)***	0.690 (0.471,0.909)***	−0.471 (−0.694,−0.250)***	−0.463 (−0.676,−0.250)***
HPV cleared	0.616 (0.330,0.901)***	0.239 (−0.026,0.504)	0.368 (0.049,0.686)*	−0.108 (−0.364,0.147)	−0.174 (−0.457,0.109)
Constant	0.866 (0.584,1.149)***	0.829 (0.530,1.128)***	0.766 (0.417,1.115)***	−0.465 (−0.782,−0.147)**	−0.538 (−0.892,−0.184)**
Model F	22.90	9.89	7.35	21.34	20.66
Number of observations	801	520	383	517	382
R^2	0.281	0.222	0.221	0.626	0.647

[1]Weighted by age group and IMD quintile.
[2]Cross-sectional models were adjusted for age, ethnicity, marital status, education and IMD.
[3]Conditional change models were adjusted for age, ethnicity, marital status, education, IMD and baseline psychosexual distress score.
[4]Beta coefficients (with 95% CI) indicating the degree of change in psychosexual distress for each screening result group compared to the reference group (i.e. the control group).
*$P < 0.05$.
**$P < 0.01$.
***$P < 0.001$.

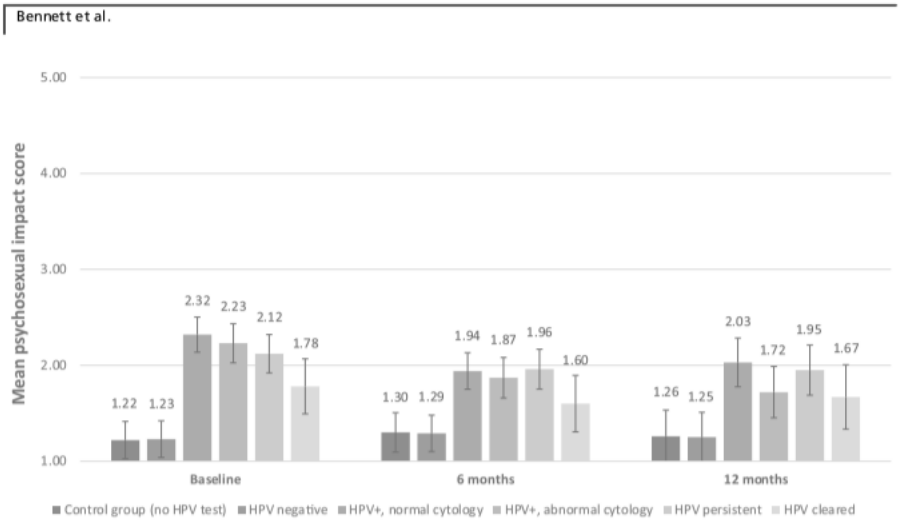

Figure 1. Adjusted* mean scores for psychosexual distress at baseline, 6 mo and 12 mo by result group with 95% confidence intervals (unweighted). *Adjusted for age, ethnicity, marital status, education and IMD.

normal cytology result with no HPV test. The differences were observed immediately after screening and were attenuated but remained significant 6 and 12 months later. HPV-negative women who had tested positive 12 months previously ('HPV cleared') also had higher psychosexual distress immediately after their HPV-negative result and 12 months later. Our findings suggest that psychosexual distress declines over time among HPV-positive women in the first 6 months.

Strengths and limitations

This is the first longitudinal study to explore psychosexual distress following routine primary HPV screening among women with different HPV and cytology results. It is also the first study to include a group of women who had previously tested HPV-positive and were found to have cleared the infection 12 months later. The main limitation of the study was the low response rate, which ranged by screening result group from 16% in those not tested for HPV to 28% in those with persistent HPV. In addition, a third of women who participated at baseline did not complete the 6-month follow up, and a further 20% did not complete the 12-month follow up. We have no psychosexual functioning data for the women who did not respond, so we cannot rule out the possibility that response to the survey was systematically associated with psychosexual distress. However, we were able to weight our data to the screening population in the HPV testing pilot sites for age and IMD, helping to improve representativeness with respect to demographic characteristics.

This study consisted predominantly of women of white ethnicity, which reflects the screening population in the UK. Previous research suggests that the stigma of testing HPV-positive may be greater among some minority ethnic groups.[15,16] Research specifically designed to explore psychosexual distress following HPV testing in minority ethnic groups is needed.

Interpretation

Our study was conducted in the context of the English HPV primary screening pilot. Although carried out in a different setting, our findings are similar to those by Hsu et al.,[9] who found that the impact on sexual relationships declined between 1 and 6 months and remained similar between 6 and 12 months. They are also consistent with Maissi et al.,[6] who found that 6 months after receiving results, psychosexual outcomes were virtually the same for women testing HPV-negative and those not tested for HPV, but significantly higher for women who were HPV-positive. Psychosexual distress scores for HPV-positive women in our study were slightly lower than in Maissi et al.;[6] however, increased awareness and knowledge of HPV since 2005 may have helped to reduce the negative psychosexual consequences of testing HPV-positive.

The percentage of women classified as distressed for each individual item at baseline ranged from 9 to 17%. Distress was more prevalent than reported by Bennetts et al.,[12] who classified 3–11% of women as distressed during follow-up investigation after an abnormal Pap smear result. The

Table 3. Percentage 'distressed'* for individual psychosexual questions at baseline, 6 mo and 12 mo and by screening result group at baseline

Have you been worried…	% (*n*) 'distressed'*									
	All women testing HPV-positive**			HPV-positive, normal cytology	HPV-positive, abnormal cytology	HPV persistent	Control group	HPV-negative	HPV cleared
	Baseline	6 mo	12 mo			Baseline			
	n = 1088	*n* = 734	*n* = 503	*n* = 251	*n* = 167	*n* = 177	*n* = 197	*n* = 233	*n* = 63
…whether you should continue having sex?	16.8 (93)	7.2 (26)	9.7 (24)	18.8 (44)	18.8 (29)	12.0 (20)	0 (0)	0.4 (1)	6.6 (4)
…others think you have had more sexual partners than you should?	16.8 (96)	10.5 (39)	11.2 (29)	17.9 (42)	16.1 (26)	15.9 (28)	0 (0)	1.4 (3)	9.7 (6)
…about whether your test result would have a bad effect on your relationship with your partner?	18.7 (98)	10.5 (36)	9.4 (22)	20.5 (45)	16.2 (23)	18.6 (30)	1.1 (2)	0.5 (1)	12.3 (7)
…whether having sex will make the problem worse?	14.7 (82)	10.0 (37)	7.2 (18)	16.5 (38)	15.2 (24)	11.8 (20)	1.1 (2)	1.0 (2)	9.8 (6)
… that you could give the problem to a sexual partner?	27.6 (154)	18.1 (66)	16.6 (42)	28.3 (66)	26.3 (41)	27.8 (47)	2.3 (4)	0.5 (1)	16.4 (10)
…a sexual partner will think they can catch the problem from you?	27.2 (150)	16.5 (60)	16.6 (41)	31.0 (72)	24.3 (37)	24.6 (41)	2.9 (5)	0 (0)	15.0 (9)

*Percentage of women who responded 'Quite a lot' or 'Very much' on the Likert scale.
**Includes women in the HPV-positive, normal cytology, HPV-positive, abnormal cytology and HPV persistent groups.

diagnosis of a sexually transmitted infection can be associated with feelings of stigma and shame[17–19] and it is possible that the stigma of having HPV may have a greater impact on psychosexual functioning than receiving an abnormal cytology result does. This is supported by qualitative research which suggested some women chose not to disclose their HPV infection to their partner and instead focused on their abnormal cytology result, which did not carry the same negative connotations.[15]

The most commonly endorsed items at all three timepoints concerned infectivity, with around 25% of women who were HPV-positive indicating infectivity concerns at baseline. This finding is consistent with a synthesis of qualitative research exploring the psychosexual impact of testing HPV-positive.[5] Transmission and the impact of HPV on a sexual partner have been identified as key topics that women want more information on, and uncertainty about these aspects of HPV can influence women's psychological response to HPV.[20] This highlights the importance of ensuring that common questions and concerns about infectivity and transmission are addressed in materials for women who test HPV-positive.

At baseline, psychosexual distress was highest among women in the HPV-positive with normal cytology group. Testing HPV-positive with normal cytology is a new result created by the primary HPV screening pathway, and because knowledge of HPV can be low[21] it is possible that women unfamiliar with this new result lack understanding about what it means for their sexual relationships. In addition, with no abnormal cytology result, there may be greater focus on HPV which, as a sexually transmitted infection (STI), may have greater potential for psychosexual impact. Psychosexual distress may also be exacerbated by the prospect of having to wait a year to see whether the infection has cleared. Reassuringly, psychosexual distress declined between baseline and 6 months in this group.

At 12 months, psychosexual distress was still highest among women in the HPV-positive with normal cytology group. However, there were smaller reductions in psychosexual distress between baseline and 12 months in the HPV-positive with abnormal cytology group than in the HPV-positive with normal cytology group. It is possible that women in the HPV-positive with normal cytology group who returned the 12-month questionnaire were the most concerned (responder bias), which is why, cross-sectionally, psychosexual distress was highest in this group.

Compared with women not tested for HPV, the HPV cleared group had significantly higher psychosexual distress at baseline and this remained significantly higher 12 months later. Although the mean psychosexual distress score was not as high in the HPV cleared group as the three HPV-positive groups, this suggests that women who had previously tested HPV-positive may still have residual psychosexual concerns, despite an HPV-negative result. A qualitative study[22] exploring women's experiences of repeat HPV testing found that some had concerns about the infection recurring and worried that it was lying dormant and might reappear in the future. Future research should explore psychosexual concerns specific to this group.

Our findings suggest that receiving an HPV-positive result can lead to elevated psychosexual distress, particularly in the short-term. It should be noted that the differences between the three HPV-positive groups and the control group were small at baseline (a difference of ~1 point on a 5-point scale) and smaller still at follow up (<1 point difference).For most women, it is unlikely that testing HPV-positive would have a meaningful impact on psychosexual functioning. There is no established 'normal' range for the PEAPS-Q, so it is difficult to determine whether these differences are clinically significant. Although we are unable to determine the number of women who are likely to present with psychosexual concerns requiring clinical services (e.g. psychosexual counselling), the study suggests that there are women who have concerns therefore efforts to address these at a population level are important. As the individual psychosexual items suggest concerns about infectivity are relatively common, simple interventions such as including information about this in results letters and leaflets for women who test HPV-positive should be considered.

It is possible that women may have additional psychosexual concerns not captured by the items we used. Future research should use qualitative methodology to explore the full range of psychosexual questions and concerns among women taking part in HPV-based cervical screening. This additional insight may help to ensure that screening information materials and results letters meet the needs of women with different HPV and cytology results.

Conclusion

This study suggests that testing HPV-positive can result in elevated psychosexual distress, particularly in the short-term. It is reassuring that psychosexual distress decreased over time; however, even at the 12-month follow up there were small differences between the control group (who were not tested for HPV) and women who were HPV-positive or had cleared a previous HPV infection. Developing interventions to minimise the psychosexual burden of testing positive for HPV will be essential to avoiding unnecessary harm to the millions of women taking part in cervical screening.

Disclosure of interests

KB received grants from the Medical Research Council (MRC) during the conduct of the study. JW, AF and LM

received grants from Cancer Research UK during the conduct of the study. EM received grants from the National Institute for Health Research (NIHR) during the conduct of the study. Public Health England (PHE) commissioned the project and paid salary costs for EM during the data collection period as well as all research costs. GDG and HK have nothing to disclose. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

JW, AF, HK and LM conceived the study. JW, EM, AF and LM developed the measures. KB and GDG conducted the analyses. KB drafted the paper. All authors contributed to the final version of the manuscript.

Details of ethics approval

Health Research Authority approval was obtained on 26 September 2016 and approval from London-Surrey NHS Research Ethics Committee (REC) on 30 August 2016 (Research Ethics Committee reference: 16/LO/0902). Section 251 approval was also obtained from the Confidentiality Advisory Group (CAG) for use of patient name and address without consent for the purposes of participant approach on 24 August 2016 (Confidentiality Advisory Group reference: 16/CAG/0047).

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. An overview of recruitment and response

Table S1. Percentage 'distressed'[1] for individual psychosexual questions by screening result group at 6-month follow up

Table S2. Percentage 'distressed'[1] for individual psychosexual questions by screening result group at 12-month follow-up ■

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APPENDIX 4.2: PSYCHOSEXUAL FUNCTIONING ITEMS USED IN THE PIPS STUDY

Since receiving your screening result...

Have you been worried whether you should continue having sex?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

Have you been worried others think you have had more sexual partners than you should?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

Have you been worried about whether your test result would have a bad effect on your relationship with your partner?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

Have you been worried whether having sex will make the problem worse?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

Have you been worried that you could give the problem to a sexual partner?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

Have you been worried a sexual partner will think they can catch the problem from you?

Not at all ☐ A little ☐ A fair bit ☐ Quite a lot ☐ Very much ☐ Not applicable ☐

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APPENDIX 4.3: METHODOLOGY USED FOR MISSING, LOST TO FOLLOW-UP AND NOT APPLICABLE RESPONSES

At each time point variables were derived by dichotomising women into two groups. For missing data, women were categorised as those who had missing data for one or more psychosexual item vs. those who did not have any missing data. For not applicable data, women were categorised as those who had responded not applicable to one or more psychosexual item vs. those who had not responded not applicable to any of the psychosexual items. For lost to follow-up, women were categorised as those who had responded vs. those who had not responded.

Differences in the number of participants with missing and not applicable responses, and participants lost to follow-up by screening result group and demographic characteristics were assessed using Fisher's exact test (for categorical variables) and t-tests (for continuous variables). Fisher's exact test was chosen over the Chi-square test due to the small numbers in some of the groups. When the numbers in groups are small, running a Chi-square test may fail to produce reliable results (Mehta et al., 1989). Under these circumstances, calculating a significance level based on the exact distribution of the test statistic results is recommended (Mehta et al., 1989). Where computational limits would not allow Fisher's exact test to be run (due to insufficient memory to calculate results), the Monte Carlo Method was used (Mehta et al., 1989).

Univariate logistic regression models were used to explore whether responding not applicable, or not responding to the 6 or 12-month follow-up was associated with screening result group or demographic characteristics. Univariate logistic regression models were not used to explore the association between missing data and screening result group and demographic characteristics due to the small number of participants with missing data. A common 'rule of thumb' based on simulation studies is that for each independent variable there should be at least ten observations for each binary category (Peduzzi et al., 1996; Stoltzfus, 2011). Logistic regression can be problematic when the numbers of observations are small and may result in biased parameter estimates and invalid tests of significance (Peduzzi et al., 1996).

Due to small numbers in some of the ethnicity, education and marital status categories, variables were recoded for regression analyses. For ethnicity,

women were coded as either ‘White (British or other)’ or ‘Ethnic minority group’ (which included women in the Mixed/multiple ethnicity, Black, Asian and ‘Other’ groups). Women who responded ‘Prefer not to say’ to the ethnicity item were coded as missing. The recoded education variable consisted of four categories: ‘Degree or higher’, ‘Qualification below degree’ (which included women in the higher education below degree, A Levels, ONS/BTEC and GCSE/O Level categories), ‘No formal qualifications’ and ‘Still studying’. The recoded marital status variable consisted of two categories: ‘Current Partner’ (which included women in a relationship, living with a partner and married or in a civil partnership) and ‘No partner’ (which included women who were single, separated, divorced or widowed).

Analyses were carried out using IBM SPSS Statistics for Windows, Version 22 (IBM Corp., 2013).

APPENDIX 4.4: PARTICIPANTS WHO DID NOT RESPOND TO THE 6 AND 12-MONTH FOLLOW-UP BY SCREENING RESULT GROUP, DEMOGRAPHIC CHARACTERISTICS AND BASELINE PSYCHOSEXUAL DISTRESS SCORE

	Non-responders			
	6 months		12 months	
	n (%)	p	n (%)	p
Screening result group		0.117		0.159
HPV negative	63 (25.3)		119 (47.8)	
HPV positive, normal cytology	84 (32.4)		149 (57.5)	
HPV positive, abnormal cytology	65 (37.8)		98 (57.0)	
HPV persistent	59 (33.0)		89 (49.7)	
HPV cleared	24 (36.4)		31 (47.0)	
Control (normal cytology)	69 (33.3)		104 (50.2)	
Age (mean years/SD)	37.42 (10.97)	<0.001	39.29 (11.26)	<0.001
Ethnicity		0.003		0.126
White (British or other)	309 (30.4)		515 (50.6)	
Mixed ethnicity	7 (38.9)		11 (61.1)	
Asian	19 (57.6)		22 (66.7)	
Black	10 (43.5)		15 (65.2)	
Other	8 (50.0)		9 (56.3)	
Prefer not to say	2 (66.7)		3 (100.0)	
Education		0.132[1]		0.140[1]
Degree or higher	132 (27.4)		229 (47.6)	
Higher education (below degree)	48 (34.3)		82 (58.6)	
A Levels	47 (35.9)		67 (51.1)	
ONC/BTEC	16 (33.3)		28 (58.3)	
GCSE/O Levels	71 (32.4)		115 (52.2)	
No formal qualifications	27 (43.5)		38 (61.3)	
Still studying	7 (33.3)		9 (42.9)	

APPENDIX 4.4: PARTICIPANTS WHO DID NOT RESPOND TO THE 6 AND 12-MONTH FOLLOW-UP BY SCREENING RESULT GROUP, DEMOGRAPHIC CHARACTERISTICS AND BASELINE PSYCHOSEXUAL DISTRESS SCORE (CONTINUED)

	Non-responders			
	6 months		12 months	
	n (%)	p	n (%)	p
Marital Status		0.030[1]		0.112
Single	61 (32.3)		107 (56.6)	
In a relationship	74 (36.8)		112 (55.7)	
Separated	3 (25.0)		6 (50.0)	
Living with partner	83 (38.4)		114 (52.8)	
Married/Civil Partnership	117 (26.5)		210 (47.5)	
Widowed	5 (41.7)		3 (25.0)	
Divorced	11 (27.5)		23 (57.5)	
IMD Quintile		<0.001		<0.001
1 (most deprived)	73 (42.7)		109 (63.7)	
2	81 (38.4)		120 (56.9)	
3	84 (30.2)		122 (43.9)	
4	55 (28.2)		89 (45.6)	
5 (least deprived)	45 (23.3)		98 (50.8)	
Baseline psychosexual distress (mean score/SD)	1.75 (1.05)	0.546	1.76 (1.06)	0.165

[1] Monte Carlo Estimate

APPENDIX 4.5: THE ODDS OF NOT RESPONDING TO THE 6 AND 12-MONTH FOLLOW-UPS BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS (WITH 95% CONFIDENCE INTERVALS)

	Unadjusted odds ratios for not responding to the 6 and 12-month follow-ups			
	6 months		12 months	
	OR (95% CI)	p	OR (95% CI)	p
Screening result group		0.130		0.161
HPV negative	1.476 (0.983,2.216)	0.060	1.103 (0.763,1.595)	0.602
HPV positive, normal cytology	1.042 (0.706,1.537)	0.837	0.745 (0.516,1.076)	0.117
HPV positive, abnormal cytology	0.823 (0.539,1.256)	0.366	0.762 (0.508,1.145)	0.191
HPV persistent	1.017 (0.665,1.556)	0.938	1.021 (0.684,1.523)	0.919
HPV cleared	0.875 (0.490,1.561)	0.651	1.140 (0.655,1.986)	0.644
Control (normal cytology)	Reference		Reference	
Ethnicity		<0.001		0.022
White (British or other)	Reference		Reference	
Ethnic minority group	0.456 (0.295,0.703)	<0.001	0.593 (0.379,0.926)	0.022
Education		0.028		0.057
Degree or higher	Reference		Reference	
Qualification below degree	0.740 (0.566,0.968)	0.028	0.766 (0.598,0.980)	0.034
No formal qualifications	0.490 (0.286,0.842)	0.010	0.574 (0.334,0.986)	0.044
Still studying	0.756 (0.299,1.916)	0.556	1.212 (0.501,2.929)	0.670
Marital Status		0.934		0.242
Current partner	Reference		Reference	
No partner	1.013 (0.749,1.369)	0.934	0.845 (0.638,1.120)	0.242
IMD Quintile		<0.001		<0.001
1 (most deprived)	0.408 (0.260,0.641)	<0.001	0.587 (0.385,0.894)	0.013
2	0.488 (0.316,0.753)	0.001	0.782 (0.528,1.158)	0.220
3	0.702 (0.461,1.069)	0.099	1.319 (0.913,1.907)	0.141
4	0.774 (0.490,1.222)	0.272	1.229 (0.825,1.831)	0.312
5 (least deprived)	Reference		Reference	

APPENDIX 4.6: MISSING DATA FOR INDIVIDUAL PSYCHOSEXUAL ITEMS AT BASELINE, 6 AND 12 MONTHS

Have you been worried…	Baseline n (%)	6 months n (%)	12 months n (%)
…whether you should continue having sex?	16 (1.4)	7 (0.9)	5 (0.9)
…whether others think you have had more sexual partners than you should?	17 (1.5)	8 (1.0)	5 (0.9)
…about whether your test result would have a bad effect on your relationship with your partner?	15 (1.3)	7 (0.9)	6 (1.1)
…whether having sex will make the problem worse?	18 (1.6)	9 (1.2)	8 (1.5)
…that you could give the problem to a sexual partner?	18 (1.6)	9 (1.2)	8 (1.5)
…a sexual partner will think they can catch the problem from you?	19 (1.7)	9 (1.2)	6 (1.1)

APPENDIX 4.7: MISSING DATA FOR ONE OR MORE PSYCHOSEXUAL ITEM BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS

	Missing data for one or more psychosexual item					
	Baseline		6 months		12 months	
	n (%)	p	n (%)	p	n (%)	p
Screening result group		0.083		0.498		0.081
HPV negative	9 (3.6)		6 (3.3)		7 (5.4)	
HPV positive, normal cytology	5 (1.9)		2 (1.1)		2 (1.8)	
HPV positive, abnormal cytology	3 (1.7)		1 (0.9)		0 (0)	
HPV persistent	0 (0)		3 (2.5)		0 (0)	
HPV cleared	0 (0)		1 (2.4)		0 (0)	
Control (normal cytology)	6 (2.9)		1 (0.7)		3 (3.0)	
Age (mean years/SD)	47.70 (12.52)	0.012	42.0 (11.52)	0.775	44.08 (11.63)	0.781
Ethnicity		<0.001		0.026		1.00
White (British or other)	12 (1.2)		11 (1.6)		12 (2.4)	
Mixed ethnicity	0 (0)		0 (0)		0 (0)	
Asian	1 (3.0)		1 (7.7)		0 (0)	
Black	1 (4.3)		0 (0)		0 (0)	
Other	3 (18.8)		0 (0)		0 (0)	
Prefer not to say	1 (33.3)		1 (100.0)		-	
Education		0.014		0.143		0.603
Degree or higher	4 (0.8)		6 (1.7)		4 (1.6)	
Higher education (below degree)	1 (0.7)		4 (4.4)		1 (1.7)	
A Levels	6 (4.6)		0 (0)		2 (3.1)	
ONC/BTEC	0 (0)		0 (0)		1 (5.0)	
GCSE/O Levels	1 (0.5)		1 (0.7)		4 (3.8)	
No formal qualifications	2 (3.2)		0 (0)		0 (0)	
Still studying	1 (4.8)		1 (7.1)		0 (0)	

APPENDIX 4.7: MISSING DATA FOR ONE OR MORE PSYCHOSEXUAL ITEM BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS (CONTINUED)

	Missing data for one or more psychosexual item					
	Baseline		6 months		12 months	
	n (%)	p	n (%)	p	n (%)	p
Marital Status		0.062		0.467		0.855
Single	1 (0.5)		2 (1.6)		1 (1.3)	
In a relationship	2 (1.0)		2 (1.6)		1 (1.1)	
Separated	2 (16.7)		1 (11.1)		0 (0)	
Living with partner	3 (1.4)		1 (0.8)		2 (2.0)	
Married/Civil Partnership	9 (2.0)		7 (2.2)		8 (3.5)	
Widowed	0 (0)		0 (0)		0 (0)	
Divorced	1 (2.5)		0 (0)		0 (0)	
IMD Quintile		0.225		0.703		0.443
1 (most deprived)	6 (3.5)		3 (3.1)		1 (1.6)	
2	3 (1.4)		1 (0.8)		1 (1.1)	
3	6 (2.2)		5 (2.6)		2 (1.3)	
4	6 (3.1)		3 (2.1)		4 (3.8)	
5 (least deprived)	1 (0.5)		2 (1.4)		4 (4.3)	

APPENDIX 4.8: NOT APPLICABLE RESPONSES FOR INDIVIDUAL PSYCHOSEXUAL ITEMS AT BASELINE, 6 AND 12 MONTHS

Have you been worried…	Baseline n (%)	6 months n (%)	12 months n (%)
…whether you should continue having sex?	82 (7.2)	63 (8.3)	53 (9.9)
…whether others think you have had more sexual partners than you should?	80 (7.1)	69 (9.1)	53 (9.9)
…about whether your test result would have a bad effect on your relationship with your partner?	131 (11.6)	99 (13.0)	73 (13.6)
…whether having sex will make the problem worse?	109 (9.6)	84 (11.0)	70 (13.0)
…that you could give the problem to a sexual partner?	119 (10.5)	99 (13.0)	71 (13.2)
…a sexual partner will think they can catch the problem from you?	129 (11.4)	100 (13.1)	80 (14.9)

APPENDIX 4.9: PARTICIPANTS RESPONDING NOT APPLICABLE FOR ONE OR MORE PSYCHOSEXUAL ITEM BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS

	Not applicable response for one or more psychosexual item					
	Baseline		6 months		12 months	
	n (%)	p	n (%)	p	n (%)	p
Screening result group		0.202		0.098		0.030
HPV negative	55 (22.7)		47 (26.4)		34 (26.8)	
HPV positive, normal cytology	50 (19.5)		33 (19.1)		20 (18.5)	
HPV positive, abnormal cytology	34 (19.9)		22 (20.8)		16 (21.9)	
HPV persistent	23 (12.8)		18 (15.7)		11 (12.4)	
HPV cleared	11 (16.7)		8 (19.5)		4 (11.4)	
Control (normal cytology)	41 (20.0)		39 (28.9)		28 (27.7)	
Age (mean years/SD)	44.08 (12.61)	<0.001	46.60 (11.23)	<0.001	46.44 (12.17)	0.001
Ethnicity		0.211		0.020		0.013
White (British or other)	187 (18.4)		147 (21.2)		96 (19.4)	
Mixed ethnicity	5 (27.8)		5 (45.5)		3 (42.9)	
Asian	8 (25.0)		4 (33.3)		6 (54.5)	
Black	8 (36.4)		6 (46.2)		3 (37.5)	
Other	3 (23.1)		0 (0)		2 (28.6)	
Prefer not to say	0 (0)		-		-	
Education		0.021[1]		0.749		0.931
Degree or higher	89 (18.6)		73 (21.6)		51 (20.6)	
Higher education (below degree)	20 (14.3)		10 (11.5)		14 (24.6)	
A Levels	19 (14.8)		20 (23.8)		12 (19.0)	
ONC/BTEC	8 (16.7)		8 (25.0)		4 (20.0)	
GCSE/O Levels	57 (26.0)		43 (29.3)		20 (19.6)	
No formal qualifications	16 (26.2)		8 (22.9)		7 (29.2)	
Still studying	1 (5.0)		1 (7.7)		2 (16.7)	

APPENDIX 4.9: PARTICIPANTS RESPONDING NOT APPLICABLE FOR ONE OR MORE PSYCHOSEXUAL ITEM BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS (CONTINUED)

	Not applicable response for one or more psychosexual item					
	Baseline		6 months		12 months	
	n (%)	p	n (%)	p	n (%)	p
Marital Status		<0.001[1]		<0.001[1]		<0.001[1]
Single	87 (46.3)		56 (45.5)		35 (43.8)	
In a relationship	10 (5.0)		14 (11.3)		2 (2.3)	
Separated	2 (20.0)		1 (12.5)		2 (33.3)	
Living with partner	19 (8.8)		17 (13.0)		17 (16.8)	
Married/Civil Partnership	63 (14.4)		58 (18.3)		43 (18.9)	
Widowed	9 (75.0)		2 (28.6)		3 (33.3)	
Divorced	20 (50.0)		16 (55.2)		9 (52.9)	
IMD Quintile		0.352		0.319		0.338
1 (most deprived)	26 (15.4)		14 (14.9)		8 (12.9)	
2	46 (22.0)		33 (25.8)		24 (26.7)	
3	48 (17.5)		46 (24.5)		35 (22.7)	
4	38 (19.8)		32 (23.4)		22 (21.2)	
5 (least deprived)	43 (22.4)		30 (21.0)		18 (19.6)	

[1] Monte Carlo Estimate

APPENDIX 4.10: THE ODDS OF RESPONDING NOT APPLICABLE BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS AT BASELINE, 6 AND 12 MONTHS (WITH 95% CONFIDENCE INTERVALS)

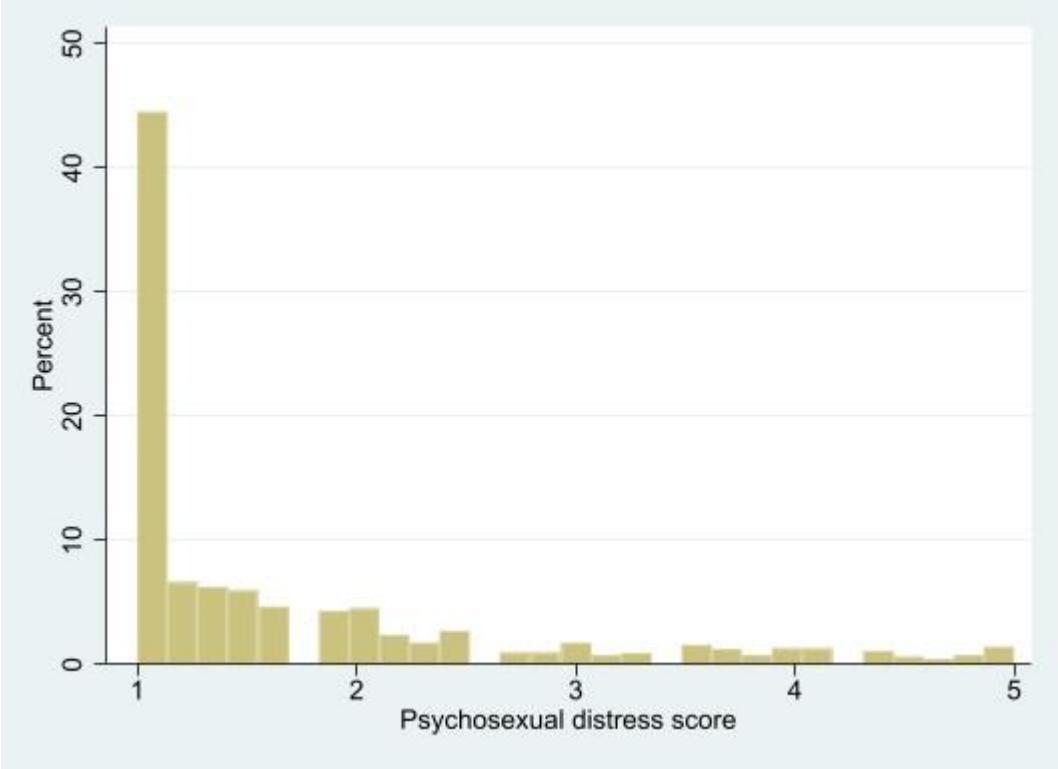
	Baseline		6 months		12 months	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Screening result group		0.227[1]		0.099[1]		0.049[1]
HPV negative	1.176 (0.746,1.855)	0.484	0.883 (0.536,1.455)	0.626	0.953 (0.530,1.714)	0.873
HPV positive, normal cytology	0.971 (0.612,1.540)	0.900	0.580 (0.341,0.987)	0.045	0.593 (0.309,1.138)	0.116
HPV positive, abnormal cytology	0.993 (0.597,1.650)	0.977	0.645 (0.354,1.174)	0.151	0.732 (0.362,1.481)	0.386
HPV persistent	0.590 (0.338,1.028)	0.063	0.457 (0.244,0.854)	0.014	0.368 (0.171,0.792)	0.011
HPV cleared	0.800 (0.385,1.664)	0.550	0.597 (0.253,1.406	0.238	0.336 (0.109,1.040)	0.059
Control (normal cytology)	Reference		Reference		Reference	
Ethnicity		0.029[1]		0.049[1]		0.003[1]
White (British or other)	Reference		Reference		Reference	
Ethnic minority group	1.742 (1.059,2.867)	0.029	1.921 (1.004,3.678)	0.049	3.055 (1.479,6.310)	0.003
Education		0.241[1]		0.647[1]		0.772[1]
Degree or higher	Reference		Reference		Reference	
Qualification below degree	1.057 (0.772,1.448)	0.728	1.093 (0.763,1.565)	0.627	1.001 (0.646,1.551)	0.997
No formal qualifications	1.558 (0.842,2.882)	0.158	1.076 (0.469,2.468)	0.863	1.582 (0.623,4.021)	0.335
Still studying	0.231 (0.030,1.746)	0.155	0.303 (0.039,2.365)	0.254	0.769 (0.163,3.618)	0.739
Marital Status		<0.001[1]		<0.001[1]		<0.001[1]
Current partner	Reference		Reference		Reference	
No partner	7.394 (5.320,10.279)	<0.001	4.424 (3.027,6.467)	<0.001	4.441 (2.802,7.039)	<0.001

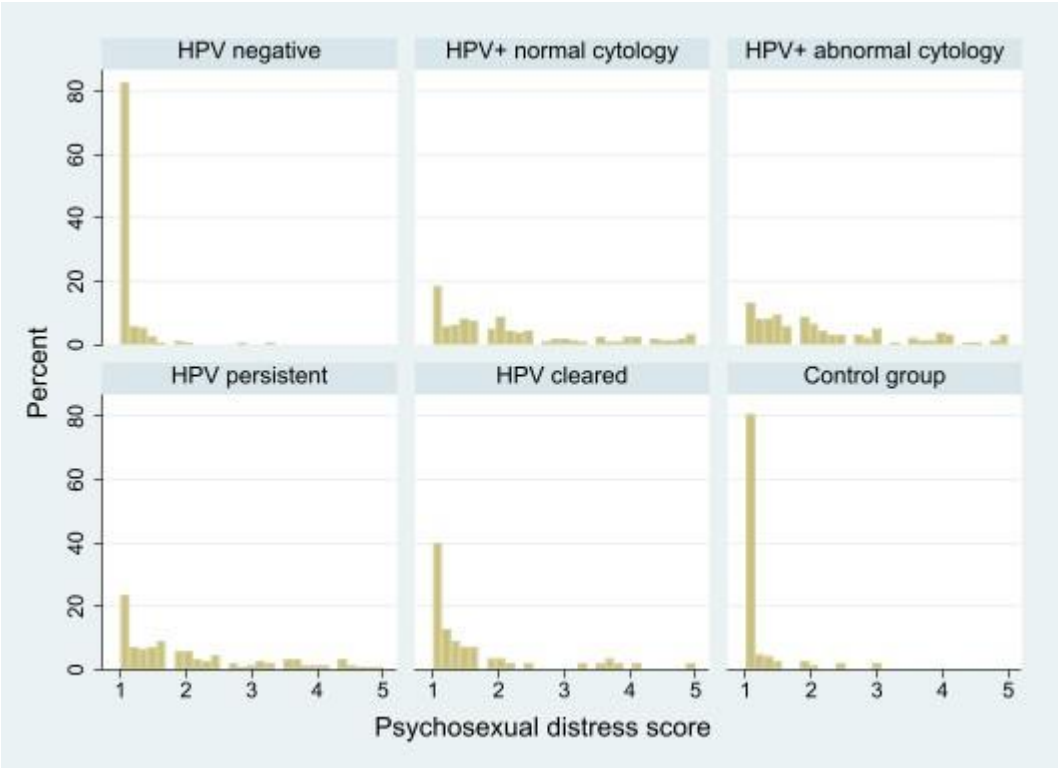
APPENDIX 4.10: THE ODDS OF RESPONDING NOT APPLICABLE BY SCREENING RESULT GROUP AND DEMOGRAPHIC CHARACTERISTICS AT BASELINE, 6 AND 12 MONTHS (WITH 95% CONFIDENCE INTERVALS) (CONTINUED)

	Baseline		6 months		12 months	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
IMD Quintile		0.359[1]		0.343[1]		0.356[1]
1 (most deprived)	0.630 (0.368,1.079)	0.093	0.659 (0.329,1.322)	0.241	0.609 (0.247,1.504)	0.282
2	0.978 (0.610,1.567)	0.926	1.308 (0.744,2.301)	0.351	1.495 (0.746,2.997)	0.257
3	0.736 (0.464,1.166)	0.192	1.220 (0.724,2.057)	0.455	1.209 (0.639,2.289)	0.560
4	0.855 (0.523,1.397)	0.532	1.148 (0.653,2.019)	0.632	1.103 (0.549,2.216)	0.783
5 (least deprived)	Reference		Reference		Reference	

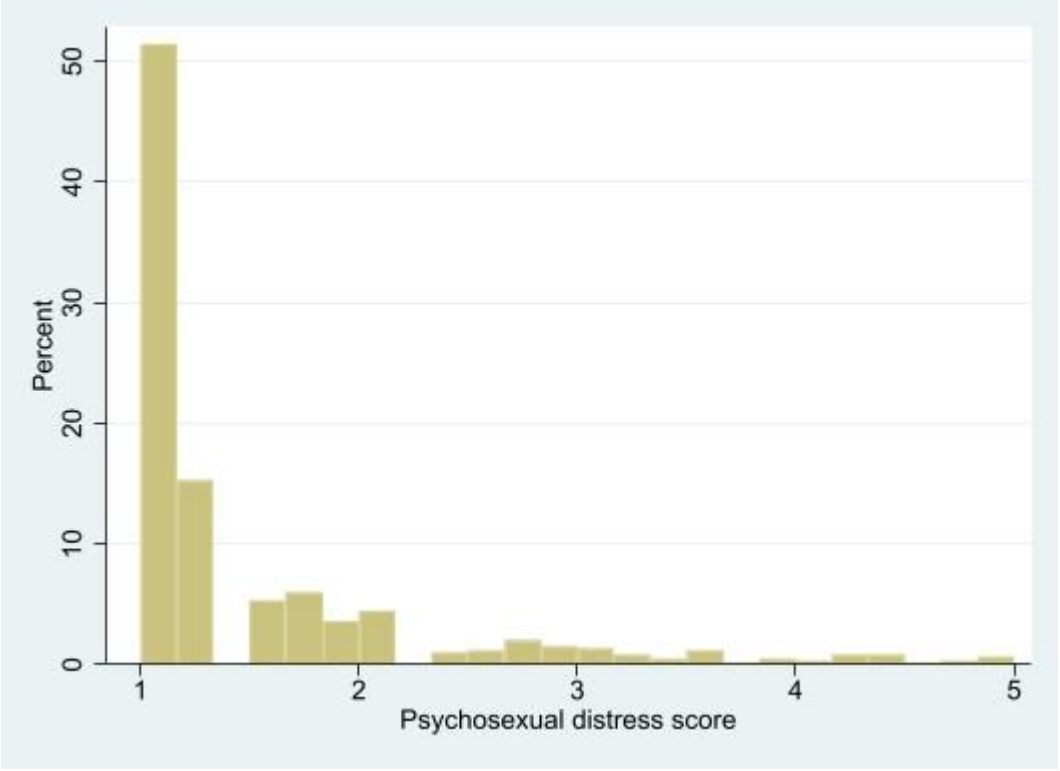
[1] Overall p value for variable

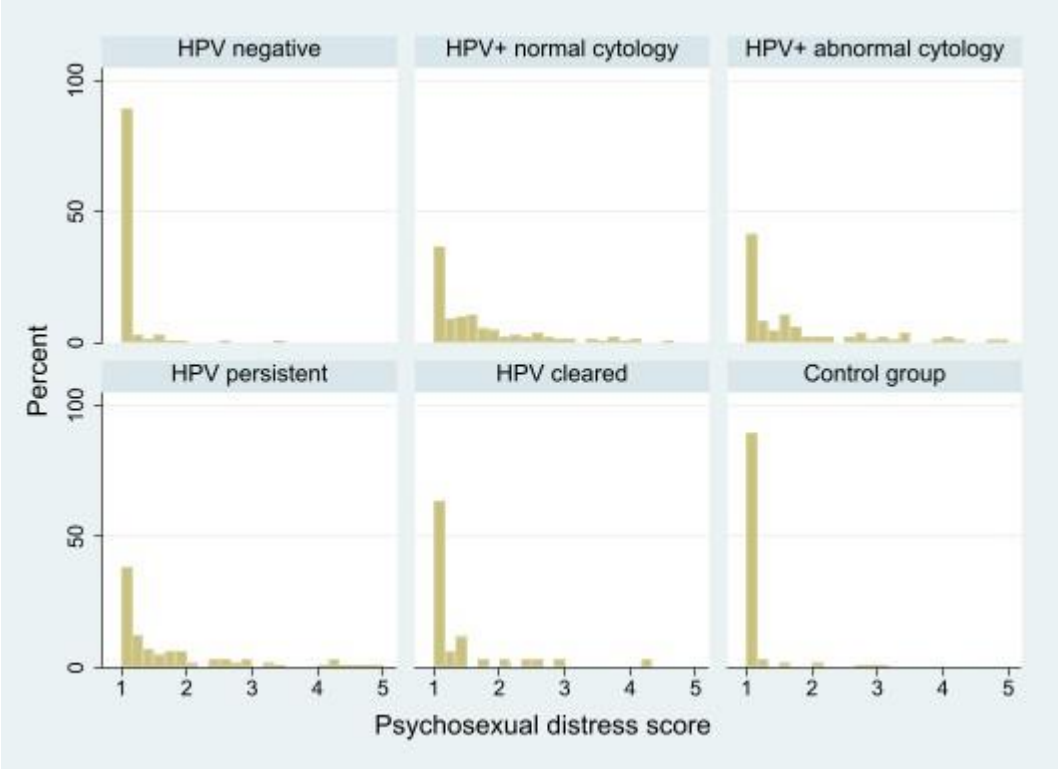
APPENDIX 4.11: DISTRIBUTION OF PSYCHOSEXUAL DISTRESS SCORE AT BASELINE, OVERALL AND BY SCREENING RESULT GROUP



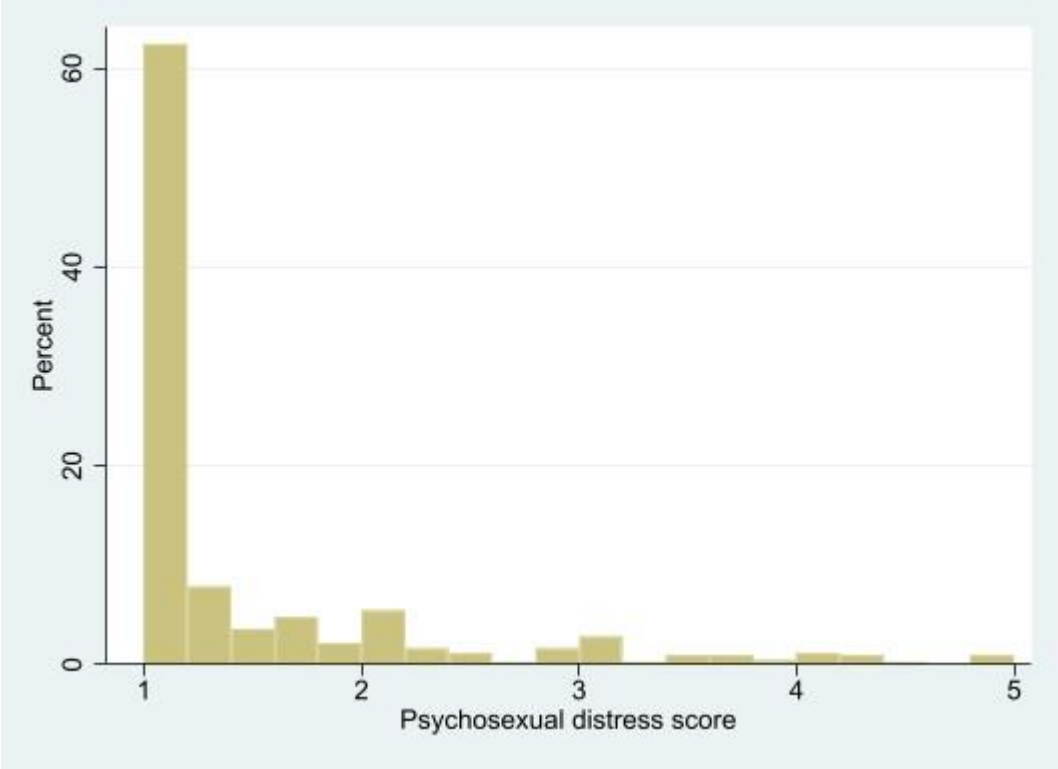


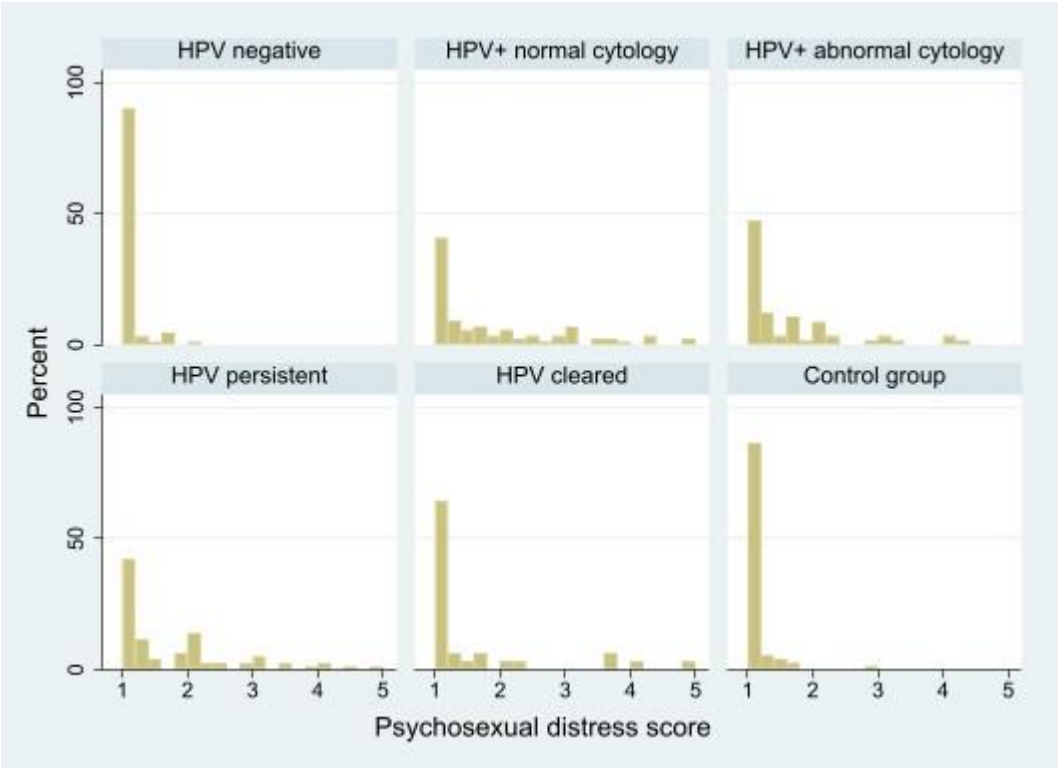
APPENDIX 4.12: DISTRIBUTION OF PSYCHOSEXUAL DISTRESS SCORE AT 6 MONTHS, OVERALL AND BY SCREENING RESULT GROUP





APPENDIX 4.13: DISTRIBUTION OF PSYCHOSEXUAL DISTRESS SCORE AT 12 MONTHS, OVERALL AND BY SCREENING RESULT GROUP





APPENDIX 4.14: CROSS-SECTIONAL ASSOCIATIONS BETWEEN PSYCHOSEXUAL DISTRESS AND SCREENING RESULT GROUP (UNWEIGHTED AND UNADJUSTED)

	Baseline		6 months		12 months	
	B[1] (95% CI)	SE[2]	B[1] (95% CI)	SE[2]	B[1] (95% CI)	SE[2]
Screening result group						
Control group (normal cytology)	Reference		Reference		Reference	
HPV negative	-0.051 (-0.242,0.139)	0.097	-0.032 (-0.231,0.168)	0.102	-0.033 (-0.273,0.207)	0.122
HPV positive, normal cytology	1.084 (0.897,1.270)***	0.095	0.605 (0.408,0.802)***	0.100	0.759 (0.517,1.001)***	0.123
HPV positive, abnormal cytology	1.051 (0.845,1.258)***	0.105	0.700 (0.478,0.922)***	0.113	0.505 (0.235,0.775)***	0.137
HPV persistent	0.916 (0.718,1.115)***	0.101	0.696 (0.482,0.910)***	0.109	0.677 (0.428,0.926)***	0.127
HPV cleared	0.486 (0.209,0.762)**	0.141	0.291 (-0.009,0.591)	0.153	0.469 (0.142,0.797)**	0.167
Constant	1.133 (0.994,1.272)***	0.071	1.123 (0.971,1.275)***	0.077	1.100 (0.922,1.279)***	0.091
Model *F*	56.12***		21.53***		15.46***	
Number of observations	898		581		418	
R^2	0.239		0.158		0.158	

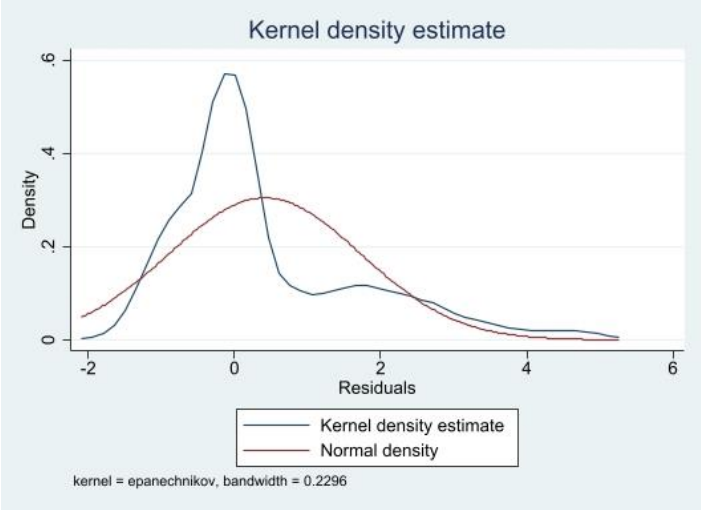
[1] Unstandardised Beta coefficients (with 95% CIs) indicating the degree of change in psychosexual distress for each screening result group compared to the reference group (i.e. the control group).

[2] Robust standard errors.

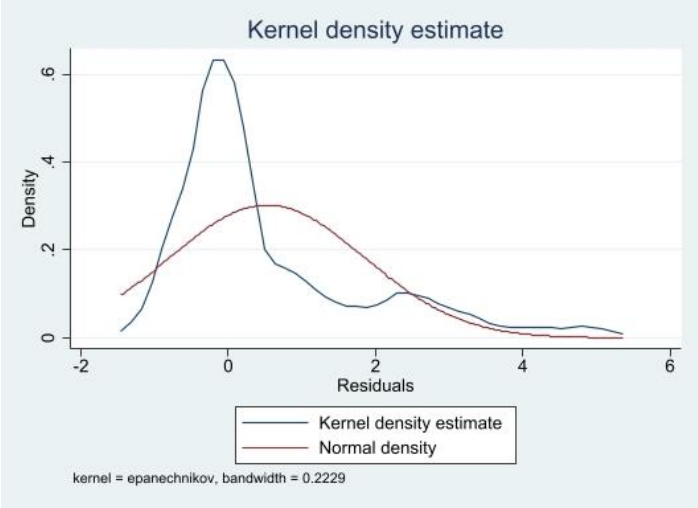
*p<0.05 **p<0.01 ***p<0.001

APPENDIX 4.15: KERNEL DENSITY PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

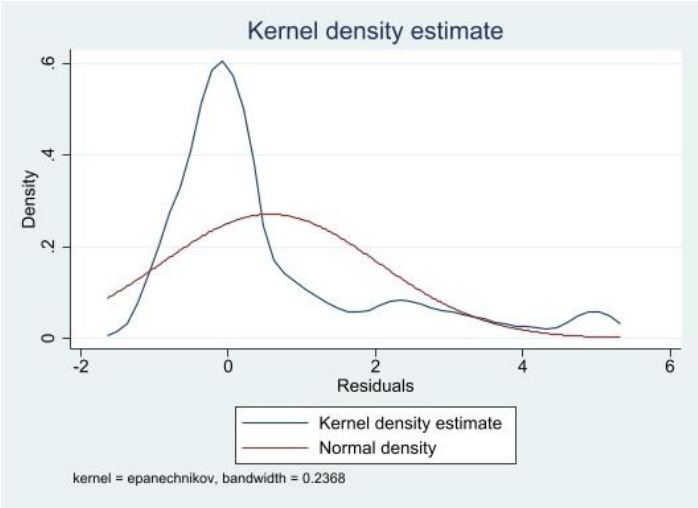
BASELINE



6 MONTHS

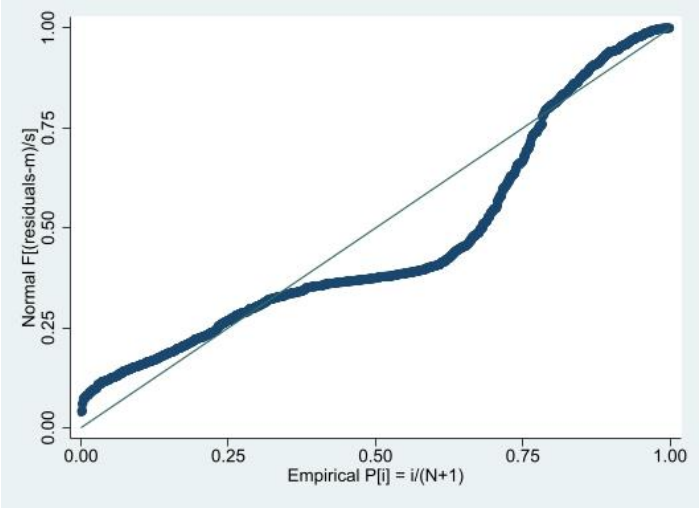


12 MONTHS

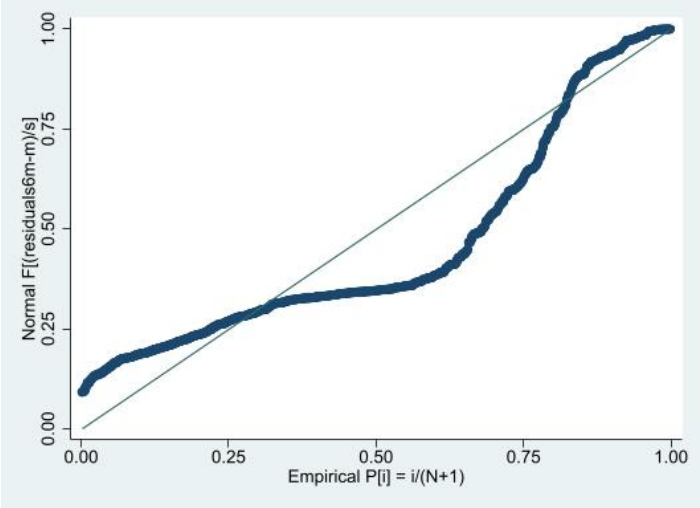


APPENDIX 4.16: P-P PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

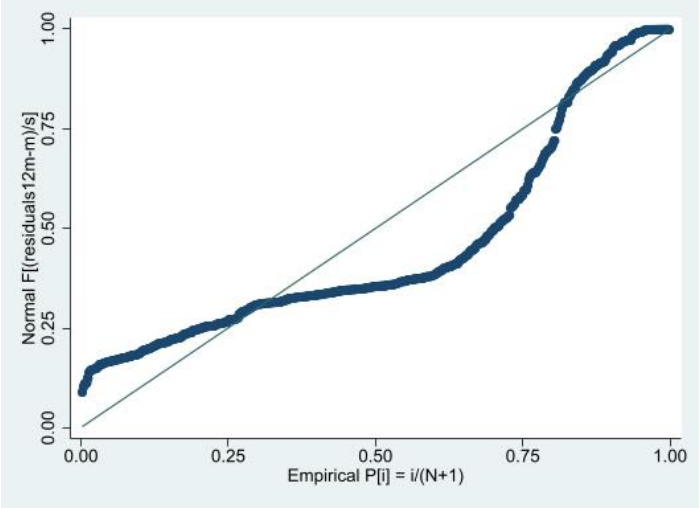
BASELINE



6 MONTHS

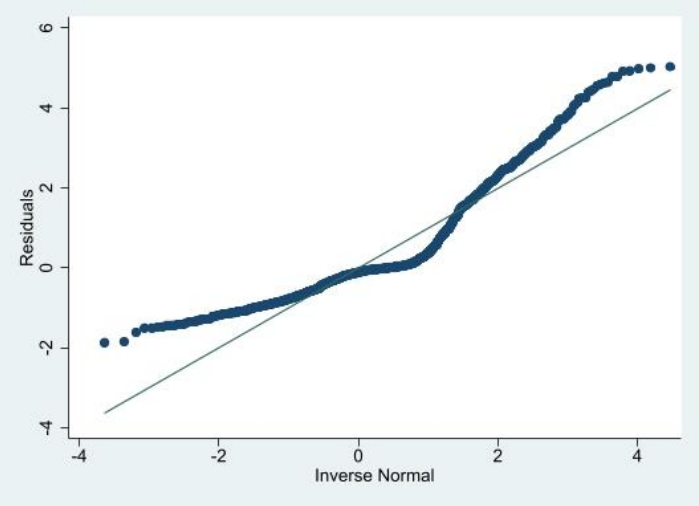


12 MONTHS

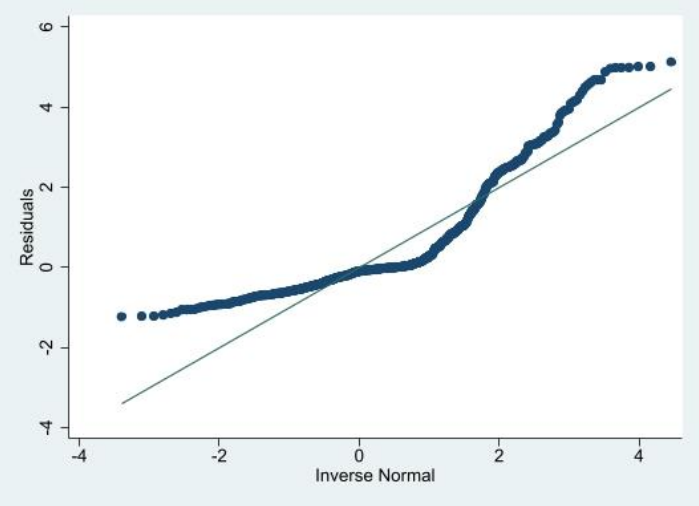


APPENDIX 4.17: Q-Q PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

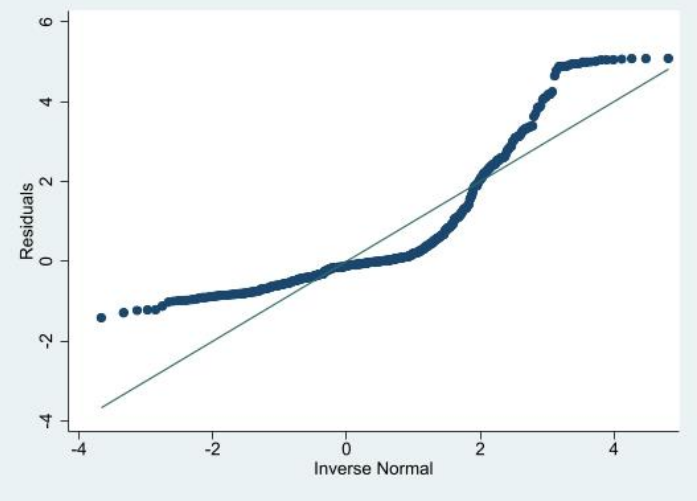
BASELINE



6 MONTHS

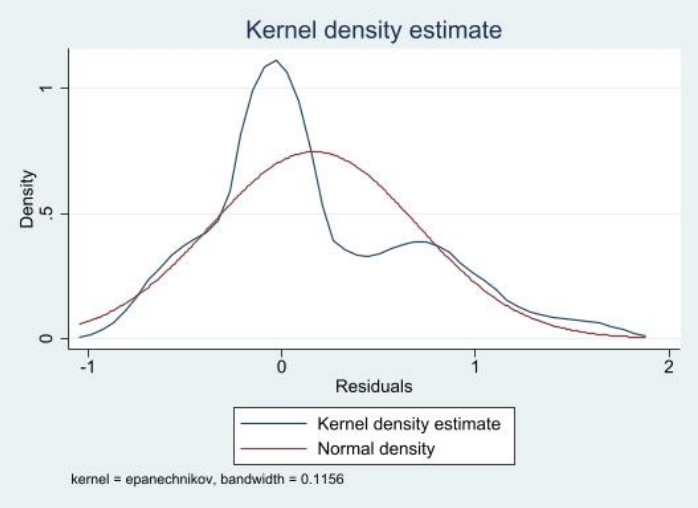


12 MONTHS

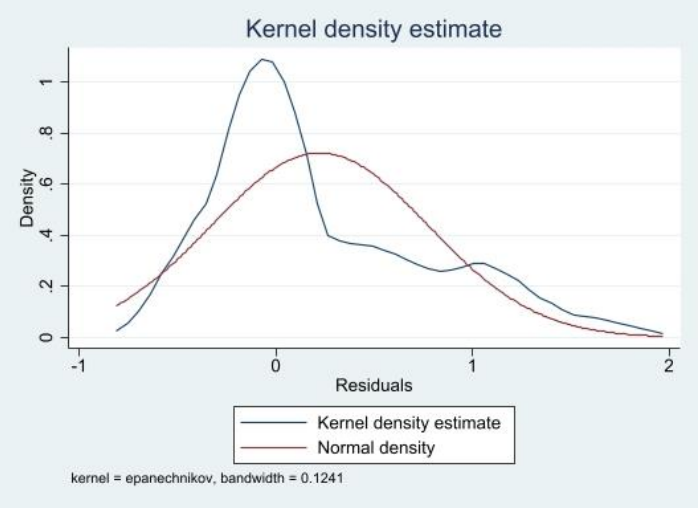


APPENDIX 4.18: LOG TRANSFORMED KERNEL DENSITY PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

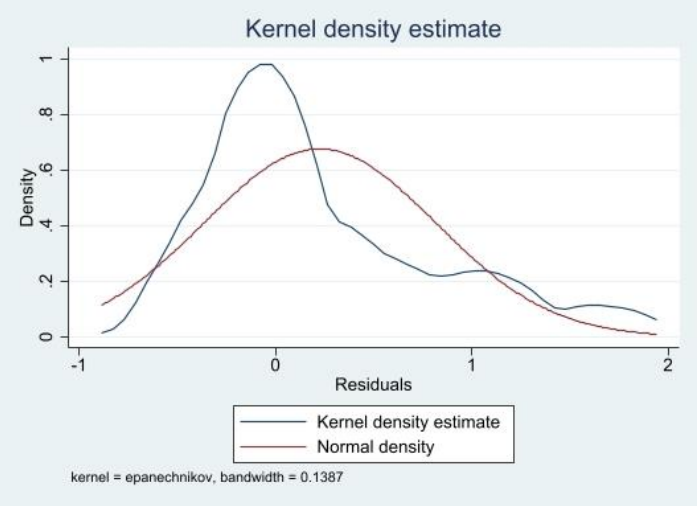
BASELINE



6 MONTHS

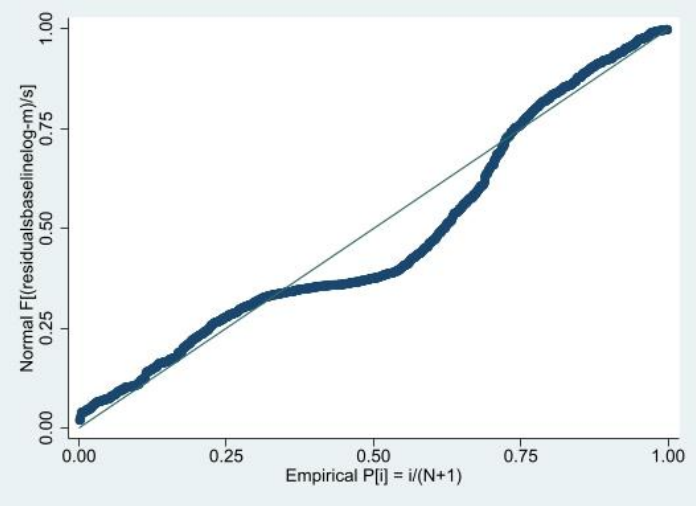


12 MONTHS

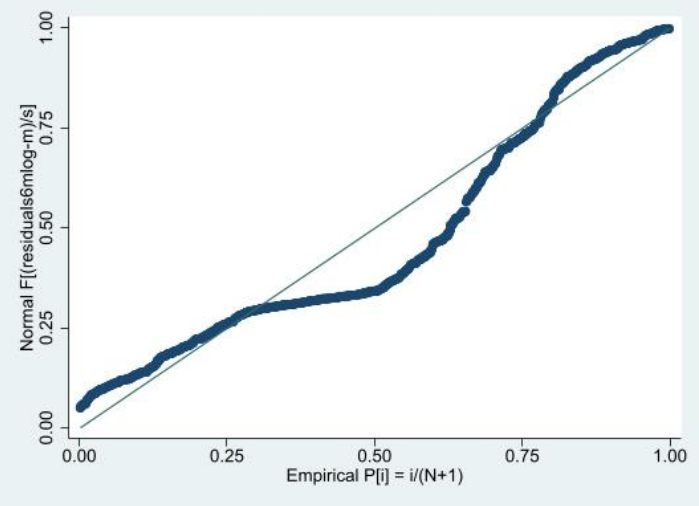


APPENDIX 4.19: LOG TRANSFORMED P-P PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

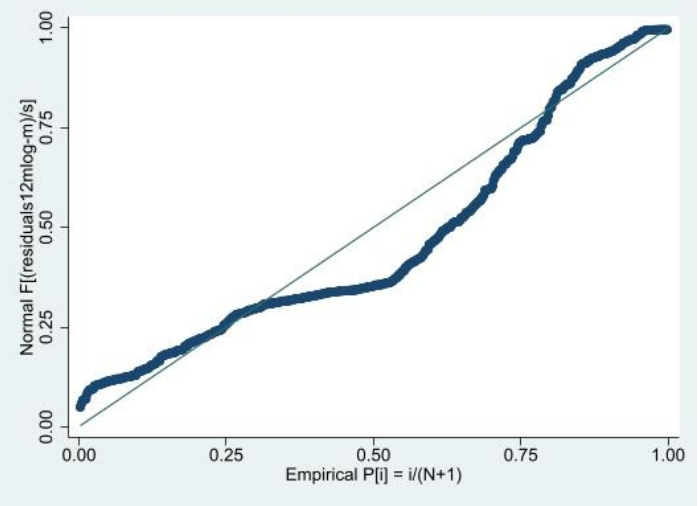
BASELINE



6 MONTHS

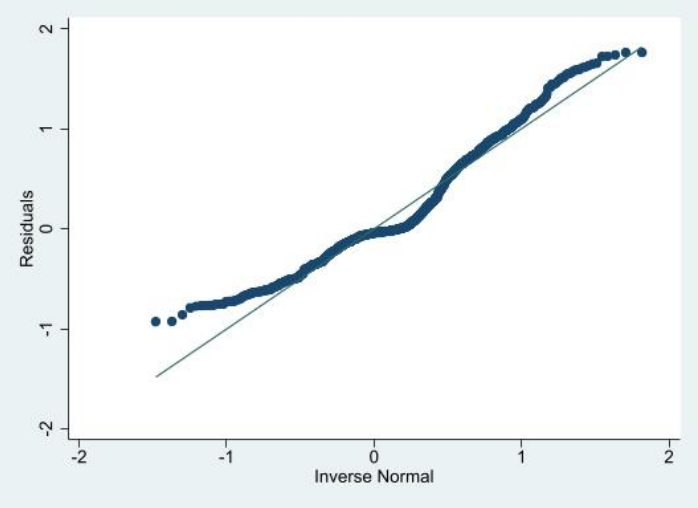


12 MONTHS

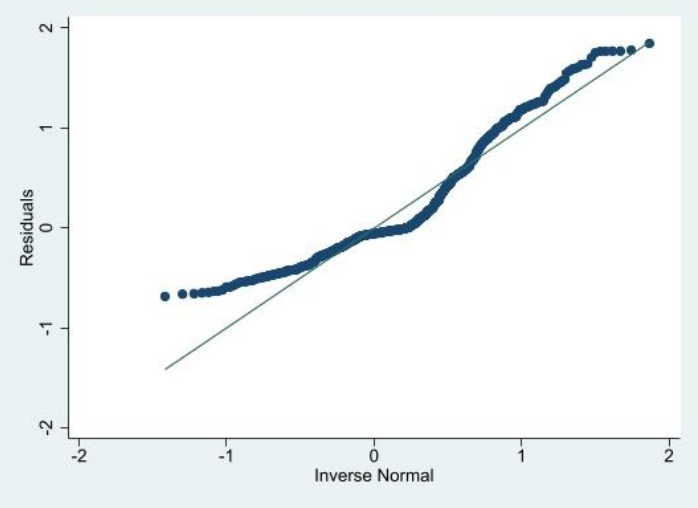


APPENDIX 4.20: LOG TRANSFORMED Q-Q PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

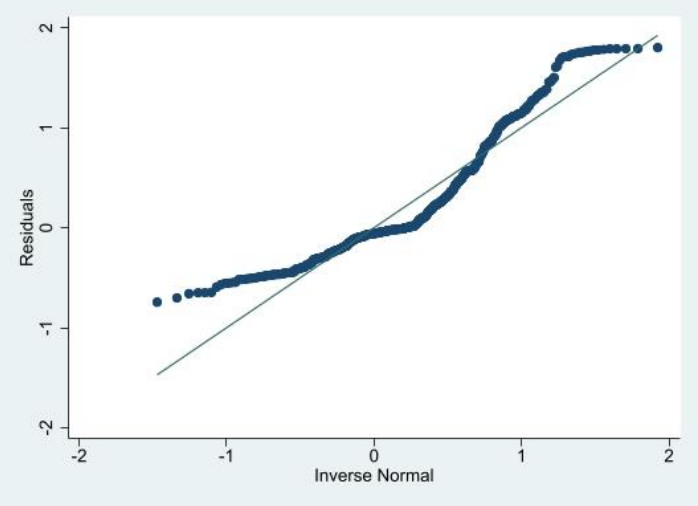
BASELINE



6 MONTHS

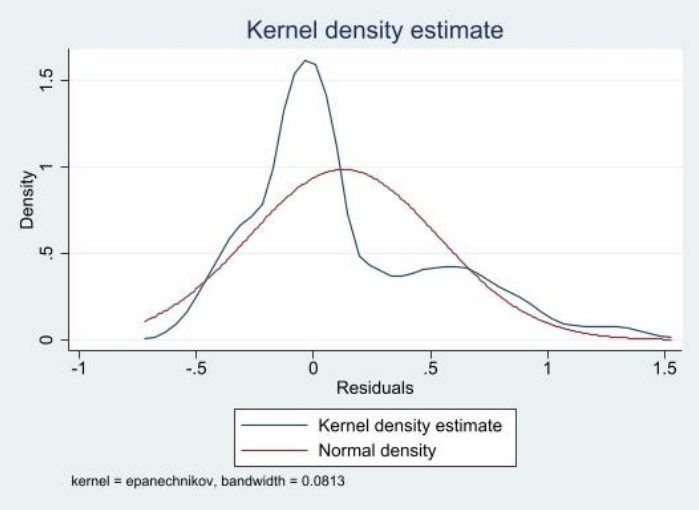


12 MONTHS

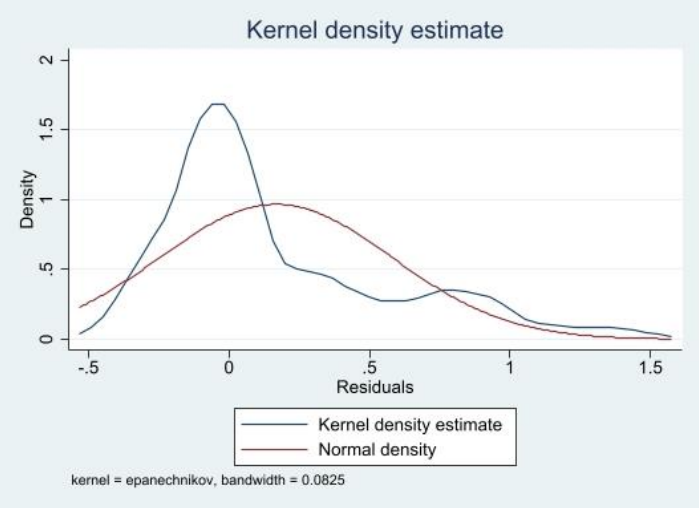


APPENDIX 4.21: SQUARE-ROOT TRANSFORMED KERNEL DENSITY PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

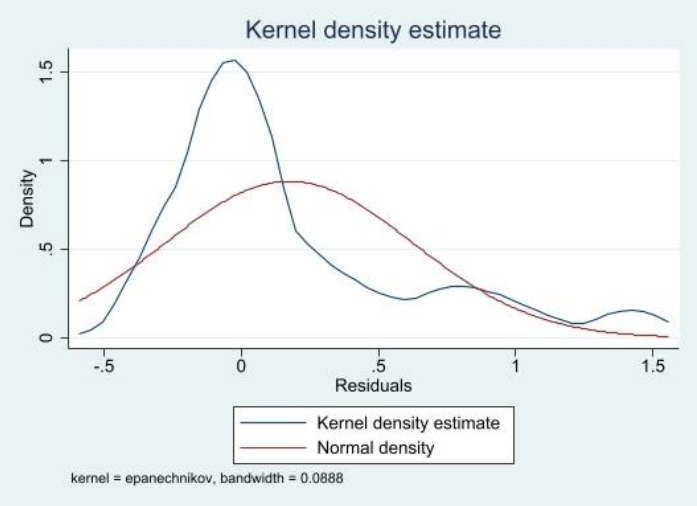
BASELINE



6 MONTHS

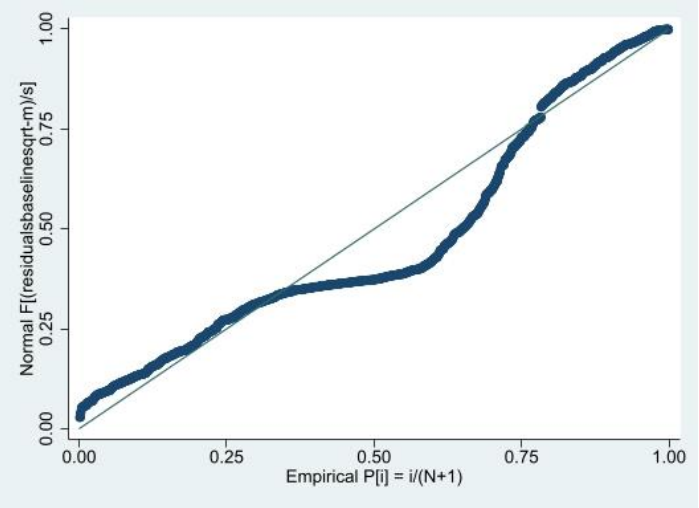


12 MONTHS

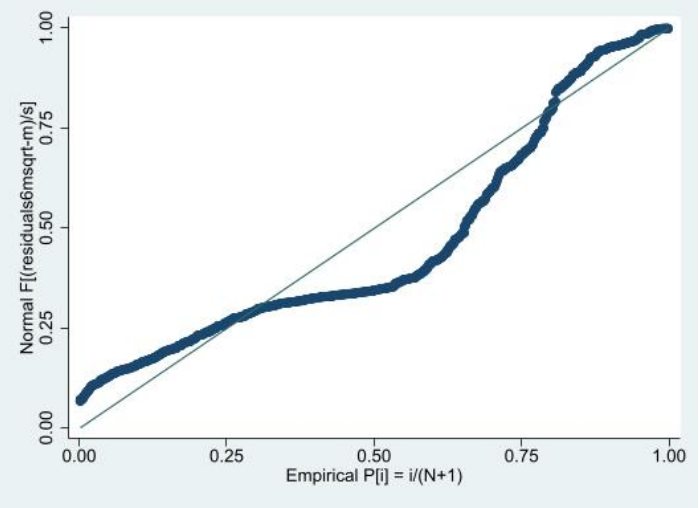


APPENDIX 4.22: SQUARE-ROOT TRANSFORMED P-P PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

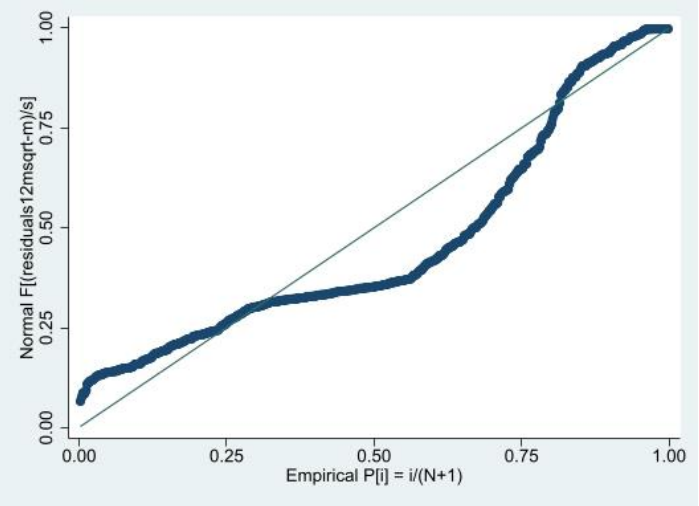
BASELINE



6 MONTHS

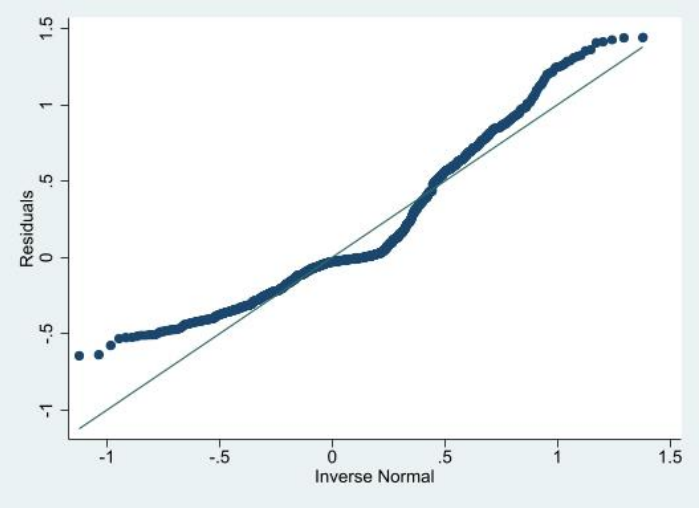


12 MONTHS

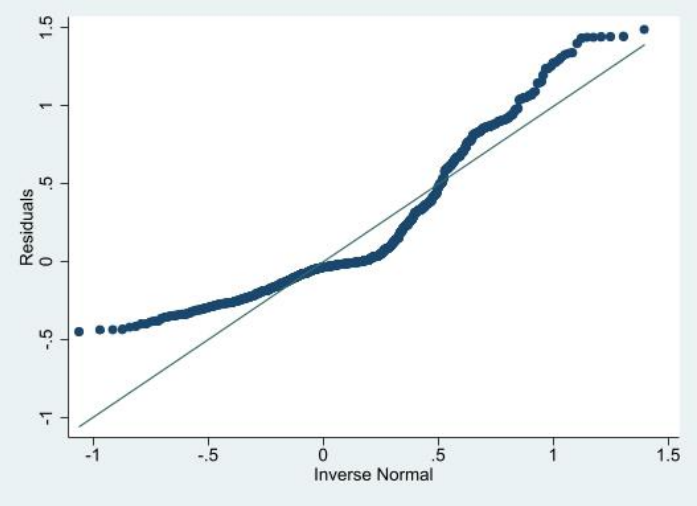


APPENDIX 4.23: SQUARE-ROOT TRANSFORMED Q-Q PLOTS FOR BASELINE, 6 AND 12-MONTH DATA

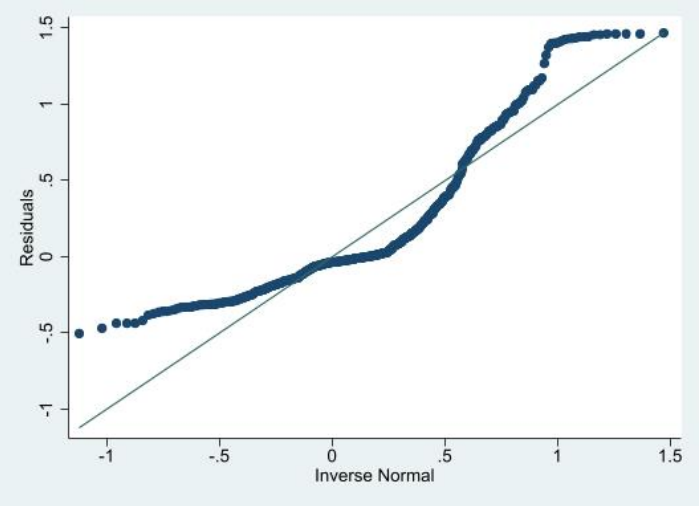
BASELINE



6 MONTHS

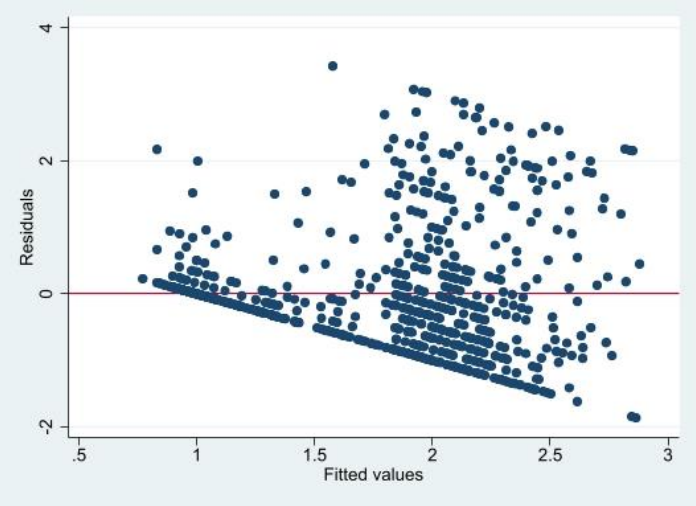


12 MONTHS

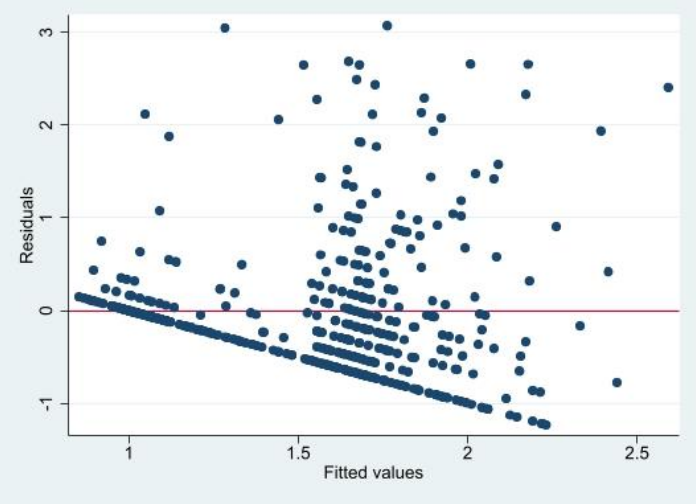


APPENDIX 4.24: PLOTS OF STUDENTISED RESIDUALS AGAINST (UNSTANDARDISED) PREDICTED VALUES FOR BASELINE, 6 AND 12-MONTH DATA

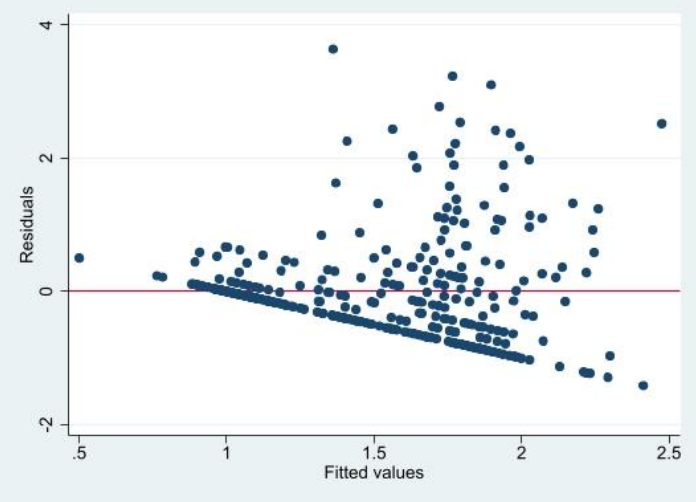
BASELINE



6 MONTHS

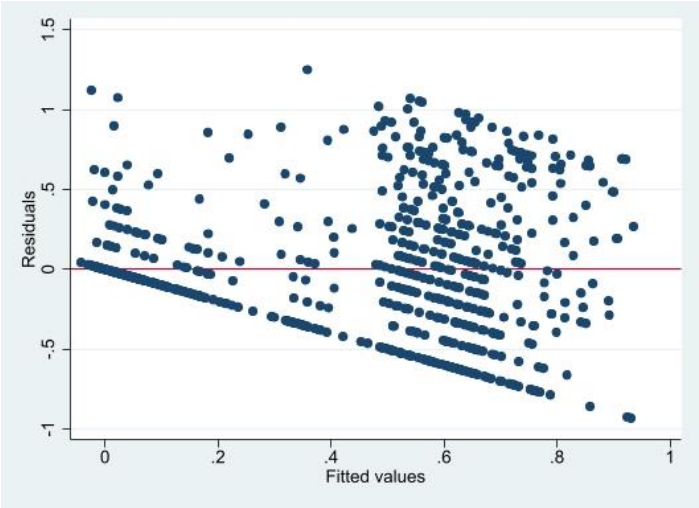


12 MONTHS

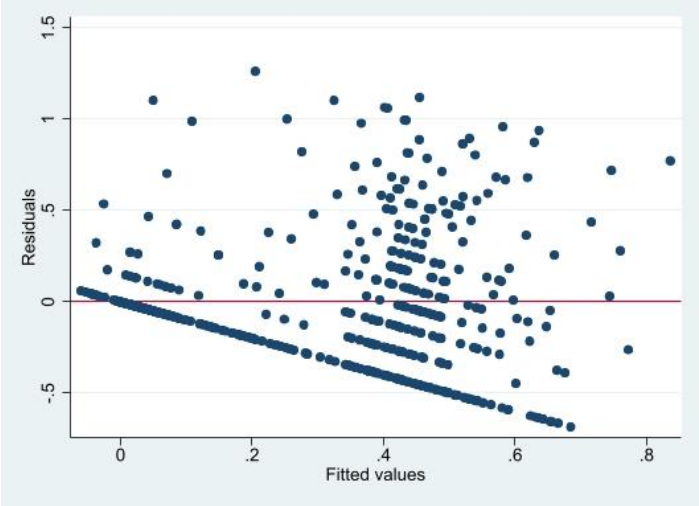


APPENDIX 4.25: LOG TRANSFORMED PLOTS OF STUDENTISED RESIDUALS AGAINST (UNSTANDARDISED) PREDICTED VALUES FOR BASELINE, 6 AND 12-MONTH DATA

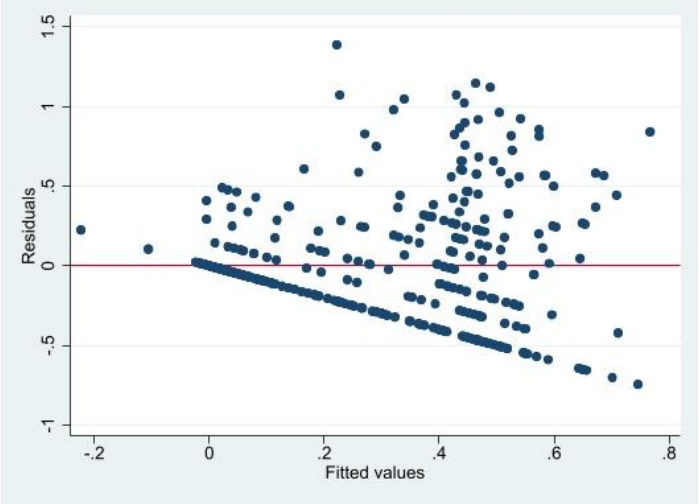
BASELINE



6 MONTHS

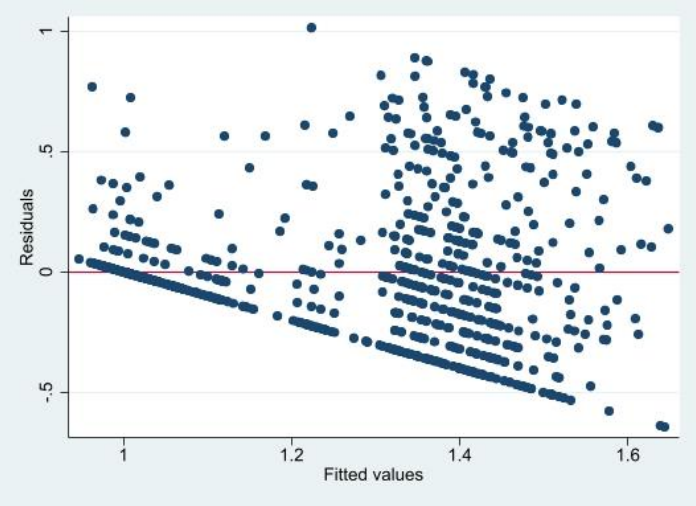


12 MONTHS

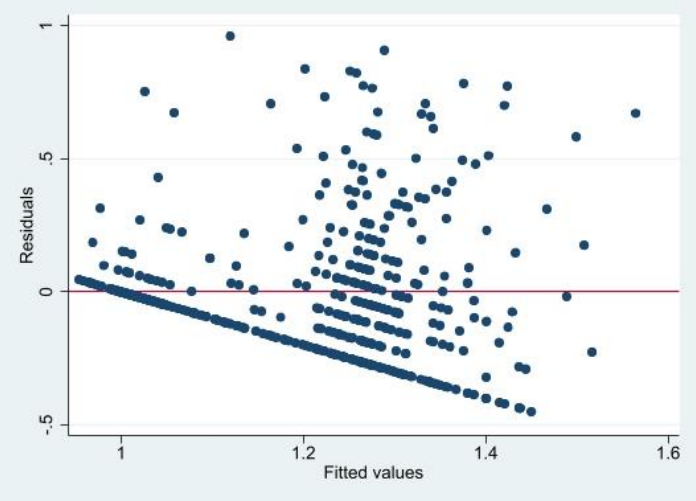


APPENDIX 4.26: SQUARE-ROOT TRANSFORMED PLOTS OF STUDENTISED RESIDUALS AGAINST (UNSTANDARDISED) PREDICTED VALUES FOR BASELINE, 6 AND 12-MONTH DATA

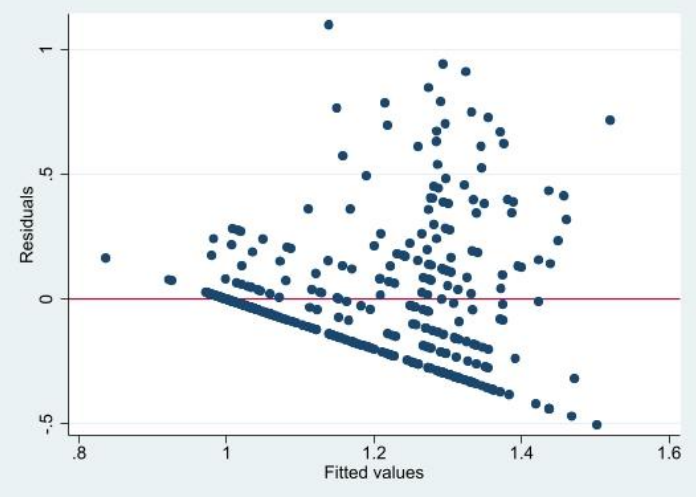
BASELINE



6 MONTHS



12 MONTHS



APPENDIX 4.27: ODDS RATIOS WITH 95% CONFIDENCE INTERVALS FOR THE RELATIONSHIP BETWEEN PSYCHOSEXUAL DISTRESS AND SCREENING RESULT GROUP AT BASELINE, 6 AND 12 MONTHS (WEIGHTED[1] AND ADJUSTED[2])

	Baseline		6 months		12 months	
	OR (95% CI)	SE[3]	OR (95% CI)	SE[3]	OR (95% CI)	SE[3]
Screening result group						
Control group (normal cytology)	Reference		Reference		Reference	
HPV negative	0.460 (0.088,2.394)	0.387	0.374 (0.077,1.809)	0.301	0.984 (0.063,15.336)	1.379
HPV positive, normal cytology	21.681 (8.742,53.775)***	10.048	7.971 (2.636,24.102)***	4.500	40.401 (5.488,297.403)***	41.148
HPV positive, abnormal cytology	17.473 (6.589,46.336)***	8.694	6.591 (1.921,22.610)**	4.145	20.535 (2.455,171.792)**	22.255
HPV persistent	16.460 (6.439,42.077)***	7.882	6.149 (1.896,19.945)**	3.692	28.708 (3.800,216.863)**	29.62
HPV cleared	6.639 (2.130,20.692)**	3.851	2.720 (0.613,12.072)	2.068	9.746 (1.006,94.445)*	11.293
Age	0.998 (0.981,1.016)	0.009	1.008 (0.984,1.033)	0.013	1.008 (0.979,1.038)	0.015
Ethnicity						
White (British or other)	Reference		Reference		Reference	
Ethnic minority	1.117 (0.487,2.559)	0.472	1.988 (0.569,6.946)	1.269	1.679 (0.359,7.859)	1.322
Marital Status						
Current partner	Reference		Reference		Reference	
No partner	1.804 (1.076,3.024)*	0.476	2.095 (1.101,3.987)*	0.688	3.427 (1.672,7.026)**	1.255

APPENDIX 4.27: ODDS RATIOS WITH 95% CONFIDENCE INTERVALS FOR THE RELATIONSHIP BETWEEN PSYCHOSEXUAL DISTRESS AND SCREENING RESULT GROUP AT BASELINE, 6 AND 12 MONTHS (WEIGHTED[1] AND ADJUSTED[2]) (CONTINUED)

	Baseline		6 months		12 months	
	OR (95% CI)	SE[3]	OR (95% CI)	SE[3]	OR (95% CI)	SE[3]
Education						
Qualification below degree	0.948 (0.634,1.419)	0.195	0.690 (0.380,1.252)	0.210	0.977 (0.484,1.971)	0.350
No formal qualifications	0.778 (0.265,2.286)	0.428	2.460 (0.801,7.555)	1.408	1.360 (0.37,5.665)	0.990
Still studying	3.018 (0.595,18.028)	2.752	0.404 (0.045,3.638)	0.453	-	-
IMD Quintile						
1 (most deprived)	1.618 (0.850,3.078)	0.531	2.821 (1.134,7.021)*	1.312	2.040 (0.649,6.409)	1.191
2	0.903 (0.472,1.726)	0.299	1.151 (0.408,3.246)	0.609	3.718 (1.231,11.232)*	2.097
3	0.672 (0.366,1.234)	0.208	2.266 (0.940,5.462)	1.017	1.337 (0.457,3.909)	0.732
4	0.855 (0.463,1.581)	0.268	1.371 (0.545,3.448)	0.645	1.788 (0.600,5.325)	0.996
5 (least deprived)	Reference		Reference		Reference	
Constant	0.034 (0.009,1.224)***	0.022	0.019 (0.004,0.085)***	0.014	0.004 (0.001,0.038)***	0.004
Number of observations	801		520		375	
Pseudo R^2	0.228		0.180		0.244	

[1] Weighted by age group and IMD quintile.

[2] Adjusted for age, ethnicity, marital status, education and IMD.

[3] Robust standard errors.

*p<0.05 **p<0.01 ***p<0.001

APPENDIX 5.1: UCL REC ETHICAL APPROVAL

UCL RESEARCH ETHICS COMMITTEE
OFFICE FOR THE VICE PROVOST RESEARCH

12th June 2019

[redacted]

Notification of Ethics Approval with Provisos

Project ID/Title: Application 6930/003: The psychosexual impact of testing positive for high-risk cervical human papillomavirus (HPV) – a qualitative study

Further to your satisfactory responses to the Committee's comments, I am pleased to confirm in my capacity as Chair of the UCL Research Ethics Committee (REC) that your application, has been ethically approved by the UCL REC until **1st September 2020.**

Ethical approval is subject to the following conditions:

Notification of Amendments to the Research
You must seek Chair's approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an 'Amendment Approval Request Form'
http://ethics.grad.ucl.ac.uk/responsibilities.php

Adverse Event Reporting – Serious and Non-Serious
It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator (ethics@ucl.ac.uk) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Final Report
At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research

Office of the Vice Provost Research, 2 Taviton Street
University College London
Tel: +44 (0)20 7679 8717
Email: ethics@ucl.ac.uk
http://ethics.grad.ucl.ac.uk/

i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.
In addition, please:

- ensure that you follow all relevant guidance as laid out in UCL's Code of Conduct for Research: https://www.ucl.ac.uk/srs/file/579
- note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely

[redacted]

[redacted]

APPENDIX 5.2: PRE-INTERVIEW QUESTIONNAIRE

Does having HPV have an impact on sex and relationships?

Thank you for your interest in taking part in this study. We'd like to ask you a few questions so we can make sure the interview is tailored to you. The information you give will be stored securely, kept strictly confidential and will only be used for this purpose.

1. Please enter the ID number that the researcher has given you:

.....

2. When did you last go for cervical screening (sometimes called the 'smear' or Pap test)?
   - ☐ In the last 12 months
   - ☐ More than 12 months ago
   - ☐ Not sure/can't remember

(If the respondent selects 'In the last 12 months' they will continue to question 2. If they select another response they will be thanked for their time and informed they do not meet the study eligibility criteria).

3. Thinking about the results of your recent cervical screening test, can you remember what your HPV result was?
   - ☐ HPV was found
   - ☐ HPV was not found
   - ☐ No HPV test
   - ☐ Not sure

(If the respondent selects 'HPV was found' they will continue to question 3. If they select another response they will be thanked for their time and informed that they do not need the study eligibility criteria).

4. Thinking about the results of your recent cervical screening test, can you remember what your cytology result was? Cytology tests if your cells look normal.
   - ☐ Normal cytology (no cell changes)
   - ☐ Abnormal cytology (cell changes found)
   - ☐ Not sure

5. Do you think your knowledge of HPV is...
   - ☐ Very poor
   - ☐ Poor
   - ☐ Fair
   - ☐ Good
   - ☐ Very good

Pre-interview questionnaire_v2

We're interested in understanding whether having HPV has an impact on sex and relationships. Please think about your most recent cervical screening test result when answering these questions and tell us how much these statements are true for you. Select one answer for each question.

6. After my most recent cervical screening test result, I am having less sex

Not at all		A little			Somewhat			A great deal			Extremely
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10	

7. After my most recent cervical screening test result, I feel satisfied with my sex life

Not at all		A little			Somewhat			A great deal			Extremely
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10	

8. What age are you?

……

9. How would you describe your current relationship status

☐ Not in a steady relationship (e.g. single)
☐ Dating or in a casual relationship(s)
☐ In a steady relationship (e.g. living with partner, married/civil partnership)
☐ Other (please specify) ……

10. Please tick the box that best describes your ethnic group (please tick one only)

☐ White (British or other)
☐ Asian/British Asian
☐ Black/African/Caribbean/Black British
☐ Mixed/Multiple ethnic groups
☐ Other ethnic group (please specify)……

11. What is the highest educational level you have completed (please tick one only)?

☐ Degree or higher degree
☐ A-Levels or equivalent qualification
☐ GCSE's or equivalent qualification
☐ No formal qualifications
☐ Still studying
☐ Other qualification (please specify)……

APPENDIX 5.3: ADVERT FOR JO'S CERVICAL CANCER TRUST WEBSITE

Advert for Jo's Cervical Cancer Trust Website

Have you been for cervical screening (smear/Pap test) in the last year and been told you have HPV (human papillomavirus)? Researchers at UCL would like to talk to women about the impact of HPV on sex and relationships. If you are interested, or for more information, please contact Kirsty Bennett by email: [redacted] or telephone [redacted]

APPENDIX 5.4: PARTICIPANT INFORMATION SHEET

DEPARTMENT OF BEHAVIOURAL SCIENCE AND HEALTH

PARTICIPANT INFORMATION SHEET

Does having HPV have an impact on sex and relationships?

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is this study being done?
Human papillomavirus (HPV) primary screening, sometimes known as primary HPV testing, is a new way of examining cervical screening (smear test) samples. We would like to talk to women who have been told that they have HPV to find out how they feel about having HPV. In particular, we would like to find out whether having HPV has an impact on sex and relationships. Our findings will help us to understand whether women with HPV need any additional support.

Why have I been asked to take part?
We would like to talk to women who tested positive for HPV following cervical screening. You recently got in touch after seeing an advert about this study and told us that you meet this criteria. We are interested in talking to women who are single as well as women who are in a relationship.

Do I have to take part in the study?
It is your choice whether you take part or not. Choosing not to take part will not disadvantage you in any way. You can leave the study at any time without having to give a reason.

What will happen to me if I agree to take part?
If you agree to take part, we will find a good time to speak to you. You can choose to do the interview over the phone or by video call (e.g. Skype, MS Teams). If you choose to do the interview by video call, only the verbal (audio) part of the call will be recorded. Before the interview begins, you will be asked to give consent by signing a consent form. We will ask you some questions about whether having HPV has had an impact on your relationship, sexual relationships and feelings about sex. The interview will be audio-recorded and will last up to an hour. You will receive a £40 Love2shop voucher as a thank you for taking part in the study. After the interview we will destroy your contact details and will not contact you again.

How will the recorded interview be used?
We will audio record your interview and this will then be written up and the recording will then be destroyed. We may use some of what you say in the interview in our reports however your name will not be linked to the written up interview and we will remove any information that might identify you.

What are the possible risks and benefits of taking part?
In the interview you will be asked whether having HPV has an impact on your relationship and how you feel about sex and sexual relationships. You do not have to answer any questions that you do not want to. There are no expected benefits of taking part in the study. However, the interviews will

help us learn about how HPV can impact a woman's sex and relationships. This will help us find out what support women who are HPV positive might need.

Will my taking part in this project be kept confidential?
All the information that we collect about you during the course of the research will be kept strictly confidential. We will not tell anyone that you have agreed to take part. Only the researcher's names below will have access to your personal information.

What will happen to the results of the study?
The results from the study will be published in a PhD thesis. We also plan to publish the results in scientific journals and present them at national and international conferences. You will not be able to be identified in any research reports, publications or presentations. You can request a copy of the results if you like.

Who is organising and funding the research?
The research is being organised and carried out by researchers at the Department of Behavioural Science and Health at UCL. The research is being funded by the Medical Research Council (MRC) as part of a PhD project.

What if something goes wrong?
If you have any complaints about the study, in the first instance please contact [redacted] If you feel your complaint has not been handled satisfactorily please contact the Chair of the UCL Research Ethics Committee: [redacted]

Contact for further information
Lead researcher: Kirsty Bennett, [redacted]
Principal Investigator and project supervisor: [redacted]

Data Protection Privacy Notice
The data controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at [redacted]

Further information on how UCL uses participant information can be found here:
www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice

Your personal data will be used for the purposes outlined in this notice. The categories of personal data used will be as follows:

- Name
- Telephone number and/or email address

The legal basis that would be used to process your personal data will be performance of a task in the public interest – research/The legal basis used to process special category personal data will be for scientific and historical research or statistical purposes/explicit consent.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

You have certain rights under data protection legislation in relation to the personal information that we hold about you. These rights apply only in particular circumstances and are subject to certain exemptions such as public interest (for example the prevention of crime). They include:

- The right to access your personal information;
- The right to rectification of your personal information;
- The right to erasure of your personal data;
- The right to restrict or object to the processing of your personal data;
- The right to object to the use of your data for direct marketing purposes;
- The right to data portability;
- Where the justification for processing is based on your consent, the right to withdraw such consent at any time; and
- The right to complain to the Information Commissioner's Office (ICO) about the use of your personal data.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at [redacted]

If you remain unsatisfied, you may wish to contact the ICO. Contact details, and further details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

APPENDIX 5.5: CONSENT FORM

DEPARTMENT OF BEHAVIOURAL SCIENCE AND HEALTH

CONSENT FORM

Does having HPV have an impact on sex and relationships?

Please complete this form after you have read the Participant Information Sheet. This study has been approved by the UCL Research Ethics Committee (Project Number: 6930/003).

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Participant Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I confirm that I understand that by ticking each box below I am consenting to this element of the study.

		Tick Box
1.	I confirm that I have read and understood the Participant Information Sheet for the above study. I have had the opportunity to ask questions which have been answered to my satisfaction. I understand what taking part involves.	☐
2	I understand that the interview I take part in will be audio-recorded.	☐
3	I understand that the findings of this study will be written up for a PhD thesis, published in a scientific journal and presented at scientific conferences. I wish to receive a copy of the results. Yes/No	☐
4	I understand that all personal information will remain confidential. I understand that my data gathered in this study will be stored anonymously and securely. It will not be possible to identify me in any reports, publications or presentations.	☐
5	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. I understand that if I decide to withdraw, I have the right to ask that any information I give the researchers for the study is not used, up to the point that the data are analysed.	☐
6	I agree that my anonymised research data may be used by others for future research (no one will be able to identify you when this data is shared).	☐
7	I understand that according to data protection legislation, 'public task' will be the lawful basis for processing my personal information.	☐
8	I agree to take part in this study.	☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Consent form_v2

APPENDIX 5.6: INTERVIEW TOPIC GUIDE

HPV: impact on sex and relationships

Topic Guide for interviews

1. **Introduction**
   - Thanks for agreeing to take part.
   - Introduce self and UCL – emphasise that we do not work for the screening programme or NHS.
   - Explain what study is about – e.g. screening for HPV is a new way of examining cervical screening (smear test) samples. With the change to cervical screening we'd like to talk to women who have been told that they have HPV to find out how they feel about their screening result, including how this has impacted sex and relationships.
   - No right or wrong answers.
   - Reminder of right to withdraw – confidentiality, anonymity, don't have to answer any questions don't want to.
   - Overview: knowledge and experience of cervical screening and HPV, questions about sex and relationships, information you were given. Length of interview.
   - Audio-recording – double check consent.
   - Any questions before we start?

2. **Knowledge of cervical screening and HPV**

First of all I'm going to ask you some questions about what you know about cervical screening and HPV. Emphasise no right or wrong answers and that it's not a test.

- Can you tell me what you know about cervical screening?
  - Purpose of screening? What is the test looking for?
- Before being told you had HPV had you heard of it before?
- Can you tell me what you know about HPV?
  - How do you get it?
- Where did knowledge come from (e.g. health professionals, screening materials, friends, adverts, online?)?

3. **Experience of cervical screening and testing positive for HPV**

I'm now going to ask you some questions about your experience of cervical screening and being told you have HPV.

- Can you tell me about your experience of being told you had HPV?
  - When were you told you had HPV?
  - How were you told you had HPV (letter/verbally)?
  - Was this the first time you were told you had HPV?
  - Have you had an abnormal cervical screening result before?
  - Do you remember your cytology result (normal: no cell changes found/abnormal: cell changes found)? What do you think the results mean?
  - Initial feelings following screening result?
  - Questions about HPV/screening result?

4. **Impact on sex and relationships**

I'm now going to ask you some questions about sex and relationships. Remind participants that they don't have to answer questions if they don't want to. For these questions it would be helpful to know whether you currently have a regular sexual partner(s) so I can tailor the questions to you.

- Did you talk to anyone about having HPV? (who?)
  - Reasons for disclosure/non-disclosure?
  - How did you feel about talking to others about having HPV?
  - Reactions to disclosure?

- **If participant <u>does not</u> currently have a regular partner:** intentions to disclose to future sexual partner?

- Has having HPV had any impact on your relationships with others? (partner, friends, family) (could be positive or negative)
  - Changes to relationship(s)?
  - Worries or concerns about relationship(s)?
  - Changes to feelings about partner(s)?
  - If HPV had an impact how long did this last for?

- **If participant <u>does not</u> currently have a regular partner:** feelings about future relationships?

- Has having HPV had any impact on your sex life? (could be positive or negative) – Remind participants that they don't have to answer questions if they don't want to**. Questions can be asked to participants with and without a regular partner.**
  - Changes? (e.g. frequency, interest, satisfaction with sex, practical changes – e.g. changes in condom use?)
  - Worries or concerns about having sex?
  - Feelings about sex? Any change after diagnosis?
  - If HPV had an impact how long did this last for?

5. **Communication and information needs**
   - Do you remember being given any information about HPV (written or verbally)?
   - Thoughts about information provided (screening leaflet, invitation and result letters, communication from HCP's)?
   - Lacking any information?
   - Did you look for information anywhere else (if so where?)?
   - Suggestions for improvements/changes to information?

6. **Closing the interview**
   - Thank you
   - Ask participant to complete demographics questionnaire.
   - Any questions or comments? Anything important to you that you haven't already mentioned? Extra comments about HPV or cervical screening in general?
   - Reassure about confidentiality
   - What happens next

APPENDIX 5.7: STUDY DEBRIEF SHEET

DEPARTMENT OF BEHAVIOURAL SCIENCE AND HEALTH

Thank you for taking part in our study

We are interested in the impact that having HPV (human papillomavirus) has on sex and relationships. The aim of this study was to understand this in more detail by interviewing women who have tested positive for HPV following cervical screening (smear/Pap test).

If you would like to talk more about this study please contact the lead researcher Kirsty Bennett by email [redacted] or telephone [redacted]

In case you feel worried about having HPV or cancer, we have included some details below about places where you can find out information or speak to someone about your concerns.

Jo's Cervical Cancer Trust

Jo's Cervical Cancer Trust provides information and support to women affected by cervical cancer and cervical abnormalities. The Jo's Cervical Cancer Trust website (https://www.jostrust.org.uk/) has information on cervical screening, receiving abnormal screening results and HPV.

The website includes an 'Ask the Expert' section where you can ask their expert medical panel questions relating to HPV, cervical screening, cervical abnormalities and cervical cancer or if you simply have symptoms that you are concerned about: https://www.jostrust.org.uk/support/ask-expert. They also have a free helpline which you can call for help and support: **0800 802 8000**

Cancer Research UK

Cancer Research UK offers a range of resources to help you find out more about cancer: https://www.cancerresearchuk.org/. They have a page specific to cervical cancer which provides information on cervical screening, abnormal cervical cells and HPV https://www.cancerresearchuk.org/about-cancer/cervical-cancer. There is also a resources and support page which includes support groups, books, videos and other resources to help individuals understand cervical cancer and treatment. Cancer Research UK also has a Nurse led helpline: **0808 800 4040**

Cancer screening in England

The NHS organises cancer screening for people living in England. Their website provides various information about cervical screening, including a section on further help and support: https://www.nhs.uk/conditions/cervical-screening/

Study Debrief_v1

APPENDIX 5.8: RESEARCH ETHICS COMMITTEE FAVOURABLE ETHICAL OPINION

NHS
Health Research Authority

London - Bloomsbury Research Ethics Committee

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

22 November 2019

[redacted]

Dear [redacted]

Study title:	**The psychosexual impact of testing positive for high-risk cervical human papillomavirus – a qualitative study.**
REC reference:	**19/LO/1762**
Protocol number:	**1**
IRAS project ID:	**264256**

The Research Ethics Committee reviewed the above application at the meeting held on 06 November 2019. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition
1	In relation to the information sheet, please address the following: • Make it clear when confidentiality will be broken and who

	concerns will be reported to. • Explain that audio recordings will be kept until Ms Bennett's PhD has been completed, then destroyed. • Removed reference to the £40 voucher and simply state that senses will be reimbursed. • Add the following "'but support will be available to you if you feel you need it from...." to the sentence "After the interview we will destroy your contact details and will not contact you again." • Explain point 6 of the consent form i.e. that anonymised research data may be used by others for future research. • Remove the following from the 'What will happen to the results of the study'- "You can request a copy of the results if you like. It may take us a while to write up the results from the study so it could take up to two years for us to send you a copy of the results" and replace with "A copy of the results will be available upon request."
2	In relation to the consent form, please address the following: • Include a point to make it clear that participants know when confidentiality will be broken, for example "I understand if I disclose ……. this will be reported to…. and confidentiality will be broken." • Add the following point after point 5,"I understand that if I find any of the interview distressing that I can stop at any time and support will be available to me."
3	As discussed at the meeting, please update the Protocol to reflect that a participants GP will be informed that their patient is taking part in the study. Please also provide a copy of the GP letter that will be used to communicate this.
4	As agreed during the meeting, please amend the Protocol and information sheet to make it clear that audio recordings will be kept until Ms Bennett's PhD has been completed.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study advert]	1	25 July 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL insurance certificate]	1	22 July 2019
GP/consultant information sheets or letters [GP Invitation Letter]	1	25 July 2019
Initial Assessment for REC [Generated by HARP system]		
Interview schedules or topic guides for participants [Topic Guide]	1	25 July 2019
IRAS Application Form [IRAS_Form_14102019]		14 October 2019
Letter from sponsor [Confirmation of UCL Sponsorship]		27 September 2019
Non-validated questionnaire [Pre-interview questionnaire]	1	25 July 2019
Non-validated questionnaire [Post-interview questionnaire]	1	25 July 2019
Other [Study debrief]	1	25 July 2019
Other [Evidence of funding]	1	10 June 2019
Other [Data Protection Registration Confirmation]		11 April 2019
Other [UCL ethical approval]		12 June 2019
Other [Researcher responses]		
Referee's report or other scientific critique report [Evidence of peer review]		05 June 2019
Summary CV for Chief Investigator (CI) [Julia Bailey CV]		
Summary CV for student [Kirsty Bennett CV]	1	02 July 2019
Summary CV for supervisor (student research) [Jo Waller CV]		
Summary CV for supervisor (student research) [Julia Bailey CV]		
Summary CV for supervisor (student research) [Laura Marlow CV]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/1762	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

E-mail: [redacted]

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Miss Kirsty Bennett, University College London

London - Bloomsbury Research Ethics Committee

Attendance at Committee meeting on 06 November 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Data Scientist	No	
[redacted]	Chartered Psychologist	Yes	
[redacted]	Paediatric Clinical Research Nurse	No	
[redacted]	Named Nurse for safeguarding children	Yes	
[redacted]	Medical Distributor/Responsible Person	No	
[redacted]	Hospital Chaplain	No	
[redacted]	General Practitioner / Medicolegal doctor	Yes	
[redacted]	Senior Lecturer in Management Studies	Yes	
[redacted]	Research Associate, Great Ormond Street Hospital	Yes	
[redacted]	Organisational Consultant	No	
[redacted]	Consultant Paediatric Neurologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
[redacted]	Approvals Specialist
[redacted]	Approvals Officer

APPENDIX 5.9: REC APPROVAL

Health Research Authority

London - Bloomsbury Research Ethics Committee

[redacted]

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

23 December 2019

Miss Kirsty Bennett
PhD student
[redacted]

Dear Miss Bennett

Study title:	**The psychosexual impact of testing positive for high-risk cervical human papillomavirus – a qualitative study.**
REC reference:	**19/LO/1762**
Protocol number:	**1**
IRAS project ID:	**264256**

Thank you for your correspondence of 23 December 2019. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 22 November 2019

Documents received

The documents received were as follows:

Document	*Version*	*Date*

GP/consultant information sheets or letters [GP Notification Letter]	1	28 November 2019
Other [Response to ethics committee]	1	20 December 2019
Participant consent form [Consent Form]	2	02 December 2019
Participant information sheet (PIS) [Participant Information Sheet]	3	02 December 2019
Research protocol or project proposal [Protocol]	2	28 November 2019

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study advert]	1	25 July 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL insurance certificate]	1	22 July 2019
GP/consultant information sheets or letters [GP Invitation Letter]	1	25 July 2019
GP/consultant information sheets or letters [GP Notification Letter]	1	28 November 2019
Initial Assessment for REC [Generated by HARP system]		
Interview schedules or topic guides for participants [Topic Guide]	1	25 July 2019
IRAS Application Form [IRAS_Form_14102019]		14 October 2019
Letter from sponsor [Confirmation of UCL Sponsorship]		27 September 2019
Non-validated questionnaire [Pre-interview questionnaire]	1	25 July 2019
Non-validated questionnaire [Post-interview questionnaire]	1	25 July 2019
Other [Study debrief]	1	25 July 2019
Other [Evidence of funding]	1	10 June 2019
Other [Data Protection Registration Confirmation]		11 April 2019
Other [UCL ethical approval]		12 June 2019
Other [Researcher responses]		
Other [Response to ethics committee]	1	20 December 2019
Participant consent form [Consent Form]	2	02 December 2019
Participant information sheet (PIS) [Participant Information Sheet]	3	02 December 2019
Referee's report or other scientific critique report [Evidence of peer review]		05 June 2019
Research protocol or project proposal [Protocol]	2	28 November 2019
Summary CV for Chief Investigator (CI) [Julia Bailey CV]		
Summary CV for student [Kirsty Bennett CV]	1	02 July 2019
Summary CV for supervisor (student research) [Jo Waller CV]		
Summary CV for supervisor (student research) [Julia Bailey CV]		
Summary CV for supervisor (student research) [Laura Marlow CV]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

19/LO/1762	**Please quote this number on all correspondence**

Yours sincerely

[redacted]

Approvals Officer

E-mail: [redacted]

Copy to: *Miss Kirsty Bennett, University College London*
[redacted]

APPENDIX 5.10: HRA APPROVAL

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

[redacted]

[redacted]

23 December 2019

Dear [redacted]

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**The psychosexual impact of testing positive for high-risk cervical human papillomavirus – a qualitative study.**
IRAS project ID:	**264256**
Protocol number:	**1**
REC reference:	**19/LO/1762**
Sponsor	**University College London**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **264256**. Please quote this on all correspondence.

Yours sincerely,
[redacted]

Approvals Specialist

Email: [redacted]

Copy to: Miss Kirsty Bennett, University College London

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study advert]	1	25 July 2019
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) [UCL insurance certificate]	1	22 July 2019
GP/consultant information sheets or letters [GP Invitation Letter]	1	25 July 2019
Interview schedules or topic guides for participants [Topic Guide]	1	25 July 2019
IRAS Application Form [IRAS_Form_14102019]		14 October 2019
IRAS Application Form XML file [IRAS_Form_14102019]		14 October 2019
Letter from sponsor [Confirmation of UCL Sponsorship]		27 September 2019
Non-validated questionnaire [Pre-interview questionnaire]	1	25 July 2019
Non-validated questionnaire [Post-interview questionnaire]	1	25 July 2019
Organisation Information Document		
Other [Study debrief]	1	25 July 2019
Other [Evidence of funding]	1	10 June 2019
Other [Data Protection Registration Confirmation]		11 April 2019
Other [UCL ethical approval]		12 June 2019
Participant consent form [Consent Form]	1	25 July 2019
Participant information sheet (PIS) [Participant Information Sheet]	2	03 October 2019
Referee's report or other scientific critique report [Evidence of peer review]		05 June 2019
Research protocol or project proposal [Protocol]	1	01 April 2019
Schedule of Events or SoECAT [SoECAT form]	1	30 July 2019